Washington State Health Care Authority
Prescription Drug Affordability Board
Meeting Transcription
May 22, 2024

Multiple Speakers: [Cross-talk].

Mike Neuenschwander: I think [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Are we ready? [cross-talk] --

Mike Neuenschwander: [Cross-talk] we are ready. [cross-talk] Okay.

MaryAnne Lindeblad: Okay.

Mike Neuenschwander: Doug's on [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] I think we are going to go ahead and try. [Cross-talk] Okay, we are going to go ahead and get started.

Hung Truong: Yeah.

MaryAnne Lindeblad: So good morning and welcome and happy to have you all here. I'm going to go around and do some introductions.

Eileen Cody: Yes, ma'am.

MaryAnne Lindeblad: MaryAnne Lindeblad, Board Chair, and turn it over to Eileen.

Eileen Cody: Eileen Cody, Board Member.

Hung Truong: Hung Truong, Board Member.

MaryAnne Lindeblad: And staff.

Simon Borumand: Simon Borumand, HCA Staff Member.

Michael Tunick: Michael Tunick, Assistant Attorney General and Legal Council for the Board.

Mike Neuenschwander: Mike Neuenschwander, the Manager for the PDAB Program here with HCA.

Ryan Pistoresi: And I'm Ryan Pistoresi, I am the Assistant Chief Pharmacy Officer here at the Health Care Authority.

MaryAnne Lindeblad: And we have one Board Member online on Zoom. Douglas, do you want to introduce yourself?

Douglas Barthold: Hi, everyone. Douglas Barthold, Board Member.

MaryAnne Lindeblad: Oh. Well. [laughter] --

Eileen Cody: Just a minute.

MaryAnne Lindeblad: No volume here.

Douglas Barthold: Oh. Okay. Hm. I can hear you okay. Just let me know, and it looks like my [cross-talk] --

Eileen Cody: [Cross-talk] You are not on mute.

Douglas Barthold: -- microphone is working, so.

MaryAnne Lindeblad: Still don't hear you.

Mike Neuenschwander: Zoom gremlins.

Multiple Speakers: [Laughter].

Eileen Cody: I have had to get one twice lately [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Oh, yeah?

Eileen Cody: [Cross-talk] Because the thing hasn't been working.

MaryAnne Lindeblad: It's early. Maybe it's still asleep. [Cross-talk] --

Mike Neuenschwander: One minute while we work through some technical difficulties here.

Eileen Cody: I want to see if Kelly comes off if you can here her.

Mike Neuenschwander: Kelly, can you test and see if we can hear you?

Kelly Wu: Can you hear me?

Multiple Speakers: Nope, nope, nope, [laughter] [cross-talk] --

Douglas Barthold: Kelly, can you hear me?

MaryAnne Lindeblad: All right, so [cross-talk] --

Douglas Barthold: [Cross-talk] Okay.

Kelly Wu: [Cross-talk] Yeah, I can hear you.

MaryAnne Lindeblad: [Cross-talk] A couple minutes here while we are waiting to [cross-talk] --

Douglas Barthold: [Cross-talk] Okay, I can hear you as well, Kelly.

Mike Neuenschwander: [Cross-talk] on speakers.

MaryAnne Lindeblad: Technical difficulties.

Eileen Cody: And Lonnie's got his hand raised.

MaryAnne Lindeblad: Yep.

Eileen Cody: Never met him.

MaryAnne Lindeblad: Oh, you haven't.

Eileen Cody: No. I don't need [indistinct].

Mike Neuenschwander: Great. But, yeah, so [indistinct] can hear everyone, so it must be our speakers on this side.

Multiple Speakers: Yeah [cross-talk] --

Mike Neuenschwander: Okay.

Multiple Speakers: [Laughter] [cross-talk] --

MaryAnne Lindeblad: And that gives us a better chance of passing it [cross-talk] --

Eileen Cody: I'd pass that now. [Cross-talk].

Mike Neuenschwander: Right? Troubleshooting?

Multiple Speakers: [Cross-talk] --

Mike Neuenschwander: Kelly, can you hear us?

Kelly Wu: Yeah, I can hear you.

Mike Neuenschwander: Can you try speaking now?

Kelly Wu: Yeah, I'm speaking. [laugh]

Eileen Cody: No.

MaryAnne Lindeblad: Nope.

Mike Neuenschwander: No, still can't hear her.

Multiple Speakers: [Laughter].

Unknown male: I'm Safety. I'm not IT.

Multiple Speakers: [Laughter] [Indistinct].

Mike Neuenschwander: So maybe we just wait for the IT [cross-talk] person to show up?

Multiple Speakers: Yeah. Yeah. Yeah.

Mike Neuenschwander: 10-minute break.

Multiple Speakers: [Laughter] Yeah.

Mike Neuenschwander: Well, once we can get like -- we can do -- [cross-talk] not everybody would be able to hear.

MaryAnne Lindeblad: Yeah.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: Time's sake, go ahead and have Mike do his report.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: And then everybody can listen in on that.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: Catch the rest of the introduction.

Mike Neuenschwander: Sounds good. Yeah. Then we will go back and or we do the presentations and make sure we get everyone online so that way everyone can ask questions.

Eileen Cody: They can hear okay, right?

Mike Neuenschwander: Yeah, I believe they can hear us just fine.

Eileen Cody: Yeah.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: That is a good idea.

Mike Neuenschwander: Okie doke. Switching gears. Um, so, yeah. Thank you very much. So some of the things I wanted to chat about a little bit are just some updates as we have been looking out for the next year on our program at work and what we were doing. We have been talking and working together as a team, trying to see how we are going to stack and allocate our work over the next few Board meetings. And so I just wanted to go with a rough outline here of our path or our vision forward and what we were hoping to do. So at today's meeting we will be talking about our policies -- potential policies for making our drug list and also discussing our drug selection methodology. The Board will be

talking to us about the drug abuse and some of the things that we need to consider. Moving on into July, you will be -- we will vote on our drug list methodology. So today is the policy we will be going over, and we will be approving or voting on that how we create the list in July. We will also need a discussion on our prioritization methodology, so once we get the list, how are we going to sort all of these drugs and decide what to choose, and potential data measures that could be used to narrow down that list. Other things we will also need to look at are if we want to make any changes to the WAC, Washington Administrative Code, as well as begin looking at our Ledge Report because we have that report due in December every year. Those reports do take a little while to put together, so just begin discussions on that. Then as we move through the summer of 2024, we will be looking at our Advisory Group applications. I know we talked about the advisory groups and how we were wanting to set that up at our last meeting, and also what candidates may have applied. So we have already been talking to our pledge team and any people that they feel might be able to help us on those advisory groups. But if the Board Members have any other people that they think would be good candidates, we can work with Simon to make sure that those candidates get the application and are able to fill that out. And then also we will have the Board start looking at the -- our weighting of our metrics for the drug selection methodology. Then in September, we can vote on the final methodology prioritizing or selecting those drugs, and then we can also vote to appoint the Advisory Group members. Then in November, we can present the list of our prioritized list of the drugs for the Board approval, and we can also discuss the -- begin discussions of what drugs we possibly might want to select for that. And in December, get the Advisory Group input on the drug selection, and then January a short list, those drugs that we have been talking about. In March, vote on the drugs that we want to select for the Affordability Review. So any questions on that general timeline and update? And all of this is, again, we are trying to be flexible as needs change, or maybe we need to look into something or do something. We've [cross-talk] --

MaryAnne Lindeblad: Doug just had something on about sharing a copy of that.

Mike Neuenschwander: Yes, yes. I will do that. So that is our general timeline. And it looks like we got our IT support here. [laugh] So we can do a short pause here while he looks at the speakers.

[pause]

Mike Neuenschwander: [Indistinct] Kelly can speak.

Douglas Barthold: Testing 1, 2, 3.

Mike Neuenschwander: There we go.

Ryan Pistoresi: Now so it's going to be very similar. It's going of the be the same administers.

Douglas Barthold: Did it work?

Mike Neuenschwander: Yeah, we can hear you now. It's a little [cross-talk] --

Douglas Barthold: [Cross-talk] Great.

Mike Neuenschwander: -- a little soft, but we are still working on the [cross-talk] --

Eileen Cody: Just curious.

Mike Neuenschwander: [Cross-talk] copy again.

Douglas Barthold: Yep. Copying now.

IT Support: [Indistinct] one more time?

Douglas Barthold: Testing, testing, 1, 2, 3.

Mike Neuenschwander: That is fine. We can hear everything [cross-talk] --

MaryAnne Lindeblad: I know, I should be paying more attention to that. [Cross-talk] --

IT Support: Okay, this [cross-talk] you just insert a file [cross-talk] with the approval. I mean you obviously talked to Dave, but yeah. [Indistinct].

MaryAnne Lindeblad: [Indistinct] They end up calling you, but it's not [indistinct]. I should be [cough] needs, but [cross-talk] --

Ryan Pistoresi: We probably just haven't done it as much, but [cross-talk] so we are now -- we will get some of the other benefits with their work, but [cross-talk] --

Mike Neuenschwander: Say one more thing, Doug.

Douglas Barthold: Yep, hello. Testing, testing.

Multiple Speakers: [Cross-talk] [Indistinct]. [Cross-talk] --

Mike Neuenschwander: One more time, Doug.

Douglas Barthold: Testing, testing.

Multiple Speakers: [Cross-talk] --

IT Support: Yeah, I think we are good.

Mike Neuenschwander: Okay.

Multiple Speakers: [Cross-talk] --

MaryAnne Lindeblad: All right. We are on. [Cross-talk] introduce himself.

Douglas Barthold: Ah, yes. I'm Douglas Barthold. I'm a Board Member. Nice to see you all.

MaryAnne Lindeblad: Welcome. Going back did we -- oh we need to introduce staff.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: Let's go around and introduce staff and start with Kelly.

Eileen Cody: Stepped away.

MaryAnne Lindeblad: Yeah, okay. Well --

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

MaryAnne Lindeblad: And [cross-talk] --

Mike Neuenschwander: Marina.

MaryAnne Lindeblad: Marina.

Marina Suzuki: Hi. This is Marina. I'm a House Economics Research Manager.

Mike Neuenschwander: And maybe Jingping is the last one.

MaryAnne Lindeblad: Jingping Xing. Okay. Jing.

Jingping Xing: Hi. This is Jingping Xing. I'm the Cost and Quality Analytics Manager.

MaryAnne Lindeblad: Great.

Mike Neuenschwander: I think Donna is online as well.

MaryAnne Lindeblad: Donna, are you online?

Donna Sullivan: Yeah, hi. This is Donna Sullivan, Chief Pharmacy Officer. Sorry, my camera is not working, so I am not on camera.

MaryAnne Lindeblad: All right.

Mike Neuenschwander: She's [cross-talk] [laughter] --

MaryAnne Lindeblad: [Cross-talk] So, Mike, do we have anyone else?

Mike Neuenschwander: [Laughter] Um, I think that probably should be it. So, yeah, Donna signed in under my name there, so [cross-talk] --

MaryAnne Lindeblad: Oh, that's why.

Mike Neuenschwander: But it says Mike. It's not Mike. [laughter] It's I'm Mike. [laughter] so I'm going [laughter] [cross-talk] --

MaryAnne Lindeblad: [Laughter] All right. Well, now we know why. Well, should we just go ahead then, with the PORTAL presentation from Dr. Rome?

Mike Neuenschwander: Um.

MaryAnne Lindeblad: Are we ready for that? Or are you [cross-talk] --

Mike Neuenschwander: [Cross-talk] Not quite. I have one more [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] One more thing, all right.

Mike Neuenschwander: -- little thing I wanted to chat about, and then we can make sure we see if the PORTAL is online here.

MaryAnne Lindeblad: Okay.

Mike Neuenschwander: Um, so the last piece of the -- it's just a short legal update on some of the things that are happening with other PDABs around the country. So the Colorado Prescription Drug Affordability Board did have a lawsuit filed against them by Amgen. The lawsuit stems from the Board's decision in February of this year to label Amgen's drug, Enbrel, unaffordable for patients in Colorado. Enbrel is used to treat to rheumatoid arthritis and other conditions. The plaintiffs argue that in Colorado law establishing a Prescription Drug Affordability Board violates the due process clause of the 14th Amendment as well as the Dormant Commerce Clause, and is preempted by federal patent laws, federal laws concerning Medicare, and other federal health programs. So I know there are some online articles about it that go into more detail but is due a brief update of some things that are happening in the other PDABs. So any general questions about from the Board Members?

MaryAnne Lindeblad: Have they got two different states now that have lawsuits? [Cross-talk] Colorado, and is there one more?

Mike Neuenschwander: Yeah. And then Oregon has had a lawsuit filed against their Drug Price Transparency Program as well. So two separate programs in two separate states, but they are related in a number of places.

Douglas Barthold: Yeah, I just have a question, and I don't know if any of us have the answer to this, but do we -- are there any examples of states regulating prices for anything that has a federal patent?

Multiple Speakers: [Cross-talk] [laughter]

Michael Tunick: People are looking at me [laughter] [cross-talk] -- I -- that is not a question I thought about, so I can get back to you on that if that is all right. But I think that is not something I have thought about, but that is a very good question.

Hung Truong: It's not on a state level. I mean the Inflation Reduction Act has some pricing mechanism in their, and that is still working its way out.

Douglas Barthold: Yeah. I mean, I am obviously not a lawyer, but it would be interesting to see because that [indistinct] violates the same patent restriction, but at least that has a federal law behind it. Ours only has a state law behind it, so I don't know if that makes a difference.

Mike Neuenschwander: You have questions?

MaryAnne Lindeblad: I think -- nope. Anything else, Mike?

Mike Neuenschwander: No, that is it for me.

MaryAnne Lindeblad: All right. So we are go -- are we ready for the PORTAL?

Mike Neuenschwander: The PORTAL will be joining at 9:00 [cross-talk] --

Eileen Cody: [Cross-talk] 9.

MaryAnne Lindeblad: [Cross-talk] At 9, okay.

Mike Neuenschwander: [Cross-talk] Right.

MaryAnne Lindeblad: [Cross-talk] So we [cross-talk] --

Mike Neuenschwander: [Cross-talk] minutes.

MaryAnne Lindeblad: [Cross-talk] We have a few minutes, great. No?

Multiple Speakers: [laughter]

MaryAnne Lindeblad: Anything that -- any questions that any folks want to talk about or kill time? What did you do on your summer vacation?

Multiple Speakers: [laughter]

MaryAnne Lindeblad: Or what are you going to do on your summer vacation?

Eileen Cody: Yeah. That's -- I was going to say, it's not summer yet.

MaryAnne Lindeblad: Yeah. Not yet.

Mike Neuenschwander: Okay, [cross-talk] we are going to do a short 5-minute break here.

[break]

Multiple Speakers: [Cross-talk].

Eileen Cody: Well, if it's entertaining.

Unknown female: If it's [laughter] [cross-talk], yeah, it's [indistinct]. So Mike, you rattled through kind of the next six, eight, nine months what you are going to do at each meeting, and you were talking so fast I don't think I got it all down. So I was wondering if you might want to just repeat that.

Mike Neuenschwander: Oh, sure. Sure, I can do that. [Cross-talk] Um, so right now in this meeting we are discussing the Drug List, developing that list and the policy behind developing that list, then also beginning discussions on the drug selection. So once we get the list, how do we select that list? In July, we will continue our discussions on the prioritization of that selection and potential data measures that could be used to narrow down that list. We will also vote on our drug policy or our policy creating the drug list, and then we will also be looking at any changes we need to make to the WAC as well as a ledger report that is due by December, begin discussions on that. Throughout Summer of 2024 we began looking at the advisory group applications, the candidates that applied for that. And then also on having the Board Members looking at weighting metrics for the drug selection on how they might want to do that. Again, if the Board Members have anyone for the Advisory Groups that they think would be a good fit to work with Simon, that way we could reach out and get them an application. September then having the Board vote on that final selection/prioritization methodology, and also working to appoint the advisory group members from applicants that we have. Then in November presenting that prioritized drug list for the Board and also continue discussions on the selection from that prioritized list of what we want to do. And in December, get Advisory Group input on that list, and then in January create a short list of drugs for the affordability review, and March, vote on the list of the drugs that we want to have for the affordability review. Okay.

MaryAnne Lindeblad: Thanks. Any other questions? Anything else? All right. Well, we just have a five-minute then, and then we will be ready for the PORTAL conversation.

Multiple Speakers: [Cross-talk] [Indistinct].

[break]

Multiple Speakers: [Cross-talk] [indistinct].

Mike Neuenschwander: [Cross-talk] we are back, right? [Cross-talk] [Indistinct] --

MaryAnne Lindeblad: [Cross-talk] All right, guys. We are going to get back. All right. So we are going to go ahead with the PORTAL presentation, so I want to turn this over to Dr. Rome. Maybe he'll want to introduce himself, and then we will go ahead with the presentation. So what happened?

Benjamin Rome: [Indistinct] here.

MaryAnne Lindeblad: Oh, there you are. [laughter]

Benjamin Rome: [Laugh] Great. Good to see everyone again. I am Ben Rome. I'm a Primary Care Internist and Health Policy Researcher in the Program and Regulation Therapeutics and Law Portal based at Brigham and Women's Hospital and Harvard Medical School. Matt Martin, our Program Coordinator, is also here today. Together we have been doing a lot of work with our team on PDAB, so it is good to be back and talking more about this. So we are going to run through some issues around actually conducting affordability reviews or thinking about how to assess affordability of drugs. Matt, do you want to kick things off with [cross-talk] --

Matt Martin: Yeah, absolutely.

Benjamin Rome: And then I will take over part way through.

Matt Martin: Yeah, it sounds great. So, um, yeah. So the focus of the conversation day is kind of looking ahead down the road a little bit while I have been focusing of considerations for conducting affordability reviews. Let me share my screen. Slide's up. There we go. The slide showing up on everyone's on the other?

Mike Neuenschwander: Yep, we can see it.

Matt Martin: Perfect. Great. So to start the conversation because we wanted to disclose that PORTAL as a group does not receive any funding from pharmacological or medical device companies, and you can see the list of funding sources that support our research on the slide here. So an outline of the conversation today, I want to start out with an overview of the PDAB process and where you are and then where we will be focusing for the remainder of the presentation, and then Ben and I will talk about some considerations for you all as a Board as you are moving through the affordability reviews and how you can assess and define what affordability may mean to you all when you are selecting drugs and reviewing them. I'm going to start out with a bit of an overview to things. So this is a familiar slide that I think we shared on our last presentation. We consider the PDAB process and our general phases. So you all have really been focusing on the first two as of right now. So identifying drugs that are eligible based on statutory criteria and developing methodologies to identify those drugs and then thinking through based on other sets of criteria and data points to select which drugs you think you would like to review for the current affordability review cycle. And so what we want to focus on today is the next step in the process. So looking ahead at the affordability review itself, this is really going to be the most intensive component of the work that the PDAB does, and we want to particularly focus on the charge you all are tasked with at the end of the affordability review in making assessments of whether or not a drug that you have selected has led or will lead to excess cost to patients in the state. We want to provide some framing around that decision and how the different components of the affordability review and framing them in the appropriate way can help you reach a conclusion in as easy a way and as comprehensive a way and thoughtful a way as possible. So in reviewing the statutes and rules that dictate the affordability review process for the Board, there are two sets of factors. There is first the one set that are the core components that you all statutorily will consider as part of your process, and the key thing to keep in mind here, too, is that during the affordability review, you are going to be presented a lot more data and information about the drugs you have selected then you may be receiving and reviewing earlier on in the process when it comes to the drug selection phase. So knowing that once you select a drug, there will be a lot more information at your disposal to make a thoughtful assessment of that drugs' affordability in the state. And so you see the various components that are listed here. We are going to touch on high level some of them later on in the presentation and are happy to do deeper dives on individual components in future presentations. But components around the price of the drug, the out-of-pocket costs that patients may face for the

drug, the existence of patient assistance programs, how decisions like formulary placement and other PBM-related policies may affect access to the drug and utilization of the drug, comparing the drug with its therapeutic alternatives, what their prices are, what their clinical effectiveness is relative to the drug that is under review. And then additionally looking at and taking into consideration input from a variety of stakeholders who you will be engaging with throughout the process. So that includes patients, individuals with medical and scientific expertise that may be particularly relevant to the drugs themselves, and other materials that the manufacturer and payers and other entities and advocates may submit as you could do the review. There is then a an in statute second set of factors that may provide additional context to the Board as you assess the affordability of drugs. So you can see these here, they kind of vary in their scope that they focus on. but this could be things like the availability of biosimilars or generics or brand name products, or the average cost of the drug in the state, the revenue that the manufacturer reports for the drugs that are being reviewed, off-label uses of the drug that may be beyond the FDA-approved indication. And then, importantly, you will also have the ability to identify additional factors that may be relevant that perhaps when you are looking at drugs at the identification and selection phase, there may be data elements that aren't in this set list that may provide additional context that may be important for you all as you move through the review. So with all these different data components, the central challenge then becomes, how do you take all of this information from a variety of sources and from a variety of stakeholders and funnel it down into a final determination of whether the drug creates excess costs to patients. And so there are a lot of different ways you can think about this, but we want to present a framework that highlights three different perspectives that you can use to assess the affordability of drugs to help analyze all of this different information and data points in a way that is comprehensive and that also allows you to reach a conclusion and a consensus as a Board. Which brings us to the next part, which is the overview of this framework that we have put forward. I also will add that at the end of this presentation we have linked to the white paper on this topic that goes into a lot more detail on the specific elements of affordability reviews and some of the more technical and data items. So that is there as a reference, and I'm happy to share that more broadly as well. So to get at defining affordability, I think we first turned to the statutory language that you all have been given when it comes to excess costs. So as I mentioned previously, you are tasked with assessing at the end of the affordability review whether a drug has led or will lead to "an excess cost to patients in the state." When you

look at how access costs are defined, there are two pathways you can look at excess costs. So you can look at excess cost as those the cost of the drug exceeds therapeutic benefit relative to other alternative treatments. So that could be in class in the same therapeutic class or more broadly, depending on the priorities of the Board, and/or you can think of excess costs as the costs of the drug that are not sustainable to the public and private healthcare system of our 10-year timeframe. So this is the more system level approach and thinking of costs. The other component here is that its excess cost to patients. And we touched on -- I believe Ben touched on his last presentation it's important to also think about which patients you are considering in this process. Is it cost to the patients who are only those taking the drug that is under review? Or is it more broadly thinking about all patients in the state who may be paying directly or indirectly for some of those costs of the drug and that budgetary trade-offs that may result for all patients who thinks that the financial impacts of these drugs. And so with this framework in mind, we then proposed in the white paper, and then I will highlight in more detail here, three different perspectives that you can use to think about the affordability of a drug. So in one angle you can look at the cost relative to therapeutic alternatives. So these may be situations where the drug -- the clinical benefit that the drug adds may not be in alignment with its cost when you compare it to other similar treatments that may treat the same disease or condition. The second perspective is thinking more targeted on the out-of-pocket cost that patients face. So there may be drugs that are out there for which there is clinical value and added benefit relative to alternatives, but the patients still, nonetheless, face significant financial burdens in accessing those drugs in a state. And the third perspective here is going back to that budgetary consideration. Are there drugs that may be cost effective and may have added benefit, but, nonetheless, they pose a financial risk to the overall state healthcare system, which can result in increased healthcare premiums for all patients and consumers in the state and also result in required budgetary trade offs that may impact other areas of spending within Washington. And so while we highlight each of these perspectives as distinct pathways, I think it's important to consider each of them during the review process and not just focus on one individual component because by taking some of these different perspectives into consideration, you can emerge with a more well-rounded view of this drug that is under selection. Particularly because some of the data elements that you may be exploring and examining may be telling different stories when we look through each of these different perspectives. And so it's important to look at it as comprehensively as possible so that you can come to a determination that really represents as

close as feasibly possible to the reality of this drugs' access and affordability within the state. And I think I'm going to turn it over to Ben now, who is going to dive a little bit more in detail on the different components that fit into each of these different perspectives on affordability.

Benjamin Rome: Great. Thanks, man. And the way these slides are set up, we are going to talk about each of these three buckets of ways of thinking about things. And on the right-hand side we have listed some of those factors that are specifically listed in statute and rule within Washington and how those factors can be bundled and actually used come out in each of these buckets because, otherwise, you just have a list of factors that are being considered. So the idea of putting these into these categories allows you to think about what the meaning of all of that information is when combined together. So first, the first step is the cost of drugs relative to therapeutic alternatives. And so for many drugs, the added clinical benefit that the drug provides may not align with its costs when compared to treatments for the same disease or condition. This would be therapy we call alternatives for the drug. Importantly, a lot of drugs have multiple different indications, so you might have to analyze the added clinical benefit separately for each indication to make a determination. We know from lots of prior research and other international assessments that many new drugs that come to market do not offer substantial clinical benefits over existing treatments that maybe second in class products or drugs where the evidence hasn't really actually -- may support that it's effective, but it hasn't actually been tested against existing lines of treatment to see if it's more effective than what's already out there. And that can be a very powerful way to think about if you have two drugs that treat the same condition, and you have no evidence that one or the other is better or safer or more effective. Maybe we ought to pay the same for those two treatments. If you go to the next slide, Matt. So how do you define therapeutical alternatives? I think it's an important step in the process for making these determinations. I think it's really hard to think that therapeutic alternatives are not necessarily going to be identical in terms of safety, efficacy, mode of delivery. By mode of delivery, I mean an injected product versus an oral drug. Right? They might be different ways of administering the treatments. There might be small differences in the safety profiles or even in effectiveness, and it also doesn't mean that products are interchangeable for patients. And I think it's very important that the Board sets up this expectation if you are going to select therapeutic alternatives for drugs upfront because, obviously, for an individual patient, there might be factors to consider for one reason or another one drug may or may not be a better

choice. And when you are looking at this on a population level, the question again is, is drug A really on a population level better than drug B? And if not, then why should we pay more for drug A? And the how the Board defines therapeutic alternatives really is going to -- should be informed by how you plan to use therapeutic alternatives as part of the review. And there are a range of options on one end you could narrowly define drugs that are within the same pharmacologic class. So, for example, TNF inhibitors. Right? So all of drugs that affect this specific TNF-inhibitor pathway would be a small subset of drugs that would be very similar in general use for the same indications. Or you can take a broader look at an indication, and you could look at all drugs that treat a particular condition and across multiple different disease classes. You can even expand beyond drugs to think about devices or surgical procedures or other types of interventions that could also be used in those particular conditions. And so, obviously, taking that broader definition might give you a bigger bucket of comparators, and maybe the prices for those competitors are going to vary more. Right? So within a pharmacological class, you might expect a little bit less variability in price, and so it's not going to be as powerful a tool. But obviously, the broader you get, the more challenges you get in actually defining for what counts and what doesn't count as a therapeutic alternative because there is more variability in those products. On the next slide, the last piece here is just to really point out that there is a big difference between comparative effectiveness and economic analysis. And both of these are tools that can be used to compare drugs to therapeutic alternatives. On the comparative effectiveness side, you are really just focused on the drug effectiveness, safety, and ease of use relative to therapeutic alternatives. And the ways you can look at that information is pre- and post-market clinical trial data that is conducted by manufacturers and often submitted to the FDA and made publicly available. There are in some cases our direct comparative effectiveness trials comparing one drug to another. Though, oftentimes, there aren't head-to-head trials. There are a bunch of placebo-controlled trials, and you may have meta analyses that try to combine that information and make indirect comparisons between different drugs. In some cases, you have real world evidence or observational studies that patients have actually used different drugs. International health technology assessments often combine these data sometimes perform their own meta analyses and make assessments about the relative benefits and net benefits of all these factors of different drugs. So many countries do those types of assessments. Again, this is without cost, just considering how well does the drug work? Or how much does it benefit patients? And then obviously, you want to take input from patients and experts to make sure you

are thinking about this correctly when you are doing these types of comparisons. In terms of the economic pieces, when you add costs into the picture, now you are asking questions about what's the incremental cost versus the incremental benefit of a drug compared to a therapeutic alternative. There always has to be some comparison. For drugs without a lot of therapeutic alternatives, many times the comparison will be standard of care or no treatment, but you have to compare to something. Traditionally, a cost effectiveness analysis is this type of model where you measure this. In modeling studies, you look at the long-term cost of a treatment and how much that is going to cost for patients to be on that treatment over time, you have not allowed the cost if the patient is not on that treatment or if they are on some alternative treatment and look at that. And then you compare that to some measure of how well the patient is doing, how long they are living over time. Efficiency frontiers are an alternative approach. I think we talked about this last time where you can map the cost and effectiveness, net benefits of each drug on a plot and then -- look at which ones are more costly -- I'm sorry -- less costly and more effective to find the ones that are the most cost effective. There is often published literature of cost effectiveness trials for different drugs, different conditions. The Institute for Clinical and Economic Review, or ICER, publishes reviews or analyses in a lot of different clinical areas. And obviously, other countries do this work as part of their health technology assessment to just to make the right decisions around reimbursement and price negotiation. And components of those may be helpful when assess -- when looking at some of these judgments. But again, just keeping in mind that you can do comparative effectiveness analysis. You can think about drugs compared to therapeutic [indistinct] without actually looking at cost. On the next slide, we are going to turn that as bucket number two. This is patient out-of-pocket costs. Again, these are drugs that are clinically effective, yet maybe patients face significant financial barriers to accessing the drug, and this can have important implications for medication adherence and clinical outcomes. And I think when you ask patients, "Is a drug affordable?" Their gut reaction is to think about this. All right, when I show up at the pharmacy counter, how much am I going to pay? And am I going to be able to pay that much to actually get the drug? When people talk about people not feeling insulin and other medicines, this is typically what individuals are talking about, and there are a number of factors that you are required to think about that fall into this bucket. So how do you inform this perspective? I think there are a number of different data elements that you are going to want to consider. First, is just data from all payer claims about what the average patient is paying out-of-pocket for the drug. Now,

importantly, there are limitations to this. Right? You don't ask for patients who don't take the drug because of cost, so you only account for people who actually fill the medicine and take it for some period of time. But it still provides an important set of real data on what the experiences are of patients. Second is insurance coverage. So how well covered? How accessible is the drug to patients who have private insurance, Medicare/Medicaid, and other types of insurance? Is it included on the formulary? What tier is it on? Are their utilization management tools like step therapy or prior authorization that restrict access depending on certain rules? Third, is how manufacturer rebates effect coinsurance and deductibles. So many of you are probably aware that generally when drug companies want to offer discounts on drugs, they do that through confidential rebates. And the patient's out-of-pocket costs can still be based on the high price for a drug. So if you have a drug that is priced very, very high but has very, very substantial rebates, out-of-pocket costs can actually be high proportional to the total cost of the drug that is incurred by the healthcare system. And finally, manufacturer assistance, co-payment cards, and patient assistance programs. Importantly, these are not going to be reflected when you look at claims data. So if a patient uses some other means, including manufacturer assistance to pay for their portion of the out-of-pocket expenses, the insurer is not aware of that. Right? The insurer says you owe 25%, but if some of that 25% is covered by the manufacturer, you may not. You are not going to see that in traditional claims data. There are data sources where you get pharmacy level data that you can see how much a patient is actually paying, but those are not going to be in your traditional all payer claims database. And also, it's important thing about health equity and, obviously, engage patient stakeholders to solicit feedback about what patient experiences are for these for these drugs. On the next slide, just a couple pieces here. So on the insurance coverage, in terms of how you get data on this, it can be challenging to collect all the information from many different insurance plans. There is a company, MMIT, that has a database that does this. They make an easy to access version of their data available on an app called Coverage. So here, we just ran Eliquis in the State of Washington so you can see what this looks like. You can see that coverage of the drug is, in general, pretty good. It varies a little bit between commercial Medicare, Health Exchange, and Medicaid. And, and you can see -- where the drugs are that preferred status, which is easily available generally with no prior authorization, or whether there are impositions and posting for patients to get the drug, or whether they are not, it's not covered at all. So this could just be a helpful framework, I think, to look through around access. On the next slide, we talked just about manufacturer systems

programs just to differentiate between co-payment cards and patient systems programs because this is going to come up as you start to think about these things. You can find information about these from manufacturers, so even if it's not in the data, you can see what programs are available. Copayment cards typically offer patients to lower the cost to less than $30 a month, often $5.00, $10 a month, regardless of what the insurance is going to charge, but they often have monthly and annual limits. So if a patient has a high-deductible plan, it might not cover their full costs for those first few months while they are in their deductible. And the programs can vary year by year, or they can go away completely if the manufacturer chooses to sunset them. They are only available to patients with private insurance, not people with Medicare, not available to people with Medicaid as well. Patients on Medicaid typically don't have high out-of-pocket costs. And there is no set income or asset criteria. So anyone can just go on the manufacturers website and sign up to get one of these cards in general, as long as they meet the eligibility criteria in terms of their insurance coverage and state and things like that. So these are commonly used for many types of drugs in some studies up to 25% or more. Patients in commercial insurance plans will use these for particular high-cost drugs. So they are highly used, although they can change over time and go away. Patient Assistance Programs by contrast have strict financial eligibility criteria and lengthy onerous application processes. The patients have to submit a lot of data to the drug manufacturer to determine whether they have qualified, and I have personally had patients who have been hesitant to go through that process. And it's also just onerous on both the patient and on the doctor, who has to fill out a lot of clinical information as well. So the use of them is more limited because they don't apply to all patients, and they are really targeted towards people with low means. But these can include people in some cases on Medicare as well as commercial insurance. All right. And then the final bucket of these three is where we are thinking about the budgetary impact on the state. Here, you are not just looking how much patients are going to pay or whether patients can access the drug but just the broader impact on the healthcare system. So -- even though drugs might be cost effective at their current price or even aligned with other products, they could still pose financial risk to the broader healthcare system or the state healthcare system. This can impact insurance premiums for all patients, and it can also require other budgetary trade offs, from state spending on prescription drugs through Medi-, Medicaid, and through state-sponsored insurance goes up, and maybe you have less money to spend on education, roads, other things that the state needs to spend money on. You know, there are some

good examples of drugs in the past decade that have met this kind of criteria, where maybe the budgetary impact is the main concern. So the hepatitis C antivirals were deemed cost effective by academics, even at the initial price point. They were priced at around $100,000 per course of treatment initially, and even at that price point because they were so effective curative treatments, this prevented all downstream complications of cirrhosis and downstream complications of hepatitis C. They weren't cost effective, but so many patients had hepatitis C, and the cost was just so high that the system couldn't absorb those costs and, therefore, state Medicaid programs and many other insurers imposed really strict regulations on who could access the treatments, which limited the public health impact. I think GLP-1 receptor agonists for obesity and diabetes are the kind of modern example of this, where they are highly effective drugs. Nobody would argue that these are drugs that shouldn't be used to reduce cardiovascular risk in patients with diabetes and obesity, but they are expensive, and the prevalence of diabetes and obesity is just so enormous that it is going to raise constraints, and we are seeing private insurers make trade-offs, decisions about whether to include these drugs in the formulary or not because doing so would mean that they would have to raise the premium substantially. So how do you inform this perspective? You know, you can look at formal budget impact analyses. You can either conduct these yourself or have a look at ones in the literature in general, but an impact is focused on a shorter time horizon than a cost effectiveness study. You are looking at a three- to five-year window, and you are not looking at outcomes, you are just looking at cost. How much does a unit cost for the drug based on how people use it, minus any savings, maybe, from fewer hospitalizations, if the drug leads to fewer hospitalizations. These analyses are typically done when drugs are first approved, and so it can be a little more challenging to do the analysis once the drug is already on the market. You can also look at state level spending estimates on the drug. I think that will be easily accessible data to you and solicit input from payers and PBMs because they are the ones who are going to know which of the drugs are really straining their system, which are the ones that are at the top of their priority list in terms of making it difficult for them to set premiums each year. So there is going to be information as to which drugs are going to meet this threshold, even if you don't have formal budgetary assessment data. On the next slide, I think this goes back to how Matt framed this at the beginning. Incorporating data from each of these three perspectives is going to be useful to ensure that you have an affordability review process that is robust to a variety of drugs. Right? There are many different -- there are a lot of drugs that are going to be eligible for

the process, and you want to be able to understand what the intensions are for each individual drug. And you are going to have to balance complex, and in some cases, contrasting information. As I just said, you can have drugs that are extremely effective, extremely cost effective but are posing strains to the system, nonetheless. So you can use all that to arrive at your ultimate decision around whether drugs create excess costs to patients. So, hopefully this is helpful. If you are interested in if we lay out these three frameworks and some additional data considerations in a white paper -- onto the next slide -- I think the white papers published on that was published by our team in collaboration with NASHP, the National Academy for State Health Policy, and it was made available on NASHP's website earlier this year through our collaboration, so you can see and read more about these considerations. So we hopefully will have time for some questions and answers. Happy to talk more about the specific data considerations as you all are thinking about moving ahead with this process.

MaryAnne Lindeblad: Thank you. This was a great presentation. Do we have any Board Members with questions? Are there questions from others?

Douglas Barthold: I have a question.

MaryAnne Lindeblad: Go ahead.

Douglas Barthold: Okay, thanks. Thanks a lot, Ben. I think we met a few years ago. Nice to see you again. Yeah, so I just have a few questions regarding some of these general recommendations and also how these recommendations also fit in with the methodology for selecting eligible drugs. And one of the things that I'm most interested in right now is the definition of a drug and whether you do that at an indication-specific level. My understanding is if you do an indication-specific level, which will be very important for how you define the length of the course of treatment. It will be very important for you to find therapeutic alternatives and also orphan drug status. And so in my mind, all of those things also apply to the stage we are at right now, where we are selecting this list of eligible drugs, I was wondering if you could comment on that a little bit to tell us about if you agree that that is important at the stage we are at right now, and if there are other implications of that choice aside from the three that I mentioned course of treatment, there will be alternatives and orphan drug status.

Benjamin Rome: Yeah, I think it's a good point. I think for the -- certainly when you are assessing drugs' cost effectiveness, or you are going to have to do that at this for different indications. Right? Because the use is going to vary, even the budget impact for different indications might vary. In terms of the selection, question of should you select only certain indications for certain drugs? I have never seen or heard of any considerations about states or others doing that. And I think it poses some logistic barriers in terms of how you define indications. It always seems nice and neat and easy to do that, but some -- I'm thinking of cancer drugs, where I look at labels, and there are just like 20 or 30 indications, and some of them could be bundled together to call multiple myeloma or some other condition, but it's first-line or second-line treatment and, you know, those considerations are really important as part of the affordability review process to understand different cost factors in different situations. I think it would be very logistically complex to do that at the selection stage. It seems like you ought to pick drugs where you have some reason to question the drugs -- some reason to believe that the drug is likely to be unaffordable for a variety of reasons. And I think the one that is hardest to predict without diving into the weeds is the therapeutic alternatives consideration. Right? So it's easy to say we want to look at drugs because of our statute and because of our priorities that where they are expensive relative to therapeutic alternatives. But defining therapeutic alternatives is challenging. You have to do it by indication. You have to look at a lot of literature to make that assessment. So doing that for hundreds of drugs is probably infeasible. I think budget impact and out-of-pocket costs you can get some of that preliminary data upfront to get a sense, I think, for all drugs as to whether which ones stand out in terms of their out-of-pocket cost number, their coverage numbers, their spending numbers. So those ones are easier to get to pick a list where you are moving towards the top of those numbers, if that makes sense.

Douglas Barthold: Okay, thanks. Yeah. No, I agree. And so, I guess, from your perspective, you are thinking of it as do less work to get -- you know -- look at fewer less complicated items on this initial set of large lists of drugs, and then when you have narrowed it down further, then do the more complex steps of [cross-talk] --

Benjamin Rome: Yeah.

Douglas Barthold: -- like it is defining therapeutic alternatives.

Benjamin Rome: Right. It ends up being -- you know these health technology assessments done by other countries and everybody, you know these are complex, resource intensive. And I think if you talk to other states that are going about this, Maryland just announced which drugs it is going to do these reviews. And Colorado has already started doing reviews. Oregon has started doing reviews. It takes a lot of effort to pull all the necessary data elements to meet all your statutory criteria and to get a nice flavor of what is real about the drug. So I think, again, you want to be judicious about how you are thinking about those elements for a broader list of drugs for your staff and just for resource reasons.

Douglas Barthold: Okay. Um, well, thanks. That is very helpful. I do have another question, but I don't know if any of them wanted -- let the other Board members if they might have anything they want to ask.

MaryAnne Lindeblad: No. Please go ahead.

Douglas Barthold: Okay. So the other question is about, again, in both -- in all of these steps, the creating an eligible list and the affordability review, the degree to which we should be considering which types of plans we can actually regulate with the upper payment limit. And I just still don't know the answer to this in Washington. I have been trying to figure out exactly the set of plans where the upper payment limit actually would apply. But let's assume that we had that list, and that was -- and that information was clear, should that be considered as we define this list of eligible drugs and conducting an affordability review? You know, for example, if you do a budget impact analysis or you only want to include the plans that would be subject to the upper payment limit, or do you include all the plans? You know? Because do we care about all Washington taxpayers, or just the ones paying premiums in these plans? So I'm just wondering if you could comment on that?

Benjamin Rome: Yeah, I know, that is also a very good question. I think, again, I will defer to you and your [indistinct] team about what the implementation side of the -- the [indistinct] would -- I would say Medicaid is the one that stands out as probably the most different from others. It's a state -- it's obviously the state program, partial state and partial federal-funded program, but the prices of drugs tend to be very different in Medicaid than in other places because they are upgraded through a rebate structure at the federal level and they are not negotiated, whereas, Medicare and commercial plans, there is all -- there is negotiation that determines what the net price of drugs is, so they tend to be

close together. There is not a lot of evidence, but they are very different. Prices are a lot -- are very different in Medicare versus the commercial market. Obviously, that might change if the IRA has stricter negotiation on certain drugs, but Medicaid can be different. The population is obviously very different. And the out-of-pocket cost issues are less important. Right? So it's more about coverage and what's on formulary, and Medicaid, in general, cannot take any drug that is participating in a rebate program off the formulary, with some rare exceptions, like OPC drugs are carved out. You are allowed to exclude those but, in general, it's a question of prior authorization and restrictions and step therapy and things that are permanent patients. Once patients can access a drug, in general, they pay very little or nothing to do it, and so it's not the out-of-pocket [indistinct] are different, the prices of the drugs are different, so therefore, the budgetary impacts different in Medicaid than it is in the other types. I think if you remove Medicaid and bundle everything else together, I don't think you would notice major differences in Medicare versus commercial. That said, there are certain drugs where they treat different populations differently. So, for example, cancer drugs, in general, are going to be more predominant in a Medicare population, just because cancer, in general, is a disease of aging. Right? And Medicare covers most people over 65, so the list of drugs, if you are looking at spending, is going to be different between different populations like commercial, Medicare, Medicaid. Those are the biggest three. Obviously, there are other smaller populations. Within commercial, there is state-sponsored insurance as well, which would probably look similar to a commercial population -- in many ways.

Douglas Barthold: Okay, thanks. Yeah, that is very helpful. And so do you -- I mean, I wouldn't expect anyone to really know this, but would --does anyone happen to know if the other states, Colorado and Maryland, have in the steps of their process, separated by type of payer in their processes?

Benjamin Rome: I know that Colorado when they present out-of-pocket costs and both for decisions around in the affordability reviews they presented, and also in the step for selection they calculated average out-of-pocket costs for non-Medicaid patients. So they excluded the Medicaid patients, because many of them are zero [cross-talk] within that population because -- but they show the percent of, and they did show the distribution in the percent of patients and the percent of spending, I think, that was Medicaid's. I think that is on their dashboard. You can see the breakdown of those three big buckets. So yes, other states have thought about -- and I think if you listen to their

deliberations on those, I think it did come into play as to which categories of patients were most effective. So yeah, I think it's come up. I don't know specifically how it will come up in Maryland, but I imagine the same will come up. Although Maryland's process is somewhat different in terms of their statute right now, they are very, very focused on state-sponsored plans. That is just the way that their -- that is their authority right now.

Douglas Barthold: Okay.

Matt Martin: [Cross-talk] To the extent that the information can be broken out by the different payer mix. I think, even if the UPL may only apply to a certain subset of those payers, having those different groups represented can be a useful comparison to this for us to get a sense of how the plans the UPL may impact how they can -- how they stack up in terms of formulary decisions and things like that for the drug that is under review relative to these other payers in the system.

Douglas Barthold: Okay, thanks. That is very helpful. Yeah. I think it does seem like it will be more important as we get further and have a more narrowed down list of drugs. But yeah. So I yeah, so keep that in consideration.

MaryAnne Lindeblad: Doug, there was something you said that I need to ask Michael, I believe. You are on the spot again. [laughter] [cross-talk]

Michael Tunick: [Cross-talk] Yeah.

MaryAnne Lindeblad: This one [cross-talk] --

Michael Tunick: Yeah.

MaryAnne Lindeblad: The lawyer. Because it's been a while since I've read the statute, but you said something about us regulating the plans. We are not regulating the plans under this. So I just wanted to clarify that. Right? I mean it's not like we are going through the insurance side of things to regulate stuff.

Michael Tunick: Yeah, yeah. Yes. So the Board isn't regulating the plans, but it is, I guess, the upper payment limit set by the Board will [cross-talk] apply to certain payers in those, yes. So those [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah. And that is what I meant by plan regulation, is if the upper payment limit applies to some plan -- and I think it applies to all the [indistinct], all the plans which are regulated by the OIC, which is the fully funded plans. And then I'm still having -- still not sure about if we have any Medicare authority. So yeah. That is my understanding right now.

Ryan Pistoresi: Yeah. And so, Doug, that is a great question. So the statute that regulates this is RCW 70.405.050(6), which says that it applies to claims for drugs by a health carrier, which is defined in 48.43 RCW. And then health plan offered under Chapter 41.05, which are the ones offered under Health Care Authority for public and school employees. And then it does say that employer-sponsored self-funded plans may elect to subject to [cross-talk] upper payment limit, so they could choose on their own. So if you think about Microsoft, Boeing, Weyerhaeuser, one of those that has an employer-sponsored, self-funded plan in the state, they are allowed to be subject to it if they choose.

Douglas Barthold: Okay, thanks. Thanks. That is helpful. I do, and I have difficulty when we talk about this separating the criteria -- the AND criteria from the OR criteria, and so I think it would be very helpful if we could have that in writing as a summary that we have in front of us all the time because it can be tough to keep it all straight. And I do think -- and I will add that I don't know if that if we think that we need the lawyer's interpretation on that, then that would obviously be preferable. So, thanks.

Eileen Cody: [Indistinct] a question.

MaryAnne Lindeblad: Yeah, I was going to say there is another question [cross-talk] --

Mike Neuenschwander: The public, usually those would be reserved for public comment.

MaryAnne Lindeblad: Public comment? Okay.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: So we will vote on that one.

Hung Truong: I have a comment and a question. So, Ben and Matt, thanks for a comprehensive review of that. I concur with everything you said. Have you done work on how we set those upper limits yet? I know it's months and

years down the road, but just how would that look? I don't know if you have done some work on that.

Mike Neuenschwander: Yeah, we do. We do have sister white papers about upper payment limits and some considerations for upper payment limits. Obviously, there is less experience with this because Colorado was the first state to have said that they are going to set an upper payment limit, and they are still in the process. It is still in the process now, but we do use this same general framework of how you can think about the reasons drugs were unaffordable in the first place around therapeutic alternatives. You can think about reference pricing to other drugs in the same therapeutic -- all therapeutic alternatives of the drug. You can think about cost effectiveness analysis to the extent that your statute allows it. In many cases, cost effectiveness uses quality of life years as an outcome, and some states are not allowed to think about that type of literature, but other -- some countries, like Germany, do this type of comparative and cost effectiveness work without quality, so it's not that you have to consider those. Then you can think about what are the out-of-pocket costs, and are those informed at all based on the structure of the rebates? So in drugs, where there is high price and high rebates, setting up an upper payment limit could be an opportunity to bring down the cost that benchmark upon which out-of-pocket costs are charged, so if patients are paying 20%, or 25%, or 30% of the drug's cost, if the upper payment limit is a lot lower, then that might lower out-of-pocket costs. And then finally, obviously, the budget impact is thinking about -- based on the price, how is this going to be accessible to -- how is this going to be affordable to patients? How is it going to affect premiums? How's it going to affect whether plans restrict access, even once it's on the formulary? Right? So it's all interconnected. So anyway, we do have a white paper that walks through in more detail some of those considerations, but it follows a very similar framework to this one, but with maybe some more details about processes that are done here in the US and internationally to do that type of work. But with the exception being we just -- nobody has set an upper payment limit yet, and so I think it's very important to think about what are the consequences of a payment limit, how it's implemented, who it applies to, and all of that is going to determine how you go about doing that process.

Hung Truong: Yeah, I think just having that information helps us to do the work right now. I mean, it's like working your way backward a little bit. Just [cross-talk] --

Mike Neuenschwander: And Matt can make sure Michael has your -- Mike or Simon can share with you all the link to both of those white papers, so you can review them to learn more about what we say there.

Hung Truong: Great. Thank you.

Mike Neuenschwander: Do you have a comment?

Unknown male: Oh no, I just -- [cross-talk] --

Multiple Speakers: [Laughter] --

Mike Neuenschwander: [Cross-talk] Sorry, to hear that. [laughter]

MaryAnne Lindeblad: [Indistinct]. Any other questions? Anything else? Mike, anything?

Mike Neuenschwander: And so, one thing I just want to point out is, these are all going to be important decisions that we need to make because there are a lot of ways that we can tackle this, so PORTAL is outlining some of the things that we can consider. And so I think these are going to be some of our, our key conversations, as we are looking through. And Kelly will talk a little bit about more of this later here. But I think these are all going to be things of how do we want to define excess cost to patients, and what measures are we going to want to use? And so I think these are all important pieces of options that we have. And so as a Board, we then need to figure out which path we want to take and which metrics we want to use. So I think this will be good. And even to Doug's point of defining certain stuff. Right? We have defined drug in our WAC. We have also talked about our policies a little bit, about defining how we want to do things. So I think, really making sure we understand and clarify those definitions. If we have questions around them, it will be important.

Hung Truong: Mike, are there WACs similar from Washington to Colorado in some of the other states more for this work?

Mike Neuenschwander: Similar, yes. There are definitely differences, but we have looked at other states WAC to help inform our own. But then, of course, our own Legislation requires different things, and then we have gone through our own internal review process to help define or clarify certain things that we need to. So yes,

we have similar pieces within our administrative codes across the state, but they are different, very substantially different in other aspects as well.

Hung Truong: Yeah, I asked the question, but we don't need to invent this if the PORTAL is helping us, the criteria, I mean and probably help us reconcile what we need to know because if we are using that criteria, and it's recommended by PORTAL and it's, I mean, 90% is in agreement, I mean, the list is already there for us to look at, and everything else Colorado has done would be similar. So I mean, it's hard for me to see how we can deviate much from the other states, just to save some work.

MaryAnne Lindeblad: Well, I was going to say, I think also that paper, if you have had a chance to read that paper, the conducting the drug affordability review sounds really helpful, and I think the background on that paper will be really helpful in terms of guidance for us in terms of how we think about this.

Douglas Barthold: Yeah, I completely agree not reinventing the wheel and using these great resources that we have in the white papers. But I guess one thing I would say is I think there are some important differences in the laws, right? So, for instance, I know that our wholesale cost, whatever criteria, is $60,000, and I think Colorado's was $30,000, so we are going to give different lists of drugs to begin with. And then another thing is, again, back to my question about the list of payers for whom the upper payment limit applies. I don't know, but I think that varies across state, and so that could lead to big differences in how to make a decision.

Benjamin Rome: I will make just two other points here on that note, and I think we talked about this last time as well, but just as a reminder, there are many drugs that are going to be eligible. Even their strict thresholds, and your staff are helping me sort out which drugs are going to meet those statutory thresholds. But there is still going to be a long list, particularly at the beginning of this process. There are many drugs to choose from, so you do have to make some strategic decisions about where to start. And second is just one question around how do you start? Broad? Or do you start narrow within just particular conditions? And I think there are reasons to do both. But, for example, if you were to -- given that you are going to look at therapeutic alternatives -- I think that is specifically outlined in your statute -- if you select a bunch of drugs that are therapeutic alternatives to one another that treat the same condition, then you can -- do a comprehensive analysis that affects multiple drugs. Whereas, if you choose drugs from

diabetes and inflammatory conditions and multiple sclerosis and many other different diseases, then you have to think about everything. And you also have to think that, ultimately, if you go down the process of determining unaffordability and setting upper payment limits, how does it work to set the upper payment limit for one drug as opposed to many drugs together? And so there is maybe a strategic decision around priorities there. Because, again, you are going to have lots of folks who are eligible to proceed, and you have some factors that you have to think about when you decide whether to proceed. But within those, there is still going to be some [indistinct], so I think, a lot of latitude to make some of those decisions.

MaryAnne Lindeblad: Anything else? All right. We will go ahead onto our next item. But, again, I want to thank you. This was a great presentation. I really appreciate it, and I'm sure we will see you again.

Benjamin Rome: Sounds good. Thanks for having us. It's good to see everybody.

Douglas Barthold: Thanks, guys. Bye.

MaryAnne Lindeblad: So next agenda item, we will turn it over to Simon, Mike, and Kelly.

Simon Borumand: All right.

MaryAnne Lindeblad: Look at the Eligible Drug List Methodology Policy.

Simon Borumand: Yeah, so I think we will just talk about this a little bit. So we will be going -- oh, Doug, [indistinct].

Douglas Barthold: Sorry to interrupt, but I just wanted -- before you start on this, can you just clarify the difference between the next two items on the agenda? It looks so similar.

Mike Neuenschwander: Um, let me look at it quick.

Douglas Barthold: Yeah.

Mike Neuenschwander: One of them is going through the policies, and we are not going to go through them in detail. Those were sent out earlier, and they are posted on the website, but just introducing the concept behind why we are drafting a policy of how we are going about the -- any other drug list. And the next one

is presentation that gets into more detail of, okay, what are the actual buckets that the drugs are being classified into? How many drugs fall into those buckets? What's an example of how that is been calculated? So one is setting the scene, the other one is a little bit more detail.

Douglas Barthold: Okay, great. Thank you.

Mike Neuenschwander: Yeah. Thank you. Perfect, Simon. [Cross-talk] Yeah, exactly. So the first one here is just the policy, which is guiding how we are doing this. So we sent this out to the Board here previously. We have been discussing over the last couple of meetings of how we would be creating this drug list according to the various buckets and calculations that we are required to consider with the Legislation. And then the next one we will go into because at the end of the meeting last time before it was asked, can we see a more examples of how all this works and how the how the calculations play out? So we will talk a little bit more about that in a draft of what drugs we will be on or how many drugs we have in each category using this policy. The one thing I will note, so we gave the policy out for the quarter review previously. We did add just at the very end on Page #4 just a note on the methodology on why, for example, we were using the high dose and duration of therapy. So I guess, Board, did you have a chance to look over that? Did you have any questions on that? I can read through it if you want really quickly. It's not long.

MaryAnne Lindeblad: Questions?

Douglas Barthold: On the stuff that I liked the note. I was -- it answered my question about that exact topic. So a great note.

Mike Neuenschwander: Okay, perfect. And I guess, Ryan, did you have any other thoughts, comments on that?

Ryan Pistoresi: Nope. But apologies that the link in there did not come out. So we can always provide that as a separate URL, I guess, if you are interested.

MaryAnne Lindeblad: Yeah.

Mike Neuenschwander: Okay.

Douglas Barthold: Oh, I see. Yeah.

Simon Borumand: I didn't realize it didn't come out.

Mike Neuenschwander: Okay. So yeah, so that was just one of the things we wanted to explain the why we are doing what we are doing here on this. So that way we are clear and covering our bases in how we are moving forward. So any other questions on the policy?

Douglas Barthold: Um, definitely. I had some specific questions on specific items in it. I don't know if it would be better to provide that in writing as questions for each item or if we are going to go through that document.

Mike Neuenschwander: Oh, we can. We are here right now, so if you have questions, let's chat.

Douglas Barthold: Okay. And yeah, I mean, this is a public facing document. Right? This is going to be describing what we are doing?

Mike Neuenschwander: Yep.

Douglas Barthold: Okay. [Cross-talk] So I don't know if it's possible to share the document with everybody. Or I should do that?

Mike Neuenschwander: There we go. I think Simon is on it.

Douglas Barthold: Great. Okay. The first thing I noticed was in Item 2. So like the -- yeah, this one identifying -- up a little higher. There. The goal is to identify prescription drugs for affordability reviews. I think this is identifying prescription drugs that aren't eligible for affordability reviews. Is that correct?

Simon Borumand: Yes.

Mike Neuenschwander: Yes.

Douglas Barthold: I think we should say that because, otherwise, it seems like we are actually choosing the ones to do the affordability reviews on, or it could, anyway.

Mike Neuenschwander: Okay, excellent.

Douglas Barthold: My next question was on the same page in Item 1(a) there. So I haven't used the First Databank data before. That is a national level database of pricing information, is that right?

Mike Neuenschwander: Yes, that is correct.

Douglas Barthold: Is there any reason that we would expect any of the drug pricing information to vary across states? So, for instance, I don't actually know if the WAC can vary across states.

Ryan Pistoresi: It might, So this is Ryan Pistoresi. To my understanding of what not the WAC would be set for many of the wholesalers in the country, and then there might be different chargebacks or other discounts that happen between the sale between the manufacturer and wholesaler, but the WAC should be the same across the country and not different between states.

Douglas Barthold: Okay, great. That is perfect. The next item in 1(c) there. So this is actually -- Ben did a good job of answering this question for me before. In 1(c) I thought indication would be very important, but I agree that it makes sense to only break it down to that level when we have narrowed down the list a little further, so we need to worry about that. Okay. And let's see. Okay, on the next page, okay, in item e., so let's see -- so it says current WAC [indistinct] -- right. So the last sentence. NDCs with no price increase in this period will not be eligible for price increase calculations and review -- oh, no, sorry -- first sentence. Most recent WAC listed for NDCs that increased in price in the calendar year. Don't we need the WAC regardless of whether or not they increased in price? I'm not sure if I was misunderstanding that, but it seemed like we would need to define a current WAC even for those that did not increase in price.

Ryan Pistoresi: So Doug, I think that is captured in 1(b), where it says the initial WAC, so I think that that is where that is captured. And then e. is specific for calculating the price changes that occurred during the year.

Douglas Barthold: Okay, great. That makes sense. Um. Yeah, I think if you are [indistinct] question I asked, but your note clarified that, so that is great. Um, okay. So in item J there, so when we -- in the second sentence of that it talks about biosimilars can be eligible for review, even if their reference biologic is obsolete, expired, or withdrawn. And my question about that had to do with the fact that -- don't we -- are we defining -- our eligibility criteria for biosimilars is based on the comparison of their price with the reference product, correct?

Ryan Pistoresi: Yes.

Douglas Barthold: So in that case, how can we have a biosimilar be eligible? How can we compare their price to a reference product if the reference product is obsolete, expired, or withdrawn?

Ryan Pistoresi: That is a great question. So going back to 1., 2., it's the initial wholesale acquisition cost of that biosimilar when the biologic was out.

Douglas Barthold: And so we would still, let's say that it was in -- do we have a timespan for that? I mean, what if that was years ago that we made that comparison?

Ryan Pistoresi: I think that is how the RCW is written is that we just look at the initial wholesale acquisition cost.

Kelly Wu: Right. So the biosimilar could be like seven years old, and at the time, the reference biologic wasn't obsolete or withdrawn or expired yet, but then now it is, but the biosimilar is not obsolete, withdrawn, or expired.

Douglas Barthold: And so that would still be eligible, even if our comparison of price occurred seven years ago?

Kelly Wu: Yeah, well, in the bill says that the drug has to be on the market for at least seven years.

Douglas Barthold: Right. Okay. Um, okay, well, I mean, it seems like that is going to be a rare situation [indistinct] where you are going to capture any drugs, but I was just kind of surprised by that.

Hung Truong: Um, when would we be able to just review that product on its own ground and not necessarily need to reference it back to whatever the plan was? Or could we do that? Or do biosimilars always have to refer back to original brand product.

Ryan Pistoresi: So this is Ryan. So the way that the RCW is written is that it does say back to the reference biological product. So the way that we did our methodology is that we looked at what AMDA or supplemental BLA was tied to the originators in the purple book, so that way we could say that this product is a biosimilar to this approved to BLA.

Hung Truong: I guess my question would be, even compared to the reference product and the criteria we will find that the biosimilar is still high and unaffordable. I mean, wouldn't that stand on its own without needing to reference it back?

Ryan Pistoresi: In the case that the biologic does not meet the $60,000 threshold -- because that has that dollar threshold, and this is a percentage one -- there are cases in which a referenced biologic would not meet 1(a), but the biosimilar would meet the criteria, so there are [cross-talk] --

Hung Truong: [Cross-talk] still look at it.

Ryan Pistoresi: There are some, [cross-talk] and I think we may see some in the future.

Hung Truong: Yeah. I think that helps answer that question does it have to reference back if it is too far away, but -- on its own standing it's still extremely [cross-talk] high and unaffordable, and we have to have a mechanism to look at that as well.

Douglas Barthold: I see. Yeah, that makes sense. Actually, I was not thinking of how it could meet eligibility on item 1 alone. So okay, that is helpful. Okay, so if we scroll down into -- this is on Page 3 now. Yeah. So that first item I., there at the top, what was the rationale for choosing the highest age range? So it says multiple age ranges, testing types, disease durations. We just chose the highest. Either we think that is maybe going to be the most expensive? What is the rationale there?

Ryan Pistoresi: So this is Ryan. When we were looking at the different age ranges that were available, there were a lot of different ones in the pediatric and adolescents, and most of the highest ones were either 18 to 110 or some other age range that captured an adult population. It was also the most wide, and we felt that that one was the one that was the most inclusive of patients that would be using the drug. So even though it says here is the highest age range, when you have the data in front of you, you see that it does encompass pretty much everyone 18 to 65, or 18 to 110.

Douglas Barthold: I see. Yeah. I definitely agree with that rationale. We want the most commonly used type of course of treatment as part of our definition. So I guess my question would be, why wouldn't we say what you just said? As the most commonly used course of treatment among adults, or the most commonly used course of treatment rather than define it by the age range.

Ryan Pistoresi: So this is Ryan. I think the way that we set up the script because one specific NDC is going to have up to six or seven or eight different age ranges depending on what the drug is, like an antibiotic, so we just set the script to choose the adult one, which was the highest one.

Douglas Barthold: Okay. I mean, I guess. Yeah. I agree. Yeah, it reaches the same endpoint. Yeah, it was just the rationale to me wasn't as clear seeing it written as defined by the age range. But I don't think it's [cross-talk] --

Mike Neuenschwander: [Cross-talk] more in terms of for the data person pulling the data out of a program. So that way it's from [cross-talk] --

Douglas Barthold: Okay [cross-talk] --

Mike Neuenschwander: [cross-talk] -- that's how we can understand it.

Douglas Barthold: Okay. That sounds good. Um, and then in Item 3, there. Let me just -- trying to remember what I was thinking about here. The high dose -- so let's see. So if they have dosing data for both acute and chronic, the high dose per day for chronic or both acute and chronic will be utilized for the course of treatment. So I guess I don't understand that language there. Are you saying you use the -- oh, it's the highest of either chronic or acute and chronic? Is that right? I don't understand how that -- how we are defining the course of treatment, the dose.

Ryan Pistoresi: So this is Ryan. So for some of the drugs, they could be used for an acute situation, or they could be used for chronic. So what we decided is that we would look at the chronic phase for this, assuming that these people who may be using this prescription drug may be using it for that chronic condition, [cross-talk] and that is the way that we would calculate a course of treatment cost.

Kelly Wu: This is Kelly. So in the FTB for disease durations, it has the categories acute, chronic, and both acute and chronic, so I was trying to reflect that here. But, yeah, it's kind of confusing because of the way that wording is for the categorizations.

Douglas Barthold: So basically, you are just going to choose the highest of any of -- if it can be used for both, we are going to [indistinct] as we define high dose, we are

going to choose the highest that it can be -- for any of the options. Is that right?

Ryan Pistoresi: Yeah. And then [cross-talk] -- oh, go ahead, Kelly.

Kelly Wu: Oh, this is Kelly. I was just going to add that there actually is a category called both acute and chronic.

Douglas Barthold: Okay.

Kelly Wu: What I was trying to say here is if the drug has like chronic or the category of both acute and chronic for the dose, then we are going to use those.

Douglas Barthold: Okay.

Ryan Pistoresi: And I think an example that we looked at was for HIV medications, so post-exposure prophylaxis versus PrEP. So PEP is going to be a shorter duration, and that was labeled under the acute use, whereas PrEP or HIV treatment were chronic, and so we would look at that as the way to differentiate between acute and chronic use within this dataset.

Douglas Barthold: Okay. Great, thank you. That makes more sense now. And I think -- yeah, all my other comments and questions were related to that indication level thing, which we have already discussed. So that is it for me. Thank you very much for providing those details.

MaryAnne Lindeblad: Any other questions?

Eileen Cody: I just have [audio cuts out]. This is more just in general for when we are developing all of our policies. There is a -- I think that we have confusion of -- I have confusion -- when we say WAC because it's Wholesale Acquisition Cost [cross-talk] --

Ryan Pistoresi: [Cross-talk] No.

Eileen Cody: -- versus [cross-talk] --

Ryan Pistoresi: [Cross-talk] Washington Administrative Code [cross-talk] --

Multiple Speakers: [Cross-talk] --

MaryAnne Lindeblad: Yeah.

Eileen Cody: So I know you have it specifically in your -- you spell it out on the first time it's used, but I think maybe in the policies we are going to have to have something just generically to spell it out.

Hung Truong: Or a WAC price. [Cross-talk] --

Ryan Pistoresi: [Cross-talk] Yeah, WAC price, I think [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] or something [cross-talk] --

Eileen Cody: [Cross-talk] That would be good. [cross-talk] yeah because it was when he was asked a question, then I was wait a minute. [laughter] --

Ryan Pistoresi: Or we could use list price because I think in statute, they use wholesale acquisition costs throughout, [cross-talk] --

Eileen Cody: [Cross-talk] Yes.

Ryan Pistoresi: -- and so I think we can use a [cross-talk] --

Eileen Cody: [Cross-talk] I remember we had some difficulties in those discussions.

Ryan Pistoresi: Which we did, yes.

Hung Truong: We have to be [indistinct] a lot of prices [cross-talk] --

Ryan Pistoresi: [Cross-talk] Yeah.

Hung Truong: -- acquisition [cross-talk] --

Ryan Pistoresi: [Indistinct]. Yeah.

Eileen Cody: Yeah. So it is just as we go forward with policies trying to make sure we are clear on what we are talking about.

Mike Neuenschwander: We can do that.

Hung Truong: Right.

MaryAnne Lindeblad: How about a 5-minute break?

Mike Neuenschwander: [Cross-talk] You're the boss. [Cross-talk]

Ryan Pistoresi: Yeah.

MaryAnne Lindeblad: Yeah.

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: No votes. [Cross-talk] --

Eileen Cody: [Cross-talk] I thought we had to vote on this?

MaryAnne Lindeblad: No.

Mike Neuenschwander: That was next time.

MaryAnne Lindeblad: Next time.

Eileen Cody: Oh, it's next time. [Cross-talk] -

MaryAnne Lindeblad: [Cross-talk] Yeah. We'll vote [cross-talk] we'll vote in July.

Eileen Cody: All right, Mike.

MaryAnne Lindeblad: All right, so a 5-minute break. Get up and stretch our legs. [Indistinct] --

[break]

Multiple Speakers: [Cross-talk] [Indistinct].

MaryAnne Lindeblad: Are we ready to go? All right. And here I'm willing [indistinct] was. All right. Well, let's go ahead and get started, and Kelly.

Kelly Wu: Okay. Can everyone see my screen okay?

MaryAnne Lindeblad: Yes.

Mike Neuenschwander: Yep.

Eileen Cody: Yeah.

Kelly Wu: Okay, great. All right. So today I'm going to, as Mike mentioned, go over some examples that apply our methodology for identifying prescription drugs that are eligible for affordability review, and then I will also show the preliminary number of NDCs that we have identified as eligible for review for each section of the bill. Okay, so in this presentation, I will briefly go over the bill in the various ways a drug can be eligible for review. We will go over some examples for the calculations for each section of the bill, and I will show [audio cuts out] results, and then we will have some time for questions and discussion, and then I will share the next steps we are working towards. So this chart illustrates where we are in the affordability review process. So right now we are at the really broad end where we have identified eligible prescription drugs for review. And then as we move along in the process, the Board will eventually narrow down and choose which drugs the Board wants to perform affordability review on. So briefly, this part of the bill that lists the various criteria that make it prescription drug eligible for affordability review. And I know we have been through the methodology in great detail for each section, so this presentation will focus more on examples showing how we apply that methodology. All right. So I'm just going to go in the order of the bill. So first up, we have brand name drugs or biologic products that have a WAC of $60,000 or more per course of treatment lasting less than one-year. So to calculate this -- and you have seen this before, but just a refresher before we jump into examples -- we are using the First Databank dosing modules, which contain drug dosing data by age category. And these are the terms that I will be using throughout this section. So the term high dose refers to the dose we will be using for our course of treatment calculations, and it's the high dose per day of a drug. So, for example, maybe most people are prescribed 5 mg of a drug per day, but the drug can be prescribed to have 10 mg a day. So the high dose in this case would be 10 mg a day. And then the high duration of therapy means the high end in days of the recommended amount of time that drugs should be taken. So for example, some people might take an antibiotic for 10 days, but it can also be for certain conditions be taken for 21 days. So in this example, the high duration of therapy for this drug would be 21 days. Also, in some of the examples, you might see that the high duration of therapy is zero, and this means that the dose for that drug is a chronic dose, so we interpret that as the dose has to be taken daily, so for

365 days a year. Disease duration refers to the duration of the disease or health-related condition associated with that NDC. So as Doug asked before, this can be acute, chronic, or both acute and chronic. So, for example, antibiotics may be associated with an acute disease duration. Antiretrovirals may be associated with a chronic disease duration, like HIV, and then something for treating asthma could be associated with both acute and chronic disease durations. And then finally, maintenance in single dose referred to the types of drug doses. So maintenance dose is the amount of dose you would need to take to achieve a steady concentration of the drug in a system, and a single dose is the amount of one-time dose you will take.

MaryAnne Lindeblad: Kelly, Doug has his hand up.

Kelly Wu: Go ahead.

Douglas Barthold: Thanks. Yeah, just a quick question. Can you tell us what years of the FDB data you are using?

Kelly Wu: Um, so for this course of treatment, we are just pulling the most recent price that the drug has on file, but in other sections, we will be using a certain time period, which I will explain.

Douglas Barthold: Okay. So but I mean, in your overarching data set how far back does the data go, I mean? Or actually what -- and how recent and how far back does it go?

Kelly Wu: You mean like the FDB in general?

Douglas Barthold: Yeah.

Kelly Wu: So they only keep -- I forgot how many price histories -- but they, I guess, in the -- sorry, I muted myself -- but I guess in the interest of space they only keep a certain amount of price history. So if the drug is like 20 years old and it had a bunch of price changes, the FDB might not have all the prices for that drug. So I will need to look into exactly how many price histories they keep, but actually for price, we are using Meta Scan. And they also keep a limited amount of price history, but it's more than what the FDB keeps.

Douglas Barthold: Okay. So I guess it's going to go back a long way, but then how about -- and then how recent? What's the -- like, if there was a price change yesterday, we

wouldn't see it, but maybe we would see it if there was one three months ago. What's the?

Kelly Wu: Yeah, so I'm not sure about their refresh process for us, but for our drug review, we are looking at prices as of January 1, 2023. And I'm guessing that next year we will look at prices as of January 1, 2024.

Douglas Barthold: Okay, so that is like our data freezes on January 1 of last year, and we will do that every year.

Kelly Wu: Yeah.

Douglas Barthold: Okay, thanks.

Kelly Wu: All right. And, yeah, feel free to interrupt me if you need any clarifications or have questions. And then lastly, billing unit is the form of the drug, so it can be each milligram, milliliters or grams. Okay. So a quick summary of the methodology we are using to calculate the course of treatment, which you have seen in great detail in the past. So first, we deduplicated the data so that each NDC only has one dosing data record for calculation purposes because an NDC can have multiple dosing data for different age groups. After that, we multiplied the NDCs high dose by the high duration of therapy in days to get the number of NDC units using a year, and then we multiply that by the NDCs WAC unit price to get the cost of a course of treatment for one-year. And the goal of deduplication is to choose one dose per NDC to use for the calculation for the course of treatment, and we want to obtain the highest amount of an NDC someone could take, so this includes choosing the data for the highest age range and choosing the chronic and maintenance doses. So this is the formula that we are using to calculate the cost of a course of treatment. So we want to take the high dose per day and divide that by the strength of the NDC, so we know how much of the NDC the person is taking per day. And sometimes the units of the high dose per day and the NDC strength aren't the same, so we may need to multiply the high dose per day by conversion factor to get it into the same units as the NDC strength so we can actually do the division. And then next, we multiply that by the high duration of therapy in days that the NDC should be taken, and then we multiply that by the WAC unit price to get the cost of a course of treatment for a year. Okay, so let's jump into our example for calculating this. So for this example, we are going to look at data for Renvela, which is a drug that lowers the amount of phosphorus in the blood of patients receiving kidney dialysis. So after the

deduplication algorithm, we have that the high dose for Renvela showed here is for patients aged 65 to 110, and that dose is 14,000 mg per day. And so in the previous Board meeting, I talked about needing to do unit conversions for some of the NDCs in order to calculate the course of treatment costs, so I purposely chose this example where a unit conversion is involved. So here, if you look at the high dose unit description column, which is the second column from the left, and the NDC strength unit of measure column, which is the last column from the left, the units are different. So the high dose is in milligrams while the NDC strength unit is in grams, so you cannot divide these unless they are in the same units. So in order to calculate how much of an NDC is used per day, we need to convert the high dose from milligrams to grams so the units match. So that translates to multiplying the high dose per day, which is 14,000 x 0.001 because 1 mg is 0.001 grams. And then after we have converted the high dose per day to grams in the same units, we can divide that by the NDC strength. So after we do that, we can multiply that by 365, because it's a chronic medication dose, and then multiply that by the WAC unit price of $17.85, and that gives us the cost of $114,016.88 for a course of treatment. And so once again, after plugging numbers into our formula, we have that run Renvela cost $114,016.88 for a course of treatment for a year, and this exceeds the threshold of $60,000 for a year. All right, I will stop for a second and see if there are any questions on the example. All right. Hearing none, so I'm going to move on, but feel free to stop me if you want to come back to this. Okay, so moving on to the brand and biologics with a 15% or more increase over a 12-month period or a 50% or more increase over a three-year period. All right. So I think at the last meetings we talked about this. I didn't emphasize that we are only looking at NDCs for this section with an increase in the period between January 1, 2022 and January 1, 2023. So as it mentioned in the policy, if the NDC did not increase in this time period, then they won't be eligible for review for this section. So the term current WAC that I will be using this section refers to the NDCs WAC unit price from the most recent price increase between January 1, 2022 and January 1, 2023. In a one-year WAC will refer to the NDCs earliest -- WAC unit price in the immediately preceding 12-month period from the date that the current WAC was set. So if the NDC had no other price increases in that period, then we will use the NDC's price at the beginning of that period. So for example, this means if we are using the NDC's most recent increase that happens, say, in December 2022, and they had three other increases between December 2022 and December 2021, we are going to use the earliest increase in that period for the one-year WAC, and if the NDC had no increases other than their most recent increase that period, then we will use whatever their WAC was as of

December 2021 as the one-year WAC. I don't know if that made sense, but the example that I'm going to go through kind of contains the scenario so, hopefully, that will make it more clear. All right, so this is the example for calculating the one-year price increase. So we will subtract the one-year WAC from the current WAC and then divide by the one-year WAC. Okay, so this is the example for this calculation. So this data is for Lovaza, which is a drug used along with a low-fat and low-cholesterol diet to lower very high triglyceride or fat levels in adults. So this drug had a price increase in December 2022, which makes it eligible for review. It did not have a price increase in the immediately preceding 12-month period, which would have been between December 2, 2021 and December 2, 2022. So we are using its price as of the beginning of the 12-month period, which would be whatever its price was as of December 2, 2021 [audio cuts out] to be set on October 1, 2021. So plugging the numbers into our formula, the current WAC is $6.12. The one-year WAC is $3.30. So that means there was an 85.45% increase in the past 12 months. All right, so then that means that Lovaza exceeds the threshold of a 15% increase in a 12-month period and is eligible for review. Okay. So the methodology for calculating the three-year increase is really similar to the one-year, except we are looking at the immediately preceding three-years instead of 12-months from the date that the current WAC was set. So the formula is very similar, except now we are using the price from the immediately preceding three-year period instead of 12-months. So we are going to go back and look again at Lovaza, but this time we are looking at what the increase was in the immediately preceding three-years of its current WAC. So that three-year WAC in this case would be either the earliest price increase between December 2, 2019 and December 2, 2022, or if there was no other increase in that time period, the price of Lovaza as of December 2, 2019. And the three-year price for this drug happens to be the price on May 21, 2021. So even though this drug has been on the market for seven years, this price for May 2021 is the oldest price in the database. So I mentioned before that one of the limitations of our drug pricing databases is that it only keeps a certain amount of price histories, so for some drugs like this one that has been on the market for a while, it may have had a lot of price changes since then, so we won't have some of the older prices. So actually, here, we might be underestimating the increase because if we assume that drug prices increase over time if we looked at an even older price for this drug, it might have been even lower than the ones that in May 2021, and, therefore, the increase would have been bigger. And so, yeah, plugging in the numbers into our formula with what we have, the current WAC being $6.12 and the three-year WAC being $2.87, we get that Lovaza increase by 113.24%

in the immediately preceding three-years. And that means that Lovaza increased by roughly 86% in a one-year period, which is greater than the increase of 15%, and it also increased by 113.24% in a three-year period, so this is an example of a drug that exceeds both the one-year and three-year thresholds for review. Any questions about this section? All right. So moving on to an example of a biosimilar with an initial WAC not at least 15% lower than the reference biological product. And so we will calculate the increase using the price of the biosimilars earliest listed WAC unit price and comparing it to the price of its reference biologic at the time of the biosimilars earliest listed WAC unit price. And so the formula to calculate the increase will be the initial biosimilar WAC minus the reference biologic WAC divided by the reference biologic WAC. And so the data we are seeing here is for Truxima, and it's similar to Rituxan. I am just winging it with the pronunciations, and it's a prescription infusion for certain forms of cancer, rheumatoid arthritis, and blood vessel disorders. So the initial WAC for Truxima was $84.56, and this was set on November 9, 2019, and its referenced biologic, Rituxan, price as of that date was $93.95, which was set on July 1, 2018. And so I think that kind of speaks to what Doug brought up about how some of -- why some of the reference biologics may be expired or withdrawn or obsolete. So we are looking at data from 2018 and 2019 here, so it's possible that between then and now maybe -- well, I know Rituxan is probably still on the market, but, for example, Rituxan could have been expired, withdrawn, or obsolete right now. But it's biosimilar is still current. So plugging these numbers into our formula, we get that Truxima's price was only 9.99% lower than its referenced biologics price at the time it came onto the market. And so that means that it's not at least 15% lower, and this qualifies Truxima for review. All right. So finally, let's see some examples of calculating the WAC cost of a 30-day supply or less and an increase of 20% or more in the past 12 months for generics. Okay, so the steps identify generics that qualify for review are pretty similar to the course of treatment steps. So we will implement the same deduplication process, so we only have one dose per NDC for our calculations, then we will calculate the price increase of the generics over the past four months, and then we will only look at the generics that have a 200% or more increase, and then out of those we will calculate the number of NDC units used for a 30-day supply, and then we will multiply that by the WAC to get the cost of a 30-day supply. And we chose to do it in this order so we could kind of whittle down the NDCs as we go, but it doesn't have to be this order because the results would be the same because the NDCs have to meet both criteria to qualify for review. And then, yeah, it's just more helpful for us because we might need to do some manual review of the

unit conversion in case some of the unit conversions aren't as straightforward. And so this is the same deduplication algorithm for the course of treatment, so I will just gloss over this slide. And so to calculate the increase of 200% or more on the past 12 months, we are using the same formula as calculating the one-year increase and the three-year increase, so this is the same slide and same formula. All right. So to count once we get the NDCs with the 200% or more increase in the past 12 months, we move on to calculating the cost of a 30-day supply or less. So to calculate that, we are going to be looking at the high duration of therapy in days. So the high duration of therapy in days is greater than or equal to 30 days, we are going to multiply the NDC units used per day by 30 days, and then if the high duration of therapy is less than 30 days, we will use the exact number of days that it is. So this way we are accounting for the cost of a 30-day supply for NDCs that may be taken daily for chronic conditions because the high dose we multiplied by 30 to reflect that and also account for NDCs that aren't taking chronically, like antibiotics, because the high dose will be multiplied by whatever amount of days, say like 10 but you are supposed to take 4. And so this formula for calculating the cost of a generic whose high duration of therapy in days is greater than or equal to 30 is really similar to the formula for calculating the course of treatment, except we are cutting off the high duration of therapy at 30. And the formula for calculating the cost of a course of treatment when the high duration of therapy and days is less than 30 is exactly the same as the course of treatment formula you saw in the previous section. Okay. So the example I'm using here is data for primidone, which is an anticonvulsant used to treat seizures. So the current WAC was set on March 22, 2022, and then one-year WAC was set on September 1, 2010, so this is an example of a drug that didn't have an increase for a pretty long time. And so the price for primidone was $0.08 as of one-year prior to March 22, 2022, which is March 22, 2021 because the price hasn't changed since 2010. And so plugging in the numbers into our formula, we have that primidone increased by 200% in the preceding 12 months. So since primidone meets one of the thresholds for review, which is that increase by 200% or more, we move on to calculating how much it costs for a 30 day supply or less. So after we applied the deduplication algorithm, we are using the maintenance dose for ages 18 to 110 for this calculation. And the high duration of therapy in days is zero, which means that this information is for a chronic dose for 365 days, so this means we will use the formula where the high duration of therapy is greater than or equal to 30 days, and we will cut off the high duration of therapy at 30. So in this case, the units of the high dose and NDC strength are the same, so no unit conversions are needed. So

after plugging in the numbers, we get that the cost of a 30-day supply is $288. And so this means that primidone meets both criteria for review. So it increased by exactly 200% over a 12-month period, which is greater than -- which meets the 200% or more increase, and it also costs more than $100 for a 30-day supply or less. So this is the end of the example section. So I don't know if anyone has any questions. Or I can move on. All right. [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Questions? Any? It doesn't look like it.

Kelly Wu: Okay, sounds good. Well, there will be a question section at the end if anybody thinks of anything. All right. So finally, after getting everyone deeply, deeply acquainted with how you applied our methodology for each section of the bill, this is what we have all been waiting for, which is the number of NDCs that are eligible for review for each section of the bill. So I'm just going to let this sink in. And there are 455 distinct NDCs that are eligible for review, and I will talk more in our next steps about how these numbers may change primarily having to do with us looking at other eligible NDCs of the same labeler as the currently eligible NDCs.

Douglas Barthold: I just asked, do you happen to know what the total number of NDCs that you assessed?

Kelly Wu: Um, no, but I can look that up, and I can mention that next time.

Douglas Barthold: It's going to be like tens of thousands. Right?

Kelly Wu: Oh, yeah, definitely.

Douglas Barthold: Okay. Okay, great. This has been a really great presentation, and it looks like -- I think the methodology looks really good, so thanks.

Kelly Wu: Thanks. All right. So I guess I will move on from this table if everyone is done looking at it. Okay. So other than the next step slide coming up, this is pretty much the end of the presentation. And I know that was a lot of material to absorb, so if you have any further questions or things you want to discuss or for me to go over again, we can talk about that now. All right. Well, if you think of any [cross-talk] --

Douglas Barthold: Sorry.

Kelly Wu: Oh, go ahead.

Douglas Barthold: Yeah, I mean, going through this, one of the things that really sticks in my mind is -- all right, one of my biggest questions I have is how important is this high dose, high duration qualifier that we are applying when we select these drugs? I think that we will definitely want to know that for remember doing the prioritization for affordability review and then even possibly at the affordability review stage. You know, it's the type of -- I wonder about this type of situation where 0.01% of users have this high dose, high duration, and so then they are qualifying as eligible for affordability review. But we are missing like the 99.9% of users who have a much lower dose, much, much lower duration, and, therefore, it's not very expensive for, and so I just want to, I guess, if there is any way that -- I don't know if you think it would be helpful now, Kelly, as you are going through this process of applying the eligibility criteria to , I don't know, including your data set or flag things that you think would be helpful for assessing that going forward, assessing how sensitive this step is to that high dose, high duration qualifier. Does that make sense?

Kelly Wu: Yeah. And I think Ryan and Donna can speak more to this as well. But I know in the affordability review process, we are going to look at utilization, so that will tell us how many people are using this dose, and maybe we will look at how many people are using other doses.

Douglas Barthold: Yeah. And then also, I mean, we may -- we might also be missing, let's say that the 99.9% of people who are using a lower dose, that also would qualify for affordability review. We might then see that the utilization at the high dose, high duration is very low and potentially miss a large number people who are using at a lower-dose, lower-duration, but still have quite an affordably. Does that make sense?

Kelly Wu: Yeah, that makes sense.

Ryan Pistoresi: Yeah. I was [cross-talk] --

Kelly Wu: Yeah.

Ryan Pistoresi: Yeah, I was going to say -- yeah, this is Ryan. So I think what we are looking at is in the statute it just says here are the thresholds for you to determine what is going to be part of the affordability review, and then during that

affordability review, you are going to get into a lot of that information about are there people below that high dose that still have affordability issues. Right? Because as you saw from the PORTAL presentation today, you are going to be looking at some of that state budget impact or the patient out-of-pocket cost, or the therapeutic alternatives. Right? And so you'll start to get a better sense of what the scope of the affordability challenge is in that population really more at that time. But because at this time we are looking at what qualifies or what could meet these thresholds, we aren't able to get into that level of detail yet.

Douglas Barthold: Okay, sounds good.

Hung Truong: And I think this is how I think we are going to look at all of it, the high dose, the maintenance, and so it's just whatever makes the most sense that would work for that NDC. I think high duration, I think about gene therapy. It's a one-time use, or it is just one episode, and it can be extremely costly. Right? And so, I think that it's a method to capture those. It's the one-time, one-time cure. I think about the Hep C back in 2013 when it came out as a three-month therapy, but it was $100,000. And so just capturing those.

Eileen Cody: And so I just have a question that I'm trying to get my pea brain to try and correlate. So #1, with the numbers that are there, so then 1(a) versus 1(b), or are there some of the B's in -- are they separate, or is it it's either/or? I'm just trying -- it's because it's -- I know the language says "or", so that is why I was trying to [cross-talk] --

Mike Neuenschwander: [Cross-talk] So are there duplicate drugs [cross-talk] --

Eileen Cody: [Cross-talk] Right. [Cross-talk] --

Mike Neuenschwander: [Cross-talk] in the two categories? [Cross-talk] --

Eileen Cody: [Cross-talk] Yeah. In other words, drug A brand drug A could be over $60,000 and haven't had a 50% increase. So would it -- do we -- have we done any identification that way? So the drug would show up at both points? That's my question, I guess.

Ryan Pistoresi: So this is Ryan. And I think when I was looking at this I did them independently, so I did not verify whether there was a crossover for the

brands. But that would be worth looking at. Right? Because I remember they were two separate files. [Cross-talk] --

Eileen Cody: [Cross-talk] Oh, that's right. [Cross-talk] --

Ryan Pistoresi: [Cross-talk] And I didn't actually look at, okay, well, this list is this drug, and this list are these drugs, but that is something we can do.

Eileen Cody: Okay.

Kelly Wu: Yeah, that is a great question. So the way we pull this data, we just went one section at a time. We didn't say if this drug is in this section, it's excluded from that section or anything like that. So yeah, there is definitely overlapping drugs that overlap the sections.

Eileen Cody: But when we start wanting to choose drugs to review, we might want to see if the drug shows up in more than [cross-talk] --

Ryan Pistoresi: [Cross-talk] Right. That's a good point.

Eileen Cody: The trifecta.

Multiple Speakers: [laughter]

Kelly Wu: All right. Well, if there is nothing else, then I will move on to the next step slide. And feel free to -- yeah, reach out to me if you have more questions. And so, as I mentioned before, we not only want to look at eligible NDCs that we identified in the table I showed, but if we select an NDC for review, we would want to look at the other NDCs that are of the same labeler, brand name, active ingredient in formulation as that eligible NDC, just to see, um, yeah, just [audio cuts out]. So as we move into the affordability review phase, we are going to identify these other NDCs related to the currently eligible NDCs. And then in the next presentation -- in this meeting, I will give a brief overview of what is coming next, which is developing a methodology for selecting the eligible drugs for affordability review. And that is the end of this presentation.

MaryAnne Lindeblad: Any more questions?

Douglas Barthold: Yes, so just a quick one. In that first bullet of next steps, is that suggesting that we could add other NDCs to our list of eligible drugs aside from the ones that you identified with your process?

Ryan Pistoresi: So, Doug, yes. So when we were doing our eligibility review, we do see that certain drugs will have various kind of subproducts in them. So I think a good example is Humira, where the Humira has a Crohn's Disease Starter Kit. And so as we are thinking about doing the affordability review, we have identified that Humira NDCs meet that threshold, and as we are looking at the utilization and the cost across all of the drugs of Humira, that we would identify those NDCs and make sure that they were part of that because we don't necessarily say that we would just be looking at one specific NDC of Humira only, we would be looking at all of the NDCs of Humira for doing that utilization review and giving you a full, broader scope of what the drug's impact is on patients' affordability.

Douglas Barthold: Okay, great. Well, that is very helpful. I'm glad we are doing that. That wasn't clear to me until just now that we could. I thought we could only look at NDCs that fell into one of those three categories.

Ryan Pistoresi: Right. So I think for an example, someone would start off on that Crohn's Disease Starter Kit for their first fill and then move into the maintenance dose, and then you [cross-talk] will be at the 40, or the 80, or whatever they need to control their disease. So we would potentially miss those people using that Crohn's Disease Starter Kit [cross-talk] because it's a one-time, it doesn't meet that $60,000 because it's just used once, but we will want to include that because we know that a patient would potentially start on that NDC and then move to a different NDC but for the same drug.

Douglas Barthold: Okay. Sounds good.

Hung Truong: Or a different formulation [cross-talk] --

Ryan Pistoresi: [Cross-talk] Or a different formulation.

Hung Truong: Yeah.

Ryan Pistoresi: Exactly. Yep. The CF is a good example.

MaryAnne Lindeblad: All right. So we are ready to move on. Kelly, your last presentation.

Kelly Wu: Oh, sorry, I was muted. Yeah, sounds good. Let me just reshare my screen. Okay. So we wanted to give the Board a brief preview of the next steps of the affordability review process. And so some of this material was discussed in detail by PORTAL earlier today, which is great because they are the subject matters in these areas. So hopefully some of this will be familiar, and you will hopefully already maybe have some ideas about how you want to approach this process. So I will talk about what the bill says about selecting drugs for affordability views. I will go over at a high level what the data measures the bill says that we have to consider when selecting drugs for an affordability review as well as some additional data measures that the Board could consider. I will bring up some discussion points and things to think about as we move forward with this process, and I anticipate we might spend a bit of time on this section. And then I will wrap it up with what the next steps are, and then we can have some additional time for questions and discussion if needed. All right. So this is the part of a process for the affordability review that this presentation will cover. So the last presentation covered the drugs that were eligible for affordability review, and this presentation will talk about the process of selecting drugs out of those lists to conduct affordability reviews on. All right. So I am going to start off with establishing what the bill says about selecting drugs for affordability review. So the bill says that when deciding whether to conduct a review, the Board needs to consider the following three things, which are the class of the prescription drug and whether it has any other therapeutic equivalents currently on the market. The Board needs to consider input from relevant advisory groups, and the Board needs to consider the average patient's out-of-pocket costs for the drug. So out-of-pocket costs are costs that aren't reimbursed by an insurance plan. So this could be deductibles, coinsurance, or copayments for covered services that aren't covered. And so the bill says that these three things need to be considered, but the Board can definitely consider more than that, which I will go through in the next few slides. And also, relevant advisory groups refer to RCW 70.405.20, and that says that the Board needs to establish advisory groups consisting of relevant stakeholders, which includes but is not limited to patients and patient advocates for the condition treated by the drug in one member who is a representative of the prescription drug industry. I see someone has their hand up.

Douglas Barthold: Yeah, thanks. I just want to clarify the language of "therapeutically equivalent." I think in PORTAL's presentation they had been using "therapeutic alternative," and then discuss how there is the big difference

between those. And so, I guess what is this? I guess we want to be clear about what we are saying here, and so is this the exact language equivalent?

Kelly Wu: [Cross-talk] Yes.

Ryan Pistoresi: [Cross-talk] Yes, this is the exact language equivalent. It does have therapeutic equivalents in this step. It does list therapeutic alternatives later on in the RCW, but for what this is, this is word for word from the RCW.

Douglas Barthold: Okay. So is it that we are looking at the existence of therapeutic alternatives as relative -- excuse me -- relevant when we are doing an affordability review? But this stage deciding whether to conduct its therapeutic equivalence that matters. Is that right?

Kelly Wu: So I will go into it and then [audio cuts out] --

Douglas Barthold: Okay.

Kelly Wu: -- consider, but the Board can also consider other things. So also therapeutic alternatives. So this is just like the three things that you must consider, but you can also consider [cross-talk] other things if you want.

Douglas Barthold: Okay, thanks.

Kelly Wu: Sure. So I'm not sure if everyone knows what a therapeutic equivalent is, so I'm just going to read off the definition, which is "a drug that contains the same active ingredients, dosage form, route of administration, and strength as the original drug, with the expectation that it will produce the same clinical effect and safety profile as the original drug. And then also, the Board can choose up to 24 drugs per year to review. So how many drugs you are interested in reviewing is something to keep in mind as well as we move through the process. Okay, so now that we have established the three measures that the Board must take into consideration, let's talk about other data measures the Board could consider. So this is an illustration of the three measures in the Board -- in the bill that the Board must consider. But the Board can also consider other data measures that they think are important. All right. So here's a diagram showing the data measures that the bill says the Board must consider when choosing drugs for affordability review. And as I mentioned, there are a whole host of other data measures that the Board can consider. And, in fact, the bill is a bunch of them under what must be

considered when actually conducting the affordability review, but they are also data measures that the Board can use when selecting the drugs for affordability review, as well. So I thought it would be great to start us off with these choices. So you can see on the bottom right I have two red light bulbs, so this is where we are open to your ideas and input because these two data measures are pretty broad. So one of them is any other information the drug manufacturer or other relevant entity chooses to provide, and the other is any other relevant factors determined by the Board. So I'm just throwing this out there as something you can think about. Yeah, and solicit ideas for any additional data measures you think should be considered that is not already on here. Next meeting, we will go into these data measures in more detail and talk about the feasibility of pulling the data for them and from the data source that we have as well as how they would theoretically be calculated. So at the moment, we aren't committed to using all of these. Right now, these are just potential options for you to choose from, and we are happy to take your ideas on what else should be considered. So this is something we are also going to talk about more on a later discussion slide. But yeah, feel free to interrupt me if you have any ideas.

Douglas Barthold: Yeah. Sorry to belabor this, but I thought that on this slide and on your prior slide we are now using alternative as a non-equivalent, and I thought it said -- and I thought Slide 5 said we must consider therapeutic equivalence, and now here, we are saying we must consider therapeutic alternatives? Is that [cross-talk] --

Kelly Wu: [Cross-talk] So that's a good point. [cross-talk] --

Donna Sullivan: [Cross-talk] So, Doug, let me [cross-talk] --

Kelly Wu: [Cross-talk] I need to [cross-talk] --

Donna Sullivan: [Cross-talk] Can I jump? I'm sorry, Kelly, I just want to jump in here. So when we are deciding to do a review on a drug, we must look at if there is a therapeutic equivalent. Once we have decided to do an affordability review and we start conducting the affordability review, we then have to consider therapeutic alternatives.

Douglas Barthold: Got it. Okay. Yeah, so I think that in the previous slide, Slide #7 is a little misleading, just because it -- and I don't know if the slides are going to public, but the, um -- because that's -- I mean, it says that we are deciding whether to

conduct review and use, and it says must consider -- shall consider alternatives. And so, I don't know. For my reference, it would be helpful to just -- make that distinction clear going forward. But anyway, sorry. Sorry to stay on this point any longer. So thanks for your explanation. Yeah.

Kelly Wu: Thanks, Doug.

Douglas Barthold: Yeah.

Kelly Wu: That is a really good point. It definitely should be therapeutically equivalent because that is a bill language, and I might have got confused on [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah, this one. [cross-talk] Yeah. [cross-talk] --

Kelly Wu: [Cross-talk] Yeah, but thanks for pointing that out.

Douglas Barthold: Yeah, okay.

Kelly Wu: All right. So here is a brief overview of the different data sources we have at our disposal to pull data from for the measures that we want to consider when choosing drugs for affordability review. And in the next Board meeting presentation, we will have more detail about the pros and cons of each as well as the feasibility of calculating the various data measures that are shown in the previous slide, but I just want to introduce you to the data sources that we have. And one of the most important data sources to us is the Washington State All Payer Claims Database (APCD). So this data set contains eligibility, medical, dental, and pharmacy claims for about 70% of the total Washington state population, and the data is collected from public, so like Medicare, Medicaid, Public Employees Benefits Board, commercial plans, and self-funded plans that can submit data on a voluntary basis. So this is going to be a great resource for us to look at prescription drug utilization and patient out-of-pocket costs. And also, as I mentioned in the previous slide, the Board can also ask drug manufacturers for data. So we have that as a potential source of information as well, but it will probably not be as easily accessible like the other data sets shown here, since they will probably be involved with a process to decide what we want and how you want it to be submitted. And we also have to keep in contact with the manufacturers and keep on top of the whole process. And same thing with the pharmacy benefits manager data. So if we want to request data from these two sources, we will need to think

thoroughly about what exactly we want to request and be really detailed. The bottom two data sources have already been used for creating the list of eligible drugs. So these are the two commercial pricing databases, FDB and Medi Span. So they do contain a lot of overlapping information, which you can tell, but they do each have some data that the other doesn't [audio cuts out] or drug price history than FDB, and FDB has information on market entry dates for drugs while Medi Span does not. All right. So this is the part of the presentation that I am hoping the Board will chew on until the next meeting. So as we go into the process of selecting drugs for affordability view, I think PORTAL also mentioned this, that you want to think also about the big picture about what your goal is, and that will also help you in choosing what data measures you want to use. So the first three points listed here: 1.) What is your definition of affordable? 2.) Who should the drugs be affordable for? And 3.) What do you want the affordability review to address? I think PORTAL has covered this really well in their presentation and also in the white paper that they linked. so I'm not going to repeat all their points again, but thinking about that may help you when it comes to choosing what data measures you want to look at and determining which data measures are more important to you than others. [audio cuts out] And I don't know if anyone else on the HCA team wants to add in anything.

Mike Neuenschwander: I mean, I guess I would say, yeah, if the Board can think about these, and when you are reading the PORTAL white paper and going over the presentation, where it's asking -- for example, defining excess cost to patients, and it's talking about some of the ways they can do that. Really think about how you want to do that, because a lot of these decisions are going to be determined -- you know, which way do you want to go in terms of how we are going to prioritize some of this data, or who we are going to be looking at, or how we are going to be defining certain things. So, yeah, I think like Kelly was saying, these are some things that if you can come back to the next Board meeting with some of your own direction of, okay, this is what I think I want to do, and we could talk about that. That will be good.

Kelly Wu: Thanks, Mike. Yeah. Hopefully, the Board will have some good information to go on and have some more ideas on what direction they want to take in the next meeting. And for data considerations, I know most of us just saw the potential data measures for the first time today, but between this meeting and next, something to think about is whether there are certain data measures that you think are more important than others when selecting drugs for review. Are there any data measures we haven't mentioned yet that

you would be interested in looking at? And do you have a strong interest or preference for any specific data measures? So again, I want to emphasize these are things we want to think about until the next meeting, but we don't expect you to have answers right away, but thinking about it will help us move forward with the next steps. So just a brief overview into what we think will. What we want to happen next is, we want the Board to choose the data measures they want to use, and then eventually we will do some sort of ranking exercise, where the Board will rank the data measures that they think are most important. And then we will try to work out a system to assign weights to various data measures based on importance that the Board ranked them as, and then we will use those two as a formula to select drugs for affordability review. [Cross-talk] But we will go into that in the next meetings in more detail.

Mike Neuenschwander: Yeah. And Kelly, along with that -- and as we are thinking about these measures to remember that this is a funnel. Right? So our first methodology is getting this drug list. Right? Where we have those numbers that we showed on, and here is the amount of drugs for each of these different categories. This next one is, okay, how do we want to select this down? So when we are choosing these data points, it doesn't necessarily mean we want to look at every single thing. Well, in fact, we definitely don't want to look at every single thing in this next phase. This is what are the key points that are going to help be out of this list of about 400 and something drugs. Right? How can I whittle this down? What are the key points that will help whittle this down to 2 or 5 or 10, or whatever we are going to be doing? And then we can think about more of the detailed points for the actual drug review, where we really go into the nitty gritty. So as you are thinking about these data and what we want to do in terms of selection, keep that in mind that this is a part of a funnel. So what are the key pieces that are going to help us select that number? And then, of course, then the other thing is, what number do we want to select? We can do up to 24 for our first year. I think that is a lot. So Colorado did five for another example, so also thinking about that number as well in terms of as we are starting to pick out how we want to select these and what we are going to select. I think that is important. And, Doug, you have your hand up.

Douglas Barthold: Yep, thanks. Yeah, I love these questions. Very interesting. Looking forward to thinking about these. And also, I'm very excited about the -- I like the ranking of different measures and the weighting. I think that is an excellent approach. I'm excited about doing that. As I start to chew on these questions,

it brings me back to the upper payment limits and for whom they apply. I think that is really important because as we -- you know, it's one thing to just kind of answer these questions in a normative sense and say what is my overarching goal or overarching definition of affordability and other things? But it's another thing to think practically about what this Board can do in terms of setting upper payment limits and for whom that applies and then define then answering these questions in the context of the actual policy mechanism that we had in front of us to make a difference with. And so I guess this is why -- the reason I mentioned is because I really want to get that hammered out, a detailed list of plans within the state. Yes and no, does the upper payment limit apply? You know, it would be great if that was an exhaustive list of every insurer in the state because that way, at least for me, I know that that will help me think about these measures and these goals and these questions. So I would be grateful if you get that. So, thanks.

Kelly Wu: Any other questions or comments?

Eileen Cody: I just have one. I'm trying to figure out how to raise -- uh, I guess it's something I'm just interested in if we would look at this whether it comes into the duration of therapy, or the amount of [audio cuts out] our state had. I mean there are differences between states of diseases, so I'm just curious if there is at any point because it would go into the health system cost or how it affects the health system. Because we have more MS. I just happen to know that in this state than say, New Mexico. You know, there is a band across the northern states. So -- and God knows the drugs are expensive for that. So I guess that's -- is there some way that we are going to be able to see or weigh in these m -- [indistinct]? I'm just trying to figure out where that fits in on the measures? Or I mean, I guess probably we are not as obese as the southern states would be the opposite thing, so we don't -- wouldn't be spending as much in that regard. So I guess, just like a comparison of whether it is as big of a problem that drugs or the affordability question for as many people in the state. I am just trying to figure out where we would fit that in or how it fits in.

Ryan Pistoresi: So this is Ryan. I think we will get into that with the All Payer Claims Database because the All Payer Claims Database will let us see what percentage of our population may be using these different MS drugs, or what may be using the different obesity drugs, assuming they meet the criteria. So I think once we get to that All Payer Claims Database, we will start to see that a little bit more that [indistinct]. But at least at this phase, we are just looking

at what is a theoretical Washingtonian using this drug, and would that person using this drug at this dose face an affordability challenge? But then after that, now, we are starting to get more into the details of who is using it and what populations. [Cross-talk]

Eileen Cody: [Cross-talk] And how it affects the system.

Ryan Pistoresi: Exactly.

Hung Truong: I think go with Ryan. I think we have to just look at this objectively. Right? The numbers tell us exactly what that is. I think when we look at the disease state, we just hear a lot from each society of claiming that this it is important and so forth because [indistinct] I think there is always the discussion of in the Northwest the MS rate is much higher. I actually would like to see the data on [cross-talk] for that --

Multiple Speakers: [Cross-talk] [indistinct] --

Hung Truong: Yeah, I used to work with a neurologist that is the top of her work [indistinct]. She is, like, we don't know why. Right? It could be the sun. It could be lack of vitamin D. I don't know, but it is just looking at the [indistinct] data to tell us a lot.

Eileen Cody: Well, yeah. I'm just thinking about public [indistinct]. You know? Whether we need to bring some of our public health data into it. That was what I was trying to think about was obesity and tobacco. We don't smoke as much and all that because of different things that [cross-talk] so that would come under a yes when we get into the system evaluation.

Kelly Wu: Are you thinking about it that way more to look at how you would select drugs to review?

Eileen Cody: Yeah, kind of.

Kelly Wu: Because it [indistinct] could be more meaningful to Washington?

Eileen Cody: Right. Correct. Yeah.

Kelly Wu: All right.

Eileen Cody: Doug has got his hand up.

MaryAnne Lindeblad: Oh, does Doug got it up?

Douglas Barthold: Yeah, I totally agree with Eileen that we want -- we care about what that drugs that are important to Washingtonians, and I think that Ryan spelled it out, that the All Payer Claims Database will allow us to see that. I also think that just going back to which types of plans we can regulate question, which I know you are probably getting bored of me talking about this -- but let's just imagine that everyone -- no. Let's say 99% of people with MS in Washington have a type of plan that we can't regulate, then would it be worth it for us to prioritize those drugs? Maybe not. Alternatively maybe we can regulate, maybe, the plans that we can regulate include a lot of people who have -- I don't know -- some condition that is really common, and maybe we -- but it wouldn't rise to the top, otherwise, if we looked at all plans together. So that is why I think it's important to consider who is in these plans, which plans we can regulate, and who is in those plans.

Hung Truong: Oh, and then to add to that, the socioeconomic portion of this because we can see what's eligible, but then what percentage of the population needs these drugs but can't afford it, so they are not on it. So it doesn't look like on a total claim data you are not going to see a high amount of it just because people can't afford to get on. But when you look at the disease itself, I mean, you might have a fairly high number of people that is beating it.

Kelly Wu: Other questions, comments?

MaryAnne Lindeblad: We're ready for [indistinct] public comment at this point.

Kelly Wu: I'm sorry, I have one more slide.

MaryAnne Lindeblad: Oh, you do. [laughter] I'm sorry. I just went right over that.

Mike Neuenschwander: Good job for keeping us on track, Kelly.

MaryAnne Lindeblad: Yeah.

Kelly Wu: [Laugh] All right, so really quickly the next steps as we move along in the process. As I mentioned, in the next meeting we will dive into deeper detail on the potential data measures. And in the coming meetings, the Board will

be choosing which data measures they want to use to select the drugs for affordability view, and then the Board will also be developing the methodology. So as I mentioned, the whole ranking and weighting thing based on information from these data measures and how they will be used to select drugs for affordability view. And then we heard your idea from last time. We will be creating a dashboard similar to Colorado's that shows the eligible drugs and the data measures that the Board chooses. All right, yeah. So that is it for me, and we can move on to public comment.

Douglas Barthold: I have one other thing that I just wanted to mention [cross-talk] as we go forward. And when do you anticipate that you'll, I think the selection of therapeutic alternatives will be important, and we know that will be difficult. Is that -- are we there? Is that part of this next step for the selection or the selection of drugs for affordability review? Or is that part of the affordability review? I can't remember.

Mike Neuenschwander: When we are doing the affordability review, that is one of the things that we need to consider.

Douglas Barthold: Okay.

Mike Neuenschwander: Or no, for the selection of the drug.

Ryan Pistoresi: Yes.

Mike Neuenschwander: Yes, for the selection of the drug.

Ryan Pistoresi: It is the equivalent.

Mike Neuenschwander: But we are not going to be selecting the drug for a while.

Douglas Barthold: Okay. I just wanted to point out there is some modern academic literature on exactly that topic, the selection. It is defining therapeutic alternatives. I like looking at it in the context of the Inflation Reduction Act. And so in the same way that the portal has those white papers that we can follow for a lot of this stuff -- for a lot of these methodological issues. I have some papers that I would recommend first for that step. So whenever you are ready, I can send them over.

MaryAnne Lindeblad: That would be great.

Douglas Barthold: Yeah.

MaryAnne Lindeblad: Has anyone signed up?

Mike Neuenschwander: I don't see [audio cuts out].

Douglas Barthold: I do see some other raised hands in the Zoom.

MaryAnne Lindeblad: Yeah.

Mike Neuenschwander: Yeah. So -- I will open up a timer, and then we can maybe start with the folks in the room and then move online. So in the room, there was Curtis. Right?

Curtis Knapp: Ready? Thank you, Madam Chair, and Board Members. I'm Curtis Knapp with Life Science Washington. We represent the full continuum of organizations that help deliver new therapies to Washington state residents, and that includes local bio techs led by scientists, doctors, and entrepreneurs, who spent upwards of a decade and hundreds of millions of dollars to develop a new therapy without bringing in revenue, academics, nonprofit research institutes that conduct clinical trials and companies that manufacture drugs right here in Washington state, and, of course, our leading cancer centers that provide top tier cancer care to Washington residents. And all of this has allowed our state to become a top 10 destination for life science innovation, and we are really proud of that. And that has made us the leader in next generation therapies like gene and cell therapy. And we have seen how in other states they are struggling with some unanswered questions about how upper payment limits are going to maintain access for patients. We have seen states select a drug only to reverse course once patients have pointed out that would cause them to lose access to important medicines. Oncologists have testified that upper payment limits could force them to use less effective, more toxic medicines, and that just increases hospitalization costs. We have seen pharmacists note how upper payment limit set prices for [indistinct] purchasers but not manufacturers. Risk and pharmacists and hospitals' ability to provide important medications. And one of our member companies modeled a theoretical upper payment limit on a cancer therapy developed, invented, and manufactured right here in Washington State, and they [indistinct] that that could cause him to have to pull it from the Washington market due to national supply chain dynamics. And as we all

know, as you all know, the realities of pricing are complex, and each step of the supply chain affects the treatment costs. So we implore you to consider decisions by PBMs, pharmacists, insurers, hospitals, on the availability of medicine to a patient. And that is important because payments to those entities are often greater than payments to the entity that actually invented that medicine. And recalling back to the PORTAL presentation, we also encouraged the Board to articulate the primary purpose of the PDAB. Is it to manage patient costs to help the health system save money, or something else? And so to be effective, we encourage advisory Boards to move voices of those who have experience in that complexity of pricing. And although we know the industry is limited to one member, we encourage collaboration and creativity to maximize industry input. And importantly, if affordability reviews should seek to directly lower cost to patients taking [indistinct], I mean the bottom line for us as Life Science Washingtonians, we want to make sure that local companies can continue delivering innovative medicines to patients invented right here and used by residents who are here. Perfect timing. [laughter]

MaryAnne Lindeblad: Thank you [cross-talk] --

Mike Neuenschwander: Is there anyone else in the room who wants to speak? No? Okay, then we will go [indistinct]. I'm just going down the list in the order that it was presented to Dharia McGrew. I will unmute you, and then we'll get a [cough] timer.

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

Mike Neuenschwander: [Cross-talk] Yep.

MaryAnne Lindeblad: [Cross-talk] Yep.

Mike Neuenschwander: Go ahead.

Dharia McGrew: Awesome. Thank you so much. Dharia McGrew on behalf of the Pharmaceutical Research and Manufacturers of America (PHRMA). Thank you for the deep discussion today and all the incredible staff work that has gone into this so far and thank you also for some of the additional descriptions and clarifications that have been added to your work in the last couple of iterations. Given the breadth and detail of today's meeting materials, we wanted to take time to write in depth feedback, so we will have

not submitted a letter for this meeting yet, but we will be submitting written comments in the near future. Additionally, it is much easier for stakeholders to provide constructive feedback on written policy as you have begun to put this out in written policy rather than slide deck presentations and ask that you continue to publish this as written policy as you move along the process. At a high level, there are a couple of things I want to point out. Today, there are still inconsistencies in how you are identifying drugs at different steps. For example, you say eligible --- a drug is a distinct NDC, but then in the very next line you say when it comes to seven years on the market, it means a drug ingredient that has been on the market for seven years. And later, I think I believe you have proposed rolling up multiple drugs in a class into a single drug. So these are -- all of these are inconsistent with each other, and we would urge you to reconcile these in a consistent definition of drug throughout your process. As you move into your identification of specific eligible drugs and publication of that, I want to reiterate previous requests that you build into your policies a timeline for stakeholders to provide feedback or questions about the data. This is complex, detailed, large, datasets here, and we have seen in other states there have been errors in the data that later need to be corrected, and sometimes they have to go back several steps if it's not caught in the first few rounds. So we ask that you publish these materials. Thank you for saying there would be a dashboard. Appreciate that. We ask that you publish these materials in a time that is sufficient for manufacturers to review and provide feedback before any votes are taken. We will have more detailed comments forthcoming, as I said, and again, thank you. I want to commend you for considered and detailed conversations at these meetings as you continue to do this work. Thank you.

MaryAnne Lindeblad: Thank you. Do we have others? One more?

Mike Neuenschwander: Yeah. Okay. I see. I unmuted you [indistinct] --

Elyette Weinstein: Did you folks want me to speak? [laughter]

Mike Neuenschwander: Um, wait, it looks like you had your [cross-talk] --

Eileen Cody: Do you want to speak?

Mike Neuenschwander: It looks like you had your hand raised. You don't have to speak, but I just want to give you an opportunity. That's why you raised your hand.

Elyette Weinstein: Okay. I wrote my question. Does this -- I'm a retired employee, state employee, and I'm a PEBB Member. Does this Board have jurisdiction over PEBB, retiree UMP, and Medicare Supplement Plan F and G? It's a rather simple question, but I'm not clear.

Ryan Pistoresi: So, Elyette, thank you for the question. This is Ryan. We will do some research and see exactly how the upper payment limits apply because it says the plan is offered under 41.05, which, as you may be aware, is the PEBB and SEBB Programs. So I think we would need to just double check on how this Board may impact 41.05.

Elyette Weinstein: Thank you. And I miss you at the PEBB meetings. [laughter]

Ryan Pistoresi: I will be at a PEBB Board Meeting next month.

Elyette Weinstein: Oh, that's wonderful. Thank you.

Mike Neuenschwander: [Laughter] I don't see any other hands raised. Anyone else want to speak, feel free to use the hand raise function on Zoom.

Eileen Cody: Ronnie Shure.

Ronnie Shure: Thank you. So I just wanted to comment on the fact in the reports that we have heard about Colorado's legal cases or barriers to completing their Prescription Drug Affordability work. And it is simply that we do need to include the pharmacological manufacturers in this process, so it is really good to hear public comment from them and to hear Board Members looking to involve them. We know that one of the barriers with costs, or one of the reasons for cost is that pharmacological manufacturers are not transparent in how they are spending their money. It's frightening to hear that they are spending money on lawyers to sue a Board instead of on working closely with a Board to find answers. The pharmacological companies want to provide the best care that they can, so I optimistically believe that they are not on a different side. We are all on the same side trying to provide the best care, but just hearing or knowing the lack of transparency and hearing that they are suing PDAB instead of working to find the best answers kind of frightens me. And it goes along with my experience with drug companies. I am a retired pharmacist and have worked with advertising and with nontransparent actions by drug companies, and there are answers there, and they are willing to work with us. So it is good to hear that that is available.

And I just wanted to share my almost pain in watching the money that is spent on TV commercials for drugs for rarely used drugs, and it just seems like the money could be spent on evaluating efficacy or decreasing side effects. I think we have a great ally in the pharmacological manufacturers, and I look forward to this Board including them in future discussions. So thanks for the opportunity to share that.

MaryAnne Lindeblad: Thank you. [Indistinct] Anybody else?

Mike Neuenschwander: Any other comments online or in person? Okay. All right. Seeing none. [Indistinct].

MaryAnne Lindeblad: All right. Well, I think our work is done here. Thank you. And I will see you at our next meeting, which -- remind me again.

Mike Neuenschwander: July 16th? 30th?

Simon Borumand: I thought it was the 30th.

MaryAnne Lindeblad: All right. We will double check [laughter].

Mike Neuenschwander: Simon, what was it again? [laughter]

MaryAnne Lindeblad: Well, that's better for you -- that's better, huh?

Simon Borumand: Yeah, 16th.

MaryAnne Lindeblad: July 16th. Does that sound right?

Simon Borumand: Yes, that's right.

Mike Neuenschwander: Had me worried there for a second.

MaryAnne Lindeblad: All right. Well, thank you.

Eileen Cody: Sorry, the 30th is Health Care Cost Transparency.

Mike Neuenschwander: Oh. [Laughter]

MaryAnne Lindeblad: You had something then.

Eileen Cody: Yeah. It could be in the same room.

[end of audio]