Washington State Prescription Drug Affordability Board Meeting
Transcription
September 18, 2024

MaryAnne Lindeblad: Well, good morning, and welcome to our September PDAB Meeting. And I'd like to go ahead and get started with just some introductions. MaryAnne Lindeblad, Board Chair. We have another Board Member here in person.

Douglas Barthold: Yeah. Douglas Barthold, Board Member.

MaryAnne Lindeblad: And then folks on the phone -- Board Members on the phone, Eileen and Hung, introduce yourselves?

Hung Truong: Yes. Hi. Hung Truong, Board Member.

MaryAnne Lindeblad: [Audio cuts out]. Eileen on? Well, we can expect Eileen, I think, at some point. She's not here. And then we have a new soon to be fully appointed Board Member, but he's on the call today. Greg, if you could introduce yourself, maybe tell folks just really quickly a little bit about yourself.

Greg Gipson: Um, yeah. Hi, thanks. Thanks for having me. I look forward to fully participating in the Board at the next meeting. Um, my name is Greg Gipson. I'm a pharmacist by training. Uh, I've been in kind of clinical practice within UW Medicine at the hospital up here for about the last 10 years and recently switched into more of a drug policy and utilization and cost role. So that's kind of my most recent specialization. I also play a large part in our pharmacy residency program up here, so I kind of have a good ear to the ground for new professionals coming into the field. Great, and thanks for having me.

MaryAnne Lindeblad: Well, welcome. So let's just quickly go around here with the staff that are here and then we'll go do the staff on the phone. Ryan, do you want to start?

Ryan Pistoresi: Sure. So I'm Ryan Pistoresi. I'm the Assistant Chief Pharmacy Officer here at Health Care Authority.

Michael Tunick: Michael Tunick, Assistant Attorney General and Legal Counsel to the Board.

Michael Neuschwander: Mike Neuschwander, the Director for the Prescription Drug Affordability Board. [Indistinct]. [Audio cuts out] [echo].

MaryAnne Lindeblad: Okay.

Mike Neuenschwander: Yes.

Jingping Xing: I'm Jingping Xing. I'm a Cost and Quality [audio cuts out].

MaryAnne Lindeblad: Thank you.

Simon Borumand: I'm Simon Borumand. I'm the Policy Analyst with PDAB.

MaryAnne Lindeblad: And folks on the phone?

Mike Neuenschwander: And maybe [cross-talk] --

MaryAnne Lindeblad: Just we'll start with Kelly.

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

Mike Neuschwander: I think I saw Marina on there as well.

Marina Suzuki: Oh. Yeah, this is Marina Suzuki. I am a Health Economics Research Manager. I'll be helping you with the affordability review.

MaryAnne Lindeblad: You said Donna will be on later?

Mike Neuenschwander: Mm-hmm.

MaryAnne Lindeblad: Okay. Anyone else you are expecting, Mike?

Mike Neuenschwander: I think that's probably it for right now.

MaryAnne Lindeblad: All right. Well, thank you, so let's go ahead and go over to Mike for the Director's Report.

Mike Neuenschwander: Great. Yeah, I thank everyone for coming out today. Always love being able to meet together in Olympia and work on some PDAB stuff. So some general updates. As we heard, we have go our fifth and final Board Member here on

track, so that will be great to round out our Board and have that done. Other things that are going on here, and I know we were discussing last time some small tweaks to the Washington Administrative Code due to some other legislative efforts that have been done over this past spring. So one of those included when we do upper payment limits, simply making sure that we have clear start and end dates for public comment, and so that was one pretty easy fix to the WAC that we were able to put in. The other was the requirement for us to be able to share information between the Drug Price Transparency Program, the Healthcare Cost Transparency Board, and the PDAB. So that is a lot of acronyms, DPT, PDAB, and the HCCT. So just making sure that we can share some data between those, we went to the HCA Data Utilization Committee to make sure we were good in terms of internally being approved to share that data between the programs, and that was approved. So now we're working through the external review of that language change within the WAC, so that should be pretty quick and painless here for this part. And then as we develop other parts of the program more fully, then we will continue to do updates to the WAC and our policies as well. So those are kind of the changes there. The other part that I was going to chat about was our draft for the Annual Board Report that we need to submit to the Legislature every December, so we sent that out in the materials. Basically, it's just a rundown of what we've done over the past year in terms of creating the Board, establishing the Chair, establishing our policies, updating the rules and the policies that we're creating, creating our initial steps of creating the advisory group, which we'll talk a little bit more about here in a short while, and a development of the initial drug list as well as just contracting with the PORTAL to help us, in terms of our program support and some of the education pieces that we've received over the past few months. So you can read those different parts of the report in more detail. It's not that long. It's what, nine pages, so a pretty quick read, a lot of those bullet points as well, but that's the -- pretty close to the final version. It still has to go through a little bit more internal review before it gets submitted to the Legislature in December. So any questions, thoughts, comments on those pieces? Okay. All right.

MaryAnne Lindeblad: Good. All right, so let's go ahead. And Mike, you're on again.

Mike Neuenschwander: Yeah. And so for this next part, during our last meeting, we had discussed some of the -- we had -- because we were creating a policy around the initial drug list and some of the language around a couple of specific parts of that policy, and I think Doug was kind enough to bring that up to us from some of

the comments that we had received from industry, so we discussed that a little bit and wanted to go back and review it internally and also get some ideas on terms of precedent and legal support. And so we have brought that back, and we have made a few tweaks to the policy. And Ryan, as our Pharmacy guru here, maybe he can dig into it a little bit more on some of the thoughts that we had and changes we made and kind of the details and the reasoning behind what we had been discussing over the past month and half or so.

Ryan Pistoresi: Thank you, Mike. So as you may see, the Eligible Prescription Drug Policy is listed in your binder. For the most part, a lot of this has remained unchanged from the last meeting, but I will direct your attention to a few points that have been updated. So under 2.) Identifying the Eligible Prescription Drugs for Affordability Review, under 1(c), it just is clarified to say that each individual NDC we consider a drug product rather than a drug ingredient. I know that some of the public comment that we had received prior to the last meeting sought to have better understanding around how we were defining prescription drug within our statue. And going to the end on number 5.) is a write up or the explanation of our methodology and what we were able to determine after reviewing the statute. So in 5(b), when looking at the RCW and the WAC, we've identified that the term prescription drug used means the drug ingredient, whereas an 11-digit NDC is known as a drug product. So if we think about what the active ingredient is, a lisinopril, Enalapril, carvedilol, kind of whatever the active ingredient is that we are using that as the term "prescription drug", but when we're thinking about a lisinopril 10 mg tablet made by a specific manufacturer, we'll call that a drug product, so that way we have clear terminology that will be used consistently throughout this program. So in terms of the Eligible Prescription Drug Policy you know we are looking at drugs at the ingredient level and at the drug product level. And when we've identified the drug products meet the thresholds as outlined in statute that those can then be grouped up together as a single drug ingredient for an affordability review. So then that way you're not necessarily saying that you're doing an affordability review on just that 10 mg tablet by that one manufacturer, you'll be looking at the manufacturer set of that drug, so the 10 mg, 5 mg, 20 mg, 40 mg, all kind of together as one eligibility review. So that is the biggest update from the previous version of the policy to the current version.

MaryAnne Lindeblad: Okay. Any questions?

Mike Neuschwander: So essentially a prescription drug would -- well, basically, it's at this label/ brand name active ingredient formulation level.

Ryan Pistoresi: That's yeah, so consistent with kind of how the statute is written, so when looking at RCW 69.41.010(10) it's talking about how these substances are recognized in US Pharmacopeia or the substance that is used to treat, mitigate, cure, or alleviate the condition. So really, our statue is looking at what is that ingredient? And so thinking about how this applies to our statue, 70.405, we're looking at it at that ingredient level. And then so going back to the point that you were saying is that [audio cuts out] slow. Yeah. So it's the same labeler. Like I said, the same manufacturer, that same brand name, that active ingredient and that formulation. So if we're thinking about a manufacturer that is making an oral tablet and then an oral solution, we would not necessarily group those together unless both the tablets and the solutions met that threshold.

Douglas Barthold: Well, but if they did meet, they'd have to -- because there are different formulations. Wouldn't those be two different drugs in our [cross-talk] --

Ryan Pistoresi: [Cross-talk] Yes, because -- yeah, so we're saying the same formulation.

Douglas Barthold: Okay, got it. Okay.

MaryAnne Lindeblad: Any other questions for Ryan? All right.

Mike Neuschwander: Okay. So yeah, that was kind of how we were working to address those questions that were brought up and clarified why we're doing what we're doing behind that. So for this what we wanted to do is give people, after we explained it now, a little bit of time to look and digest, and also because we made some of these updates to the language in case there is any public comment that comes in, to give them some time to look at that. Though the idea was to discuss this, answer any questions that we had, and then approve it at the next Board meeting in November.

Eileen Cody: So a hold on it then.

Mike Neuenschwander: Yeah.

Eileen Cody: Yeah.

Mike Neuenschwander: Correct.

MaryAnne Lindeblad: Okay. Great.

Mike Neuenschwander: Um [Cross-talk] --

MaryAnne Lindeblad: Are we ready for the next?

Mike Neuenschwander: Okay.

MaryAnne Lindeblad: All right. Simon, I think this is yours.

Mike Neuenschwander: So the next task is to vote to appoint new advisory group members. And folks remember last meeting we talked about there were five [indistinct] in the advisory group. I will go through and list off their names. The Board Members have all looked at their applications, and they have decided that they're okay with appointing all of them. So Jim Freeberg, Executive Director of the Patient Coalition of Washington, Ronnie Shure, Pharmacist and President of Healthcare for All Washington Laura Berry, CEO of Soundview Medical Supply, Tim Lynch, a Pharmacist and Senior Vice President and Chief Administrative Officer of MultiCare, and Dharia McGrew, HD and Director of State Policy for PHRMA. Do we want to do like a motion to vote?

MaryAnne Lindeblad: Oh, that's, yeah. So we need a motion in order to go ahead and appoint these Advisory Board Members, do I have a motion?

Douglas Barthold: I vote to -- I move to vote.

MaryAnne Lindeblad: Do I have a second?

Hung Truong: Second.

MaryAnne Lindeblad: Moved and seconded to approve the list of -- excuse me -- advisory group members to have a vote. All those in favor, say aye.

Douglas Barthold: Aye.

MaryAnne Lindeblad: Aye.

Hung Truong: Aye.

MaryAnne Lindeblad: Any opposed? Been moved, seconded, and voted, so we will officially appoint those five individuals to our Advisory Board.

Mike Neuenschwander: All right.

MaryAnne Lindeblad: That was easy. Thank you.

Mike Neuenschwander: Thank you. And so for those five members all reach out soon, and we can get you started on onboarding.

Douglas Barthold: Actually -- sorry to interrupt. I just wanted to say we do have a quorum, so with the [cross-talk] two members, yeah, in person, plus I see Representative Cody. Yes, [cross-talk] we do have four. Yeah. So all four, three needed for a quorum.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: Thank you for the reminder. [laughter] [Cross-talk] But we're good.

Simon Borumand: I'll reach out to those appointed members and get them onboarded. Just as a reminder that the goal for that group is to help with the investigation of each drug selected by the Board, meant to provide a written report to the Board with their findings as to whether or how the drug will beat excess costs. The expectations are bimonthly meeting of the Advisory Group, and then ideally attendance of the Advisory Group members will be at least bimonthly PDAB meetings. They will select a leader from within that core advisory group. They will combine input on the first drugs that will be selected for their affordability review, and then they will work on a final report to advise the PDAB on the excess cost of a drug. And the factors that go into that report are laid in the Advisory Group policies that we all put together, and how exactly we will go about putting together that report will be a matter for them to discuss first thing, so looking forward to working with everyone.

MaryAnne Lindeblad: So, Simon, you'll be pulling them together?

Simon Borumand: I'll pull them together [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Okay, thank you.

Mike Neuschwander: Yeah. And I think the idea is, as Simon mentioned, do every other month but staggering it so that way they can kind of see what happens here, meet the next month, and then so we kind of -- every month will be something going on from our side, but that way they can kind of be updated with the decisions that you are making in the following month. We'll address any questions or things that they have on that. And again, as this is all brand new with the Advisory Board, there is going to be a little bit of a learning curve as we put this together. And then as we go through the drug selection process, they will give their input on that, and then we will work to expand and add additional members per the specific drugs that we are going to be reviewing that would have an expertise or a specific interest in those. So lots of good things to come. A little bit of building the plane as we fly it type of thing. But so far, I think we have been doing a pretty good job of that. So yeah. That's kind of the next steps, and if the Board Members have any questions on the Advisory Group, always feel free to reach out. The other thing, too, is so the Advisory Group won't be subject to OPMA as they are not like a decision-making body. They are providing advise as an intra-advisory function. So those meetings will probably be virtual, and so we won't have to do quite the same set up as we do for our regular Board Meetings. And of course, Advisory Board members are always welcome to attend these regular Open Public Meetings and bring their findings forward as needed.

MaryAnne Lindeblad: We look forward to meeting them.

Mike Neuenschwander: Yeah.

MaryAnne Lindeblad: So, great. All right. Well, now we are moving into the [audio cuts out] part of the meeting today. So we got representation now. I'm talking about the data dashboard and the weighting of the drug selection criteria. So we have Rashena and Jingping who will be taking the lead on this one.

Mike Neuschwander: Yeah, so -- and just make sure, Jingping, because sometimes the microphones don't pick up stuff super well, just to project up and out.

Jingping Xing: Good morning, everyone. This is Jingping. I'm the Cost & Quality Analytics Manager at the HCA. Today, we will continue the topic of selecting prescription drugs for affordability review. We will first go over the data measures that can help us select drugs for affordability review, then we will all discuss how to rank the drugs in the Eligible Drug List, and we will

provide you a preview of the Eligible Dashboard, which can serve as a tool to help you select the drugs. And hopefully, after this presentation and the following discussion, we are able to select the drugs to go on for the affordability review. The eligible drugs in the eligible drug [audio cuts out] for generic drugs. For generic drugs to be eligible on the list, it has to have a WAC cost of $100 or more for a 30-day supply or less, and at the same time has a price increase of 200% or more in a 12-month period. Among the 649 drugs we have identified, most of the drugs were qualified because its WAC cost is over $60,000 or more per year for course of treatment. One question we need to think about is should we select drugs from each of these categories, or should we just focus on the categories with the most eligible drugs? That is the prescription drugs with a WAC cost over $60,000 or more per year or per course of treatment. Before we -- let's first review what the statue has said about whether to conduct affordability review. When deciding whether to conduct affordability review, the Board should consider the class of the prescription drug. Were there any therapeutically equivalent prescription drugs available for sale? The input from advisory groups an average out-of-pocket cost for the drug. The Board can choose up to 24 drugs per year to conduct a review. [Audio cuts out] [indistinct] touch the data measures for selecting drugs a little bit in our last meeting, and today we will go over this one by one. On the left side is the data measures the Board should consider according to the Legislature, and on the right side is the data measures we have created based on our discussion with the Board Members. The first one is the number of people using the drug. This is defined as the count of distinct individuals who had applied for the specific prescription drugs in 2022 and with a variable created based on Washington All Payer Claims Database. And over 70% of the Washington population was represented in this database. This slide shows the distribution of the number of people using the drug by eligible category. The number of people using the drug varies widely. There are some for certain drugs, there are only a very few people using the drug. And for drugs with less than 10 people using the drug, we can exclude them, and we can set up a threshold for the number of people who use the drug [indistinct] the drugs [indistinct] we can focus on the drugs with at least 2000 people using the drug. The next measure is total plan paid amount. That's the dollar amount that was paid by the health plan. It is the cost to the insurers. The total plan paid amount with the highest for drugs with a WAC cost of $60,000 or more per year per course of treatment. The median of the total paid amount is over $465,000, and the mean is over $8 million. The corresponding measure is the average plan paid amount. That's the dollar amount per person per year that was paid by the health

plan. Drugs with a WAC cost over $60,000 or more per year per course of treatment, the median average plan paid amount is over $17,000, and the mean is over $37,000. The total out-of-pocket cost measures are what the patient has paid for the drug. It is the sum of co-pay, coinsurance, and deductibles. For drugs with a WAC cost over $60,000 or more, the median total out-of-pocket cost is over $10,000, and the mean is $236,000. The average cost -- average out-of-pocket cost measures the dollar amount per person per year that was paid by the patient. For drugs with a WAC cost over $60,000 or more, the median average out-of-pocket cost is $269, the mean is $776. The total paid amounts look at what the patient's total amount was paid by health plan and patients, and then it has a total cost to the society. The total paid amount was high -- also was highest for drugs with a WAC cost over $60,000 or more per year or per course of treatment, and the median is $485,000, and the mean is over $8 million. The average paid amount is the dollar amount that was paid by a health plan and patients per person per year. with a WAC cost over $60,000 or more, and the median average paid amount is $17,000, and the mean is $38,000. The next measure is the patient liability. It looks at what the patient has paid relative to the total cost of the drug. The higher the patient's liability, the higher the patient's burden. The patient liability ranges from 0% to over 60%.

Mike Neuschwander: So real quick -- hold on Jingping.

Jingping Xing: Mm-hmm.

Mike Neuenschwander: So that was a lot of information and statistics in a relatively short period of time, and I know each of these tables has a lot of numbers on it. So I just want to stop just for a second and give the Board Members a breather. Do you have questions on what she has been talking about or what some of this stuff means?

Hung Truong: Hey, Mike, I have a question.

Mike Neuenschwander: Go for it.

Hung Truong: It's Hung, Board Member. On the total paid amount, on some of these it is from the insurance report, right? The Washington ACP, that's just the payer reporting out? Do you [Cross-talk] --

Jingping Xing: [Cross-talk] Yeah, [cross-talk] --

Hung Truong: Do you -- is that the net cost that we are looking at, or is that just -- and what I mean net cost is after rebates are applied. Or is that before any of that? Do we know?

Jingping Xing: The most of rebates because it is what actually showed on the claims. I don't think it [indistinct] rebates.

Donna Sullivan: Hi, Hung. This is Donna. The data set -- the All Payer Claims Database, I believe is what was being used, and that does not include rebates.

Hung Truong: Okay. So the amount could be significantly lower. We just don't know. [cross-talk] --

Donna Sullivan: [Cross-talk] Not necessarily for copay or for patient coinsurance. Typically rebates are not passed through [cross-talk] to the patient at the point of sale, so that the total paid amount might be significantly lower, but the patient out-of-pocket [cross-talk] --

Hung Truong: [Cross-talk] Yeah, it won't. It won't affect out-of-pocket, just -- yep, I understand that.

Douglas Barthold: And total plan paid as well is a lot lower or could be a lot lower.

Ryan Pistoresi: Could be, yeah.

Douglas Barthold: Yeah.

Hung Truong: But we also are probably missing like manufacturing coupons and so forth that do affect out-of-pocket. And we probably don't have that either, not with the same [cross-talk] --

Ryan Pistoresi: I think that's part of the affordability review.

Mike Neuenschwander: Yes [indistinct], Ryan?

Ryan Pistoresi: Oh. I think the patient copay assistance is one of the criteria that would come up in the affordability review phase, but I think as we are looking at the eligibility that is information that we cannot request from the manufacturers

yet until we know which drugs would be subject to the affordability review, but I could just double-check the citation on that.

Hung Truong: Okay, thank you for the information, Ryan, and Donna.

Mike Neuenschwander: Any other questions on these tables here with the various data points? Okay. All right.

Ryan Pistoresi: And, Hung, just to confirm it. Yeah. So the dollar value and accessibility of patient assistance programs offered by the manufacturer for the drug is one of the criteria that the Board shall consider when conducting a review. So right now, we don't have that data, but if you select drug X, we can go to drug X as manufacturer and request that data be provided for the Board to consider.

Mike Neuenschwander: Okay, any other questions? Okay, just when we go through large buckets of data, I like to take a moment to breathe and pause for a second just in case someone feels like the slides are passing them by. So okay, thank you, Jingping Xing. Now we can -- you can keep going.

Jingping Xing: The next measure is therapeutic equivalence availability. It was defined as to have the same ingredients in the same concentration with the same pharmacokinetics. If any of these factors differ, the drugs are not considered as substitutable. It was a variable that was created based on First Databank Database. And in our analysis if the biologic product has a biosimilar, it is also considered as having a therapeutic equivalent. If the drug has the same inactive chemical ingredient dosage strength and dosage form as the brand name drug, we think that this brand name drug has a generic. Last but not least, we check if the drug must not put thresholds of the Legislative definition. Remember at the beginning of the presentation, I think that the drugs were identified through four separate processes, so some of the drugs can meet multiple thresholds. When we're [indistinct] --

Douglas Barthold: I just have a question about the generic availability. I just might have lied to the therapeutic equivalence [indistinct]. So same dosage strength, and so we're requiring that to determine if the generic is available, and it's not the same sort of level of identification that we use when we're defining a prescription drug, as Ryan [indistinct] before. So like the generic lisinopril at 10 mg but not at 15 mg, we're saying there's no generic available for the 15 mg one?

Ryan Pistoresi: So this is Ryan. I'm just double-checking what we had and see. So it was the same label or brand name, active ingredients, and formulation. So here the difference is in the strength [cross-talk], and so there are some situations I know in which different strengths may or may not be generically available depending on patent, [cross-talk] whereas in this, this is identifying it as the same ingredient from that same manufacturer.

Douglas Barthold: Yeah. And I agree with what we're doing on the Eligible Drug List Policy. I'm just curious if here we should this should be if -- we're getting into the spirit of what we're trying to do here because I can understand if there's a huge difference in the dosage strength and, yeah, we would say like that there is not a generic equivalent of one or the other. But like in the example I gave where like if you think about it -- actually, maybe a better example is a 10 and a 20, where if there's a generic available for the 10 but not for the 20, we, of course, think that there's a generic available for the 20 because you could just take two 10s. So does that -- do we -- I mean, I just -- is this how the First Databank also defines the generic availability, or do we need to decide that?

Ryan Pistoresi: I think this is how they decided because this is at the drug product level, so the NDC level, I think that's kind of where that comes in because we're looking at a GPI-14, which then groups all of the drug strength, dosage form, and ingredients. So that's kind of how their hierarchy is. GPI-14 for Medi Span and then GCN sequence number for First Databank. Sorry.

Douglas Barthold: Okay.

Ryan Pistoresi: I believe that's how their drug reference table is set up.

Douglas Barthold: Okay, um, well, I mean I -- so I guess that's sort of we're just taking what we can get from that data, and people want to be careful about using this when we're weighting our criteria. And I guess we'll eventually be able to look at this as we if we do an affordability review and we decide on a drug, we wouldn't want to deem something unaffordable that has a generic equivalent at a different dose. And I guess if there's any way that we can remove dosage strength from our -- this definition, that would be great, but if that's just what we have at First Databank, then we just have to keep that in mind as we use this variable going forward.

Ryan Pistoresi: So this is Ryan, and one thing that we could do is we could pull the data as it is defined in First Databank and then do a group at that ingredient level, so that way if half of the products, half of the NDCs have a generic and half don't, we could then group it up as the ingredient and say there is a generic for this ingredient.

Douglas Barthold: I like that a lot.

Ryan Pistoresi: Okay. So that's a step that I think we'll look to do as we are putting the generic availability together.

Douglas Barthold: And I don't if there is a similar issue with therapeutic availability. I haven't read that [indistinct] in much detail yet.

Ryan Pistoresi: So this is Ryan. Looking at this methodology, we would be using the Orange Book, which I believe is at that NDC level to say, what is AB rated? What is B rated? So we could also do something similar where we get the individual ones for those NDCs and can lump it up at the ingredient level to say here are some AB-rated generics, and even other A- or B-rated generics for that ingredient for that brand alternative.

Douglas Barthold: Okay. Um, I think that sounds great. I'm just -- this doesn't have the dosage restriction though from what I have seen here.

Donna Sullivan: So I am curious of when you are saying dosage. I think on the previous slide it might have been a little confusing where it says dosage strength. It would be the same dose. It would be the same strength. So I'm not sure when you are using dosage what you are -- what that means to you.

Douglas Barthold: Uh, I was thinking about the distinction between like a 10 mg pill and a 20 mg pill.

Donna Sullivan: So that would be two different dosage strengths [cross-talk] --

Douglas Barthold: [Cross-talk] Right, and I think that's a problem then because then we would say that one of those [indistinct] like, let's say that we say that the 10 mg has generic availability, but the 20 mg doesn't because there is no generic 20 mg. But just because there is no generic 20 doesn't mean you can take two of the generic 10 mg, and so that is why I think Ryan what he said was good. It was

to sort of consolidate at the ingredient level [indistinct] with this information.

Donna Sullivan: Yeah, we would -- we might want to talk about that because oftentimes just because that assumes that two 10 mg is cheaper than one 20 mg, which isn't always the case, so I think we would have to consider that on a case-by-case basis where it makes sense to do that.

Hung Truong: Yeah. And I think Doug talking about if say the 20 mg is a brand because they just increase the dose and then they make it into the brand, just worry about that, right? That's their example?

Douglas Barthold: Yeah.

Hung Truong: Yeah, and you know most providers if it makes sense to prescribe two 10s for a 20 instead of using the brand, they would. I think most insurance will probably restrict that type of scenario, right? [Cross-talk] Because it's not like we're not going to let you fill up [cross-talk] with the brand if it's not on the formulary.

Douglas Barthold: I agree that is what a provider should do, but for us as we make a policy about if we are going to set an upper payment limit, we wouldn't want to set an upper payment limit on the 20 mg branded one but [cross-talk] --

Hung Truong: [Cross-talk] Absolutely.

Douglas Barthold: I think there is already something that they can substitute for it.

Hung Truong: Yeah, yeah.

Mike Neuenschwander: Well, and I think, too, there is a couple -- so when it comes to especially as we're going into like upper payment limit territory [cross-talk] we will have the drug review, which will go into a lot more depth, right? This level right now is just a little bit more of a coarse filter, which again without rebates and all this other stuff isn't going to be perfect, but it's trying to get us in the ballpark of, do we think this is a drug that is worth reviewing? So I definitely think when it comes to like your concern about upper payment limits and kind of getting into the nitty gritty of stuff, that's where the drug review will go into a lot more of the detail where, again, this is just trying to help us eliminate [cross-talk] --

Douglas Barthold: [Cross-talk] Yep, sounds good.

Mike Neuenschwander: -- so.

Jingping Xing: There are 14 drugs [audio cuts out] with multiple thresholds. There is one drug with a WAC cost over $60,000 or more per year over the course of treatment at the same time has a price increase over 50% over a four-month period, and there are 13 drugs that have a price increase of 50% over one year and at the same time has a price increase over 50% or more over three years. We went through all the data measures, and we have to prioritize our data measures so that we can just look at limited number of data measures and to make decisions. In our last Board meeting, we have agreed to prioritize [audio cuts out] data measures. There are the number of people using the drug, average out-of-pocket cost, total out-of-pocket cost, total paid amount. Also we need to think about whether the drug has a therapeutic equivalent or generic drug for the brand name drug. The lack of therapeutic equivalent in the market limits competition and may contribute to the high price or price increase. And when a drug has a therapeutic equivalent, we need to -- should we de-prioritize the drug? And at the same time, we need to think about with the therapeutic equivalent drugs what was widely used in the market and the price difference between the prescription drug and the therapeutic equivalent drugs. It is just something we need to think about. And also if the drug meets multiple thresholds of the legislative definition showing prioritize these drugs. We have the drug list and also the prioritized data measures how to rank the drugs in the Eligible Drug List. Colorado has done this through the dashboard, and they prioritize their drugs through a waiting and ranking process, and the five data measures they have decided to prioritize are patient count, change in the WAC price, patient out-of-pocket costs, total paid amount, and average paid per person per year. For these five prioritized measures, they ask each Board Member to rank these five measures and some of the rank to get the total rank. The number one ranked data measure is the total utilization, the second one is WAC's pricing change, the third one is patient out-of-pocket cost per person per year, and the fourth one is total paid amount. This one is average paid per person per year. Then they asked each Board member how much more important is #1 compared to #2, and how much important is #2 compared to #3? When they ask how much importance #4 compared to #5, the first Board member thinks that #5 is 25 more important than number -- uh, #4 is 25% more important than #5, and all the other members think that there is no difference in importance.

After they got the relative importance from each Board member, they averaged it and further normalized it to 100% to get the weights. They apply the weights to each of the data measure and sum them together to get the score, and their final list was sorted based on the ranking -- the rank of the scores. Our one limitation of this method is that the score is calculated based on data measures in different units. Three of these measures are in dollar amount, and one is just a number count, and the other one is the proportion. So it makes the final score hard to explain because what does it mean to add a dollar amount with account with a proportion? Because of the limitation in the [indistinct] method, and we hope to like -- we are proposing three different methods that are more simple and straightforward. The first method is to sort the drug list by the selected data measures sequentially. [Cross-talk]

Douglas Barthold: [Cross-talk] Before we get into these methods. So this is -- you're proposing methods that could be used to the Colorado weights?

Mike Neuenschwander: [Cross-talk] In place of.

Douglas Barthold: Okay. Because I think our planner said it was our sort of weight system is a little different than theirs.

Mike Neuenschwander: Yeah, and so that was some of the questions is, you know when we were talking between the last meeting and this meeting, there was some concern around how will this weighting work and trying to figure out the best way to do that? And so we were looking more in depth around Colorado's and how they did it and some of the difficulties around that, because one of the things we're trying to do is come up with a clear way that I think what we are trying to do is avoid anything that looks like it's just kind of our [audio cuts out], right? Because that's when we are going to be selecting these drugs, we want a clear way that we are going to do this, and so sometimes it can be a little bit difficult to understand with weightings and rankings and now some of the questions is like how exactly are they going to implement this in a very concise way? And so we were looking at the Colorado way, and it seems like it could be a little bit more difficult than maybe it needs to be. And so that's why Jingping is like, okay, here's a couple other proposals of things that we could do to try and maybe do it more simplified, cleaner, and kind of to the point of what we are hoping to get to.

Douglas Barthold: I think I agree with that. Certainly, like the actual get the application that waits, I'm eager to see what she has in store for us for that. But this how we arrive at the Column G there, the basic normalized weights there, I think that our system was better than theirs for like having the Board members allocate whatever we have. What do we have, 25 points to allocate? Allocate 25 points, and then use those to calculate a weight on each of these criteria, and then basically arrive at Column G that way rather than this, like, how much more important is this to you than that? So as long -- I mean, I guess like are we going to -- is that what -- are we sticking with that? I guess like I would like to see how we're -- what we're going to use [cross-talk] for our weights.

Mike Neuenschwander: Yeah. And so we've -- well, and so not everyone gave us their weights, too. other things, we weren't able to actually, like, go through and finish that because there is, again, that question of exactly how does this work? So then we have come up with some other ways that's maybe not quite so much around the weight but more just around a prioritization of sorting. And so Jingping will walk through some of [cross-talk] these other scenarios to, again, maybe just a little more clear cut, simplified, and to the point.

Douglas Barthold: Okay. Um, well, yeah. I mean I think that whether we do a priority -- if we just have to rank the criteria just like they did. I don't like that because it assumes that the difference between 1 and 2 is the same as the difference between 4 and 5, whereas, like -- I don't know if you [indistinct] the weights that I submitted, but I gave zero points to most of the criteria, then I gave all my points to -- I gave almost all my points to two of them and then I give like one point to somebody or something else. So then that's how I allocated my 25 points because that is what I think is important. So I give you that's a better way to do it than just a straight up ranking. I also completely agree that this is an incredibly important and complex thing, and so like, I would like -- I think the Board should discuss that with each other as we -- I don't know if that is on the schedule for [cross-talk] today or next time or whatever, but then we can discuss why we are giving our weights the way we are.

Mike Neuenschwander: Yep, yep. And we'll have time. We'll have time to chat.

Douglas Barthold: Great.

Mike Neuenschwander: So just trying to walk through some options of possible ways to think about this here.

Douglas Barthold: Cool. And just somewhat related. I assume when Greg joins the Board, he will also be voting on the way to the ranks or whatever?

Mike Neuenschwander: Yeah.

Douglas Barthold: Okay, great. Yeah.

Hung Truong: I concur with Doug about giving us an opportunity to make our case on why we ranked a certain way.

Mike Neuschwander: Yep. Yeah, I know. No, don't worry. They'll definitely be time for discussion.

Douglas Barthold: Great.

Jingping Xing: So the first method we proposed is to sort the drug list by the selected drug data measures sequentially. So we can sort the drug list first by the average out-of-pocket cost, then by the total of out-of-pocket cost, then by the total paid amount, and lastly, by the number of people using the drug. It will give us a sorted drug list, but the -- order of the variables that we selected to sort matters. So if we decided to sort by the number of people using the drug first, then by the average out-of-pocket cost, then by the total paid amount, it will give us a very different list. And the problem with this method is that it looks like that we are here, we are sorting by three variables. After we sort by the number of people using the drug, unless there is a tie, it will not be -- unless there is a tie, it will be -- it will not be sorted by a second or third variable, so the list is maybe like driven by the first variable we have [indistinct]. The second method is to sort the most important data measure and then look at the rank of the other two measures. If you feel strongly about one measure, for example, here, if we think that the number of people using the drugs was the most important data measure when we are selecting the drugs, we can [audio cuts out 00:52:59 to 00:53:35] --

Mike Neuenschwander: Technical difficulty. Hold on one second here. Hang on. Jingping and Kelly are just looking for -- making sure she's got the right thing.

Jingping Xing: So if we think that the number of people with the most important factor, we can sort this from the highest to the lowest. And this slide shows the Top 40 drugs with the highest number of people using the drug. Then we can look at the two other dimensions of that drug. That's the average out-of-pocket cost and total paid amount. We can rank these drugs by average out-of-pocket

cost and by total paid amount to get the rank and sum of these ranks. Here, the third row. On the third row is the drug with the third highest number of people using the drug. This drug ranked 48th in the average out-of-pocket cost and ranked number 1 on the total paid amount. So we may want to prioritize this drug over the first one that has the highest number of people using the drug while the average out-of-pocket cost only ranked 125, and the total paid amount only ranked 8. The third method we propose is a little bit different because we sort the drugs individually by the prioritized data measures that look at the sum of the rank of these data measures.

Ryan Pistoresi: Jingping, are you changing slides? [Cross-talk]

Mike Neuschwander: [Cross-talk] Maybe we could go back a slide. Maybe we could get back into the presentation.

Jingping Xing: After each ranking, we will get the individual rank, and we can sum up these ranks to get the final rank. So here this method we put equal weight for each of these variables, and it also helps solve the problem of adding data measures in different units because here we are just adding the ranks to get the total rank. [Indistinct] --

Douglas Barthold: So I like method three. I think it's the closest to what we want, but I think it can be improved further by weighting each of like the four variables here. So I think we identify six variables, so we would have six, so we have six. Each drug would have six different numbers. We would weight those by the average number of points given by the Board members to that variable. Does that make sense? I mean I don't think that's like -- I don't think that would be like much more difficult than exactly what's done right here. Because, like you said, this treats all four variables equally. But like, let's say that the Board members gave 90% of their points to variable 1, then that should get a .9 weight, and then the other .1 gets allocated for the other three variables.

Donna Sullivan: So this is Donna. Are we still talking -- I thought this method did not include the Board members providing points. It was really just ranking based on where it fell [cross-talk] --

Mike Neuenschwander: [Cross-talk] Yeah.

Donna Sullivan: -- based on the data that's here. There is no subjectivity to this method.

Mike Neuschwander: Yeah. So right now, this one is just based on where each of these data points falls within their respective lists and adding it together. Yeah, so this one as Jingping is showing, it does not have the weighting or added to the rankings.

Douglas Barthold: Those variables were chosen by the Board.

Mike Neuenschwander: Yeah, yeah.

Douglas Barthold: So there's some, a little bit of sort of subjectivity there.

Mike Neuenschwander: Yeah. Yeah. So I mean the variables themselves are this is what the Board feels is important, but then Doug is suggesting adding the weighting to these ranks to get us a modified list with the weights and ranks combined. And so that's not what Jingping was talking about, that's what Doug is suggesting that we could do. So those are [cross-talk].

Douglas Barthold: [Cross-talk] I think all of the rankings are really useful because, like you said, it in turn allows you to compare one that measures dollars to one that's a binary measure to one that is like a number of users. The rankings sort of they take care of that unit problem, and then just in order to account for the fact that we think different variables are more important than others but, you know, maybe all are still important. That's where the weights come in.

Mike Neuenschwander: Okay.

Jingping Xing: [Audio cuts out] add the weights into this exercise to come up with the final rank.

Douglas Barthold: Yeah. So like the Column G on Slide 35, you basically take the weighted average of the variables using those weights from Column G, except our Column G from the Washington PDAB is getting way better, so [laughter]. but really it is. Um, yeah.

Mike Neuenschwander: Okay. Well, let's -- maybe we can both do the rest of Jingping's presentation here, and then we can kind of dig more into the -- have open discussion on the methodologies and kind of the next steps that we want to go through.

Jingping Xing: So we are developing Eligible Drug Dashboards to help you to select the drugs. We want to give you a quick look at this dashboard. So in the Summary

page it shows the composition of the drug lists by the eligible category and also shows the top ten drugs in terms of number of people using the drug, and top ten drugs for the total paid amount. And on the upright side is the distribution of the WAC cost for drugs with a WAC cost over $60,000 or more per year per course of treatment. We also have a lookup page. You can look up by NDC to look at the drugs' details and information. Like the example here is Humira. It was eligible because the WAC cost is over $50,000 or more per year per course of treatment, and the therapeutic class is an inflammatory TNF-inhibitor. It has a therapeutic equivalent. In 2022, Washington has 33 people using this drug, and the average out-of-pocket cost is over like $1000, and then the patient's have about like 5% of the total cost. In the next page we listed the drugs that meet multiple thresholds of the legislative definition. Like the first one is the COPD drugs, which were qualified because it meant like it increased the price 15% over one year and at the same time increased its price over 50% for three years. We can like work on to modify this dashboard to make it work with you, for you, and you can play with it, and so you choose which method is the best one. So we hope that after this presentation we can finalize the data measures that we want to prioritize and finalize the methodology. We have the [indistinct] method and the other three methods, and we can incorporate the weight into the ranking process for our final like to choose it as our final criteria to sort the drug list. And we will be developing and modifying this dashboard to make it available for you to choose the drug. And our final step is just to select the drugs for affordability review. I think we can discuss how to improve this -- the methodology.

Mike Neuschwander: Okay. So then I think this brings us to the part that everybody's been eagerly awaiting here, Um, so

Douglas Barthold: Maybe just me.

Multiple Speakers: [Laughter]

Mike Neuenschwander: I can say Doug looks excited, so --

Douglas Barthold: Finish it [indistinct] are we going to talk about the dashboard at all? Or do we go to the [cross-talk] --

Mike Neuenschwander: [Cross-talk] Yeah, yeah, or [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah.

Mike Neuenschwander: -- any questions you guys have on the dashboard?

Douglas Barthold: I was want to say I think it looks great. Um, and so that's -- is that live? I mean I assume that's not live to the public, but you have -- it's --

Mike Neuenschwander: Yeah, it's still in a draft mode, and we need to get approval to share it.

Jingping Xing: First we have to finalize it.

Mike Neuenschwander: Yeah, yeah. Finalize it and then approval to share it for the Board to play with, so [cross-talk] --

Douglas Barthold: [Cross-talk] And so that will be for the 455 drugs that are eligible for affordability review?

Mike Neuenschwander: Yeah, so you can look up the information on them [cross-talk] --

Douglas Barthold: [Cross-talk] That's pretty cool.

Mike Neuenschwander: -- and kind of see. Yeah.

Douglas Barthold: And then we're just kind of listing all of the data that we have up to this point regardless of what we think [indistinct] that data is supported or not.

Mike Neuenschwander: Yeah, yeah. I mean it has quite a bit of information on it related to each of the drugs.

Douglas Barthold: Um, and will it sit -- so it -- is there -- will there be any display of sort of like the information about the data and methods? Like this number was calculated in the Washington All Payer Claims Database, which represents this set of plans and comprises 70% of Washington or something like that.

Mike Neuenschwander: No. Jingping?

Jingping Xing: Yeah, we could add that into [audio cuts out] [indistinct].

Douglas Barthold: And as a sidenote, maybe this is just a topic for a later discussion, but you could definitely write -- you could publish like a peer review journal article

about these methods. I think it would be well received and very interesting. But anyway, that was actually a separate question I had, so I will bring that up later.

Mike Neuenschwander: Any other questions on the dashboard?

Douglas Barthold: Do you anticipate that the dashboard will have like a flow of like here's eligible, and then you -- we adapt to the ones that we do to the -- once we do the affordability review, and then we'll display the results of that separately, and then we'll kind of like have this flow like give the funnel of purer and purer drugs?

Jingping Xing: [Indistinct] the rank is the way we should use we can show the final list in another page as the drug -- the top drugs we should consider for [audio cuts out].

Mike Neuenschwander: Okay.

Eileen Cody: This is Eileen. I got a question on the drugs that are on multiple lists, so this kind of goes back to the earlier discussions about the quantity. Like on the nitroglycerin patch that it's all these different doses. So if we -- I guess I'm trying to figure out, would we treat that the same, or -- each individual one would have to have it if we decided to do a drug review, would we have to decide for each one?

Mike Neuschwander: And so with the different dosages -- Ryan, correct me if I'm wrong -- we were treating -- we were going to treat all of those as a single drug review.

Ryan Pistoresi: Right. Yeah. So this is Ryan. So if we're looking at the list that's up here now, like that Nitro-Dur you see, it's on there a few different times as a drug that had over a 15% and over a 50% increase. So if you were interested in Nitro-DUR, that could be one individual drug review, and we would look at all those NDCs. We would look at the different utilization. We might see that some of those NDCs don't have any utilization, but others do, and from there then we'd be able to kind of track down and create a more robust affordability review that actually looks at what impacts this drug, and this price increase has on Washingtonians.

Eileen Cody: Right. Good. Thanks. That's what I was just trying to clarify in my mind how that would work, so thanks.

Mike Neuenschwander: Okie doke. Any other questions on the dashboard? Okay. Well, let's maybe hop in here a little bit more deeper into the awaiting discussion and some of our options there. So again kind of what Jingping was saying is go through, and we have some options in terms of sorting the selected data measures sequentially, so just picking. So say we say utilization. We talk amongst ourselves, and everyone decides that utilization is the first way we want to organize it and then just go through and then sort and whittle that list down to a smaller list using the other measures as the Board votes in order of importance to get us a smaller list to pick from. Or if we want to pick a count first and then look at the ranking, or we want to do the sum of the rankings to kind of pick that up. Or as Doug was suggesting, then add the weighting to the sum. So I guess kind of opening that up here for questions, comments, thoughts, ideas, and what the Board is pondering.

MaryAnne Lindeblad: I'm still pondering.

Douglas Barthold: Everyone knows my thoughts.

MaryAnne Lindeblad: No. [Laughter] I do like to know you would support.

Douglas Barthold: Well, so can I ask [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] for suggesting. I mean that makes sense to me.

Douglas Barthold: So, MaryAnne, have you submitted your -- the weights that like [cross-talk] --

MaryAnne Lindeblad: I believe I submitted it, yes [cross-talk]. But I'll be honest with you, I can't remember what I did [cross-talk] --

Douglas Barthold: [Cross-talk]. I switched mine up, but [cross-talk] --

MaryAnne Lindeblad: [Cross-talk] Yeah.

Douglas Barthold: Um, how about Hung and Eileen? Have you guys talked about the weights?

Eileen Cody: Well, I guess that I've kind of wanted to see -- look over the numbers and see where things are at. It's hard for me to know at this point. I think that like ranking the number of people that it affects is important, but then I also want

to look at how -- what the high cost it is, too. So, you know, it's like I guess I haven't decided.

Hung Truong: I haven't thought about it as much, Doug. I think total pay and number of people on it, I think, it's up there for me. But you know, I stepped out when Donna came in to talk about that. I think she mentioned something about that we're not looking at the ranking, where we just look at this objectively just by the number itself. I'm sorry, I missed that discussion. I also like that as well.

Donna Sullivan: Right. And so this is Donna. Yeah. So my suggestion was to do this -- not assigned points and just to look at the rank, and I'd have to go back and remember my math in my head to remember if the higher the number was the least affordable or if the lower number was the least affordable, but I think it's the lower numbers are the ones that are least affordable, and that we would just go by rank here without applying weights. But that treats -- kind of treats everything equally, but I understand the desire to kind of choose which one of these four may feel -- that you may feel is more important than the others.

Douglas Barthold: Yeah. The reason why I definitely agree with the simplicity of this is really nice. But like so in, I guess, our previous decisions we've decided on the six variables, right? And so in my opinion -- so, for example, if the drug meets multiple thresholds, I don't -- I gave that zero points because I don't think that affects consumer patient portability at all. The fact that it met three different thresholds to get onto the Eligible Drug List, which says nothing about what patients are paying, and so I give that zero points. And so I don't want it going into like at least my contribution to this -- to our decision about the affordability reviews. Like, that ranking for drugs, I don't want in there. I have feelings about the other five variables as well, and I -- and all the other Board Members will, too, and so I think that's why like this weighting method to express our preferences.

Mike Neuenschwander: Well, because there are the four ranks which, right [cross-talk] that you have to have the dollars or the usage, so there is quite varied. The other two ranks are does it meet multiple thresholds, and is there a therapeutic equivalent? They're both kind of a binary yes or no. So when we get the list, we can see, here is our rank of this other stuff, but say, for example, we don't want to look at all 400-some odd drugs, right? That's like too much. But if we can use this to get it down and like, okay, here is based on our sorting or ranking criteria, here's the top 25, and then you can see the binary selection

on the other side saying, okay, and this drug does meet multiple thresholds, and this drug also has a therapeutic equivalence. So then like, if we were looking at those top 25 and like, oh, this one does have a generic or something, maybe we just [cross-talk] toss that one off the list, you know? Or if there are five that have a generic, we can toss those off the list, which then takes our list to 25 down to 20.

Douglas Barthold: Yeah.

Mike Neuenschwander: And then that makes it easier to [cross-talk] --

Douglas Barthold: Sorry, I definitely take your point that like these two variables that are binary, you're going to have less variation in [cross-talk] --

Mike Neuenschwander: [Cross-talk] Yeah. They're more informational, I guess, is the way I would look at them.

Douglas Barthold: You can still rank according to binary, but [indistinct] there's going to be a bunch that do and a bunch that don't [cross-talk] --

Mike Neuenschwander: [Cross-talk] Yeah.

Douglas Barthold: -- in other ranks, you know? So [cross-talk] --

Mike Neuenschwander: [Cross-talk] Yeah.

Douglas Barthold: So a bunch of #1s and bunch of #2s. But the -- and so, like, you know, so I guess just speaking from my own opinion, like I get talked into that type of thing where we like used those as a secondary thing, these binary ones, but even within the four numeric ones, I still think that weights are really important there, and I can give it some more. Like if they're within those four, I give all my points to two of them and zero to two others. Like, for instance, there's a lot of redundancy between number of people using the drug and the total out-of-pocket and the total paid because those are all weighted by the number of people using the drug. And so if we give equal rank -- equal weight to all four of these, we're giving extra weight to number of people using the drug because that factors in the total out-of-pocket and total paid. So like, I gave all my p -- within those four, I gave a lot to total out-of-pocket because that captures just the total out-of-pocket burden for the whole state, and then I also give a lot to mean out-of-pocket because that captures if there's going

to be -- there should be mean out-of-pocket among users because that captures if there are some very expensive drugs for a small set of people who maybe aren't -- maybe it's not a big population within the state -- and so if we miss that for the total out-of-pocket for the state, but mean out-of-pocket captures it. So anyway, I'll just say I think that I feel strongly that the weights should go into whatever our kind of -- I don't want to call it a sum of ranks. I think should be like a weighted average of ranks.

Mike Neuenschwander: Weighted sum?

Donna Sullivan: So, Doug, this is Donna. Are you suggesting possibly removing maybe the total out-of-pocket [cross-talk] --

Douglas Barthold: [Cross-talk] No.

Donna Sullivan: -- variable?

Douglas Barthold: Actually, I gave most of my points to out-of-pocket. But I'm not suggesting we remove any of them because I recognize the other Board Members are going to have different preferences for what they think is important. You know, the degree to which -- how do we define affordability? Is it like -- is it if every -- if 100% of Washingtonians have to pay, like, I don't know, $200 a month for a drug, or if 1% of Washingtonians have to pay $1000 for a drug, how do we weight those two? You know? And that to me is just a matter of preference and so I think that, like, the Board Members submitting their weights to describe how they give preference to these measures is a good way of, I don't know, reflecting the will of the Board in this final ranking.

Donna Sullivan: Yeah. And I also want to point out that patient out of -- affordability to the consumer is not -- is only one factor in determining affordability. We are looking at the total affordability of the drug to plans because those impact premiums as well, and premiums are not part of this measure. So I just want to caution on ranking consumer out-of-pocket costs really high compared to the average -- to the total [cross-talk] paid amount.

Douglas Barthold: And I -- go ahead.

MaryAnne Lindeblad: Oh, no. I was just -- I appreciate you just saying that because that is what I have been sitting here thinking about is really about so there is the cost of the individual, but then there is the overall cost of in terms of what it does to

drive the premium. So is it to an individual, or do you think about it spreading across the [cross-talk] population that is -- thinks [indistinct] particular health plan or what, [cross-talk] so I think [cross-talk] --

Hung Truong: [Cross-talk] Out-of-pocket is based on the insurance you have and the plan you buy. I mean if I have a high deductible, [cross-talk] my out-of-pocket is going to be high. Sorry. And it's also based on formulary on where it is and what the pay of formulary.

MaryAnne Lindeblad: All those come into play with this, and so it's getting down to you have four or five variables, or do you [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah.

MaryAnne Lindeblad: -- yeah, go out to [cross-talk] something that becomes almost ridiculous.

Douglas Barthold: I recognize that these things kind of -- I totally did take the point about effects on premiums, but as this stands, we don't have any reason to believe that -- let's say that we are able to reduce -- if we -- so the total like plan amount, or just even the total paid, which if we can somehow reduce that, we say that -- maybe we should save the insurers a bunch of money, the actual resulting improvement in affordability like via premiums is very indirect and long term and affects all of Washington, which is good as opposed to affecting the people who are -- for whom this drug may be very unaffordable for, and that we can get with that by ranking with out-of-pocket costs. Like, we don't -- we, I guess, as far as I know, we can't even see the premiums, right? [Cross-talk] Yeah.

Ryan Pistoresi: [Cross-talk] So this is Ryan. I think premiums may be one of the criteria that you will be able to get. We do get some of that information through our prescription drug afford -- I mean our Drug Price Transparency Program, which we may be able to use as they can share data. I was just going to follow up to what Donna was saying earlier is that at the phase that we are in saying that for prescription drugs chosen for an affordability review, the Board must determine whether the prescription drug has lead or will lead to excess cost to patients, and then excess costs is defined earlier in statute as the cost appropriate utilization of a prescription drug that exceeds the therapeutic benefit relative to other alternative treatments or the cost of appropriate utilization of a prescription drug that are not sustainable to private and public healthcare systems over a 10-year time frame. So I think to Donna's

point when you are thinking about the premiums, I think that is where that part of excess costs come in, and I do think to your point that out-of-pocket cost does fit within what is sustainable because if patients can't afford their out-of-pocket costs because everything is a high-deductible health plan in the future, and that is where the healthcare system is going, and I think that fits that as the criteria. But I do see why we have the six that we have right now.

Douglas Barthold: You can also -- you can like -- so we're on a similar vein. Do you think that high out-of-pocket costs leads to poor adherence or just generally worse health. And that can lead to unsustainable costs to the healthcare system as a whole and to the plans via other types of medical costs that go down the road from poor adherence. So um, yeah. I mean I -- so it's just that's really helpful. I like to hear like what -- how we should be -- is this excess cost definition sort of our target measure of affordability?

Ryan Pistoresi: With doing the affordability review?

Douglas Barthold: Okay.

Ryan Pistoresi: Yeah.

Mike Neuenschwander: And we'll be discussing that more [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah, I saw that on the agenda, yeah.

Mike Neuenschwander: -- later today [cross-talk] [laughter], so if you're interested in that, we're going to have a lot more meat and potatoes on that specific topic shortly. So in terms of this -- and again, so this is just to help us rank it and -- get us down to our top, whatever, 25 that we -- you know, take it from 400 to our top 25 that we want to look at. So once we get the list, these other variables, it's not like they're going to disappear, right? Like, [cross-talk] we'll still be able to see those variables within that list, and then you'll be able to consider that when we go through [cross-talk], but here it's just helping us to get it -- get them to the top of the list to take a look at.

Douglas Barthold: So Mike, I usually agree with you when say like, let's just cut down a list here -- let's [cross-talk] just like use this simple measure to cut down a list, but I don't think the weighting is like -- our weighting is not -- it's not even a complicated thing to incorporate to get a weighted sum of ranks rather than just the sum of ranks. [Cross-talk] And so, and I do think that [indistinct],

again, it's just my opinion. I don't know if we should vote on it or whatever, but the -- I do think that like without the weight, it's a significantly biased measure towards that, you know, that -- well, it certainly doesn't reflect my preferences for how to prioritize the drugs.

Mike Neuenschwander: Yeah, yeah, and I'm not saying we shouldn't. But I'm just saying, like, even with the ranks, it's not like the -- it's not, you know, [cross-talk] if you have a preference for one thing over the other, it's not like the others are going to disappear [cross-talk], right? When that final list comes, we can still see everything and then choose based on all the info.

Douglas Barthold: Okay.

Mike Neuenschwander: Um, but that being said, then we need to kind of -- and, Doug, I think I know where you're wanting to go on this -- but with Eileen and MaryAnne and Hung, I guess, thoughts in terms of ranking, selection, and how you would like us to see this list put together.

MaryAnne Lindeblad: Well, I would say just sitting here listening to this conversation that I appreciate the idea of doing some weighting because in the -- to me, the bottom line is, is that customer going out the door their ability to afford that drug? And that to me needs to be the highest priority for us. So to have some way of looking at that ranking in that sort of way. [Indistinct] I think at this point, I mean it really needs to be consumer driven in terms of how we make this possible for that individual to afford their drug. And when you had to go to the drugstore and pay $900 for a drug, you know, some people can do that, some people can't.

Mike Neuenschwander: Okay.

Eileen Cody: Well, I'll just say that at first, I didn't -- I was thinking that we didn't really need to add in any of our old personal rankings, but I think, Doug, you made a very good point on how so many of these of what we're measuring here are really tied together because of the number. Like if it's a high number of people and a high cost, then it's the out-of-pocket and what the plans are paying are going to both, you know, they're kind of the same thing, really. I mean there are percentages in it, but it puts both -- both measures go to the top, but I still need to think about how because I also like the idea of simplicity in trying to keep it as simple as possible, so I will have to think about which direction I think to go.

Hung Truong: Can we try through ranking? I have a feeling that if we do the ranking, and then we pull it up and compare it to this, we might see a lot of overlapping. And so is it the 26 drugs that we can choose from? I think the majority of them will be on there for us to choose from.

Mike Neuschwander: So then I think I'm hearing the general consensus is so we can go forward using the summing of the ranks and then weighting -- applying our weights to that. So there's a -- we distributed our points among the Board Members and then basically we then -- I'm just thinking out loud here, so -- times the rank by [indistinct] if the first one got 75 out of 100 points, times that by a .75. The next one got 10 out of the other times that .1, then add those together to get the new sum is kind of the idea behind that.

Douglas Barthold: Yeah.

Mike Neuenschwander: Okay.

Douglas Barthold: Okay.

Mike Neuenschwander: So Jingping gives us a thumbs up. Ryan, Donna, as our pharmacy experts, any thoughts, ideas, questions, concerns on that?

Ryan Pistoresi: Not right now. I think it is possible, and I'd be curious to see kind of how those weights and scores come out, and then from there we could put it together. I wonder, and I'm just kind of thinking about what you were saying with the different weights. I'm wondering that if we look at the rank for like the most costliest one and then the next most costliest two, if the most costly is like $100 million and the second most is only $1 million, is that important for you to differentiate at this stage, or are you okay with just having the rank of one and two? Because then that would also require some adjustment in the methodology to account for these differences in scale.

Mike Neuschwander: Well because I think, though, Ryan, because when we rank it and it comes out when we get our top 25 or whatever, then we won't be worried so much about the weights per se anymore, but we'll have that top 25, and we can see the 10 million versus the 1 million, and then looking at it, the Board can say, oh, this 10 million one is speaking much more [cross-talk] is obviously way ahead of the others and is speaking to us [cross-talk]. So I think that when we bring to the next step, then we are just looking at the list, then we get

those binaries. Does this have a therapeutic equivalent? Yes or No. Does this have -- does this meet multiple thresholds, which might be important to someone?

Douglas Barthold: Yeah. So I completely agree with Mike on this. I guess the one question I have is like, so when I submitted my weights, it was for six variables including the two [cross-talk] binary. So do we need to [cross-talk] --

Mike Neuenschwander: [Cross-talk] I think we'll revise that and do it for the four and then again have the binary be more kind of the informational [cross-talk] on that as well.

Douglas Barthold: I'm okay with that, but it is effectively making the two binaries the least most important? And I was already kind of close to that anyway, but I don't know how the rest of the Board feels, so.

Eileen Cody: There's a question in the chat or the Q&A box that you might want to look at.

Mike Neuschwander: I can't see it.

Eileen Cody: I'll do it. Is there a difference between the five variables chosen for weights against the six selection criteria for deciding whether to conduct an affordability review?

Douglas Barthold: Wait, is that what we're deciding?

Eileen Cody: Yeah, that's just --

Douglas Barthold: I guess we just need to decide if we're okay making therapeutic equivalent availability and generic availability as well as multiple thresholds, tiebreaker, but then putting them in a tiebreaker category rather than having them in our base ranking. And, yeah, like I said, I'm okay with that, but [indistinct] I'd like to hear from the others.

Mike Neuenschwander: Yeah. Okay. MaryAnne? Eileen? Hung?

MaryAnne Lindeblad: Yes [cross-talk] uh, yeah. I mean, I'm cool with that. Yeah, I'm fine with that. I have a feeling that we're going to be tinkering [cross-talk] a bit more as we run these.

Hung Truong: I'm fine with it.

Mike Neuschwander: [Indistinct]. Any other thoughts or questions then?

Douglas Barthold: It really only does effectively matter if there's a tie between that 25th drug on the list that doesn't make the criteria, and then it seems extremely unlikely that this decision will make a difference on that, and so.

Mike Neuenschwander: Okay. Um, so then I think we kind of have a direction then. So we'll go with weighting the sums of the rankings, with the two binary choices being more informational afterwards. And then I think with our new Board Member, Greg, maybe do we want to -- now that we got all five here -- for our last meeting. We didn't know that Greg was in the running here. Do we want to redistribute the points and do 20 per Board member and then have everyone who didn't vote on it -- or give those points on the four measures?

MaryAnne Lindeblad: I think that's fair. We should do that.

Mike Neuschwander: Okay. And so then that way for our next meeting then we can come with our weighted and ranked list here for the Board to review. And then we'll have the whole list, but I mean do we want to, I guess, focus on like the top 25? And I'm just -- I was just saying a number just to keep it within, you know [cross-talk] --

Douglas Barthold: We can only conduct 24 affordability reviews per year, right?

Mike Neuenschwander: Well, yeah, and then that's going to be another question for our next [cross-talk] Board meeting, is how many do we actually want to do -- in terms of capacity wise. I can give you a pretty solid promise that I don't think we'll be doing 24. [Laughter]

Douglas Barthold: Okay. My point is just that only that that's tough with the really [indistinct].

Mike Neuenschwander: Yeah, yeah. So yeah, we can have the whole list, but maybe we can discuss and focus on just those top 25 than to try and whittle that out. Okay?

Douglas Barthold: Sounds good.

Greg Gipson: I'm sorry. So just to make sure I understand my assignment. So each one of the Members will have 20 points to distribute for ranking? Is that correct amongst these four variables?

Mike Neuenschwander: Yes, sir.

Greg Gipson: Okay, gotcha. Thank you.

Mike Neuenschwander: Yeah, and we'll send everything out here in e-mail with the details. And Greg, we can chat. I know you weren't here at the last meeting where we were kind of originally putting this idea together, but now that we're flushing it out more, yeah, I can catch you up on any details or questions that you might have.

Greg Gipson: Okay, that'd be great. Thank you.

Mike Neuschwander: Okay. Any other thoughts or questions around that? Doug, I can see you're having [cross-talk] --

Douglas Barthold: [Cross-talk] Yeah. I just think that, like, the four variables, total number of users, so that's total numbers of people with at least one claim?

Ryan Pistoresi: Yep.

Douglas Barthold: Yeah. Okay. Average member paid amount, that's average member paid amount per month among people with at least one claim in that month? Or among people with at least one claim in the year? Okay. So you can have zero months as well as -- let's say if you use it in January, then you will have zero for the rest of the months. Okay. Then member paid amount is basically just the -- it's essentially Column 1 x Column 2. Right? Number of users times the cost per month?

Mike Neuenschwander: No because the number of users is different than the number of claims.

Douglas Barthold: Right, okay. So but it's not for -- isn't Column 2 is about -- is it about per claim, or is it amount per 30-days for a 30-day fill?

Mike Neuenschwander: Jingping, do you know if that's per claim per 30 days or per year?

Jingping Xing: [Indistinct].

Mike Neuenschwander: Column 2, the average member paid amount.

Jingping Xing: That's for during a year, so that is per year. [Cross-talk] --

Douglas Barthold: [Cross-talk] Okay. But should that be per 30-day supply rather than per claim?

Jingping Xing: I don't think it's utilization over a year, right? [Cross-talk] It didn't measure like [cross-talk] --

Douglas Barthold: [Cross-talk] Oh, so is it just average annual out-of-pocket for anyone with at least one claim? I thought of that, too. I just mean that, like, that we want to be clear about this. And then [indistinct] so then in that case it is just Column 1 x Column 2. Yeah. [Indistinct] weights.

Mike Neuenschwander: I want to say, Greg, if you have questions, too, feel free to chime in. I just want to make sure you're staying and keep getting the information answered that you need.

Greg Gipson: Okay. [Cross-talk] Yeah, thanks. I just didn't want to overstep. I'm not an official Board Member. I don't want to be chit chatting all day. But I think I'm good. Thanks.

Douglas Barthold: Slide 18 is the relevant one here?

Ryan Pistoresi: Yes, I think. There's 10, 15, and then 16.

Douglas Barthold: Okay. And actually, that simplifies things because then you don't have to worry about the claim is for 60 days or 30 days or whatever, it's just out-of-pocket costs in the full year.

Mike Neuenschwander: Yeah.

Douglas Barthold: Yeah, for anyone with at least one claim. And then the final column is just total paid, so total out-of-pocket costs of the plan. Okay. Sounds good.

Mike Neuenschwander: Okie doke. Um, any other questions on our weighting next steps then? Okay. So next time what we can do is we can come here, we'll readjust the weights here, especially now that we have our new Board member, and then

we can come with that weighted list based on the ranking since we have got that all kind of ironed out now, which I think is going to be a little bit more of again a straightforward way of being able to get this list put together in other ways that we could have possibly done. And yeah, we can come in with that list and just kind of start talking about how many drugs we want to select and what drugs we want to be looking at as well. So I think that will be a lot of good discussion, really, moving us toward the actual affordability reviews, so then we can do the actual selection early next year and start on that.

Douglas Barthold: Sounds good.

Mike Neuenschwander: And then we can also make sure we get the policy for exactly what we we're doing and how we're doing that together as well so that the actual -- we're at the part of here's how we're running things.

Douglas Barthold: People will end up with the document that we typed out earlier? [Cross-talk]

Mike Neuenschwander: [Cross-talk] Exactly, yeah because -- so developing our policy and our methodology for each stage of this drug selection and review process. Okay. So that takes us on to our next piece. Do we -- does anyone need to take a short break, or are we wanting to just keep going on? We have two more pieces left, I think, for the meeting today.

MaryAnne Lindeblad: I vote we follow through.

Mike Neuenschwander: Follow through? Okay. Great. So then that -- oh yeah. [Indistinct]

MaryAnne Lindeblad: [Audio cuts out] [Indistinct] I'm not offended.

Mike Neuenschwander: Just give me a little whack on the back of the head if I'm getting too excited.

MaryAnne Lindeblad: All right. So the next agenda item, Marina, is going to talk a little bit about the affordability review [indistinct] outline [indistinct]. Marina.

Marina Suzuki: Okay. Let me share my screen. Let's see. Okay. Is it coming up on your end? All right, great. Yeah. So the next topic we're going to discuss is about the affordability review outline. So [indistinct] selected [indistinct] the more pressing matter here right now, but we also want to plan for the future when

we have to conduct affordability review. And the first step is to solidify your wants and needs to conduct the affordability review. So a few months ago, I reached out to each Board member to ask what kind of information you are looking at for the affordability review. Those were very broad questions. And I also sent you a copy of our Legislation language. So our Legislation lists a certain factor [audio cuts out] we have to consider as part of the affordability review, but we can also consider additional items if you want to or if anything helps you to determine the affordability of a drug. So let's start. So really, the objective today -- so let me see if I can hide this somehow. Hold on. Yeah. So those [indistinct] today is just to introduce and to discuss the outline for the [indistinct] drug affordability review, and also to collect additional interests or suggestions that you may have. So, again, really, we want to sort of define what you need and what you want to see for the affordability review here. So no voting is needed, and I am picturing this is going to be a work in progress all the time as we move all of those collecting different feedbacks, inputs from our stakeholders as well, and hopefully, you will keep making improvements in the process. So it's not going be like set. Yeah, I don't think it's going to be any [indistinct] form, especially the first few years. We'll see how it goes, and we'll keep making changes based on what's working and what's not. All right. And let's see. All right. We also -- just a very overall process, so right now we are in the preparation. We are trying to develop data collection form on our end. And again, I reached out individually and kind of gathered your input, so now you'll get the compiled list today. And also another thing we have to do is to set up a secure PORTAL for stakeholders to submit the appropriate or confidential data or information to us, so that's also ongoing in the background. And Greg, I know you are a new member, and I didn't have a chance to reach out to you. I'm sorry, but you'll see what's compiled so far, and if you have any additional requests, feel free to reach out to me, and I'll make sure to incorporate whatever the suggestions you have. All right. Okay. And yeah, so we will be creating a secure PORTAL for data submissions. We will be creating the data templates and also information submission forms for each stakeholder, and also, we'll be conducting surveys among different stakeholders, especially like the patient's advocacy groups or subject matter experts, so that they can help you make the decision at the end. So that's all the preparation we have to do first, and we'll collect information during surveys. And also, there will be some steps that we have to verify the data on our end, and also we may have to hold some meetings in case any questions come up from our stakeholders. We may have to set up some one-on-one if they want to discuss some confidential data with the agency, and we may have some group

meetings together if any clarification is needed from the patient advocacy groups. So I'm assuming just like do a survey [indistinct] data, but I think we'll do a survey. We'll look at the data. If further clarification is needed, we may need to set up some meetings, so that's going to be Step 3. And then all the information compiled, otherwise, will be presented to you at the end. So again, this is going to be a long process I am imaging, and any patience and any guidance from every one of you is appreciated. But this is the overview end. So for today what you'll get is a compiled list of what kind of information you want to see for affordability review, and how all the elements or factors compiled are based on the Legislation requirements. So the Legislation spells out the Board has to consider NNN, NACD to do that affordability review, so that is all part of the outline for sure. And also any special requests you have are now compiled into this outline, so you'll see that. And also, I reached out to the PORTAL external consultant members to get their advice because we are also developing the data collection forms [audio cuts out] stakeholders. I reached out to the other states' PDAB and also states without PDAB, but some states are doing a direct pricing review. So we collected some forms that they're using to see some of their language that they're using, and also, they got formats for the table. So that something that will be consistent between states for our stakeholders. Yeah. So everything is now compiled, and now we're getting the outline for the affordability review. And one thing I will point out is we, as an agency, do not have all the data we need, so we have to reach out to our stakeholders, including manufacturers, patients, payers, PBMs, and also perhaps wholesalers again also. And also, we are going to get some internal data source, including [indistinct] Medi-Span, All Payer Claims Data, DPT data. So DPT is our Drug Price Transparency Program. It's like a sister program we have at the agency, and they do collect data from manufacturers, PBMs, payers, so they do have some data that we may be able to use. Also, we will use that to verify whatever the information we are collecting. And also, we have contracts with other external consultants. Also, we will get their guidance as well as we move on with affordability review. And manufacturers, they have a fine if they do not submit information to us, but no other stakeholders. So here, I'm hoping -- this is like a wish list. We hopefully will hear from everyone because it kind of affects all the parties listed here. But we may or may not get all the information depending on the drug or the timing or how much help we can get from each stakeholder. So this is, again, this is our wish list, but we'll see how it goes. All right. And this slide and next slide gives you the first headline of the outline, so just the big sections of the affordability review starting with the background information, efficacy, safety. So it starts from Section 1 to the

next slide, and it has up to section 16. And I kept the language or the wording from the Legislation. Also, I did the wording. It's just as it is from the Legislation. Okay. But I just want to go one by one. So for like, let's say, Section 1, it's going to be just the background information about the drug. So we'll just [indistinct] on the report. What is the generic name? What is a brand name? Drug class, NDCs under review, and also indications, approval dates by the FDA. Do they have any open drug status? So this is just a reminder that we are not reviewing any drug with the open drug status only. If they have multiple indications, and one of them had the open drug status, that is still eligible for the drug review. So yes, we may have some drug having the orphan drug status as well. And we will also check on the drug shortage status, and also we will need some manufacturer contact information as well. So this is just a quick background section. That is the first. And yes, we are [indistinct] I think we are all clinicians and have a clinical background, but we may or may not be totally familiar with the drug being selected. So we are going to collect some information about the drug from the manufacturers asking, what does this drug do? What is the efficacy? Are there any safety concerns we should be aware of? So this is -- we're not checking the efficacy or safety. This is more for our education and for the education for the public as well because at the end the report, it's going to be available to the public, and I just needed some sections to educate about the drug, not just only for the Board members and us but also for the public as well. So I'm assuming this is just some brief few paragraphs talking about the drug. Okay. And this is a big part of the affordability review. So it's about the drug pricing information, and some of the pricing is spelled out in the Legislation, and some of the pricing requested by you, and this is the list. So you're going to get WAC, AWP, NADAC, AMP, and also looking at the whole therapy duration, what is the most current WAC. Also, we are going to correct information on any discounts, rebates. And I heard the net price is going to be, I think, that's the one that's going to be really helpful. With all the rebates and discounts going on, what is the actual net price? So we're going to ask that to the manufacturers, wholesalers, PBMs. And also, we are collecting some data on drug pricing in other developed countries as well, so we'll have a whole picture of what kind of pricings are out there. And also, any other discounts, special discounts the manufacturers are offering to some special entities, [indistinct], we will be collecting that. So this is all the pricing information we will try to collect. We don't know how much information we can get, but we'll see, but this is the whole list that we've compiled so far. And the next section is about Manufacturing, Delivery, and Administration Costs. So we are going to ask what was the cost for the

research and development, and to keep product producing [indistinct] the medication. What is the cost to keep a supply? And also, we will be asking what is the marketing, advertising, or lobbying project or expenditure for the drug? And also, if there's any delivery cost associated with the selected drug will be [audio cuts out] collecting that information as well as the cost of our administration. So this is the [indistinct] syringe for injections. We are not selecting any drugs that have been administered in the hospital or infusion center. Those are not eligible for affordability review. So right here, saying administering costs, it's more like a syringe and other supplies. And if the manufacturers have any other administrative costs, the last one is just a kind of catch-all information that I can't think of, then they can still submit that information. So this is section 4. And also, we want to look at the cost to patients, and this information will most likely come from our payers or carriers. We will ask about what's the patient's copay, coinsurance, and also again look at like the premium, deduct [audio cuts out], and also the average amount responsible by patient by claim. Some of this information is not drug dependent. It's more like what are the medications we're going to be selecting for the affordability review? It's not [indistinct] may not be specific to that, but I'm hoping that we can kind of sort out the patient groups with that medication and patient groups without that medication, and how many of them are reaching their out-of-pocket maximum or something like that. So we'll sort it out hopefully, with the carriers and payers and get some additional information for you about costs to your patients. So this is the Section 5. And the Section 6 is the Price Effect on Consumer's Access to the Drug in Washington. So this is looking at more state-specific information, so we want to look at, okay, what is the prevalence or incidence rate for the indicated conditions in our state? And also, we want to look at the utilization of the drug in our state, and also the cost. Are they different from the nationwide? Are we like a super-user of the job or a super-spender of the drug? So we can take a look of that. And I think the coupons and patient assistant program discussion already came out but, again, no collect that information. So what is the patients' eligibility? What kind of availability for the assistance programs? So we will gather that information as well as the actual dollar amount that they're providing or the quantity of the drug that they're providing through these programs. And also, we will gather information on the coupons. Are coupons available? And if it is, what are the potential limitations to their use? So those are the information we will be collecting from manufacturers. And we kind of discussed this already, and you'll be getting the information at the point of the selecting drugs. But yes, a part of the report will define whether they have any generics or biosimilars.

So that's Section 8. And also, you'll look at some therapeutic alternatives, both for availability and for the pricing of them. And again for this, we have to look up for each indication, and it's a bit tricky to define the therapeutic alternative [audio cuts out] the same class drugs, the same indication, same rating in the clinical [audio cuts out] or guidelines. Then, yeah, that most likely use therapeutic alternatives, but it's possible that we have to look at a different class of medications that may have a similar recommendation of the clinical guidelines. So, again, this is where we can get some help with the subject matter experts and also from patients as well. We kind of have to look at where it fits in the treatment landscape. What's the placing for our [indistinct]? Is it supposed to be first-line, second-line, third-line, etc.? How strong the guideline recommendations are and the overall cost, as well as we wanted [indistinct] of the safety/efficacy differences between the alternatives. So those are going to be summarized as well, hopefully, with some help from external consultants as well. And the Section 10 is going to be a Cost-Effectiveness Analysis. So we'll ask for the cost effectiveness for each approved indication from manufacturers, and it's most likely they have some kind of model they created prior to the marketing. So we'll be asking for the model so that we can figure out how the drug pricing was done at the beginning, what kinds of things were considered. And we also as an agency subscribed to ICER Analytics. So that's actually our preferred platform. If the manufacturers also subscribe through the ICER Analytics and they have a model there, that is probably the best model we can get because it's so interactive for you to see how the pricing changes with the current parameters. So hopefully, that's something we can gather from the manufacturers. And this is still to be determined for the current stakeholder surveys. Again, we will be surveying the patient's medical or scientific communities for their expertise. And I think survey content will be highly dependent on which drugs are going to be selected. So we haven't actually developed any surveys yet, but this is to be done in the future as well as we'll be gathering input from our advisory groups as well. All this is something to come in the future. And also, I have the Legislation allows us to collect any additional information from drug manufacturers so [audio cuts out] might help us is to figure out what kind of [audio cuts out] exclusivity they have on the drug as well as the patent, expiration date, if that's applicable, and also, if they have any special lifecycle management and costs associated with that, we want to collect it. And for each approved indication there will be collecting some market competition and contacts, some revenue information, and we'll be asking them for the budget impact analysis, and hopefully, we'll gather the model on that as well. That's Section 14. Section 15 is about the

PBM, the drug tier system. Do they require any prior authorization for patients to use the drug? Is there any step therapy they have to go through to get the access to the medication? So that information will be collected from PBMs. And the last section is just off-label usage. So if there is any off-label use of the drug, then we want to know about it. So we'll gather that information as well from the manufacturers. And I believe this is the last section of the outline. And the last thing I just want to point out is what you will achieve by gathering all this information, and the first step or first decision after you hear all the information is to determine whether the drug is having the excess cost or a potential leading to excess cost in the future. And what does excess cost mean? It's actually defined in the Legislation, so I put it here for your information. Is the cost of appropriate utilization of pres- [audio cuts out] drug that exceed the therapeutic benefit related to other alternatives. Or the second bucket is defined as cost of appropriate utilization of a drug that are not sustainable to public or private healthcare systems over a 10-year timeframe. So those are the two big definitions of excess costs. It kind of clarifies the definition, but still some [indistinct] for you to define more specifically. And the PORTAL members will be presenting on this right after me, so you'll hear more at the next presentation. But some of the perspectives for you to consider to determine whether to provide pricing that leads to excessive costs is one. Yes, the cost relative to the alternatives, and also, too, is out-of-pocket costs, and also the impact to the access for the patients and conditions and other providers. But also, we want to think about the whole system, the states, public, private payers, and Washingtonians in general because if the drug is too expensive, again, that tends to lead to a higher premium, so everyone is paying higher monthly premium to the insurance every month. So again, it's not just the out-of-pocket cost to the patients themselves but also everyone participating in the healthcare system in general as a consumer. So that's a broader view about excess cost. But just pointing out that we don't want to just focus on the out-of-pocket costs to the patients. All right. And this is my last slide. So right now you have a kind of comprised list of the outline for the affordability review, and I think it's already pretty comprehensive because I reached out to everyone of you and looked at other states and gathered input from our external consultants as well. But if you have any additional requests, suggestions, wants, needs, it's not too late. Please let me know. Yeah. And if you can e-mail me, that's probably the best because then I can kind of do a check-off list when I'm creating the information correction sheets. Yeah. So again, if you have any big items or you know that I wanted to hear about X, Y, Z, and it's not in the outline, let me know as soon as possible because we are [audio cuts out]

developing the information sheets or data collection sheets for our stakeholders. So that's what we're doing right now. And once we have templates for our stakeholders, we will post it on the website, and we'll gather some inputs and feedback from our stakeholders as well. So that's our next step. Yeah. So that's where we are. And I think that -- yeah, that's it. Any questions or like a burning request you have right now that you want me to know?

MaryAnne Lindeblad: Any questions? Don't see any, so thank you. Thank you, Marina, appreciate it.

Douglas Barthold: Yep. Thanks a lot. That is a very comprehensive list. I kept on thinking of things I was looking for, then you got them all [cross-talk] --

Marina Suzuki: [Cross-talk] [Indistinct] yeah, I think you may have wanted details on a specific request once you see the information collection sheets. But I think in terms of big [audio cuts out] items right there, so I'll move on from here. Yeah. Well, thank you.

MaryAnne Lindeblad: And thank you. Is Dr. Rome on?

Mike Neuenschwander: Um, the PORTAL team is on, but I'm actually going to request we take just a quick break. We have a technical thing to resolve.

MaryAnne Lindeblad: Oh, okay.

Mike Neuenschwander: All right.

MaryAnne Lindeblad: Okay. So well have a little break while there is a technical difficulty.

Mike Neuenschwander: Maybe like a 5-minute break.

MaryAnne Lindeblad: Okay. So 5 minutes, folks.

[end of audio].