

**Washington Prescription Drug Price and Purchasing Summit  
June 14, 2016**

Dan Lessler: Good morning everyone. It is 9 a.m. and we are going to get started on time because we've got a packed day ahead of us. My name is Dan Lessler. I'm the Chief Medical Officer at the Washington State Health Care Authority and I want to welcome everyone here today to what we have titled the Washington Prescription Drug Price and Purchasing Summit. And this is the first convening of you all who are here, stakeholders, legislators, others to really engage a robust discussion, and really what I would say what the big picture, what this conversation is about, is how do we get to value in our pharmacy purchasing?

As I travel the state and talk with colleagues, pick up the paper, I would say there is not a day that goes by where prescription drug prices and the cost of pharmaceutical care doesn't come up. So this is a really very hot topic, a very, very important topic and we're delighted that you're all here to talk with us today, to have this conversation.

We've got really a diverse group here, which is terrific. People will all sorts of different expertise and backgrounds and we're particularly delighted that we have a number of legislators from the Washington state legislature here today. I wanted to begin by just... if they could just stand up and introduce themselves we would welcome that. I see there's some right there.

Woman: [inaudible]

Eileen Cody: Chair of the House Health Care Committee from the 34<sup>th</sup> District right over there. You're not too far from my district.

Dan Lessler: Close by. And...

Man: [inaudible]

Dan Lessler: Maybe you could describe where that is for folks who might not know.

Man: [inaudible] Garfield and most of Franklin County.

Dan Lessler: Another beautiful place in the state. So we're a big group and we're, as I say we have a packed agenda. What we wanted to do is just ask people, at your tables, if you could just introduce yourselves to each other. Just take a moment. We're not going to go around and have everybody introduce themselves individually, but I just want to take a moment and if you know each other you can... I'm sure there is something you could think to comment on for a minute or two. Folks, make sure you've introduced yourselves. And when we actually get into the discussion part of, which... and there will be a lot of discussion of these conveying today, we're going to ask people to... when you speak to always begin just by saying your name and where you're from so people will get to know each other.

I suppose people sat with folks that they know. We should have mixed you all up a little bit more. But you'll have a chance across the day to get to know one another.

I'd like to introduce Donna Sullivan. Donna is the Chief Pharmacy Officer at the Health Care Authority and has just been, I think, an incredible leader for the Health Care Authority in our pharmacy policies and our pharmaceutical purchasing and I just have to say it's a real pleasure partnering with her at the HCA in this work around pharmacy. So here's Donna. She's going to say a little bit more about the goals for today.

Donna Sullivan: So I want to be able to... I like to walk around when I talk so I don't use my hands. First of all I want to thank you all for coming. We're going to talk about the goals today. The number one goal is to make it through our agenda on time. The other thing that we really want to look at today, the reason why we called you all here, is to take kind of a deep dive about prescription drugs, what's going on on the national trend with prescription drugs, what's going on with the state, and really understand pricing, different purchasing strategies that we can

look at, what are some of the cost drivers that we're seeing behind prescription drugs, and how that impacts our members, our employees, our Medicaid members, and other residents, you know, within the state of Washington.

So in the morning we have kind of set the agenda to tee up what is the issues with prescription drug pricing and some purchasing strategies. In the afternoon we're going to focus more on potential solutions. And then above all what we really want to do is engage you, as purchasers, as stakeholders, in a dialogue and come up with some robust discussion about potential strategies on moving forward.

Dan Lessler:

So we really are teeing this up to have a lot of conversation and we want to have people thinking outside the box. Now that brings me to one of my favorite New Yorker cartoons, which is here. I was thinking about this this morning because I do have a cat and I was reminding Jack that he needed to think inside the box at the same time that I was thinking that all the people here really needed to be thinking outside the box. So we do want to engage a robust conversation, you know, all ideas are welcome, you know, this is a difficult problem and we need all your best thinking.

With that I want to introduce Ray Hanley. Ray is going to facilitate our conversation today and I'm delighted that we have him here to be able to do that. Ray is the Director of the Prescription Drug Program at the Washington State Health Care Authority. He probably knows more than anybody, or at least as much as anybody in this room, about purchasing prescription drugs. Ray also has just a fabulous background in policy and health policy and I think one of the... one of the interesting facts I learned about Ray, actually some number of months ago, is that a number of years ago he used to work in the other Washington, Washington, D.C. He worked at the Brookings's Institution and actually was a colleague of Alice Rivlin at the time. Some people might know Alice Rivlin, who is the former director of OMB and budget director, I think, congressional budget director. In fact, he and Alice Rivlin co-authored a book called Caring for the Elderly with Disabilities Who Will Pay. The issue of economics and health care are very familiar to Ray and we're delighted that he's

going to sort of move us along, ask provocative questions, and make sure we get as much out of today as we can. So, Ray?

Ray Hanley:

Thanks, Dan. I appreciate everybody coming today. It's an exciting day. We have got a lot in store. All together I think there are 14 people that will be presenting over the course of the next 7 hours and it's going to be a jam-packed day. I got a lot of last-minute instructions, as people do in this role. So my job actually today, and I guess it fits well with maybe a Brookings's background is to be the social engineer. So I'm going to try and help move things along and one of the first things I wanted to say is that I'd like you to turn off your cell phones and I'd like to instruct you that the restrooms are right down the hall to our right.

I'd like you to know that you're actually part of a rather large experiment. This is a dialogue that we're doing today and we haven't done anything quite like this before. What makes it different is that rather than having a lot of talking heads that will sometimes run over, we're actually going to try to keep the speakers to a relatively short period. That's to encourage you to ask questions. Those questions I would ask you to put in the form of a question rather than a comment. And we will have a chance to collect your comments at the end of the day. We'll talk about that a little bit later. But to actually facilitate the questioning there's some little index cards on your tables. You may have noticed that, and pens as well. So if a speaker is speaking, and like I said we have a lot of them today, if you would just write down your question and hold up the card, and we have spotters. We have two people and I'll introduce them in a moment. They will be going around the room and picking up the cards and then we'll ask you to direct your question to the speaker once they finish their presentation. So this is a way to just hold your questions and try to encourage a dialogue towards the end. So we're basically holding the speakers, just so you know, to about half of the time that's allotted. Okay? So the other half of the time, more or less, will be left to questions.

At the 10-minute mark for the speakers, and we have a lot of them in the room here, or so, about halfway through, Leta, who is sitting up

here will actually hold up a card to try to tell you that it is time to bring your discussion to an end. After that we'll give you a couple of minutes to wrap up. We talked about the index cards. We talked about the spotters. I wanted to also say that, you know, Dan and Donna were instrumental in putting this together. This is a huge step for HCA. But they put it together, we're pulling it off, and I'd just like to introduce a couple of the people who are actually in charge of pulling this off and one of them is Leta Evaskus doing the technical stuff and in the back of the room are Judy Hall and Rachel Berg who will be our spotters today. If you have any additional questions or you're not sure about what's going on, please, just check in with one of them.

If we don't get to your question, if you have an additional question, please leave it on your table. We're interested in trying to collect as much information in an informal process as we can from folks. That's what we're up to.

I guess I want to take you through just a real quick look, if you haven't looked ahead at the agenda, we're going to... at closing we're going to have a 3 o'clock break towards the end of the afternoon, if all stays on time, and then we're going to ask you to answer some questions, which are actually open-ended questions, about what's the important lesson. So you can be thinking about this during the course of the day. What's the most important lesson you're going to take away from the summit and why? What's the potential next steps for the state to take away and why? And what additional topics should the state be investigating around prescription drugs? So again, I just want to bring you back to this thesis, this idea that this is a dialogue. This is not a bunch of talking heads. This is not a webcast. This is to help you to help us try to create a very informed dialogue. So with that we're going to turn it over to Kai... Yohan, I'm sorry.

So Yohan Cho is a consultant at GFK. He specializes in drug pricing, in [inaudible] research and committed landscape assessments, as well as market access strategies. Yohan has led a number of numerous engagements involving strategic insight for commercial development of small molecule and biological products across a number of

therapeutic areas, including oncology, hematology and infectious diseases. Yohan is a member of the Oncology Center of Excellence at GSK and he leads numerous projects leading to high profile oncology therapy. Through his experience at GSK Yohan has become familiar with the market access implications, numerous markets globally including the United States, the EU, Japan, Canada, Australia and emerging markets. So I hope you'll please help me welcome Yohan.

[applause]

Yohan Cho:

Thank you so much for that introduction. Thank you everybody for having me here, especially Donna and Dr. Lessler. I had an opportunity to talk with them two weeks ago at another conference and I'm more than happy to share my perspective on this stuff and some of the things I've learned in my career as a consultant working in drug pricing, as well as [inaudible].

For this talk today we're going to be touching upon a few different topics. [inaudible] view this time for introduction because a lot of things I'm going to be talking about I'm just going to be introducing and we're going to have other presentations that are going to go into a little bit more detail around that. We're going to start the conversation today with some things you probably already know about, stuff that happened in 2015. Understand the drug trend, drug trend in terms of spending and pricing and really why we are here today. Then we're going to talk a little bit about some of the things we can expect in 2016. Not all of it is a concern. Some of it is actually... might be opportunities for you to expand your drug spend if you do it the right way. Then we're going to talk a little bit about what's going on in terms of what other payers are doing, not just here, but on the national perspective. So what commercial, Medicare, maybe what some other states are doing in terms of trying to manage that drug spend. Okay?

These are just some of my disclosures. I won't spend much time on that. So let's start the conversation today and try to understand what happened in 2015. 2015 was the year in drug pricing. We all read the Times. We all read the Wall Street Journal about everything that

went on. In terms of drug spend across the board for both commercial payers, Medicare and Medicaid there was an increase in drug spend. Not too surprising [inaudible]. When you actually take a look at it, most of that increase you can see was in specialty drugs. So a lot of things that we're going to be talking about today is going to be focused on specialty drug spending. Because even though utilization actually went down for a lot of folks [inaudible] business such as Medicaid, drug spending went up significantly. You can see Medicare 27.9% increase in drug spend. A lot of that is oncology drugs, a lot of that is for older patients, but you can see that there is something that really needs to be done in terms of managing that specialty drug spend.

Now this isn't anything new. This has been happening for a while now, we all know this, there's actually... from 2013 to 2014 was one of the largest increases in drug spenders, about 27%. Okay? It actually decelerated a little bit, but only to 21%, which is still pretty significant when we're talking about \$150 billion expected [inaudible]. Now you can see here it looks continued. So there is something that has to be done about that. So drug spend will increase about 17% over the next few years and that's just a generous estimate. It could be much higher than that. If you actually look at the pipeline we're talking about 255 different specialty drugs that could be in the market before 2020. So that's a lot of drugs. Now if you actually look at Medicaid these are the top five drugs for Medicaid drug spend. Not too surprising, HIV, hepatitis C, I'm actually not going to spend too much time on this because there's going to be some more talks that are going to go into a little bit more depth about that. But we can see by hepatitis C, which is actually pretty interesting, is that despite overall that the total drug spend went down a little bit, but you can see utilization went down 40%. So what does that mean? Well, that can be attributed to a few different things. So we're all heard about Medicaid programs doing things to try to limit access to these very expensive drugs. Whether making them only available to very sick patients, but not everybody can do that. This actually might be a little bit misleading because if you actually look at the source this comes from Express Scripts. So this is only counting for drugs on the pharmacy benefit. In actuality one of

the things that a lot of Medicaid programs are doing, or a lot of states, is that they are actually carving out drugs like hepatitis C away from the pharmacy benefit and putting them on fee-for-service. So they are still paying for these drugs even though it's not being recognized in charts like this. Okay?

So this is the understanding of what happened in 2015. So what can we expect as we go into 2016? Well, we can expect the trend of therapeutic classes where they are typically... or historically weren't a lot of drugs becoming more crowded. IPF for example in 2014 there were no [inaudible] drugs that were indicated for that and you had two that came out on almost the exact same day—[inaudible] and then BBI's product. You can see areas like hemophilia B where there's only four products. Now we're starting to see longer active products. These are products that have higher unit costs and even though you're supposed to have less injections, because it's actually supposed to bring down drug prices, they still don't know if that's the actual case. So there are a lot of kind of questions around that. If you look at oncology and that chart I showed before kind of showed the breakdown of the different therapy areas in terms of drug spending increases, oncology is a major issue. Drug classes like melanoma, CML, RCC, you're seeing very expensive drugs that we all know about—immunotherapy, PDL1, these are now starting to crowd these classes creating extreme... just creating a very crowded therapeutic area with a lot of different products that are very expensive. We're actually going to talk a little bit more about it's not just about more products are coming out, but about how they are being used, and a lot of them being used together.

So looking at 2016 we're about halfway through. I think we have nine approvals that have already come out. I think there is one that just came out last week that's not on here. Do you actually look at the drugs on here? One thing I should point out, these are almost all specialty drugs. These are expensive drugs and their peak sales are supposed to be in the millions of dollars. I think every single one except... I think every single one except two is supposed to have billion dollar peak sales. So these are all blockbuster specialty drugs. Okay? Now there's some interesting cases that I highlighted here.



These are drugs that are the top of Medicaid. So this is MS and hepatitis C. Zepatier is actually pretty interesting and we're going to talk a little bit about this and what it means when competition comes out and what that can actually mean in terms of being able to manage these drugs and manage to spend. So Zepatier is for hepatitis C. We're all familiar with [inaudible] and hepatitis C. When Sovaldi came out we'll talk a little bit about that and what that actually meant on drug spend. But Merck did something very interesting as they came out here. So it became a very competitive area. So you saw prices go from \$84,000 for Sovaldi and \$91,000 for Harvoni down to rebates of 40 and 50%. [inaudible] actually came out and they undercut it by 40%. Their list price is \$50,000. On top of that there are probably contracts and rebates as well. So you can see that there is going to be some areas where you can start to focus on in terms of trying to manage that drug spend. Competition is one thing you should be looking out for.

Now I say not everything is going to be concerning because there are some things that might bring some relief. So there's going to be a number, generics are already coming out for some very big drugs. [inaudible] is going to be one of the first small molecules in oncology for targeted therapy. Now when [inaudible] came out in 2003 or 2000 this was supposed to change everything. Right? It came out in [inaudible] disease, very high price, small molecule, used in more and more indications every year. So this is going to be hitting generics and how this is going to be managed by payers is still up in the air. Okay? It's still going to be a specialty drug. I think it's only about 6%... is the first generic is only about 6% off of list price for the branded. So payers are going to be able to treat this different ways. Are there going to be new tiers? We talked about especially generic tiers. There's some things that definitely work at... look at and try to determine if... see if that will work for you. Crestor, which I believe is the third highest spending traditional drug out there, that's going to be going generic as well. So there's a number of opportunities in terms of managing some drugs that have typically been very, very high [inaudible].

Now 2015 was also something very interesting in terms of biosimilars. It was the first year that a biosimilar was approved in the U.S. So in the U.S. we are actually pretty far behind in terms of biosimilar [inaudible]. This has been going on for a long time in the EU. Now there's still a lot of things in terms of understanding how and what you can do to manage biosimilars. So we can talk a little bit about this later, but just in terms of whether this is interchangeable or not, which determines whether it can be substitutable or not by a pharmacist without physicians consent. So Neupogen was the first drug to come out with a biosimilar or a biosimilar of Neupogen was the first biosimilar to come out and then we already [inaudible], which is the biosimilar for Remicade, another very high spending specialty drug come out this year. Now neither of these drugs are interchangeable. 2016 can be a windfall for biosimilars. There could be up to seven different approvals for different biosimilars. And these are biosimilars for things like Humira, more competition for biosimilars for Remicade. So there's a lot of opportunity here, but people still aren't quite sure on what you can actually do with these drugs. So you can see, as you look down the road, there's going to be more and more biosimilars coming out for some big drugs—Lemtrada for MS, we're talking an Avastin for oncology, Herceptin. So there may be some opportunities in terms of understanding what you can actually do with this and how that can impact your drug [inaudible].

Now the other thing I wanted to bring up about 2016 is a trend which we called stat combination or brand-brand combinations. So this is something that you can start to see. If you actually look at it a lot of trials now are currently for the stat-stat combinations, brand-brand stat combinations. You see oncology has a lot of them. So every time you see PDL1 and PDL1 with another drug this is an example of a brand-brand combination. So Avastin with... or Yervoy with nivolumab, things like that. Now there's already a number of brand-brand combinations already out there and there's more that is going to be coming. Now this creates a situation in that trying to understand how to manage these different drugs is going to create a situation where there can be very, very rapid drug spend for these different classes. So oncology is actually an area where management... [inaudible] management is pretty minimal in the U.S.

So what are you going to do when every single therapy, when guidelines, they start to talk about using a lot of these very expensive treatments together. So you can see here... we like to use this little graphic. This is a little graphic. This is a brand generic at the [inaudible]. So when it is a generic-generic for a payer, not a problem. When you start stacking up brands and generics, well, it starts to become a value consideration. So is it worth it? Is it better than what it's supposed to be compared of? And then we start to look at brand-brand. Well, these are some situations where it can really put some payers in a bind in terms of how they are going to be able to cover these types of drugs. Okay?

The second portion of this, or a third portion of this talk is I want to focus on how payers have been reacting to this. So we all know about Sovaldi and what happened here. We can call this the big bang moment in drug pricing. A lot of things came out when... before Sovaldi came out and understanding what are we going to do about this? We talked about patient warehousing, large patient population, expensive drugs, a drug that shows a great benefit not just in terms of efficacy, but in terms of [inaudible] and tolerability over current treatment. Now this really set the stage in terms of what payers started to do or what payers were able to do in terms of managing these drugs. Right? There was a lot of press. Competition started coming out. You start to see different things in different ways in terms of how payers... in terms of getting the payers the tools to be able to kind of manage their spend and then also to hold something against the manufacturers.

Now this is something we can talk about in depth, but I'm just going to go over it very briefly. This is essentially the fixed basis [inaudible] economics. This is a paper about this that's very helpful. Now what I want to come across on this slide here is understanding the types of drugs and where are some areas that are going to help you. For example, if you're a state Medicaid program, if you're a state pharmacy director, and you're trying to manage your pharmacy budget, things like focusing on things like fast-pays where it's expensive with short-term healthcare costs that might be something more beneficial to you. As opposed to if you're CMS or if you're at

Kaiser-Permanente where you have patients who are there for a long period of time and you start to recognize those benefits from long-terms costs, slow-pays might be something of more of an area of focus on in terms of being on the managed [inaudible] costs later on down the road. In fact, diffuse-pays are expensive and they decrease nonmedical costs. Now while we all want decreased costs overall that might not be something for a state Medicaid program. They aren't actually going to recognize the benefits. So it's really identifying what are those different drug types and where are some areas that we should be focusing on in terms of trying to manage that spend.

There's a lot of confusion and there's a lot of talk about what's drug pricing, what's drug spending, and we can go into that. So drug prices are the list price. We all know in the U.S. that not everyone pays for list price. Drug spending is what is actually paid for at the pharmacies and providers after the rebates and the contracts. It's what the payers actually spend. Right? Now what we're all trying to do here is understand how we take those drug prices and reduce it so that you're reducing your drug spend. And the ways of doing that is contract. And contracting is with providing the rebates, these are getting a better price, these are some things that are worth exploring. So three factors come up in terms of finding different drug areas that are best for contracts. Competition is number one. We all see this with hepatitis C. So a lot of people, when they would try to go to... when they would try to go to Iliad and try to talk to them about, "Hey, where's some contract opportunities we can do for you to try and manage our drug spend for Sovaldi?" I think a lot of people thought, "Well, not right now." What you saw as soon as [inaudible] came out from ADVI(?) immediately rebates started being offered for both. It was a price war. And you're already starting to see from just one drug prices... or drug spend going down 43% from drug pricing. And then we talked about Merck. We actually [inaudible] their drug prices. They just undercut everybody and they are still at the... discounts on top of that. Now if you actually look at PCSP9 you have two drugs that came out almost at the exact same time. So competition was immediate and what happened? Immediate contracting, immediate rebates. The other part of this in terms of

payers is utilization. So you want to identify those drug classes where utilization is high. Right? Because rebates is going to be based of the utilization of the drug price. So in order to recognize that it has to be for high utilization type areas. If you actually look at something like IPF, which I showed you there, it's a similar situation as PCSP9. Two drugs come out, very expensive, almost the exact same time. The competition is there; however, IPF is a [inaudible] disease therefore utilization is... it's not worth it for a lot of payers to look into that in terms of understanding the contracting or trying to find [inaudible] opportunities.

These are some secondary factors, which is number of patients, pharmacy benefit, lack of clinical differentiation, so these are some things where you can kind of basically play with, look at those different factors and determine what's best for you in terms of trying to manage what the drug spend is in certain areas.

Payers, if there is a contract opportunity, how are they actually doing it? And basically what we did is we broke it down into [inaudible]. Stripped the prior authorization criteria, which you guys I'm sure... a lot of people here are familiar with. Using closed and value-based formularies, which we're going to have a talk about, and outcomes based contracts, which we'll be talking about a little bit later on today as well, and shifting drugs from medical to the pharmacy benefit. Now different payer types are using these tools to different extents. Commercial MCOs can almost try to use the... commercial private payers can use almost all these tools and they are today. For PBMs a couple of them it doesn't really make sense for them to sometimes use these outcomes-based contracts and you actually hear about that. When these first came out a lot of the criticism came from the PBM and the express script and [inaudible]. Medicare they are held to a little bit more legal statutes so they can do these things somewhat. Medicaid I think part of the reason why we're here is to try to understand what are some of the tools that are available for them [inaudible].

So stricter prior authorization criteria. This is something that everyone uses and this is you think that you can add criteria in terms

of determining, you know, who is medically necessary to use a drug, and stuff like that. This is an age-old tactic that works pretty well. However, different states, different laws, impact their different Medicaid administrators being able to use these types of tools. Closed database formularies – I'm actually not going to go into this because we're going to have a talk about this from Kai Young and she's going to talk a little bit about one payer, one private payer's experience using this value-based formularies.

Now this is outcome-based contracts. So there's been a lot of talk in the news about these new types of contracts for private payers. One part is understanding, does this work for other payer types? So one of the first ones to come out was for the new drugs, the... I believe this one is for Entresto. Now these outcome-based contracts are actually tying the manufacturer to make sure... to basically have them... payers pay for their drugs based on the performance. So these are tied to being able to perform at least as well as clinical... as the clinical trials. Now there's a lot of different things to discuss about this and we will a little bit later today on whether it's feasible, how they work. There's a lot of questions on if it's worth it, the administrative burden, but this is just one way at least considering on how to manage your drug spend. So basically holding it to the manufacturer's to have their drugs perform in the way that they are advertised.

The other one is for the PCSP9s and we can go into more detail on this example a little bit later after John Carlson's talk.

And the last one is the shifting from medical to the pharmacy benefits. And this one is a little bit tricky, but a lot of private payers do this because drug spend is also related to reimbursement. So how they reimburse different providers, different pharmacies, and there's a lot of gray area around that as well. When we actually talk about biosimilar system gray areas, it's things to discuss [inaudible] as well. So this is definitely an opportunity to look into because a lot of times what you see for the drug price it doesn't tell the full picture. Reimbursement for different providers is going to be different. It might be ASP based. It might be AWP based. For hospitals it could be

something even crazier than that. It's essentially a mark-up for some crazy price and then they just mark it down for a discount to be in the network. So there might be some opportunities to actually look into this by not focusing on the drug pricing part of it, but actually how you're reimbursing different providers for these drugs.

So what we want to do today is understand what's going on today; whether some of these different solutions work for you and then maybe later on down the road what are some other different things that we can be doing? So we talked about value frameworks. So these are things like the [inaudible] and the [inaudible]. That's coming out there. Understanding cure-based pricing and how that might be different for chronic diseases. Indication-based pricing. There's been a lot of discussion around that. Drugs come out, orphan diseases and then they move into larger patient populations with the... times up. So I'm going to end it there, but there are some things to discuss and basically what we want to do is get that discussion going, try to understand what your options are and see if they are going to work for everyone here. I think that's it.

[applause]

Man: While there is discussion about biosimilars and the preparation for them, do you see them having a big dampening effect on the cost trends in the future or...

Yohan Cho: So if you actually look at biosimilars, biosimilars are very interesting because there's a lot...

Man: [inaudible]

Yohan Cho: Yes, that's right. So just... a biosimilar is essentially a generic or... when a biologic products loses its exclusivity other manufacturers can start to develop it and they are called biosimilars. Now a biologic product is something that is, I guess, very difficult to develop and manufacture. These are coming from things like blood that were common in. So there's a lot more... it's not so easy as a small molecule where it can be easily duplicated. So for a biosimilar to

come out it requires a lot more evidence. It requires a lot more clinical trials and it requires the ability to demonstrate that it works just as well as the reference product or the biologic. So biosimilars has been something that has been coming out for a while in the EU. It's been out there for about 10 years. A lot of our most high spending branded drugs are these biologics. So these are the Humira's, these are Remicade's, a lot of the injectable oncology drugs. So for your question, Ray, are biosimilars something that is going to reduce the cost? So in terms of the prices so far we're only seeing 6 to 10% decreases in branding, which is much different than what you see in EU where we are already seeing 20 to 30% decrease. Now what's going to happen is that even in biosimilars it's going to follow the same kind of trends as you see in brand drugs and that's the competition. As more biosimilars come out for the same drug, and more competition increases it's going to drive the price down and that's what they are expecting. Now the problem with that is that generics... it's very easy for a manufacturer or a [inaudible] manufacturer's or many of them to come out and produce a whole bunch of the same generic. Biosimilars, like I mentioned before, requires more evidence. So you're going to see less of a rapid movement of this competition. So there's going to be a little bit of a lag time. Now the second part of that question, is it going to reduce a spend? And that's the reimbursement part of it. And so originally when the biosimilars came out CMS had a policy, at least for Medicare, where they are going to reimburse these drugs the same way they did for reference prices. So what that means is that the providers actually see the benefits of that because the gap in terms of what they pay for and what they are being reimbursed as is going to be much higher. On the other end, the payers, they don't see any benefits. Right? All you're doing is just basically giving more money to the providers. Now in August 2015 CMS started to release new guidelines on that. And basically what they're doing is that they are saying now we are going to set their own ASP price for the biologics. As we have a whole bunch of biosimilars come out we're going to pool that all together, set that price, and it's going to be an ASP plus 6%. Right? Now before that ASP price is set they are going to do it based off of what? So if the drug price is reduced for the biosimilars then yes, you should see some savings and be able to use that.



Now the second question about this is the interchangeable and substitutable part of it. So in order... if you actually look at generics, if you go to the pharmacy and they give you... you have a prescription for Lipitor. Right? The pharmacist themselves can automatically substitute the generic for the brand. That's called substitutability. Biosimilars is a little bit different. Now the only way that a provider or a pharmacist can substitute that is if the drug is designated as interchangeable. In order to be designated as interchangeable the manufacturer has to establish that the biosimilar is efficacious. There is going to be no loss in efficacy and there is going to be no loss in safety. It's essentially the exact same drug. And that requires a lot of money and that requires a lot of different trials—head-to-head studies and things like that—a lot of time. So far of the two biosimilars that have been approved, which is Inflectra for infliximab or Remicade and filgrastim or Neupogen, Neulasta, for both those drugs they are not interchangeable designated. So they would have to basically go to the physician and get a consent. So the pharmacist would have to call the physician and say, "Hey, can we use this interchangeable product or this other biosimilar for this?" So what that actually means and how much of a hurdle that is going to be is still up in the air. But there's a lot of strategies to look into this because I'm telling you right now all the manufacturer's for both biosimilars and the brand drugs are trying to understand what this reimbursement scheme is going to look like, what that actually is going to mean for spending. What that actually means in terms of administrative hurdles for physicians and providers to use these biosimilars. So I would say, to answer your question, Ray, it's still up in the air.

Woman: One of the questions I have is you talk about competition, but I work in the MS field and that's not working there, because as every drug comes out the prices of all the drugs raise to the price of the new drug.

Yohan Cho: That's great. Yep. That's a drug price question, as well, though. MS is kind of interesting because it's for Medicare. You have different drugs. Some of them are small molecule. Some of them are

injectable so they are on the [inaudible]. Some of them are Part B. Some of them are Part D. That brings an interesting dynamic towards it as well. Now yes, the prices go up. However, when there's competition it's not that they reduce the actual list price of it, it's that they offer the payers a rebate or a contract. So it's something that comes in on the back end. So essentially... let's take a drug that's on the pharmacy benefit. There's two drugs – drug A and drug B. Drug A has been on the market and let's say it's \$10,000 a month. Drug B comes out and it's about the same price. So both of these products are going to... both of the manufacturers of these products are going to a commercial payer and they are going to say, "Listen, if you give me preferred status or even formulary... exclude the other product, we'll give you a rebate for every single script that you fill. It can be 20, 30%." So the pharmacy will pay for the drug, the drug will be reimbursed by the payer, and then for every script they will get a rebate back that will actually reduce the spend of it. So the drug price doesn't actually change or it doesn't actually go down, but their drug spend goes down through the rebate.

Woman: The patients are paying like 50%.

Yohan Cho: That's a great point because a lot of times the co-pay and the co-insurance is based off the list price or [inaudible] price. So as the prices still go up, the manufacturer still profit and the payer... a lot of times the patients are the ones paying for it, especially in the co-insurance. So you bring up an absolutely great point. It is completely warranted and that's something that's worth looking into. So who is really ending up paying for it in the end? Right? Because the patients certainly don't see the rebates. So they are still paying higher and higher co-insurance with the specialty drugs while the payers might be seeing some savings in terms of the rebate. Hopefully it gets passed on to premiums and things like that, but...

Ray Hanley: I think we have time for one more question.

Woman: I'm interested in... if you've done what you're doing now prior to the Affordable Care Act passing, because we all know that Pharma made a big deal as part of that passage of a bill and we can no longer legally

get drugs from Canada and other things. So this whole drug pricing thing depends on who you are as to what price you pay and really as Representative Cody said, consumers are being hit hard from this. So do you have any insight as to when Pharma is really going to care about the people who live in the United States?

Yohan Cho:

I can't say necessarily. I can't speak for all Pharma to say how much they care about things like that. They do offer a lot of pharmaceutical manufacturers... one of the strategies that they do, and I'm not saying this is all out of the goodness of their heart are offering a lot of their patients assistance programs and things like that to help patients in terms of their cost share and what they have to pay for. Now a lot of that is probably more having to do with going around formularies and what payers are trying to do in terms of managing the drugs and just getting the patients the drugs anyway. But I think there is a recognition that as these drugs become more expensive and they go on the specialty tier and they are subjected to a co-insurance as opposed to a flat co-pay then yes, there are some things that they need to consider in terms of when they increase the drug price, the co-insurance [inaudible] cost sharing goes up and things like that.

Ray Hanley:

I apologize for the time constraints, but please put your questions on a card, leave them on the table, and we'll try to pick them up as we can. I'd like to ask you all to thank Yohan for setting a great table.

[applause]

Right now you can hear dialing in the background and what that means is that we're actually reaching out to CMS. Okay? Our next speaker is John Coster who is a Medicaid drug rebate program and he's going to talk about how it works. After John has given his talk we'll have a break and you can see that in your agenda. So if I can I'd like to introduce John Coster. Hopefully he's going to be available. He's the director of the Division of Pharmacy at the Center for Medicaid and CHIP Services, which is a component of CMMS Medicare and Medicaid services. He's responsible for policy and operational issues relating to the Medicaid Pharmacy and Prescription Drug Rebate Program. He holds an MPS and a PhD in health policy

from the University of Maryland Graduate School and a BS in Pharmacy from St. John's University. Prior to joining CMS he served in various senior government affairs positions and at safety net hospitals, as well as Professional Pharmacy Association.

John Coster: Hello?

Leta Evaskus: Hi, John. This is Leta. So we can stay with your presentation, please say next slide when you want us to move on. John, can you hear us? John?

John Coster: Hello?

Leta Evaskus: Okay. Can you hear us? John, can you hear us?

Ray Hanley: Somebody had another question for Yohan while we're getting John on the line. Let's go ahead, please. One thing I forgot to announce is that we are taping this. So if you would please say your name. We know where you're from.

Iman Eletreby: I'm from Amerigroup Anthem. So do you think with the emergence of generic drugs that oncology guidelines will start to be established? MS guidelines will start to be established where they are sort of recommending Class I, Class II, because of the pipeline that's emerging?

Yohan Cho: So, yes. That's a really great question. And in terms of guidelines today when you look at things like [inaudible] and things like that we don't actually identify, you know, whether or not this is generic available or whether or not there will be a biosimilar available. It's more about just what the drug is and how it should be used. Those types of things, not necessarily if you're looking like NCCN, but as you actually start to look at things like the Icer evaluations, right, for multi myeloma and maybe potentially even things like the ASCO value framework for cancer. When you start to actually look at costs then those types of things might help patients, physicians, whomever make decisions based off of a generic availability or a biosimilar availability and things like that. So how it gets working to the

guidelines is still up in the air. If you look at guidelines today they haven't worked that in. But as more of them start to become more value-based then possibly, definitely.

Woman: I had a question about the patient assistance program.

Ray Hanley: Could you state your name, please.

Christina Christopherson: Part D Program Manager for DDA. I had a question regarding the patient assistance programs you mentioned from the manufacturers. So the vast majority of those programs exclude any patient enrolled in a federal program. So what would be available to our patient populations? None of our patients are eligible for any of them.

Yohan Cho: Yeah. That's another great point that you bring up. Some of the reasons for that is... well, there's a couple things. Like I mentioned before a lot of times these PAPs are maybe, I'm not going to say a woven sheep's clothing, but they're essentially to try to get access to the drug. So to go around different things that payers are trying to do in terms of formularies and stuff like that. Now those types of issues might not necessarily be the case for these federal programs. So we talk about like Medicaid and Medicare and things like that because Medicaid, a lot of state administrators aren't able to manage the drugs in ways that private payers can. At the same time for like a Medicaid or state Medicaid program a lot of times these patients don't have very high cost sharing anyway, if at all. So it's not as much of an issue. Medicare is completely different because you're talking about the donut hole, you're talking about coinsurances, 80 to 20%. So, yes, that becomes an issue and what are manufacturers doing to support those patients? I think you have to look at them in an individual basis because in the end they also recognize that if the patient just can't afford the drug then they are not going to take the drug. Right? So that's just... it's something that is a consideration and trying to understand that it's going to be a case-by-case basis. So I think the main point is that these PAPs are there to help patients, but they are also there to help the manufacturer as well. So they are doing it to help themselves, as well.

Ray Hanley: Another question for Yohan?

Bruce Smith: Thanks. I'm from Regence. We're talking today about drug pricing and purchasing. How much of drug pricing is a pharmacy benefit versus a medical benefit more or less kind of in general?

Yohan Cho: In terms of it being an issue?

Bruce Smith: As far as drug costs to health plan, to Medicaid, to Medicare? How much of that comes in as a medical claim versus part of a pharmacy claim administered by a pharmacy benefit?

Yohan Cho: Right. It impacts both if you are talking about from a payer's point of view in terms of how you reimburse things. Right?

Bruce Smith: I just want to know, is it 50/50? Is it 80/20? How much of drug cost...

Yohan Cho: Oh, how much do drug costs come from...

Bruce Smith: How much of a drug cost becomes a pharmacy benefit that patients have out-of-pocket or they pick up pills or injections at the pharmacy versus it is something they get infused in a facility and there's facility fees and provider fees.

Yohan Cho: Right. So there's definitely some data around that if we're talking about specialty drugs and I can't tell you off the top of my head how it is split up between the pharmacy and the medical benefit in terms of drug price. Let's say drug spend. Because the thing about it is that a provider on a medical benefit is reimbursed it's a lot more difficult, it's a lot more difficult to track as opposed to the pharmacy benefit, the way things are adjudicated and stuff like that. Like I mentioned before providers, you know, office, administration, physician administered drugs, you know, these are reimbursed different ways for different providers. Sometimes it's an ASP basis, sometimes it's that thing I mention where they just essentially set a margin on the drug and then they just bundle it up together with their services and then it's just a reduction in price to be in network. So it's a little bit harder to actually understand what that drug spend is in the medical

benefit because it's just a lot harder to track, it's a lot harder to adjudicate than on the pharmacy benefit, essentially. I'm not sure what the exact figures are on that. But one of the things that we had mentioned is some of the things that payers are trying to do is to be able to shift from the medical to the pharmacy benefit. Two reasons: (1) they have more tools, more mechanisms to manage those drugs, and (2) they are taking it a little bit more outside from the provider and being able to track this and things like that and being able to reimburse everybody at the same rates as opposed to having all these different payment models.

Ray Hanley: Thank you. We have John Coster on now. Thank you, audience. And if you have additional questions, please leave a card. Leta?

Leta Evaskus: Hi John. Can you hear us?

John Coster: Yep. I'm good.

Leta Evaskus: Okay. Let me turn you up. Please say next slide so that we can stay with you.

John Coster: Okay. Are you on the first slide? The cover slide? The title slide?

Man: Yes.

John Coster: Okay. Hey, do you want me to just go ahead and start?

Ray Hanley: Please, John.

John Coster: Okay. All right. Well, first thank you very much. My name is John Coster. I'm the Director of the Division of Pharmacy for CMCS, the Center for Medicaid and CHIP Services, which is part of CMS and I'm sorry I can't be physical there with you this morning. I was going to say this afternoon, because it's almost 1 o'clock here. And I do appreciate the invitation extended to me both by Dan and Donna to talk a little bit about how the Medicaid Drug Rebate Program works and how it can be used effectively to better manage pharmacy spending.

The rebate program is about 25 years old now and it's helped states during that span of time. It has helped to better manage their drug costs. Before I go into a little bit more of a description of the program and how it works I think it's important to understand there are many different government purchasers and some are purchasers and some are payers and each kind of gets a different price for their prescription drugs. For example, the Veteran's Administration probably gets the best prices for prescription drugs of any federal purchaser because they are a different buyer. Medicaid gets its prices through the rebate program and they are not as good as the VA because Medicaid is more of a payer. It doesn't actually buy drugs and take possession of drugs. Most Medicaid pharmacy dispensing happens through your community pharmacies, your chains and your independent pharmacies who actually buy the drugs that are dispensed and then Medicaid gets a back end rebate.

Medicaid controls spending in many different ways, all of which I'm sure the state of Washington currently uses. It controls spending by reducing the overall costs of the drug product; primarily through the rebate program. It can control spending by limiting or managing the types of drugs and the scope of drugs that are available, and it can also manage drug spending by how it reimburses the pharmacy providers in the state.

The Medicaid drug rebate program applies both to the outpatient prescription drugs that are dispensed to Medicaid patients both in the fee-for-service and Medicaid managed care programs in the states, but it also applies to physician-administered drugs. So with that as a little bit of background let's go to the next slide, which is titled Medicaid Drug Rebate Program.

So back in 1990 congress decided that Medicaid was paying too much for prescription drugs and because Medicaid wasn't a direct buyer of prescription drugs, it was a payer that we needed to implement a mechanism for the states and the federal government to reduce the cost of the prescriptions that they bought for and paid for Medicaid patients. So congress enacted, in 1990, the Medicaid Prescription



Drug Rebate Program and the fact is right now prescription drugs are an optional benefit in Medicaid programs to this day even though every state provides prescription drug coverage as part of its fee-for-service and Medicaid MCO benefit package. What the Medicaid Drug Rebate Program requires is that if you are a manufacturer of a prescription drug and you want your drug to be covered by any state Medicaid program you need to sign an agreement with the Secretary of the Department of Health and Human Services (HHS) and what you agree to do is you agree to pay specific rebates on the drugs that are dispensed to Medicaid patients. Right now more than 600 drug manufacturers, both manufacturers of brand name drugs and generic drugs participate in the Medicaid Drug Rebate Program. Almost every manufacturer participates because they recognize the importance of the Medicaid market, both fee-for-service and managed care. So the manufacturers sign an agreement with the Secretary in order for their drugs to be covered by Medicaid. There are certain exceptions to that meaning the states have to cover those drugs of the manufacturers that sign an agreement with certain exceptions, and we're going to talk about how states having to cover all of these drugs can manage their drug spending, but manufacturers are required to pay rebates by law to states on a quarterly basis. So we're now in the second quarter of 2016. At the end of this month, the end of the second quarter, and then the states will bill manufacturers for rebates based on the utilization of that manufacturer's drug for the second quarter of 2016. That extends to both the drugs that are dispensed in fee-for-service Medicaid for fee-for-service Medicaid patients. Those that are in managed care organizations and physician-administered drugs. Those are that are administered like the injection and the infusion drugs, which are usually administered in outpatient hospital departments or in physicians' offices.

Now the MCO that you contract with may negotiate their own rebates with manufacturers but the state also collects rebates on those prescription claims. So the state of Washington, like every other state, is now earning significant rebate revenues every quarter from manufacturers on the drugs that are dispensed to Medicaid patients both in fee-for-service and in Medicaid managed care organizations.

The next slide will show a little bit of the history and we don't have to dwell too much on this. But OBRA 90 was the law that created the Medicaid Drug Rebate Program. The program has been in existence now for over 25 years. Originally the estimate was that the program would save \$3.4 billion in federal and state money over five years, but last year alone the program brought in about \$26 billion for federal and state governments. Discounts were extended in 1992 to other federal purchases—the Veterans Administration, the Department of Defense, and also 340B entities and clinics like family planning clients, Ryan White clinics and other federally-qualified health centers. In 1993 the law was changed to allow state Medicaid programs to use formularies. So even though, as I said at the beginning, that their QUID(?) pro quo is manufacturer's pay rebates in return for states providing access to the manufacturers' drugs with certain permissible restrictions.

On the next slide you'll see in 2002 we issued guidance on how states could negotiate supplemental rebates with manufacturers, which has been an extremely effective tool that states are using to further manage their drug costs. So in addition to states getting basic rebates from manufacturers for drugs dispensed to Medicaid patients, they can also negotiate supplemental rebates both on fee-for-service and MCO claims. In 2005 under the Deficit Reduction Act we were told to issue new rules around how pharmacies would be paid for generic drugs. Generic drugs are a huge cost saver for Medicaid. Right now, and I don't know what the percentage is in Washington, probably 80 to 85% of all your prescriptions are probably being dispensed as generics, but probably 80 to 85% of your spending is for brand-name drugs. So brand name drugs tend to be five to six times more expensive than the average generic. So any policy that you can use that helps to encourage the use of generics where appropriate will probably save you \$100 plus per prescription. In 2010 the Affordable Care Act, the basic rebates were extended to MCO claims. Prior to that states were not able to collect rebates on claims dispensed to Medicaid patients in MCOs. So that has helped tremendously. In a state like Washington which has a good percentage of your

population in managed care that you're also saving on prescriptions that are dispensed to Medicaid patients and MCOs.

On the next slide you'll see congress enacted in 2015 a penalty on generic drug products that increase faster than inflation. One of the things I had mentioned is that there is a special rebate in the law for manufacturer's that inflate their prices faster than inflation—faster than the CPI. That comes back to states in the form of additional rebates. That was put in the original law only for branded drugs to protect the government against manufacturer price increases. It was extended in 2015 to generic drugs and that will go into effect this January so that price increases on generics that are faster than inflation, the states will also receive rebates on manufacturer's that increase their prices faster than the CTI.

On the next slide, controlling costs and promoting quality, what are some of the key points? So how does your Medicaid program primarily control drug costs? Well, drug costs are a function of a number of people getting drugs, the cost per prescription, and the number of prescriptions being dispensed. So you can certainly control cost by limiting eligibility. You can control it by limiting the number of prescriptions, which is certainly not always in the best interest of patient care. Or you can control it by managing the cost per prescription. And what most states have done is they have used the Medicaid Drug Rebate Program and supplemental rebates negotiated by the states as the most effective way of managing their drug spending. We also, at this level, we set broad parameters for state Medicaid pharmacy reimbursement. So in addition to what you collect in rebates there's also setting reimbursement rates for pharmacies. How much are you going to pay pharmacies for the drugs that they dispense? If you look at spending and Medicaid about 80% of it is for drugs, about 20% is pharmacy payments. Some states it is less than 20%. So focusing on pharmacy reimbursement may or may not get you the long-term solution for spending that you want. But it's clearly important for the state to look at how they pay pharmacies for prescription drugs with respect to both what they reimburse for product, and what they reimburse for dispensing fees. And we just changed the rules such that every state over the next

year will have to transition to a reimbursement mechanism based on the actual costs that pharmacies buy drugs for, as well as paying them more accurately for their dispensing fees. That may or may not save the state money depending upon what your reimbursement was before. But now that the states have to cover all drugs of manufacturers, that was the original law, the states would have to cover drugs of any manufacturer that provided a rebate. What was also written into the law were the mechanisms that states could use to appropriate manage drug use. Clearly it was not the intent of congress to say that the states would not have their ability to manage their drug costs. So in addition to rebates the states also can use prior authorization, which is essentially a mechanism that requires the physician of a pharmacist to get approval from the state or its contractor before a particular drug can be dispensed. These are generally used for high-cost drugs or drugs that have special indications for patients or where special monitoring might be used. States can use preferred drug lists, which are very much like formularies. Most states use preferred drug lists as a way of leveraging supplemental rebates from drug manufacturers. So the state of Washington may have a preferred drug list for its fee-for-service population and you would use that list and you would use that process as a way of leveraging greater discounts or rebates in the form of supplemental rebates from drug manufacturers. And then the state is required, every state is required to have a drug utilization review program. This is more of a back end program where the state looks at patterns of use or miss-use of prescription drugs to better assure appropriate drug use for patients in your program.

On the next slide you'll see the rebate amounts that are paid to states. For branded drugs the state gets a discount of about 23.1% of the average manufacturer's price, the AMP. Without going into too much detail this is a... AMP was created as part of the law in 1990 to help benchmark what the manufacturers would pay their rebates off of, what amount? An AMP essentially represents the average amount of revenue that manufacturers receive from the sales of drugs to retail pharmacies. So the state's getting about a 23% base rebate from manufacturers on innovate or brand-name drugs, patented drugs, single-source drugs. Plus they are getting that inflation

adjusted rebate that I spoke about a minute ago. For generics or non-innovators it's less, it's about 13%, but starting in January it will be a special inflation adjuster for generics as well. And then you also get rebates for blood clotting factors. It is less of a rebate than for innovative drugs, and there's also a reduced rebate for drugs that have solely pediatric indications.

On the next slide you'll see again the opportunity to collect supplemental rebates. Most states have entered into single or multi-state supplemental rebate pools that generate rebates that are at least as large as the rebates that you get from the national rebate agreement, which I just described. There's about... every state... almost every state has a supplemental rebate program in place for fee-for-service, about 10 have them in place for MCOs. We think there should be much higher participation by states in MCO rebates. You're getting a basic rebate on your MCO claims, but if you don't have a supplemental rebate agreement in place you're potentially leaving millions of dollars on the table in supplemental rebates for MCO claims. Those are policies you need to speak to your MCOs about to see how those could work in the state. So states used prior authorization and preferred drug lists to leverage further supplemental rebates from drug manufacturers further lowering their costs. This is probably the single... I won't say easiest, but next step that any state can take that has a large MCO population to reduce their spending on prescription drugs, and that's leveraging manufacturers to collect supplemental rebates on MCO claims.

You'll see on the next slide some background on the fact that the Affordable Care Act required the states to collect rebates, basic rebates on MCO claims except in certain circumstances such as if the prescription is being dispensed by an HMO or 340B because there's no double discounting on 340B drugs in any part of the Medicaid program.

On the next slide you'll see some of the state drug management options that exist, which the state is probably using right now. Cost-sharing is generally a very effective way of helping to steer patients to particular drugs. That's generally the case in the commercial

population and Medicare population because they are so nominal in the Medicaid population that are \$1.00 or \$2.00 or \$3.00. It may not be a really effective tool although given the low-income nature of this population it could be. But cost-sharing is one way to reduce spending. The prescription limits, some states have prescription limits. They only allow a certain number of prescriptions per month, a brand, of generics. That's not something the agency tends to promote just because it can lead to rationing of care and, you know, could limit the ability of very sick patients to get all the number of prescriptions that they need. But some states do have prescription limits and they use a prior authorize override if the patient need additional medication. Adjusting the dispensing fee – the state again can look at how much it pays pharmacies. Again, the pharmacy reimbursement is generally not the biggest driver of Medicaid drug spending. It's generally the cost of the drugs, notably the branded drugs. But you could take this opportunity now that the state has to submit a new state plan with respect to pharmacy reimbursements to determine if pharmacies are being paid too much, too little or just right. Disease Management Programs – there are several states that have programs that target management of specific disease states, helping Medicaid patients better take their medications, they... Medicaid patients tend to be on multiple medications, chronic conditions, they may not understand fully how to manage their drugs. I think you'll generally find that a significant number of hospital admissions are due to drug adverse reactions or drug mismanagement. So there are several states that have waivers that allow them to establish disease management programs where they pay providers to help manage the medications of Medicaid patients so that you could potentially get better outcomes.

On slide 11 you'll see, you know, other management tools the states can use, expanding their prior approval programs to include more categories of drugs, especially high-priced drugs. Prior approval can be effective, but it could also be expensive and it can also be burdensome to prescribers and pharmacies, not to mention patients. But it is a way that many states use to manage access to particular classes of drugs. Supplemental rebate agreements we've talked about. That's using preferred drug lists and prior authorization to

negotiate higher rebates than are managed under federal law. Implementing a preferred drug list, again, within a crowd of therapeutic class you allow manufacturers to compete against each other to see which one is willing to give the highest rebate for an equally effective drug, you know, within a class you can also have a generic only potentially or a step therapy type approach that would allow for a patient to try one drug first before moving on to the next drug. Some states have obtained waivers for specialty drug contracting. We didn't talk a lot about specialty drugs, but my guess is if you asked your Medicaid program which category of drugs is the fastest growing in both an expense and number they would tell you specialty drugs. Specialty drugs are not fully defined in any one place, but they are generally expensive drugs that require either special types of storage or administration instructions. Some of these are dispensed solely through specialty pharmacies. Some states have selective contracting to one or two specialty pharmacy providers for these specialty drugs. So, you know, when you look at your spending it would be interesting to see what's really driving it. Is it the traditional oral drugs or is the specialty drug category? Some states have mandatory generic substitution policies. You must try generic first if one is available in that particular category. And then an evolving opportunity exists in value-based purchasing. This is still relatively new, especially with Medicaid programs, and that is the state would work with manufacturers so that the manufacturer would bear some of the risk in the use of the drug, you know, if the drug does not work the way the manufacturer says it does on its labeled indication, then the state would get part of its money back. You know, if someone has to... the manufacturers have to step up with these high priced drugs and have a little skin in the game so to speak. So we have... hearing more and more from manufacturers about a desire to talk to states about value-based purchasing so that, you know, the manufacturers would bear some of the risk for the use of their drugs in Medicaid patients. CMS will have a little bit more to say about that hopefully in the very near future.

Ray Hanley:

John?

John Coster:

Yes.

Ray Hanley: I'm facilitating the meeting. We're running a little bit late. Could you wrap up so we can take a few questions? Can you stay on the phone for just about 10 minutes afterwards?

John Coster: Yeah. I have one more slide and I'm done. On the DUR program, again, this is a tool that states have effectively used to help manage drug costs and also improve quality. The DUR program allows them to identify, on the front end prescriptions that might be potentially problematic to patients such as, you know, the patient comes into the pharmacy, the drug is a therapeutic duplication or the patient has a drug disease contraindication, and then there's the second phase, which is ongoing retrospective analysis of claims to look for patterns of fraud abuse or overuse, sometimes leading to walk-in programs where patients are then required to only go to one prescriber or one pharmacy. So that's a fast-talking overview of the Medicaid program and I hope that was at least helpful to contribute to some of the discussions you're having. So I'll stop there and I'll see if there are any questions I can answer.

Ray Hanley: Thank you, John. I really appreciate it. I'll try and get some questions to you. So we've got one in the audience right now. Please state your name.

Bob Crittendon: One quick question. Back in OBRA 90... well, actually this is a comment. OBRA 90 came in and it actually cost us money here in the state. Our budget went way up. But my question has to do with price variation. We're talking about rebates, but my understanding at the pharmaceutical... or the pharmacy level the prices vary fairly frequently and we have a rebate program that rebates the state. How do you... do you have any agreements with the manufacturers for price stability over the course of the year?

John Coster: No. We don't have any authority to enter into price stability agreements with manufacturers. So, you know, although I will say that, as part of the supplemental rebate agreements, that states negotiate with manufacturers, which we're actually not privy to with respect to the terms, that there could be a minimum rebate that's



paid or a price guarantee that allows the state to have predictability in what it's going to pay over the year. So at our level we just administer the basic rebate program and oversee approval of state plan amendments to enter into supplemental rebate agreements, but the actual supplemental rebate contracts we don't necessarily approve. Those are between the states and the manufacturers and some of those, if not all of those, may have components of price stability in them.

Ray Hanley: Thanks, John. We have another question in the back.

Victor Collymore: First of all, thank you for your presentation. I couldn't help but notice that perhaps you touched upon this indirectly, but you didn't mention in terms of management options, medication therapy management, nor did I hear any discussion of efforts to profile individual providers for excellence in pharmaceutical prescribing habits.

John Coster: So when I... that's a good point. When I talked about disease management programs I probably should have mentioned under that category that there are states that, as part of disease management programs, include medication therapy management. So I think there's about a dozen states that have approved waivers of some type that allow for payment to pharmacies for MTM. So I would put those under, you know, disease management programs. Generally, you know, the state has to come in with a waiver to authorize a disease management program, which includes medication therapy management. What was the second part? I'm sorry, the second part of your question?

Ray Hanley: The second part, John, was on physician profiling. About profiling the...

John Coster: Um, you know, we have not heard of states doing that. We know that the states are looking at prescribers that might be not excellent, meaning that they over-prescribe or they, you know, have prescribing patterns that cause concern. I'm not aware of states that do the opposite, although it sounds like a good idea. The state has a DUR program, Washington State has a DUR program. There's nothing

prohibiting them from doing that themselves, but it's not a strategy I've heard states use in that way.

Ray Hanley: John, we have one more question.

Josh Carlson: Hi. I'm with the University of Washington. Thanks for your comments. I was wondering if you could speak to the ability to use cost-effectiveness data. You mentioned that as part of the preferred drug list as an option there, as well as perhaps any barriers to establishing risk sharing or outcomes based agreements. I know you said CMS is looking into that and maybe coming out with more of that later, but anything you know at this point?

John Coster: So I understand that states can use mechanisms, including cost effectiveness, you know, data to determine their PDLs. In fact, Washington may do that and other states may do that. Most states when they create their PDLs or formularies have P&T committees. In fact, every state is required to have a Pharmacy & Therapeutics Committee consisting of physicians and pharmacists. I don't know what process the state of Washington uses, but my guess is that P&T Committee not only helps to set parameters regarding the DUR program, but also may consider, you know, using that data and other clinical data to set parameters around which drugs are prior authorize, which drugs are not prior authorize, or whether there is another clinical criteria. So we don't have... we're silent, the law is silent, and you know, we would encourage states to use cost-effectiveness data as part of their decision making with respect to how they determine their preferred drug lists.

Ray Hanley: Thanks, John. We have one more question if you have time.

John Coster: Sure.

Louis: I'm from Group Health. You mentioned generic drug program during your presentation. I'm a little curious about how does your generic drug reimbursement correlate or not correlate to a PBM [inaudible] list.

John Coster: Well... so every state... what we do at the federal level is we set federal upper limits for multiple source drugs or generics. So that's based on a formula in our law that requires us to pay... to set folds at a certain amount of the weighted average amp for a particular generic group. And what the states then do subsequent to that is up to them as long as they fall within the folds in the aggregate. So some states now are using our NADAC (National Average Drug Acquisition Cost) survey amounts to set generic reimbursement and that's based on surveys of retail pharmacies. Other states can use other AAC reimbursement as they move forward. It's up to each state to figure it out as long as they stay within the aggregate. We publish a folds list every month. We put out one at the end of March, new federal [inaudible] limit list, and we did at the end of April and May. So we put out three. We'll put out another one in the next couple of weeks. So we update those every month. Mac lists for... if you're talking about mac lists for managed care organization, I don't know they determine them, but I think the pharmacies also scratch their heads sometimes because they don't know how you determine them. But those are all over the place. We don't have any transparency into how Medicaid MCOs set their max and the folds we set don't apply to MCOs, they only apply to fee-for-service Medicaid.

Ray Hanley: Thanks, John. I'm going to impose on you for just one more question if I can.

James Bryan: Hello. I'm with the Washington State Department of Veteran's Affairs. Has CMS looked at anything to address a problem with non-use? A lot of retail pharmacies have automatic fill programs. I have personally witnessed a caregiver picking up a month's supply of her prescription saying, "Oh we don't need this anymore. We've got three months sitting at home. The patient's not taking it anymore." Do you have any data about or states that have tried to look at that problem?

John Coster: You mean under use versus over use?

James Bryan: Under use or even nonuse that a prescription is still being filled and the patient is not taking it. Similar to a pill counting program for

example. Or is there any states who have said, “Okay, we won’t let a Medicaid providing pharmacy automatically fill prescriptions.”

John Coster: We’ve gotten this question before about automatic refill programs. I don’t think we’ve said anything officially on automatic refills. I think there is concern by some states that those could be problematic with respect to just automatically refilling, but, you know, any claim that’s not filled and picked up should be reversed. So we do an annual DUR survey of states and one of the questions that we’re going to be adding to that is on this issue of whether or not states have policies in place with respect to automatic refills because we’ve heard enough about it at this point that we think it’s important to alert states to the fact that if they don’t they may want to have some policy on it. But I don’t think we have an official policy that we’ve made states aware of. Some of it is state specific, as well, with respect to what the states can do.

Ray Hanley: I want to thank you for joining us today. Great presentation. And I just wanted to ask the audience to please thank him.

[applause]

Ray Hanley: And with that, John, we’ll let you go.

John Coster: Okay. Thank you.

Ray Hanley: And for the rest of the audience if you have additional questions, again, please put them on the cards and leave them on your table. We now move into a break. We’re running about 10 minutes late with our little technical glitch, but what I’d like to ask you to do is if you could get back here... maybe give me five minutes back. If you could be back by 10:40, which gives you about 12 minutes, that would be great. And we’ll just pick up at 10:40 from there. Thank you very much. Bathrooms are to your right. There’s coffee in the back.

I’d like to call the meeting to order. Feel free to mill about as you need to. Just a couple quick announcements. The first thing is the spotters who are picking up some of the questions asked if you would

put the name of the speaker on there, as well as your own name. That will help us to know where those questions were directed. That would be a big help for us. The second thing is, this little blue thing here is going to be increasingly valuable to you as the day goes on. So this is actually a parking... it validates your parking. And Judy who I introduced at the onset she has copies of these. Be sure to get one of these from Judy if you don't have one already.

My name, again, is Ray Hanley. I'm the Director of the Prescription Drug Program. I am somewhat new to this position. I've been with the program for about 10 or 11 years now and actually that's where I first met Dan Lessler. He was our founding chair for the P&T Committee. I work with Donna Sullivan and Leta Evaskus in the program and I took over for a personal friend and a guy who actually shaped the program a great deal. His name is Duane Thurman. So anyway, let's to go the first slide, Leta.

My job today is to talk a little bit about what HCA does in the prescription drug world. So we've got two different prescription drug programs and I want to make that distinction very clear. The first is something that we just heard John at CMS talk about, the Washington State preferred drug list. And the Washington State PDL has been around, it was actually formed around 2002 and it went live in 2004. It involves three different state agencies that work together on the preferred drug list and we'll talk a little bit more about what the PDL is. It's the Department of Social and Health Services for Medicaid. We've got the Health Care Authority for public employees and we have the Department of Labor and Industries for worker's compensation. Those are sort of the three founding agencies that work on the preferred drug list. The second program we have, which is not related to the PDL directly is the Northwest Drug Consortium. The Northwest Drug Consortium is all about a supply chain and I also want to take this opportunity to just mention that I have my colleagues from Oregon, Missy Dolan, who runs the Oregon Prescription Drug Program, as well as the administrator for the consortium here, our MODA team. So if you have any additional questions about the consortium that I can't answer we've got the brains in the room.

So basically Washington joined forces with Oregon through an interstate agreement back in 2006 to try to pull our drug purchasing, to try to make a larger pool for purchasing, to get the best price for participants. Right now we have about 950,000 people that are in the consortium across the two states and spending is approaching about \$1 billion. It has three major components, the first is something called a discount card for the uninsured. It is somewhat unusual in this day and age now of health reform, but back when we were initially formed there was no Medicare Part D. Roughly 30% of people over 65 in America had no prescription drug coverage whatsoever. So it really started off in its early years as a drug coverage program and expanded into other markets. We have employer groups that we offer mail and retail to, and we have something that's very transparent, our transparent contracting with our vendor. We've recently added, within the last... recent is now five years. We've recently added facilities to the consortium purchasing and we have a representative from the Department of Corrections here, William Hayes, who is a member of the consortium, as well. So that's a broad overview. Let's talk about the first program.

This was established by legislation. Like I said there's three major components. We've got the Pharmacy and Therapeutics Committee, the P&T Committee, and we'll talk a little bit more about that. We've got Evidence-Based Preferred Drug List, and then we've got the Endorsing Practitioner & Therapeutic Interchange Program. Say that five times fast. So we administer this program for HCA... for Medicaid we administer it for the public employees and for the worker's comp program here in the state and again we implemented it in 2004. Next slide.

For those of you who are a little bit visual, this is a broad overview of the way that the program is set up. So this is just the process that we go through. And the PDL is really all about process. So basically we get information from the Oregon State... or OHSU. We have a representative from OHSU here today, as well, for the drug evidence, the DERP program. The P&T Committee then makes recommendations based on the evidence. So the P&T Committee is

actually reviewing the evidence for the drug classes and then making recommendations. Then, independently, and at a different point in time the staff conducts a cost analysis and makes the PDL recommendations to the agency directives. So the P&T Committee's job is done once they make the recommendations and we move on to the cost analysis. The agency directors, we talked about who that was, Medicaid, the Health Care Authority or PEB, and worker's comp. They approve the PDL recommendations from the cost analysis. The staff, who you met, sends out notices about the PDL updates and then the agencies go about implementing the preferred drug list according to their own benefit structure. So that's how it works in broad strokes. Next slide.

This is the P&T. Who are they? A lot of you know about P&T committees and a lot of you are very well versed in this. Basically we have 10 members of the P&T Committee that will be sitting in this room tomorrow, it's just a coincidence, and their areas of clinical expertise are a broad geographic example from the state, as well as their four positions... four pharmacists, a physician's assistant, and a nurse practitioner. We generally meet quarterly, but lately we've been meeting about once every other month. Their job, and this is the critical thing, is to evaluate the safety and the efficacy and the effectiveness of the drugs. That's where their job begins and ends. They make recommendations in the state about the development of the PDL. So their job then is to determine which drugs are equally safe and effective, or have advantages for special populations, but again, and I can't emphasize this enough, they don't consider cost in the recommendation. And there's also an opportunity for public comment that goes on as well. So people can actually have a say. To the best of my knowledge, and I may be wrong about this, to the best of my knowledge this may be the only public meeting of a P&T Committee in the United States. So it's a little bit different here. But it's an open public process and comports well with the way that Washington likes to do business. Next slide.

So how do they do it? How does the P&T Committee do it? We participate in this thing called the Drug Effectiveness and Review Project at Oregon Health Sciences University, the DERP Project it's

called for short, and we access evidence-based reports. These evidence-based reports are all on a drug class. Basically we set up, with other states who participate, some of the key questions that drive the research in the drug class. There's a critical evaluation of the evidence, including the grading of the evidence. A research-controlled trial as opposed to something that's antidotal. So the quality of the studies, and the strength of the studies are actually part of the review, as well. Pharmaceutical companies are, you know, with that new blockbuster drug that's out, but it's not yet in the research literature, they have an opportunity to submit dossiers to DERP and we have made a deal with the drug companies that we'll re-review a particular drug class on about an annual basis. And when we re-review the drug class we re-review that same cost analysis. Next slide.

We talked just briefly about the preferred drug list. I'm going to go a little faster because I'm going to try and make up that 10 minutes we lost. The preferred drug list itself is an evidence-based list of drugs that are used by participating state agencies and the preferred drug is a drug that's been selected by the state agencies and recommended by the P&T Committee and based on a cost analysis. Now a non-preferred drug is a drug that wasn't selected due to either inferior safety or efficacy or due to cost or it may require prior authorization for coverage or it is placed on a higher cost tier. So again, we've got preferred and non-preferred drugs. Next slide.

Let's talk about the cost analysis. So the cost analysis we heard John Coster talk about supplemental rebates. That's part of our cost analysis, as well. So the state obtains rebates... I'm sorry, obtains bids for supplemental rebates from manufacturers prior to the meeting. So we're having a meeting tomorrow. They know what classes. We let the manufacturers know what classes we have so they can sort of sweeten the spot if you will. They can submit a supplemental rebate for the Medicaid program as a way to reduce the rebates that already exist through federal legislation. The analysis itself is done from an actual real firm. Right now it's Milliman. They conduct the analysis of each one of the drugs. They use the supplemental rebate offers, as well as the rebate offers that come through federal legislation, and



they determine which drugs provide the lowest net cost to the state. And why is that important? Why do we have three agencies? They are purchasing sometimes differently. So sometimes one agency may have to pay a little bit more, but it's the lowest net cost. It's an average across the three. The directors of the agencies then go about, or their designee, make the final decisions as to which drugs will be included on the PDL. This is heavily process oriented. And then the state notifies the stakeholders and implements the PDL changes. And if you think that is a little bit archaic, let's talk about the endorsing practitioners. The endorsing practitioners... there's two very, very unique features to our preferred drug list in this state and I think that there is really nothing like it around. Basically the first is the endorsing practitioner and it's a prescriber who reviews the preferred drug list, which we public, and then notifies us, the other way, that they have agreed to allow something called therapeutic interchange. Okay? So that's where you are going to interchange a preferred drug for a non-preferred drug. The pharmacist then, so at the point of sale, the pharmacist then can automatically interchange the preferred drug for the non-preferred drug, if that's what is written on the prescription, and then notify the prescriber of the changes and there's a couple of exceptions. The first is there is something called refill protective classes. They are listed up there. And the other exception would be if the practitioner is an endorsing practitioner who signed up for it and writes DAW for dispense as written. So that's a way to write around the preferred drug list. In these situations the pharmacist will dispense the non-preferred drug and there are some exceptions to that like generic first, but we won't go into that. Next slide.

So for drugs that are not included on the preferred drug list, those that are prescribed by non-endorsing practitioners, a pharmacist will dispense the prescribed drug according to each agency's benefit design. Prior authorization and generic substitution, which are laws in state and federal government, may apply. People do ask us how many endorsing practitioners have signed up for the program and the answer is about 7,500. Then they say, "How many practitioners actually write scripts in the state?" Well, that's really hard to say. It's probably closer to about 18,000, and it differs by agency. But in

general what we've found is that these are the high writers. Basically the people have signed up as endorsing practitioners studied by... JLARC actually found about 41% of Medicaid prescriptions were written by the endorsing practitioners currently. So that's basically how it runs. It's a lot of process here. There's some tradeoffs that have to do with the way they are dispensed, and we've actually... I might alert you to something that Donna shared with me recently that [inaudible] has found a JAMMA(?) article where they found therapeutic interchange is a very strong cost-saving tool. So let's move into the second drug program.

This one is not so much about process and this one is really about the supply chain. So the... this is basically our joint purchasing initiative with Oregon and I introduced Missy earlier. It's the Northwest Drug Purchasing Consortium. It was established by the legislature back in 2005 and what it really offers is a model... pharmacy benefit management contract that can be tailored to individual purchaser's needs. Participation is mandatory for state agencies that can purchase prescription drugs directly unless they can demonstrate they can achieve greater discounts by using another purchasing mechanism. What does that mean? Here's an example. The Department of Health currently pays for childhood vaccinations. That's underwritten by CDC and so CDC actually provides them with a great deal, it looks a lot like a debit card, to go out and make their purchasing because it is federally subsidized. Another example would be the Ryan White funds that are used for AIDS. So there are certain agencies that I... we can't come close to even touching their pricing, but there's others that we can. Who can join the consortium? Well, let's see, it's local government, state government agencies, which I just talked about, the private sector, and we do have some private sector folks, labor organizations, and as I pointed out earlier our current account is about 950,000 people in the consortium and our spending is about \$1 billion. Next slide.

I think one of the best things about the consortium that I can mention is that we are no longer an experiment. We are basically moving towards a growing pool and this shows our growth over the last 10 years. You can see that the slightly higher line is Washington. So no

competition. And Oregon is just below us. But you can see that we are growing. Next slide.

This is just a quick overview of who is in the consortium and I tried to make it as simple as possible. There's a discount card, which I talked about initially, and the discount card population appraises about half more or less. The other half are employer groups, which include the Uniform Medical Plan, as well as Oregon Teachers. Then we have our growth in the facility side. We have the Department of Corrections and some small hospitals in Oregon. That's who comprises the members of the consortium. Next slide.

I've got a number of slides that you can see in the back and we're not going to have a chance to get to them. They really have to do with the analytics of the consortium, but I just wanted to do a little bit of a sales pitch here. Why would anybody want to join? I mean I've actually gone to meetings where we've got Microsoft and Boeing and we've got employee benefits people talking and I get to talk about the consortium and one of the questions I get is, "Why would I ever join something the state has started?" I think there really are some good reasons and take a look at the analytics and the sample. You've got clinical pharmacy expertise, we have a very flexible program, we've just introduced another network so that employers have a choice and not just one network, but two. Our prices are better than commercial rates available to other large groups in Oregon and Washington because we are purchasing from such a large pool. It's backed by, at least for our vendor and Most Favored Nation, which is jargon for the fact that we will get the best price that they offer in this state. We have market competitive pricing and it's audited annually by a third party, an independent third party. Okay? And basically we're setting our benchmark to try to compare ourselves to other large groups in the Northwest. We also provide audits, which go about checking whether or not the contractor who is currently providing the benefits are actually doing what they said according to the contract. We offer local mail order... local services are very important. We have local mail order. We have a local specialty pharmacy as well. Next slide.

One of my favorite aspects of it is it is 100% transparent contract. Okay? All pharmacy discounts are passed directly to the member groups and there's no thread, no margin kept between the contractor... kept by the contractor. The administrative expense is a per claim fee. It's fixed. It happens to be fixed for the next few years due to some recent negotiations, which I'm pleased to say we were talking about multi-year things a second ago. We've got the contracts oversight is by Oregon and Washington. I would guess that we probably meet two to three times a week to do monitoring. We have Most Favored Nation. We have basis of reimbursement reporting, a lot of tools that employer groups don't often have expertise on staff to do. Finally, I just wanted to put in a point... the point that we have a very competitive group purchasing organization for our facilities and we get wholesaler discounts that are actually backed up by additional affiliation with a large northwest group. My time is up and Leta is signaling at that. I just want to flip through the last few slides before we take any questions.

What the consortium is about really is about good price and great service. Okay? We have a lot of people who have stayed with the consortium. We haven't lost any. So if you've come for the service and you come for the price, stay for the analytics. We basically are able to take a look at the key performance indicators... and what this is is key performance indicators across all of our employer groups in both of the states. Okay? So we're not identifying any particular group. And you can see that things like we've got an 11% increase in trend that our PMPM went up by about 33%. We could look at the generic dispensing rate and the cost per script. Then on the third... farthest over we can take a look at what the members are paying and currently it's about 13% of the overall price, and we can look at... it's about \$12.00 per member per month is their out-of-pocket. So basically there's about seven or eight slides that I've thrown into the back here. You can flip through the next one. This looks at about 11% change from the prior period in specialty and we've heard a lot about specialty. Next slide.

When we focus on utilizers, you know, utilizers are about \$1,300 per user. We've had about an 8% growth in scrips per user since last

year. Okay? So we're starting to identify where some of these [inaudible] points are. Next slide.

The generic spend fill is about \$2.00 per member per month in the consortium. Our brand went up about 7% and specialty went up 33%. Next slide.

This slide basically talks about a change in average cost year over year.

The next slide after that talks about specialty versus traditional spend.

Then we go into the next slide which talks about the breakdown about pocket spending by members.

And then finally the last one talks about trend drivers. What is driving trend from time 1 to time 2? So these are the analytics that actually back up the consortium. Like I said we accept all takers. We try to expand our features so that we can attract more people. We bid on RFPs. We recently... MODA recently bid on King County up here. So we're always looking for new business and new members. With that I will conclude my presentation about the two programs at HCA. Any questions?

Kathy Brown: Hi. Thank you very much for the presentation. I'm from Premera Blue Cross. Just a question about your PMPMs. Are rebates considered in the PMPMs? Or are those just over here?

Ray Hanley: No, they're not. However, that's a great question because we are working on trying to bring that in. That's one of our next steps is to bring that in. So we'll have a net/net.

Kathy Brown: Yeah, especially as rebates are coming to be a bigger driver.

Ray Hanley: Yeah, since 2013 they have become much more popular. Any other questions? Please state your name.

Jim Rickards: Oregon Health Authority. When you negotiate your supplemental rebates do you do that through a larger group? So Oregon we're part of the SSDC. Are you part of a group like that that negotiates your supplemental rebates?

Ray Hanley: Currently we are not. We're looking into... I'm trying to explore some of those avenues, but we've been, for the last 10 years, we've been standing alone and taking in supplemental rebates at the time of the preferred drug list. The P&T Committee...

Jim Rickards: And do you do that in partnership with your MCOs in negotiations or is it just you?

Ray Hanley: No, not currently.

Jim Rickards: Thank you.

Ray Hanley: Any other questions?

Missy Dolan: Ray, will you expand on what you said about lowest net cost and how the PDL impacts some agencies differently than other agencies and what kind of push back or acceptance that has produced?

Ray Hanley: That's a great question. There's no easy answer to it. It really depends on a lot of times the drug class, the amount of the spend, and a lot of controlling. So, you know, one of the funny things that we've found with regard to winners and losers is that drug companies often don't know what's going on at the state level. So they might not have figured out that Medicare Part D is taking away a lot of the seniors from Medicaid spend. So they will expect to get a rate return on a low supplemental rebate bid for a particular drug use for seniors. In the long run we have actually been able to do it only through the goodwill of all of the agencies working together and trying to look at the better good. Because there are winners and losers. It doesn't always work that way. Many times all of the agencies can benefit by it. But sometimes we do have to, you know, nobody has really stood their ground, if I can use that expression, and said, "I'm not budging off of this." The other thing that we have is we have the ability to

implement, based on the agencies benefit structure. So agencies can actually use other tools for utilization management to try to control a drug that they may find to be maybe not as cost efficient for them. Any other questions? No? Good.

[applause]

Ray Hanley:

Let me find my place here. So our next group is some people that are doing the same thing I did. It's the other state... this is basically the state Pharm Ds. And we've got Donna Sullivan, Jaymie Mai. Donna Sullivan is from the Health Care Authority. Jaymie Mai from Labor and Industries. Western State Hospital is Katy Tomisser and from the Department of Corrections it's William Hayes. What I'm going to do is I'm going to kind of turn over the room to them in the following way and they may or may not remember this instruction. But we've got some slides and there's about three or four slides for speaker. I guess Katy is up first. If you all want to sit up here that's fine. We'll go through the slides. I'll turn it over to them and then they can turn it back over to me. If you could hold your questions until each one of them has gone through their three or four slides that would be great. Then I'll grab the podium again.

Katy Romisser:

I'm from Western State Hospital and I'm representing the DSHS institutions today. So there are three state hospitals—Eastern State Hospital, Western State Hospital and Child Study and Treatment Center. Western State purchases the drugs for Child Study and Treatment Center so it's all included in our totals. There are also four DDA institutions that house long-term residents with intellectual disability. So they are included in the DSHS spend. So this was calendar year 2015. The spend for the seven institutions. We used to spend a lot more actually than we're spending now; largely based on the generics that became available with the atypical antipsychotics. So atypical antipsychotics pretty much drive our budget. So that's [inaudible].

These are the top drugs by cost. The long-acting antipsychotic injections are usually near the top. Western State tries to control the use of invega sustenna because it is more expensive than Risperdal

Consta. So again long-acting antipsychotic injections are a big spend for us. But look at chlorpromazine is one of the top five and that's a 50-year-old drug, but the generic manufacturers consolidated and the price went through the roof. And so now I believe it's about \$8.50 a tablet. So it's back in our top five spend even though it's such an old drug. We don't use a lot of chlorpromazine because we're stupid or we're cheap, it's because the old antipsychotics, in our populations, work better often than the newer antipsychotics. And we have a large population of, you know, refractory long-term people with mental illness. Developmental disabilities I can't speak to as well. I have a DDA guru here with me, but that is their top spend and Abilify is on both theirs and ours and Eastern State and that is expected to drop off now that the generic is available for that. The last one on the DDA list is for one patient, I believe. It's a specialty drug not reimbursed and just one patient driving that cost.

And then because we have a lot of long-term residential patients some of our drugs used by utilization are kind of simple like acetaminophen, but these are in units purchased for calendar year 2015.

At the state hospital level we have a new P&T Committee that's joined and so that's one mechanism that we've used recently to try to control some of the drug spending. We try to restrict long-acting injections and it may sound counter-intuitive, but if you think about it we have people that maybe never leave and they are on other oral medicines. So the long-acting injection is so expensive if they are not anticipated to leave within four to six months, you know, some of the people could be on it for years. And we still have people that do end up on these for years if they refuse to take anything orally. And recently DDA joined... they were able to join with the state hospitals in the premier purchasing group. So they're getting more discounts and rebates now and their spend then would probably decrease over the next calendar year. They were just able to do that maybe last January. Prior to that they were on a different contract called Minnesota Multi-state, but now they are with us and I think things are going to be better for them.



Does anyone have questions? You want to wait? Okay.

William Hayes:

I'm the Director of Pharmacy, Washington State Department of Corrections. Our new central pharmacy, which is about two years old services 13 facilities around the state, around 16,000 offenders. In 2015 we spent about \$20 million on prescriptions for our patients.

As you can see, the top two medications are for hepatitis C. We have a biologic. Aripiprazole is the antipsychotic that Katy was speaking about and insulin is in our top five. This is actually pretty similar to the other correctional entities around the country. Their spend is about the same as ours, not their spend, but their spend is about the same as ours.

Our utilization is basically due to having a large amount of patients from all levels. Just typically this is what you would see... probably in the community. Everybody takes ibuprofen and Tylenol. Albuterol is probably high because it is counting one inhaler at a time and we have a lot of patients that take it. The other two – antihistamine and calcium.

Management strategies for controlling the drug cost was mainly... our biggest one was connecting with the prescription drug consortium and connecting with the GPO premier so that we could purchase our drugs at a lower cost. Another big piece is formulary control. Before centralization the former director helped to establish a centralized formulary to control utilization of medications. Primarily that led to a high percentage of generic utilization and our non-formulary process helps to control use of those items that are newer in the pharmacy world. We take a look at primarily the data that supports the use, but we also look at cost since we are a general fund agency we need to make sure that the choices that we make are cost-effective, but primarily we look at the usefulness and safety of the drug. We have a managed care system in DOC – the Offender Health Plan, which our Chief Medical Officer was very instrumental in putting in place. That helps us to ensure that we're treating the patients according to medical necessity. Our prescriptions also go with that. The managed care system, aside from the Offender Health Plan has protocols in

place that guide treatment with the most appropriate medication for that condition. Centralization of pharmacy has actually been good for us because it helps us to monitor all of our purchases and our formulary in a central location where previously we have five pharmacies that managed the facilities they served individually under the formulary, but the control of it was a little bit harder having people at multiple locations around the state. It also gives us the ability to control our purchases, better manage a single inventory rather than five inventories. So I look at that as a good strategy for control. Barriers – constitutional requirements, the eighth amendment basically... and the eighth amendment and legal decisions after that basically tells us we are required to give our patients medical care, which most of the time equates to the medical equal to the community standards. A barrier... we're a general fund agency. We don't have any reimbursement from outside resources from the federal government. All of our money comes directly from the state fund. The biennial budget cycle is a barrier to us because it makes it difficult for us to say this is the amount of money that we need because we have to look two years in advance to say this is what we think the cost of the medication is going to be. So that's a little difficult for our agency. We wish we have more access to 340B pricing, which I'm sure the other agencies do, as well. I know that the legislature and the UW worked with us to see if we could find a way to access that, but it is something that is very difficult. The aging population is a barrier since our patients stay with us for a long time. They age and their medical care increases and since the population overall is aging it's seen in the correctional environment, as well. As you see in our top drugs by cost specialty medications are a big piece. There are others that are coming in that we're seeing more and more for our higher [inaudible] patients. The lack of correctional pharmacy regulations is a complicated piece, because pharmacy laws really looks at hospitals, long-term care, and retail pharmacy. It doesn't speak to correctional pharmacy at all. We're actually a conglomeration of all of those and any creative strategies that we try to put in place are often blocked by the regulations that cover pharmacy. So that's one thing that makes it difficult for us to find ways to control our costs.

Jaymie Mai:

I'm the Pharmacy Manager for Labor and Industries. Next.

So just to give you a little brief overview about Labor and Industry we administer the fifth largest worker's comp program in the nation and you can see there the number of workers that we cover in Washington State and the number of employers. Ray mentioned earlier than we are a participant of the Northwest Consortium for rebating and mail orders for our pensioners and we also are a participant of the preferred drug list. We spent last year roughly about \$17.5 million on prescription, which is about 3.4% of our medical spend. Next.

So here I didn't do a top 5, I did a top 10 for a couple of reasons. One of them is to show you number 7 and the increase in cost that we experience based on utilization of Harvoni, hep C and the other is to illustrate the increase in baclofen in terms of pricing. And that comes to play a little later when we talk about barriers for us. But that's our top 10 by spend. A lot of our drugs are either in pain or pain type treatment because of injuries and the other is mental health. Okay? Next.

This is top 10 by utilization and again really a lot of spend or prescriptions are relating to pain treatment in our population. Next.

In terms of management strategies, like I said earlier, we're part of the consortium and PDL. We can develop treatment guidelines to control inappropriate utilizations. We have prior authorization and clinical criteria, as well to help us control or management our costs and we have a fee schedule, but the... I think our challenge is really in controlling high cost innovative drugs such as the hep C and then the, you know, increase in generic... old generics pricing where we're seeing consolidation of manufacturer's or things like that where it's driving huge price increases in generic products. We're having, you know, we're struggling in how to control that.

Donna Sullivan:

Thank you, Jaymie. I'm the Chief Pharmacy Officer for Washington Health Care Authority. I manage our Medicaid pharmacy benefit, as well as our public employee's pharmacy benefit through the Uniform

Medical Plan and for fee-for-service Medicaid we spend just over \$155 million on prescription drugs and I want to point out that this is the dollar amount before federal rebates. I put it on here because I don't have the federal rebate information from the managed care plans and I didn't have rebate information from UMP so I wanted it to be comparing apples to apples. If you look at the fine print down at the bottom of the slide after federal rebates our fee-for-service program spends \$101 million... I'm sorry, \$111 million approximately on prescription drugs. But with the three programs combined we are putting out-of-pocket over... close to \$1.4 billion in calendar year 2015. It's a significant portion of our total healthcare cost.

So looking at our top 10 traditional drugs what I did is I broke them out by the three different programs and for the fee-for-service program on this particular slide I was able to give you the cost net of rebate because there are enough products within those classes or within those drugs lines that it's not disclosing the proprietary nature of those federal rebates. But aripiprazole, the generic form of Abilify was the number one spend for most of the health plans as far as Medicaid fee-for-service and the MCOs, as well as PEB. Lantus/Solostar is another high cost drug and it's an insulin product so it's used for diabetes. Its cost has increased over 37-1/2% from 2014 to 2015 and you're probably wondering if that's a type-o that it looks like Medicaid fee-for-service is a negative \$303,000 paid and the answer is no, that's not a type-o. John Coster talked about those... the consumer price index and the additional penalties that manufacturers have to pay if their drugs increase too quickly. This is what happens for the fee-for-service program is that those drugs then become... we actually make money on some of those medications. So as they are becoming more and more expensive to commercial payers or my fellow agency partners, they are becoming increasingly cheaper for the Medicaid program through that CPI penalty. So I'm not going to dwell too long on those.

And then the next slide is our top traditional drugs by utilization and it's very common. You don't pay medications, antibiotics and things like that. Again, the costs are up there. Net of rebate for fee-for-service, and I don't want to go through those one by one. But these

are mostly... when you look at utilization it is generic drugs, ProAir is for asthma. It's going to lose its patent shortly, sometime this year, so we're hoping that those prices will come down on that medication as well. And then the next slide what I wanted to do was really break out the difference between traditional drugs and specialty drugs so that those top spends on the first slide that was traditional drugs. So that doesn't include... didn't include the hepatitis C, the drugs for rheumatoid arthritis and all of that. I break that out because otherwise if we look at just the top 10 drugs all we look at is the top 10 most expensive specialty drugs and three of them being for hepatitis C. Again, Harvoni is our number one drug and by spend across the three different programs. The managed care plans for Medicaid, those expenditures are carved out of the managed care plan themselves and paid by fee-for-service, but I attributed it to the managed care plans because that's where the population is. And then we look at Truvada for HIV, norditropin which is a growth hormone which has been around for a very long time, but there's no biosimilar to it because of the regulatory process that was just recently approved. And then we have other high cost medications are Humira, it is a medication where we actually have a negative number. I didn't put the rebates on this slide because some of these drugs only do have one product and I can't disclose the federal rebates in any form that you could actually calculate what those are themselves. So these are not net of rebate. The fee-for-service is net of rebate, but the managed care and the UMP dollars are not.

And then for the last slide our management strategies, again, we are participating with the Washington preferred drug list with both Medicaid and UMP. We do an extensive prior authorization on medications for... our Medicaid fee-for-service. We look at expedited authorization that allows the pharmacy to insert a claim or a code on a claim to allow it to be adjudicated without going through a full review. We have quantity limits. We have aggressive reimbursement rates for generic drugs, as well as brand name drugs. For our specialty program with Uniform Medical Plan what we have implemented is something called split fills for certain drug classes where the drugs are very toxic. So instead of dispensing a full month's supply at a time where the patient might take one dose and

never take that drug again, we're dispensing them in 7-day supplies, 14-day supplies, and our specialty pharmacy at Arden is working really closely with those patients to make sure that they're able to tolerate their medication and then after a certain period of time when the doses have been adjusted and the patient can stay on it then we will adjust the dispensing to a month at a time. And their cost is divided so that they are not paying for multiple co-pays for multiple dispensing. So they pay the same amount. For PEB we also have cost share as far as co-insurance and then member premiums, as well. So just a quick thing, I think my barriers are the same as everybody else. My biggest barrier for Medicaid is the Medicaid Drug Rebate Program. It doesn't sound like it should be, but it puts a lot of rules on Medicaid where we're forced to cover these drugs and the only options we have to control costs are to put up barriers in front of the providers in order to shift utilization to what we want it to be.

Ray Hanley: Do we have any questions for our panel?

James Bryan: On the Truvada cost do you know how much of that or do you have any data as being used as pre-exposure prophylaxis versus treatment? Or is it even available for Medicaid recipients?

Donna Sullivan: I'll take that. No, we don't. We don't get the diagnosis on a prescription claim when it comes in so I don't know what the utilization is for.

Ray Hanley: Another question in the back.

Missy Dolan: I have a question for William. You mentioned that you are... one of your barriers was the lack of regulation and you have to rely on regulation of LTCs and retail, etc. and that that has actually prevented you from some creative solutions. I just wondered, can you give us an example of one of those solutions that you weren't able to do because of that?

William Hayes: So one of the more recent solutions that we tried to put in place was utilization of robots essentially in our facilities to control the amount of drugs that we had to place in the facilities, rather than giving every

patient their own supply, we were going to utilize a dispensing machine that held all of the drugs and would only dispense one at a time. So that would cover both the inventory, but also reduce the waste on the other side, which is another major issue that we deal with. And the current regulations, which luckily the Pharmacy Commission is looking at and going to change it to make it a little bit easier for everybody, but at the time it was a barrier to us. We had to figure out how we could use them within the regulations. So that is the easiest example to promote.

Ray Hanley: Thank you, William. Another question? That was Missy Dolan for the transcript.

Victor Collymore: I have two questions, actually. The first one was for the person who presented the top drugs by cost and utilization, is there some difference in the population between Western and Eastern State Hospital that would account for the differences in the drug profiles?

Katy Tomisser: There is a difference. Eastern State takes more acute patients. They can take people that have not been stabilized. Western State usually there's a... well, there's a long waiting list if you're reading the newspapers, but there is also... people have been in usually other facilities for a number of weeks. So Eastern State has a little more chaos, if you will, with their patient population. They also... they didn't have the formulary pushback, I think, from the pharmacists. They didn't have the support. And so now they do that we've joined forces to have a formulary that's the same for the three state hospitals. They are going to have more ability to enforce a formulary whereas in the past they didn't.

Victor Collymore: Thank you. And the second question was for Donna. To the extent, you may have done this, when you compare fee-for-service versus the MCOs is there any evidence that the Health Care Authority has that would suggest the tools that the MCOs are employing to control costs have been more efficacious than the fee-for-service or the northwest consortium or not?

Donna Sullivan: That's a good question. We haven't looked in that... I think that granular between the different plans. It's really difficult. The different, you know, the five plans they have five formularies that are different from the Washington PDL. They all have different tools. Some of the plans do use more restrictive prior authorization policies. Other ones are a little bit more liberal. So it's really difficult to tell to what extent if one plan is doing a better job than the consortium or... I guess the other thing is I don't know what you pay to pharmacies so I don't know your reimbursement rate. I don't know what your rebates are that you might be negotiating on supplemental rebates with manufacturers. So without that level of transparency I don't think we could actually compare you to the consortium at this time, but we can work on that.

Ray Hanley: In the interest of time, it is 11:30 and we're trying to get back on track. Please just write your question down, the name of the speaker, and I really appreciate it. I want to thank you panel very much for today.

[applause]

Ray Hanley: So our next speaker is Bill Ely and Bill this is for moving the slides. Bill Ely has 35 years of experience in the insurance industry. He's both a consulting and a corporate roles. Bill currently is the Vice President of Actuarial Services and it includes overseeing functions, actuarial functions in the Northwest and Hawaii regions of Kaiser Permanente, as well as the actuarial functions for the individual and the small group lines of business nationally. Bill has held elected positions in the Section of the Society of Actuaries Professional Organization. He currently serves on the board of directors for Oregon's Temporary Reinsurance Program. He's been involved in many internal and external working groups related to the implementation of the Affordable Care Act, and coordinating care organizations. So with that, Bill, I'll turn over the podium to you.

Bill Ely: Thanks, Ray. Well, I mean this actually is a big day for me. Number one, as an actuary I don't get out much. Number two, a couple of firsts. First time I've ever spoken before this group of people bar a



couple of individuals, and I actually think it's the first time I've ever been introduced without someone making a reference to the one actuarial joke in the world, "Oh Bill's the extraverted actuary. He looks at your shoes." So with that as sort of a background I've come today to talk about premium development and pharmacy costs and drug cost. Prior to launching into that there needs to be some consideration that Kaiser Permanente sort of wears a different hat than a lot of folks in the industry on this issue and other issues. As most people are aware we're an integrated delivery system. So not only are we the health plan, we also have pharmacies, we also have, you know, professional physicians and professional care delivery staff. So in the pharmacy arena we see sort of both sides of the equation, both the cost from a health plan standpoint and we see the cost that our members are impacted with or our patients are impacted with. Then we also see those same two views, if you will, from the provider side of the equation. In general, for those of you who don't have a lot of familiarity with Kaiser Permanente, nationwide we have about 10 million members. So some slide earlier mentioned... talked about the scale of pharmacy purchasing that we're trying to achieve here in the state like, you know, finding Washington and Oregon purchasing cooperatives. So Kaiser is a lot bigger than that and we use our 10 million members to leverage the best pharmacy pricing, you know, we can get. So that's an important consideration when looking at, you know, sort of the impact that prices have on us, as well as our premiums and our members. In general, to get non-actuarial, but just sort of, you know, state a basic tenant up front in terms of our perception is we are all in committed to driving, you know, affordability and quality for our members. And frankly the cost of physician drugs are a barrier to providing that affordability. We're revamping, you know, transforming how we deliver medical care to try to achieve that goal of affordability and quality and it's time for the pharmacy companies to do the same thing. Next slide, please.

So a little background. I've got a few slides here today and we probably aren't going to get to cover them all because of time. So what I really want to concentrate today is sort of to give people some familiarity since I understand, you know, it's not on everybody's top of mine of how actually insurance companies set premium rates and

what the impact then is of how the pharmacy pricing flows through those rates. And it different depending on what line of business you're in, which I'll discuss in further detail. We also... one interesting thing about KP is... and I have to caveat in terms of what I'm saying today is there is going to be some simplifications made. So one, you know, if I was to give a 10-minute presentation without making simplifications you'd think my job was easy and you wouldn't value my credentials as much. So number one, it has to be simplified. But then also Kaiser is a little bit of a different animal and I want to draw this out because it actually has some ramifications with some of the other conversations I've had with people in this room around, you know, ALPAC, all pay or all claims or all pay our claims database, APCD, about Kaiser's data and how it impacts our premium, as well. As an integrated delivery system the encounters, what we call encounters, the interaction between our employed professionals/physician and the members we don't capture as a claim. We don't have a claim system in general that processes those claims and in the same way as a fee-for-service health plan. So when I talked today about claims and premium development based on claims we'll make the assumption that... I'll refer to our internal encounters as claims. The reality is we have a bunch of things that we do in the name of, you know, quality, as well as to make the member experience and the outcomes desirable, that we simply can't capture on a fee-for-service claim. So the classy example getting a little bit dated, and finally there's some recognition in the coding community that hey, we might need to add some of these things, but that is emails. You can email your doc back and forth in the Kaiser system and there's a cost associated with that, but that's not something we can code on a fee schedule basis and, you know, capture that in claims experience. So we call those types of services that we provide that aren't able to be captured in a fee-for-service claim as we term integrated care management which represents the things that we do as a provider that helps either with, you know, outcomes, quality, affordability, or all of the above, and we lump that under the integrated care management background and build that into our premiums, but not as a specific claim.

So at the very simplest level when we set premiums for a group, basically what we do is we take projected amount of costs, medical cost, pharmacy medical, claims if you will, and we add to it retention and retention is basically a component for administrative expenses and for margin. So in essence projected cost for medical care versus projected cost for admin and profit is how you get the premium overall. I would point out, because of minimum loss ratio regulations, that that box of retention, administration cost and margins is limited. Depending on the line of business we have to pay out 80 cents or 85 cents depending on the line of business on every dollar or premium collected so the component for administrative cost and margin is relatively small. For margin it is really, really small at least compared to some of the margins on the provider side for, you know, from pharmacy companies and others. It's a tiny piece in the scheme of things.

In addition, so when I say projected medical expenses what we're doing is we're taking historical claims experience and trending that forward, typically two years, I just did some ACA filings so we were working off the 2015 calendar year experience, claims experience to project what our premium needs would be in 2017. So typically it's a two-year period, same things work for the group at the group level as well. So we've got these items that, you know, form our premiums. So how do we get that down to the individual group level? So how does a group get their premium? Well, basically it's a function of the claim expenses plus retention so the projected premium based on that group's specific experience, their claims experience, and we weight that together with the same calculation for all of that risk pool with similar demographic characteristics together. Flip the slide there.

So for instance, for our largest groups, 1,000 member groups and this is a simplification, different carriers have different formulas, as well as some additional factors they put into the formula, but for our largest of say 1,000 members and up all of their future premium rate is based on their specific historical claims experience. For groups that are smaller, say going down to under 200, all of their premium rate is based on a demographically-adjusted experience for groups like

them. So all small groups, all large groups that is what we refer to as the manual rate. So I went around here and maybe a little bit too detailed for the basic concept of how you drive premiums is you've got a component that is related to a group's specific expenses. You've got a component related to the pool as a whole, large group, small group, individual, and you just rate those two numbers together to get a group-specific premium based on size. And the bigger the group is the more we rate their experience. The smaller the group is the more we rate the overall experience of the pool. So for those of you... I can't, you know, yeah, the next slide is fine.

I'd lose my actuarial credentials if I didn't put a formula up there. So that all boils down to projected expenses equal your group projected claims times credibility, that's the weighting to their experience plus the manual rate times one minus credibility and then if I've got a group that's all 20 year olds I don't want to set their... their manual rate needs to reflect all 20 year olds, as well so that's my meant to about demographic adjustment. I take the pool that is sort of adjusted to make it relevant to 20-year-old males. Next slide.

Small group and individual premium rates are just a special case of what I just talked about and that's where there is no wait on the group-specific experience. It's all pool driven, adjusted for demographics. And for those of you... there's one little quirk, which I could talk hours about, which I'm sure you don't want, on the Affordable Care Act and we're actually pricing to that not on... Kaiser's pricing to that not based on the experience of Kaiser. We are pricing to what would be the experience of Kaiser if we got a 1.0 relative risk? And so every carrier in the market is pricing to what they believe the appropriate market premium is for a 1.0, in other words an average risk profile relative to all the other carriers and then let's say Kaiser gets a bunch of favorable risk, you know, therefore we have lower medical costs. Your premium gets adjusted that you received by the federal government through a risk adjustment mechanism, similarly if we got a bunch of sicker individuals our risk would be higher and so we are... our claims would be higher. We would need more revenue than was in our market average rate so we get some risk adjustment funds from the federal government that

ultimately comes from other carriers. It's a neutral calculation. It's a revenue-neutral calculation. So real quickly, next slide.

So there's three ways that pharmacy costs can impact premiums. So one I mentioned that depending on the group size there's your group experience component. Simply enough if there's pharmacy cost in the experience, if they increase it goes up, and that carries in too. Or they can get in through the overall experience of the pool for those groups that have that component. Then also I mentioned we typically trend two years out so we're using 2015 data to project 2017 rates now. So there's a trend component in our projection of how much is it going to increase between 2015 and 2017? And so if we know, you know, there's blockbuster drugs coming along we know drugs are going to roll from brand to generic with different cost implications and we can factor that into our trend experience. And finally, as co-pays and co-insurance for members increase your actual premium would decrease, but you're really just shifting those costs over the members that have the higher coinsurance or copays. Don't have time. Here's a fun actuarial fact that you can take home and study that basically shows unless your member components of coinsurance and copays increases fast as your medical costs do, your premiums increase faster. And drugs typically, for instance, are on a copay basis on a lot of plans. So if your copay plays... stays the same, but pharmacy prices go up 20% your actual premium increase due to that is higher than 20%.

Then there's a bunch of numbers of Kaiser specific stuff that you can look at at your convenience in your packet and I'll take questions.

Ray Hanley:

Thank you, Bill. Do we have any questions? I have a joke. Do you know what the difference between an actuary and an economist is? They are both good with numbers, but an economist lacks the personality to be an actuary. Any questions? I do have one question. Oh, there's one over there. Go ahead. Please state your name too if you would.

Lauren [inaudible]: Pacific Business Group on Health. Does Kaiser deal with rebates also? Do you get rebates and factor that into formulary development and premiums?

Bill Ely: We do get rebates as an organization and we do reflect the value of those rebates ultimately into the premium development process. I don't have the specifics of the magnitude or the numbers, but we price net it.

Ray Hanley: Do we have a question right over here?

Iman Eleteby: I'm from Anthem More America. Because of your integrated system have you guys been able to manage your specialty trend better than the market?

Bill Ely: We would like to think so. So yes, we do. But like anyone else, one of the issues that I didn't have time to go through from a premium calculation standard, you know, our contracts with our groups and with individuals are one year. So a lot of the cost savings that the pharmacy industry will say, "Hey, you know, cure this disease state today you'll benefit from 10 years from now." You won't see that into the premium if in deed that benefit happens until 10 years later. But I think we have managed the specialty drug cost a little better than industry average, but it is still a huge barrier for us in terms of driving affordability. What do you do with blockbuster biologicals? I mean...

Ray Hanley: Another question?

Woman: So other health plans and Medicare and Medicaid have to deal with this notion of the pharmacy benefit... the drugs sold through the pharmacy benefit versus drugs sold through the medical benefit because it is so often sort of siloed into two different payer infrastructures. But in Kaiser's case with the integration you don't have that in a structural kind of way. One of the key distinctions, as I understand it in those... in having drugs paid separately like that, is that the medical benefit does not... is not accompanied by NDC coding, which makes it difficult to really dig in and understand like

what is going on with the drugs? How are they administered? What's the cost? What's the... it's everything. Right? Total black hole there in part because of that. But in your world where it's all integrating you don't have separate PBM versus medical benefit. Do you deal with that? Do you utilize NDC coding across the board? Do you in fact operate as if those are two different pots? Can you talk a bit about that?

Bill Ely:

And I'll talk from my world, which is the health plan perspective. Though we're integrated from a provider and health plan perspective the regulatory requirements on submitting Medicare bids, the... you know, the reporting we have to do that very often buckets these drugs in the same, you know, categories that you're talking about, you know, medical benefit versus Rx benefit. So we, for lack of a better term, don't get away with being able to combine them. We have to split them out. Having said that, you know, underlying all of our data and calculations is a medical record system. So we have the ability just because a claim might be coded as a J code on the drugs, on the medical, we probably can parse some additional information out from using the medical record, it's just... it is an effort and it's not like you press the button and the data is, you know, spurts out. So we do have to deal with some of the same issues that you're talking about that most health plans do and to separating those.

Ray Hanley:

One more question here.

Dan Lessler:

I'm from HCA. Because you are, again, an integrated system and I know this afternoon we're going to talk a lot more about so-called value-based pharmacy purchasing, I'm curious, I guess, what your... if you have a perspective on that in terms of as a strategy and particularly in the context of an integrated system?

Bill Ely:

Yeah, I think I'll... I would defer that question to people more on the provider side of the house and negotiation side of the house if you will. Having said that from a health plan perspective and from an actuarial perspective we obviously, you know, find value in the calculations of, you know, driving formularies, looking at drugs and the outcomes they provide. And trying to understand both, you

know, short-term and long-term, you know, what the impact is on medical outcomes. But I... so I think that this concept of taking... of including drugs and specific drugs in general as part of a holistic care of the patient is important. And to the degree that a particular drug, you know, shows more promise than that in terms of driving healthy outcomes, avoiding other medical expenses, I mean surely we would, you know, point our formulary and our negotiations toward that drug over others that don't provide that.

Dan Lessler:

Thank you.

Ray Hanley:

Another question over here?

Woman:

Just a question about regional variation and how you factor that into premiums.

Bill Ely:

So in essence we set... Kaiser sets premiums at the regional level. So California premium is based on a different set of experience than is... are the premiums in the Northwest. Within the Northwest then we start looking at other geographical, you know, subsections. So, you know, we're big in Portland, you know, Clark County, you know, in Washington and Salem are probably our predominant service areas in Long View. And so we look at different cost patterns or what the experience shows in those different areas and then we make a decision whether we, you know, put an area of factors to rate for that or not. In general, I think there's only one area right now in large group... on small group that's carrying an area of factor.

Woman:

So that's even for national companies or national groups?

Bill Ely:

Correct.

Ray Hanley:

Thank you. We've got time for one more question, Bill?

Bill Ely:

Sure.

Jim [inaudible]:

Oregon Health Care Authority. You may have mentioned this, but when we talk about some of these new breakthrough therapies like



hep C, the pushback I hear is that, “Well, if you spend this money up front then you’re going to save all the money you’re going to spend on a liver transplant or liver cancer in the future.” So that’s not past experience that’s, you know, future savings. So real briefly, how do you factor those types of future savings into your premium discussion especially when it comes to [inaudible]?

Bill Ely: To be straight forward, we don’t. So my contracts are on a one-year basis. So if I’m going to save immense amounts of money 10 years out ultimately that will be reflected in that premium 10 years out. So, you know, experience in 8 years I know what’s coming, I know what my liver transplant rate or whatever has been dropping and we can build it in going forward. But you can’t build it in now for what’s going to happen in 10 years unless I’ve got a relationship with a group that’s going to last for 10 years.

Ray Hanley: Thank you. We’ll take one more from one of our presenters.

Man: You mentioned not taking into account for the premiums. Now I don’t know if you have any idea around this, but how about in terms of making like decisions on formulary and access and things like that? Would that take into account, you know...

Bill Ely: Yeah, I don’t have as much insight to that, but in general sort of, you know, mission number one at Kaiser is taking care of our members. So it’s a pure... and I have some summary slide of it or some bullet point, but the decisions around, you know, formularies and which drugs to include are clinically-based decisions, they aren’t cost-based decisions.

Ray Hanley: Thank you, Bill. Could we have a round of applause for Bill? Thank you.

[applause]

Ray Hanley: Well this has been a little bit like drinking out of a firehose for some of you guys and I realize we’ve covered a lot of ground, but it’s now getting to be time for lunch. So we’ve got the... outside we have a

buffet we're hosting for you all and I have just a brief instruction, which is if you're on that half of the room if you would go through those doors and if you're on this half of the room if you'd go through those doors you'll be... and Leta has some further instructions.

Leta Evaskus: Actually, if all of you can go out the center doors... okay, go ahead.

Woman: So these are instructions from the caterers. They changed their beautiful plan. Right? So, yes, they want the people on this side to go out that door and the people on my right, your left, to go out that door and then come back in the middle.

Leta Evaskus: Okay.

Ray Hanley: And then come through the center. The last thing I wanted to say, too, about that, please come back in and enjoy your lunch. We're going to try and pick up our next speaker at about 12:30 and it's Robert Judge who is going to talk a little bit about the effect on consumers. But, please, if you will go out. Bon appetite and we'll speak to you again in about half an hour. Thank you.

Robert Judge: So first to get a sense of the rising costs of specialty drugs and other high cost medications and their impact on kind of the delivery of healthcare services it's important to look at the underlying trend of what the industry is experiencing. Since 2010, and another speaker referred to this earlier this morning we've seen the share of the specialty drugs, the percent they take of our total spend on drugs and increased by about 260% since 2010. So in five years it's gone up about 260%. Some of that is through innovative new products. Some of it is just manufacturers increasing prices, but while back in 2010 specialty drugs and high cost medications accounted for about 13-1/2% of our total drug spend. Last year it was about 35% for UNP specifically, 44% and we project it's going to be 50% of our total spend in 2018. That trend is kind of unsustainable for reasons I'll get into in just a bit. You know, but to be fair, you know, it's gone up because we've got some really innovative new therapies out there touching populations that have no treatments or kind of some optimal treatments in years prior. So while all of that is goodness we

have a cure... or a potential cure for hepatitis C, which we never had and we had, you know, really painful treatments to treat that previously. That comes at a huge, huge cost, but the kind of the really dark side of the story is we've got this year over year increase, you know, therapies that have been in the market that are just really kind of [inaudible] bites out of that apple and that's really an area I think as an industry we need to focus on. Next slide.

So if I look at kind of the share that high cost drugs make in our spend, you know, I mentioned that it went from 13-1/2% to 35%. I think it's really important to put it in context. 35% of our spend, soon to be 50% of our spend accounts for... pays for drugs that is distributed to roughly less than 2% of our members. So about 1.9% of our members. It accounts for about 1% of our prescriptions. So when we're staring at the face of looking at 50% of our drug costs being used to treat 2% of our population that is a very frightening picture for us, especially if you look at the drug pipeline and what's coming down and it's really bigger molecules, really targeting really small populations of people at really exorbitant costs. So it's an issue that as an industry specialty drug solutions need to be developed that maybe sit out separate from how we look at traditional drug spend. Next slide.

So there's lots of techniques that payers use to kind of help manage drug spend and control it. So as we work to kind of implement those strategies to minimize the impact of drugs on consumers it's creating situations where these drugs, even though you might have the example of rebates that we used earlier that says really it offsets the net cost of a drug that you pay for, but you've got this trend that sits underneath it and that trend either gets absorbed in terms of copayments or absorbed in terms of premiums impact on members. That increasing impact on consumers is really placing some of these drugs out of reach for consumers and making... it's driving these growing clamber for cap the copays for consumers. So at least their out of pockets are limited and what that will mean is it will be picked up by premium and everyone is going to pay for it at some shape or another. So this is chart really depicts the cost of drugs represented as a percent of our total medical cost. It's a little bit of an eye chart. I

apologize for that. But what it shows is that for our respective markets—commercial, Medicaid or Medicare what portion of drugs represent as a [inaudible] percent of our total spend. And for our commercial lives even with these increasing drug prices and new innovation therapies we're still seeing our medical costs increase 13-1/2% on the commercial side, roughly 25% on our Medicaid costs even though we have new therapies and they are supposed to lower the medical costs for treatment down the road. We're not seeing that.

I mentioned this a little bit earlier about this niggling little problem of year-over-year price increases. I think it's really important for us to focus on this for a bit. Consumer price index raised 1.7% in 2010 or 2013 to 2015 yet these... we've seen in therapeutic classes where you might have multiple drugs in a therapeutic, you know, prices ranging... price increases ranging, you know, 30% to 120% in the therapeutic classes that I just picked... I didn't cherry pick these. And this is a problem. If you look at Humira it's a drug that's been around since 2008, hasn't changed its formulation since it came out in 2008, but its price since 2013 has gone up almost 60%. Tecfidera came out as a brand new product in 2013 really an innovative product, it's an oral product for non-relaxing MS. It's gone up 270% from manufacturing prices increasing since 2013. Hard for me to justify how that happens. Now we talked about rebates on the back end to help offset that, but dollars to donuts I've not seen my rebate values go up 270% for Tecfidera. So there was some question this morning about what does this do on medical costs? Are we seeing drug prices help offset medical costs? The answer to that, not yet. Bill, when he spoke, said, as an underwriter or an actuary I don't project that which I can't count. And, you know, some of these will have downstream impact savings, but until I see it I don't count it. I looked at hepatitis C because it is the poster child and granted this is a long developing condition, but we've seen our costs for hepatitis C medical treatment really go up a couple percentage points since the new therapies and direct acting agents came out a couple years ago, but we've seen the cost of those drugs go up 1300%. So our drug prices went up from \$108 on average PMPM for a patient being treated with hep C to, you

know, close to \$1,500 PMPM yet the medical costs have not been offset.

So what does this mean for consumers? There's... as payers while we have for the exchange marketplace and certainly Medicaid marketplace challenges helping members offset their copays, but in broad areas, whether it's a self-insured plan or a fully insured group or on Medicaid there are vehicles that we use to help cap, you know, the amount of out-of-pocket expenses that consumers have to pay. And those could be maximum amount of pocket costs on... for combined... for medical combined pharmacy. It could be a co-pay max on a drug. Those are vehicles that help kind of limit the impact for members, you know, our average out-of-pocket expense for all of our populations about \$188 per drug in specialty. The other side of that though is the manufacturers because the manufacturers realize if it's a \$5,500 drug and the member pays \$180 I'll give that \$180 away to pick up the manufacturer, you know, payment on the rest. So you have the [inaudible] of these patient-assistance programs or other charity programs which are very, very useful on those limitations on where you can apply them for Medicaid and/or Medicare, but the advent of those programs and the availability of those programs I think is a real, you know, a huge benefit for many consumers. In our marketplace we have... and I'll end on this point, because this is kind of where I wanted to get to. These patient-assistance programs are pretty lucrative in terms of what they mean in terms of actual real net cost impacts for members. When you apply the average patient-assisted programs about \$163 against our population and we make sure that every patient has a specialty drugs tries to get into a patient-assistance program to offset that. So the net out-of-pocket that a patient pays for a specialty drug is about \$25. Again, that doesn't address, you know, your Medicare population or the... some of your members on the exchange, but those vehicles, and certainly making sure that manufacturers continue to have those patient-assistance programs is really important. So from a legislative perspective when you see copay programs come out it's really a way for manufacturers to step away from patient-assistance programs because their copays are capped. That's kind of what we're seeing in our marketplace. Now if you look down... and I'll end on this note,

because this is all about what do we do? You know, we have things like prior authorizations, quantity limits, step therapies and those types of techniques to help manage the high cost of drugs or manage the appropriate therapies so you have the right drug at the right price for the right patient, but as we look at what we need to do down the road it may be looking at selecting preferred agents within the therapeutic category now that we have multiple drugs for a therapeutic category coming to market for specialty items. It's being aggressive and using biosimilars even though the fed is just publishing what's a test of a biosimilarity. Using... really creative use of your value-based rebate agreements with manufacturers. It's really good to see that they are approaching the table to do that, collecting the data to substantiate is the hard part. Establishing preferred distribution channels for drugs so you can optimize the price that you pay and how you pay for them. And, you know, looking at closed formularies, which may create some angst for some people, but excluding some products that have [inaudible] value or no value, you know, doesn't move the bar a whole lot in terms of when they come to market. Maybe they don't make it onto the formulary. Those are all things that we're looking at to help try to cap our costs going forward. That's it.

Ray Hanley: Thank you, Robert.

[applause]

Ray Hanley: Do we have any questions for Robert? Please state your name, too.

Liz Bentley: Hi. I'm from Kaiser Permanente. I just had a question regarding the patient's assistance programs. You mentioned some of the benefits, but do you see any potential drawbacks of relying on those programs?

Robert Judge: Yes. So manufacturers, they're manufacturer-driven programs. The criteria that they use are non-uniform. They are particular to the manufacturer's program and product. So as an example with our Harvoni and Sovaldi products there were some really aggressive and helpful Gilead pay programs that were used when that product was

first out there. But then they changed the criteria, which limited individuals ability to kind of get access to those programs. And so not having it uniform and having it... I don't know that I'd build a strategy around it, but they are very useful.

Ray Hanley: Any other questions?

Dan Lessler: This might be a question that leads to a theme that sort of reoccurs throughout the afternoon presentation. You touched upon the idea of a drug being cost-saving. And in my experience, my reading, there are virtually no drugs that are... and you might be able to find one or two that are cost saving. They are cost effective, which means that you have an incremental benefit, but at an incremental cost and to the extent that you add many cost-effective drugs, which could be good in terms of the outcome you desire, the net outcome from a financial standpoint is that you increase cost. I'm wondering if you could comment on that because I think this notion of cost savings and this has come up a lot with hepatitis C where the best, and we've got a health economist in the room, so I'm going to defer to Scott here in a second, but, you know, the best [inaudible] was published about a year ago in the Annals of Internal Medicine, a cost effectiveness analysis of those drugs, which, you know, I think depending on how you looked at it was around \$25,000 to \$30,000 per life year saved. That's net additional cost. And yet, you know, if you go certainly amongst the general public and you say using these drugs you're going to save money. So what's your perception of that at MODA? How do you guys think about that idea?

Robert Judge: I'd love to, you know, as a country I'd love to be able to adopt kind of England's use of kind of valuing the value of medications and being able to assess what they do in terms of extending people's lives. We don't do that here. So when we look at a drug and we're evaluating for inclusion in our formulary it's a clinical assessment. Is the drug effective against the population that was studied? And how does that impact our utilization? How it is paid for and the cost of that is after a formulary decision is made. So... and that's part of our challenge as a society dealing with that. The... but I think your observation is right. There may be cost-effective options out there that help achieve a

desired outcome, but not at a less expensive option. It bears itself out when you look at medical costs that have a tremendous amount of drug utilization as part of the therapy management for that. You don't see a lot of offset to that. At the same time many of these drugs are chronic condition drugs that you'll use for the rest of your life and as prices go up, you know, the cost of treatment goes up. So we've not solved that as a society yet here.

Ray Hanley: Any other questions? I have one for you Robert. So I heard you say that specialty drugs could be 50% of spend... drug spend per program. And they effect of 2% of the population. Make you philosopher king for just a moment. Do you see any backlash in particular programs when you have a disproportionate share of spend going to a very, very small number of people?

Robert Judge: That sounds like a death squad. You know, that 2% sees the benefit from it is priceless. You know, when you have people suffering from very, very horrible conditions where it's priceless to have something extend their lives/the quality of their lives. So I don't... I try not to get into those blow back kind of discussions or decisions. I think that as we evaluate new therapies it's legitimate to say a new cancer therapy extends the life for 10 months. Is that something that needs to be considered when you factor that drug for inclusion on a formulary? And clinically that's the right discussion to have, not whether the price relationship makes sense.

Ray Hanley: Fair enough. Anyone else? Thank you. Let's give Robert a big round of applause.

[applause]

Robert Judge: Thank you.

Ray Hanley: So our next speaker is Jane Beyer and Jane is going to talk... she's from the Center for Evidence-Based Policy, I believe. She's going to talk to us about something called the SMART-D Initiative. She said she wanted to run her discussion a little bit different. She might actually include another audience member and she wants to sort of



go through her slides quickly and encourage a little bit of discussion. That's what Jane wants out of this. That's what Jane gets. Jane is currently the Program Officer with Milbank Memorial Fund at OHSU Center for Evidence-Based Policy. In that role she supports state legislators and executive branch agencies in their efforts to develop and implement evidence-informed health and social services policy to improve health outcomes for people that they serve. Previously Jane served as Assistant Secretary for Behavioral Health and Services Integration for the Department of Social and Health Services from 2012 until 2015. She also served as Senior Counsel to the Washington State House of Representatives democratic caucus from 1988 to 1994 and again from 1999 to 2012. In that position she handled both a broad, broad range of health care issues, human services and criminal justice issues with a focus on Medicaid and access to healthcare. From 1995 to 1998 Jane served as the Washington State Medicaid Director. With that I'd like to welcome Jane Beyer.

[applause]

Jane Meyer: [inaudible]

Ray Hanley: Yeah, that's be great.

Jane Meyer: [inaudible]. I'm a mother. I know how to multi-task, but I'm not that good. Okay. So hi everybody. The reason that Ray made that comment about what I want, I get, is because of all the years in 2003 and 2004 and 2005 when I was a legislative staffer and I made his life hell. So just by way... a bit by way of introduction the... you heard reference to OHSU and the Center for Evidence-Based Policy previously. It was actually drug costs that were the impetuous to establish the Center for Evidence-Based Policy 10 years ago. And the Center has two collaboratives. It has the DERP collaborative, which is the Drug Effective Review Program and then it also has a collaborative called the MED collaborative, Medicaid Evidence-Based Decisions Project. Both are multi-state collaboratives and essentially the states come together and pool their resources to have the Center do evidence research work for them to try to help them actually use evidence to drive policy. And then Milbank Memorial Fund is an

endowed operating foundation that essentially has a mission of helping state policy makers use evidence to help inform their policy work, as well. So the two organizations really sort of fit together hand and glove.

So I wanted to talk to you about the SMART-D project. This is a project that the Center started working on about six months ago. It's funded by the Laura and John Arnold Foundation and I'll talk to you at the very end about the other organizations that are being funded with that program or that initiative of the Arnold Foundation. But really it's a matter of, in terms of the rationale for the project, you all heard John Coster talk about the Medicaid Drug Rebate Program, you heard Donna talk a little bit about the state Medicaid agency's frustrations with the Medicaid Drug Rebate Program and really this project all boils down to trying to help states basically provide prescription drug coverage in a manner that promotes the use of the most clinically effective drugs to get better outcomes from Medicaid clients while also working to manage prescription drug costs. Sounds impossible, right? But we're working on it.

So in terms of the project goals as I indicated we are trying to help the state reach this goal by working with a set of states to develop alternative payment models for prescription drugs. That can be linked to volume, can be linked to clinical value, but basically to have more flexibility to try to design those models. And then also provide Medicaid leaders with the opportunities to shape the national conversation on prescription drug pricing, innovation, and use. We have three phases to the project—phase one is basically... we are calling it discover, but it is basically a lot of research, a lot of research, working with some really, really skilled consultants and experts who are helping us. And I'm going to talk mostly about phase one today. That phase ends in July and then phase two begins in August. August of this year through April of 2017 where we essentially get to hard work of working with states to actually define alternative payment models and do state-specific technical assistance and then also implementation in phase three. Again, pending interest by states, because it's the states who would take these models up, and also continued interest by the Arnold Foundation in supporting the

project. And those of you who work with me know that I do my thing about connecting the dots where I always try to figure out what are all the pieces that we need to have together to actually achieve anything? And so when we think about phase one of the project we think about components that have to be taken into consideration in order to actually have a fit with, and develop alternative payment models. And so as we think about it the pieces that we are thinking about, and these are activities in phase one, what are the drugs coming in the pipeline over the next three to five years, how are alternative payment models used in the commercial market and in other countries? What are Medicaid programs currently doing? What's there sort of baseline practice around controlling prescription drug spending? What are the legal pathways that states can use because the Medicaid Drug Rebate Program is inflexible, but it is not completely inflexible, and we all know that there is waiver authority in the federal Medicaid statute as well. And then also an area that I have really been trying to focus on is I've talked about SMART-D and we've done the teamwork. Prescription drugs are one piece of whole person care. And so really thinking a lot about how, if we're developing alternative payment models and working with states, we can try to do it in a way that becomes part of the state's broader delivery system transformation efforts. And these are the points... the specific activities I'm going to go through in the next slides.

The pipeline analysis – that is not my area of expertise. But essentially we're going through a process which I think a lot of other payers are doing now and have been doing for a long time and that Yohan talked about earlier to assess new drugs in the approval pipeline and try to work with our participating states to try to give some sense of what the potential fiscal impact is for their Medicaid programs. Current practices for alternative payment – we're partnering with GFK and Yohan who is putting together... they are putting together for this project a really great overview of how alternative payment models for prescription drugs are being used, again, commercially in the United States and internationally. And I think the greatest value of that report is to really make concrete to some of the states that we're working with what options might be out there and then equally important, what kinds of arrangements have

manufacturer's showed a willingness to enter into? So if after I do my quick talk people have questions about that I'll haul Yohan up here to answer those questions.

As John Coster indicated a bit we look... states are trying to be as creative as they possibly can within the MDRP rules to try to manage prescription drug expenditures. So we did a report for our med collaborative that really did a deep dive that looked at what states are doing and so many of the things we've already talked about—preferred drug list, prior authorization, but what we've also seen is states real willingness to step back and again think about trying to influence prescription drug use and spending by more whole person care management approaches. So we've seen really interesting things with respect to hemophilia. We've seen interesting things with respect to hep C treatment and other high-cost medical issues. Many states and their managed care organizations are using specialty pharmacy networks. Again, both fee-for-service and managed care. The majority of states participate in multi-state purchasing pools which are often representing the states in negotiations with manufacturers around supplemental rebates. We are seeing states pay a lot more attention to the 340B program which was referred earlier. Some efforts through increasing provider participation in 340B programs. States are taking different approaches. Some states are saying, "Okay, it's a 340B provider and we're paying you what you paid for that drug. We're paying you your 340B price, which is often lower than the Medicaid price even net of rebates." Other states are trying to engage 340B providers in discussions and initiatives by saying, "We understand that your price for the drug is lower than what we would pay you for Medicaid, can we talk about some sort of a shared savings arrangement?" So that we keep the interest in, for example, FQHCs and rural health clinics in participating in Medicaid and these kinds of initiatives. We've seen a couple of states who are pairing relationships with... who are pairing working with a 340B provider to design kinds of center of excellence approaches where you're working with a limited number of folks who have unique medical needs. It's interesting, we've had discussions about pulling sort of medical clinician-administered medications out of the medical benefit and putting it into the pharmacy benefit. We are seeing some

states doing that and applying prior authorization policies to those benefits. We see a fair amount of variation among states and how states work with their Medicaid MCOs. Some states say to their Medicaid MCOs, develop your own formulary. Texas is unique. Texas defines all formulary that all Medicaid managed care plans need to use. Some states give the MCOs more flexibility with respect to their prior authorization criteria. The big change in this area is that the final rules that were just issued by CMS for Medicaid managed care contracting are very, very clear about the fact that the Medicaid Drug Rebate Program protections apply equally to managed care as they do to fee-for-service. So some states I think are having to reign in and be a little bit more prescriptive about their managed care plans practices in that area.

Then we're seeing states who are interested for managed care organizations that are contracting with PBMs in seeing whether there are opportunities to participate in the kind of multi-payer value-based initiatives that the PBMs are taking.

In terms of legal and compliance analysis – essentially what we are doing here is we are looking for legal pathways that states can take to implement these alternative payment models. So we are... we have our base understanding of here's what the legal framework is now. We're looking at options that are both within the MDRP program and potentially outside of it via statutory exceptions, via waiver, etc. We are realizing that if we are developing legal options we need to have options that work both for states that do fee-for-service contracting and for states like Washington that are heavily managed care oriented. We are again stepping back and looking at a whole person approach. We're not looking... we're not limiting ourselves to legal pathways that are just negotiations between a state and a pharmaceutical manufacturer. We're looking at where there are opportunities around value-based payment to pharmacies or to physicians or to hospitals. And again as I indicated earlier we're looking for opportunities to align with broader state efforts.

We are realizing, and that's why this is a great opportunity today for me to hear through your questions what you're thinking about and

what you would want to know, that we have to hear from others. So we have a SMART-D advisory committee that has a pretty impressive list of folks who are participating across clinicians, consumers, academic researchers, pharmaceutical manufacturer's, foundations, all of the advisory committees supported by the Milbank Memorial Fund. We've had great discussions with state Medicaid agencies who have been willing to say, "Okay, I'm willing to sit down and have a discussion." There's about 13 states that have done that so far. We've had great discussions with Medicaid managed care organizations and with PBMs because we know that in states that are heavily managed care like Washington State if you're going to talk APM models then you're probably going to be talking with MCOs and their PBMs unless you want to do a carve out approach, which some states have done for some of the high cost drugs.

And so... and then the one other piece of phase one that we're engaging... that we're doing is we are looking at how, once we have all this information, we engage state policy leaders, we engage state legislators and we have already engaged and started some discussions with CMS on this project and what we hope to do.

So phase two... and so the documents and the research that we're talking about we will probably have... we will be providing to the Arnold Foundation and then distributing more in probably a late July/early August kind of a timeframe.

For phase two essentially this is where the really hard stuff comes. This is the, "Okay, we've done our homework. We've done our research, how do we actually design alternative payment models that we can have discussions with states about?" We have an exhaustive kind of readiness tool so the states that step up and say, "Yep, I'm really serious about this. I really want to work with you on this." We will go in. We will do sort of a readiness assessment with them. We will help them look at their cost projections to try to get a better sense of whether a business case can be made for pursuing it. We'll provide specific legal technical assistance to states because we all know that state legislatures have responded differently to these issues across the states. So it's not just federal law compliance, it's

state law issues, as well. And then at the end of phase two the hope is that we will have a small set of states who will say, “Yep, I’m ready to rock ‘n roll.”

And with phase three that would be going back to the Arnold Foundation and saying, “Here’s where we are, here’s what we’ve done. We have states that are ready to do this. Do you want to support the actual implementation?” So just to give you a bit of context, the Arnold’s Foundation prescription drug portfolio strategy is not just the SMART-D project. They are funding ICER to support their work on looking at value and clinical effectiveness of drugs. They are supporting the initiative for medicines, access and knowledge, which I think is looking more at sort of the federal drug approval process. Harvard Medical Schools have asked... no, Memorial Sloan Kettering is Peter Bach and the drug [inaudible]. Harvard Medical School, Johns Hopkins/Bloomberg School of Public Health, the Institute of Medicine on some of their work, and they’re funding Kaiser Health News to hire two reporters and work exclusively on this issue. So, that’s the SMART-D project.

[applause]

Jane Beyer: Yohan, you want to come up here in case there are questions that come up?

Ray Hanley: Do you have any questions on this SMART-D project for Jane?

Jane Beyer: Or even beyond questions, what should we be looking at? What should we be paying attention to?

Ray Hanley: Yeah, if I could just set the stage. It is that, you know, really this morning it was drinking from a firehose. We set a background with what’s going on in the nation, what’s going on in the state. We’re now moving into sort of the strategy away from tactics. This is really our first fore into this. So, please, let’s talk about what we need to do like Jane said. We’ve got one right over there. Thank you.

Lauren Vela: I'm with PBGH. So in your phase one, which sounds like a lot of research and fact-finding, did you talk with... I mean basically there are three PBMs that have the bulk of the footprint in the commercial population, did you talk to those three PBMs and see what they're doing in this space? It seems like they... I mean some of them are hearing or looking at it might be an exper... you know, a lab or sorts.

Jane Beyer: We haven't talked to all three of them because all three of them weren't interested in talking to us. We talked to one of the big three and we've also talked to a couple of PBMs that work with big Medicaid MCOs and they have been great about sharing the kinds of work that they have been doing on their commercial book of business and so we've been learning from all of that and that will all feed in. I think that the reactions that the PBMs have sometimes is, "Oh my gosh, it's Medicaid, it's the Medicaid Drug Rebate Program rules, are we going to be able to take the work that we're doing in the commercial world and adapt it into the Medicaid world?" Which is why in part some of the legal research that we're doing is such an important component of it. I'm biased, I'm a lawyer, what can I say.

Man: Yeah, just to add onto that. So the PBM portion of it... if you actually look at in the commercial world the outcome-based contracts that have already come about the PBMs are some of the first to kind of criticize them. Some of the reasons behind that is that in terms of budget visibility and what they have visibility over, a PBM is only concerned about the pharmacy benefit. So these are things where it's an outcomes base that is coming from medical claims and stuff like that. The PBM they're not going to have visibility over that and they're just not going to have their skin in the game. So the PBMs are very important whether they're working with the state Medicaid programs or wherever they are because these guys are gate keepers to collecting certain types of data. They have IT infrastructure. There's a lot of things where we need to bring them in as partners, most likely, but it's really just to understand, you know, they have their own books of business. They have their own business interest so how do you work with them to get them to assist you in this, but at the same time, you know, they just might not be interested because they might not see the incentive and the rebates in that.



Ray Hanley: Another question?

Bob Brittondon: I appreciate the talk. It seems we are looking at care management and try to influence the market, but we also heard early the competition actually has driven the cost down more than anything else. And it seems to me we're kind of hemmed in by the federal government and the certain rules. Are there things... I mean is that really true? Do we have enough flexibility and are there things we should be doing federally, as well as locally to make this work?

Jane Beyer: Okay. So I will say that the legal pathways that we're looking at provide some flexibility. They do not completely overturn MDRP and I doubt that the federal government would be interested in an 1115 waiver approach that completely overturns MDRP. And I think the Arnold... I think... so two things are going on through the SMART-D project we're going to be educating a lot of state policy makers about the MDRP, about how you work with it, how you don't work with it, etc., etc. and our expectation is that those state leaders that we're educating and that we're working with are going to have the opportunity to voice their opinion on the federal level and the Arnold Foundation, as part of its broader portfolio, clearly understands that there is a federal law agenda here and federal law issues. And so while we're one piece of it that's working exclusively with the Medicaid program and states, the other entities that are funded are going to provide other opportunities I think to identify federal statutory and regulatory issues.

Man: I mean in terms of our own foundation and what they're trying to look for for these types of things I would say, you know, with the care management and when we're talking about [inaudible] of excellence, Jane and I brought up hemophilia. So one of the things that I see in terms of some lessons learned from there is that [inaudible] 340B is... 340B is a lot of gray area. As more providers become cover entities it's very hard to really distinguish who are 340B patients, which drugs are being purchased at 340B prices, which ones are not? When you filter that all into a care of excellence like an HTC in hemophilia where almost everyone that's going through the HTC, except for maybe

Medicaid, but they are carved in. Most people are going to be getting at 340B prices. It's a little bit easier to track and identify who are the people who are actually... or what drugs are actually being purchased at 340B prices and how to work with that for the 340B savings and the Medicaid rebates and all of that. So I think for a lot of people because there is so much confusion, so much gray area, so many things to track and being able to track and being able to trust your partners and stuff like that, working with these cares of excellence centers of excellence might help to at least clear up that picture a little bit.

Ray Hanley: Thank you. Another question right here.

Iman Eletreby: You mentioned Texas and the MDRP and the state-run PDL markets. Are you guys looking at sort of that strategy in terms of some of the state-run programs that are sort of forcing the state-mandated PDLs and not necessarily managing to the lowest net cost, but really sort of more chasing rebate revenue versus the MCO model?

Man: The Texas thing that's not going to be like that much longer. They are going to change that.

Jane Beyer: Well, it's up for review by the legislature.

Man: Yeah. So it possibly...

Jane Beyer: It could change. I would say that we are not... we are not advocating one position or another with respect to state's policies on prescription drug coverage and managed care contracting. What we're there to do is to say, "Here are potential pathways." And Yohan is right that single PDL provision is up for review by the legislature I think in 2018 or either... or maybe by even the 2017 legislature because I think it expires in 2018. And I know that there has been controversy in Texas about whether that's the right strategy or not. The minority of... a small minority of states use that. There's a couple of states that still completely carve prescription drugs out of managed care purchasing. Like Washington did until 2014. Right? It was January 2014 when we did the carve in? Oh, right, of mental

health drugs. Right. Some states completely carved prescription drugs out of managed care contracting still. I think Missouri does.

Man:

I think the biggest take-away par from all of this is there is not going to be one solution that's going to fit in every single state. States operate in very different ways and doing this research and talking to these different people I was actually surprised on how differently each state operates. Goals are set differently. The pressures that they face are different. So what might work in a Texas or what might work in a Washington might not work in an Arkansas or Missouri and things like that. You know, they have... it goes all the way down to the granular level and how they can collect data, what systems they use, I mean these are all... the challenges and barriers are going to differ from state to state and that is just the way it is. So Jay mentioned hopefully finding two or three states. They might not necessarily be able to implement the exactly same APM. They might have to have different ways of doing it. It has to fit on what their environment looks like. So there's just no way they are going to find once solution, but with the idea behind it, it's understanding what they have, what they have to work with, what are their goals and needs, and then try and help them in using these alternative payment models or these outcome-based agreements or things like that.

Ray Hanley:

Got another question in the back there?

Victor Collymore:

So I just want to follow-up on a couple of your recent comments. You say you're not advocating for anything and you say Medicaid is different in every single state. So where are we going to get consistency in terms of best practices? How are you going to... if you do all this research you've got to get information about outcomes and have a perspective on what the best process is likely to be. Otherwise it's just a morass of choice points and the state, health plans, medical groups, have to have some concept... idea of about what's the best choice to potentially make. And when you have a disease there's a drug of choice for it, it does not differ whether you're in Maine, Washington, Florida or California. So there has got to be some consistency of approach.

Jane Beyer: I think what I would say is, for somebody who has been doing Medicaid stuff for a very long time, I don't want to tell you how old I am. The way the Medicaid program... the best way that states learn what works is by learning from initiatives in other states. I mean Yohan is right, you've met one Medicaid program you've met one Medicaid program, but there are core features and it is not unusual where one state has had good experience with an initiative. Having other states say, "Okay, now that I've seen that initiative, now that I've seen that it has had some success, yes, I want to look at that." And so I think the consistency comes in issues like what federal authority am I using? And what are my outcome measures? What am I looking for? I'm looking for better health outcomes. I'm looking for a better opportunity to manage my prescription drug cost. So I think that's how... that's... I'm using what 40 years of, you know, the Medicaid program has been around 50 years now of how states innovate within the Medicaid program and then share those innovations.

Man: Yeah. That's the system we work with. The U.S. is designed to have a fragmented payer system. People get their insurance depending on their social economic status, depending on their age. They go to different people for their health insurance. So these are the things that we have to work with. I agree with you, there should be a standardized way. We should have the same approach. It should go across, but that's just not the cards that we're dealt right now and that's what we're trying to navigate and understand. So eventually, like Jane said, you see one person do it the others will follow, hopefully that's the case. But right now we can't just come out and say, "Listen, you have to do these types of things," because some people just won't be able to do the way they are set up.

Ray Hanley: Great question. We've got one right up here.

Gary Franklin: I'm with L&I. Are you seeing any evidence yet of legal risk or challenge to the emerging alternative payment models?

Jane Beyer: So what we have is... states have done very, very little with APMs because of the perceived inflexibility of the MDRP and so really what

this whole project is about is trying to see how we can navigate within MDRP and conceivably with waiver authority outside of it to try and actually move these kinds of models forward.

Ray Hanley: We've got one right back here.

Linda Parlette: I'm a pharmacist and a state legislator. So the fellow from Kaiser, his first key point was the current market for drugs in the United States is broken. It's time for a new drug pricing model that rewards needed biomedical innovation at prices patients can afford. My question to you will all of your years of experience in the Medicaid program, why isn't this group that you're participating in taking the lead to address a new system which would benefit all of us?

Jane Beyer: So part of it is... let's see... I would say that the Arnold Foundation's strategy overall is to have just have that discussion because they're a foundation that came out of its private sector folks and their fundamental argument is I'm used to being a business, I'm used to working in a market. There is no functional market when it comes to prescription drugs. And so that portfolio of projects that they funded I think are all designed to be able to build the case for the kind of discussion that we need to have. The Center was funded to basically work on that on kind of a micro level. It's to say where can we find state partners who, as Yohan said, given the system that we have until things change, can push the edge of the envelope to at least make some progress on that issue. And using the classic example of states as laboratories to advance policy improvement. So I think it's on both levels. It's the broader Arnold Foundation level and then it's the piece of the project that the Center is working on.

Ray Hanley: One more question back here.

Jim Rickards: I appreciate participating in the SMART-D program so far with you. Have you seen in your research any interesting or promising legislative concepts in any of the states that you have been working with that are developing that maybe aren't passed yet? I think when I talk about the pharmacy cost issue people right away say, "Oh, it's too big, pharmacy is too powerful. It's going to take a legislative fix."

Have you seen any glimpses of what a legislative fix or solution might look like?

Jane Beyer:

So I think when people talk about legislative fixes there's the distinction between federal and state. What we've seen... I mean it's interesting. When we think about state legislation often the state legislation that's been enacted more often than not is doing things like pulling drug classes out of consideration for preferred drug lists. So it's more contrary to what we're trying to do. I would say that where you've got legislators who are very, very interested in sort of like broader health system reform to the extent that an initiative like this can be fit into that initiative it makes it easier both, I think, to try to have those discussions with state legislatures and it also makes it easier, I think, to have discussions with CMS when states are going to be doing state plan amendments, potentially, or waiver amendment... or seeking waivers or like Oregon has an 1115 waiver. So if Oregon chose to do this amending the 1115 waiver to basically say prescription drugs are one piece of the way that we need to get better value out of our healthcare system. That's how I would... to me that's the most palatable way to approach a discussion that's a legislative discussion on that. I don't know how the other legislators in the room feel about that.

Man:

Yeah, I mean if you look at 2015 there were what, something like 3,000 or 2,000 house bills passed at the state level around drug pricing. And how many of those went through? I think maybe Vermont. So maybe look to Vermont to see, you know, what they're doing and what they're... a lot of these things... the scope of this project is to understand the legal constraints now and how to not necessarily circumvent them, but how to work with them. Of course we would love to propose ideas of yeah, I passed this law, I passed that law, but it's not so cut and dry. Right? We can come up with a million different ideas, but it doesn't necessarily mean it's going to get passed and it's going to actually end up with anything. So, you know, we try and manage... it's a small win. So we start somewhere. We start with a template. You get an alternative pay [inaudible]. You try to implement it. You see what the challenges are with it. You see what the potential benefits are. And then you go from there. It's a

very, very crazy time and in terms of what we see from other states, yes, we have seen states who are actually making movement and doing these things. We're not going to call them out today. But it might be something to look at in the future. And who knows if this is something that's going to work in the long term, but you have to try something. You're not going to get anything done by doing nothing. So it's like... this is all about just trying something new and trying to manage those specialty drugs costs.

Ray Hanley: That would be a great way to end this talk because we have to move on. We are trying some new things. I want to get a round of applause for Jane.

[applause]

Ray Hanley: I know for one that Jane is open to more input. So, please, if you didn't have your questions answered or additional questions, come up, leave them on your table. So our next speaker today is Scott Ramsey who will be talking about the high cost of cancer treatments and Scott... Scott is a general internist and a health economist. He wears two hats. He's a full member of the Cancer Prevention Program, the Public Health Sciences Division at Fred Hutch and he directs the Fred Hutch Institute for Cancer Outcomes Research, which is a multidisciplinary team developed to clinical and economic evaluations of new and existing cancer prevention screening and treatment technologies. In addition, Dr. Ramsey is a Professor at the School of Medicine, School of Pharmacy, and Institute for Public Health Genetics at the University of Washington. Trained in both medicine and economics, Dr. Ramsey's research was focused on economic treatments for lung, colorectal and prostate cancer. Please welcome Scott Ramsey.

[applause]

Scott Ramsey: Thanks. Good afternoon everybody. I'm going to be talking a little bit about some research that we've been doing in collaboration with Regence and Premera with their data looking at the cost of cancer care in Washington State. I'm going to do a few things, I'm going to

talk about the cost of drugs, but I think it's important to talk about that in terms of the overall cost of cancer care. I'm also going to talk a lot about the variability in the spend across this state for cancer. And then finally I'm going to talk a little bit about the out-of-pocket burden as we've estimated it for patients. As was mentioned I direct the Hutchinson Institute for Cancer Outcomes Research. We're actually devoted to try to improve quality and reduce costs for cancer in Washington State. We have a network that includes most of the major oncology providers, a large group of patient advocates, and researchers, and the payer community. We're all about transparency and working to try to find shared solutions. In terms of transparency I'm just going to show you my financial relationships, too. I think that's important.

It's important to understand the spend for oncology drugs in terms of what's going to happen in the future. It's bad now. It's going to get much, much worse and that's largely because the number of cancer patients in the U.S. and in the state is going to rise substantially. Current projections are it's going to increase by 75% by 2030. That's due to population growth and the aging population. The good news is that we are more successful in treating cancer, but the challenge is that that means people will have cancer as a chronic condition and their life-time costs will be higher. So really this, coupled with what we're seeing in terms of the drug spend trend and actually other treatments in cancer is just not going to be sustainable. I mean we could spend our entire health budget on cancer and there wouldn't be anything left for any other disease.

This is a... I heard Peter Bach's name. This is Peter Bach's now pretty famous graph showing the increase in drug approval prices over the last several years. It is an exponential curve and the average cost of a new oncology product is somewhere between \$10 and \$15,000 per month.

I pulled this directly out of a CMS website that I would encourage people to go look at. It's the Medicare drug spending dashboard. So this is the total Medicare spend for cancer and not cancer. So this is \$3 billion versus \$13 billion. I know you've had some discussions



about Sovaldi. So let me just throw in if we exclude Sovaldi the number of billions fall off of that spend. But look at the spend per user for cancer versus non-cancer. So this is someone on the Medicare program. If you exclude Sovaldi it's \$80,000 versus \$2,700 and if you look at the patient... the beneficiary's out-of-pocket exposure it's \$7,200 versus \$344. This is annual spend. So there is just a huge discrepancy between the cost of treating cancer and the cost of treating other illnesses at least as measured by the Medicare program. So we're, you know, we're going to talk a lot about cost here. But I want to emphasize what others have said that, you know, we're trying to provide information to the oncology community and actually a wider community on costs and cost components for cancer so we can support better decision-making, but we are involved in promoting value. So cost is only one part of that discussion. We have to talk about what you get for what you spend. That said I'm going to focus on what we spend today, mostly.

So a little bit about the database that I'm going to show you the results from. So what we did is we combined health care claims from Premera and Regence over these dates. So these are total claims for all members. We linked that with our state [inaudible] cancer registry over the same time period and we found 88,000 patients who were linked and then among that we have 35,000 patients who were enrolled at the time of diagnosis. So these numbers here are what our data are drawn from. It's the commercial plans. We're working closely with Dan Lessler to bring the state PEBB and the Medicaid data into this and we've already purchased Medicare and we're going to be putting that in. So hopefully at the end of the year we're going to have 70 to 80% of all members in our database with cancer.

I'm going to talk about cancer cost by phase of care. And we kind of break phases down in our research world into four different components—the diagnosis, which is 30 days prior when patients are being evaluated and the cancer is diagnosed. The initial treatment phase, which is essentially the first year that patients are being treated. We don't count the continuing care phase. That's for people who have gone through treatment and are in a phase of remission and are being monitored and the other thing I'm going to show you

some data is costs of care at the end-of-life, the last 90 days prior to death. Again, for the cancer patients.

What we did to measure costs is we looked at all insurance claims paid. We have all claims by both of the providers, which includes inpatient, outpatient, everything, the drug spend. So what I'm going to show you is not the bills, but actually what the payers paid to the provider groups. We also adjusted all of this to constant dollars just to make it easier to track.

The patients that you're going to see in this analysis are adults who have had one of the cancers listed here. Just to keep things simple we focused on people who... that cancer was their first and only cancer. Some people get multiple cancers. That makes it complicated to attribute costs. So it's your first and only. And then they... we wanted to keep things simple so these folks had to be in the same insurance provider over the period that we were observing them. So they were not skipping back and forth between providers.

So this is a breakdown focusing on those cancers. The cost of cancer by phase. This is the average cost. So you can see the dollar trend here. These are the five cancers of interest. Notice that the diagnosis costs are a relatively minor component. This first year treatment component is the most significant component. Notice for leukemia and lymphoma it is substantially higher than for these other solid tumors. But also important to note that the spend at the end-of-life is not at all trivial. It is very, very substantial in that 90-day period prior to death.

So let me drill down a little bit more focusing only on this first year following diagnosis when patients are in their initial treatment. So we're going to look at all types of treatment—surgery, chemotherapy, radiation therapy, although I'm going to drill deeper into chemotherapy since this is a drug cost program. But again I want to give you a sense in terms of context of where chemotherapy costs fall in the bigger picture.

These are the treatment components. This is how we break things down. We have information from the cancer registry that allows very specific categorization of patients by their stage at diagnosis and their clinical characteristics. But when it comes down to treatment we rely on CPT and ICD codes to break things up into the different components. So you can see how we define surgery, chemotherapy, radiation therapy, and anything that didn't fall into these buckets we lumped into other. And that could include things like diabetes or if you broke your hip or if you heart attack or you had hypertension. That's in the other category, but things that were specifically linked to payment codes for these oncology services we've broken out and we'll show you separately.

So here's the breakdown in terms... in that one-year treatment period in terms of the spend for the five cancers that we've been looking at. Notice, as you would expect, as you go from the very early stage, the in situ and local to the more advanced stages across all of these cancers the spend goes up. Now leukemia and lymphoma are slightly different animals. So there's acute and a chronic type of leukemia and there's Hodgkins and non-Hodgkins. And obviously acute leukemia is often a medical emergency and it's an extraordinarily expensive condition as you can see here. But going back to the solid tumors notice that as you move out of local stage the chemotherapy, which is the dark blue here quickly becomes the dominant spend component for these individuals with cancer. And, you know, in breast and colorectal we are seeing through screening a shift to higher proportions of patients in the early stages. Lung, unfortunately, is mostly a later stage disease. But it's important to note that even in colorectal more than... well, about 40% of patients are being diagnosed at regional and distant disease still. And those are very, very expensive conditions to treat.

Now I'm only focusing here on the chemotherapy portion of the... what I just showed you. So again this is a high level and so we have different components of pharmacy spend, supportive care, infusion services—those are what's paid to the offices for infusing the in-office chemotherapy, the actual drug costs themselves, and other things that would happen during that visit that are related to the

chemotherapy. So what you can see is supportive care is about 10 to 20% of the spend. So those are drugs like anti-nausea drugs, [inaudible] stimulating factors to increase white blood cell counts. Infusion services are relatively minor. The big spend, though are the chemotherapy drugs. And you can see that the costs of these, you know, services; for example, for distant stage colon cancer well over \$100,000 about \$125,000 for that first one-year period of treatment. Many of these patients, particularly the breast and the colorectal patients who have distant disease or regional disease will have chemotherapy well into second and third years. So this is really just a little window of the total spend.

Now this was put together a little hastily. We were trying to come up with a picture to show you the spend trend on chemotherapy between the beginning and end periods of our database. And what we decided to do is just show you the most expensive drugs, at least in terms of the cost per patient between 2007 and 2014. I think there's some echoes of what we've heard here. So one is trastuzumab. Notice that the cost for the same drug, same patients, the cost has gone up substantially. So these are inflation-adjusted. Still much higher. Rituximab has fallen a little bit, but notice that the cost per patient has gone up, again, a branded product. Oxaliplatin went off patent and so it fell substantially both in terms of cost and in terms of its ranking. This is Avastin, which is also a very expensive drug. It's actually had added indications since 2007 and the cost of that drug has gone up. So it has moved up into second place. Pertuzumab is a newer drug, but you can see that for drugs that are on both sides, the costs of those drugs is going up. The manufacturers are increasing those costs and correspondingly the costs that Premera and Regence pay for those drugs is going up substantially.

Now I mentioned this issue of variability in costs and we did this by linking these data with the oncology clinics in Western Washington and what we're going to show you is data on the largest oncology providers in our state. To be in our database they had to have at least 30 patients with that cancer type in the database. And what I want to show you... what you're going to see is a picture of tremendous

variation in cost that's actually hard to explain based on what we know in terms of the stage and what's recommended for treatment.

So up here is case mix. Down here is the cost. This is focusing on the treatment phase that first year. This is breast cancer. I'm going to show you the other two solid tumor cancers in a moment. So what this is is the spread in terms of case mix by clinic. So the dark blue is in situ. The next one is local stage. So a lot of patients, as I said, being diagnosed at local stage. Regional and distance. And as you move to the left the case mix is more severe. In other words these clinics are treating more severe patients than these clinics. That said there isn't a huge difference with the exception of in situ, which grows as you move along, but there is a massive difference in per-patient cost between the most and the least expensive clinics and what you'll see is really dominating the difference. Again, going back to that dark blue line showing chemotherapy that is what drives the difference in the regional variation in clinics. We have done some analysis where we have adjusted for case mix and tried to compare for clinics who were approximately equal. So for example these clinics over here on the left have pretty... approximately equal case mix, but you notice the difference between them. I mean there's a very large and substantial difference. A lot of it being accounted for by the chemotherapy spend. What we think is going on there is selection of products and intensity of use of those products over time. We're in the process of analyzing that. So these are the top clinics in terms of patient volume and spend and you can see the variation there.

This is colorectal cancer. Again, going from the clinics that see the most severe patients here to the least severe mix of patients. There's a little less variation in case mix here. But there is a lot of variation in cost of treatment by clinic. Again, you can see treatment volume... I'm sorry, chemotherapy spend is driving it.

Lung cancer the same story. In fact, there is even less variation in case mix here, but there's a two-fold difference in spend across these clinics.

The last thing I'm going to talk... well, second to last thing I'm going to talk about is end-of-life care. This one we don't have to adjust for case mix. This is everyone with those solid tumors that has died. Just a note, there's a lot of care that oncologists view as suboptimal. Chemotherapy more than 25% are getting chemotherapy in the last day of life. Expensive imaging, a lot of people spending their last 30 days of life in the hospital, more than 50% and a number in the emergency room. This is the spend, again, going by clinic from the most to the least expensive clinics for the last 90 days of life. So the outcome is all the same here, but the spend is very different and you can see there is a huge difference in the use of chemotherapy, radiation and to some degree surgery. I honestly can't explain why there is such a big difference between these clinics because it is solid tumors and the outcome, as I said, is the same.

The last thing, a little bit about estimated out-of-pocket costs. I do a lot of research in what's called financial toxicity of cancer. It's a new type of toxicity in addition to nausea and vomiting you now go bankrupt, unfortunately. And we've looked at this and I can point you to literature on that. So what we did to estimate out-of-pocket spend is we looked at what was paid, charged by the provider, what was paid by the insurer, what was allowed to be paid, and that was actually paid, and the difference is the estimated out-of-pocket. So this is for the treatment phase only, as I said, that first year of therapy. These are the estimated out-of-pocket costs and these are commercially insured, well insured patients by phase. And you can see for breast cancer it ranges between around \$3,000 and about \$7,000, actually not a lot of variation across the solids. The scary one to me is leukemia. Estimated out-of-pocket costs of nearly \$17,000. That's just for the first year. Keep in mind that the average... 60% of Americans have less than \$1,000 in their savings account. So these are devastating costs in a well-insured population.

Limitations – there's a lot of limitations to our claims analysis. All we have is what was paid for by insurance. That's not the full financial burden to patients. We're focusing on utilization. We don't have clinical information here about outcomes. We have that in another presentation. And it is just the two blues plans in our state.

In conclusion, at least bringing you back to the topic of this conference, you know, the chemotherapy spend is what's driving this and it's very high in all phases except the earliest phases of cancer. There's a lot of variability across clinics that I cannot explain based on what I know are guidelines for treatment. So we need to look into that and that's one area where I think we can reduce spend for our cancer patients. The other place where there is huge variation is end-of-life. We know chemotherapy the end-of-life does not lengthen life. It does not generally improve quality of life. So that's an area we need to work on with our oncology community and patients. And the last point is that this is a very, very expensive disease to patients. The financial burden on them is substantial. We're seeing a lot of... since I've got into this I've heard from a lot of patients about the tremendous burden that this cancer diagnosis brings on them even when they have good insurance. Thank you.

[applause]

Ray Hanley: Let's just start right back there.

Neil: I'm with MODA. I appreciate your presentation. On your horizontal access you had clinics. Are you going to differentiate hospital outpatient-based clinics and the standalone because their billing is very different and usually on the hospital outpatient the infusions are a lot more.

Scott Ramsey: That question came... we actually... this is very, very fresh data. We just presented this last week to the clinics and we showed the clinics where they were on these bars. And that was one of the first questions that came up. And it's a little tricky identifying hospital-based from claims, as you probably know from pure ambulatory. We're working on that with the clinics right now. I can tell you the obviously thing, of course, is the difference is substantial, but we don't have an exact number yet.

Gary Franklin: On the selection of drugs extreme variation issue obviously one thing I would want to look at is dollars for docs and whether there is a financial conflict of interest. You must have started to look at that.

Scott Ramsey: I'm not sure how you mean conflict. Most oncologists actually half of their revenue is from the drugs they prescribe.

Gary Franklin: What I'm talking about is the money that they may be getting from the drug companies for honoraria and other things that you would find on websites like dollarsfordocs, some of which are in the hundreds of thousands of dollars. So that might have something to do with the selection of the drugs.

Scott Ramsey: That's an interesting point. We haven't looked at that. In theory you can go to the Sunshine Act website and look up how these doctors are, you know, what kind of money they are getting from pharma for consulting and ad boards and such. I know in my own personal case I've looked at that and it's wrong. I mean they list... I listed what I consult on and they have companies that I haven't consulted for on there. So I don't quite yet know where to get that. I'm not sure that's... well, it may be influencing them at the point of prescribing. I think the big thing is that they get... the reimbursement spread is pretty huge for some of these branded drugs and I'm more worried about that driving the use here.

Woman: Just a quick question, Scott. Does the... our table was questioning on the out-of-pocket cost if the out-of-pocket max figured in to the out-of-pocket cost that you noted. Specifically, like leukemia for \$17,000.

Scott Ramsey: Again, this was the difference between paid and allowed. So if the max kicked in that would truncate it. We've shown this data with the patients and they all say it's low. I don't, you know, there's limitations with that out-of-pocket and I understand exactly what you're saying. Most commercial plans have a max out-of-pocket spend. But that's how we calculated it.

Missy Dolan: Does the... does immunotherapy play into the chemotherapy here?



Scott Ramsey: There's not enough immunotherapy to make a real dent in this yet. That said, the cost of immunotherapies are going to... they are going to be substantially higher than what we see here. It's going to be another big hit for budgets... health budgets. I hope they work.

Woman: One of the things we hear about sometimes is... one of the challenges is around getting the right diagnosis the first time. Can you speak to that? In your experience is that a big problem? Cost driver and clinical efficacy wise?

Scott Ramsey: So by getting the right diagnosis do you mean getting the correct cancer diagnosis?

Woman: [inaudible]

Scott Ramsey: Um... the... the short answer is I don't know what we have from Cedar(?) is the pathological confirmed type of cancer and the stage from the charts. That's how Cedar gets it. The path to get there can be highly variable and we don't look at that. We do look at that diagnosis phase as the 30 days prior to the date that the registry says they were diagnosed and we see that amount of spend there. It does vary a lot from patient to patient, but it's a relatively small component and we don't know how much... at least I haven't looked at how much misdiagnosis is going on before the final pathology confirmed diagnosis.

Liz Bentley: I'm with Kaiser Permanente. My question was just around the variability and oncology treatment in using that to provide feedback. One challenge I can see with that is that oncology treatments change so frequently and its now something like, you know, guidelines for treating blood pressure where it's stable for a number of years. So do you have any suggestions or ideas on how to address that?

Scott Ramsey: Well, yeah, although I would argue a bit that it is not changing that fast. There are new treatments that have come online. Those are primarily the original FDA occasions... indications are usually for people with distance stage disease. For people with in situ, local and even regional stage disease things don't change that much. That said,

if you look at the guidelines for oncology you could drive a truck through them in terms of how variable, you know, the amount of different regimens that are allowed and the cost of those regimens varies dramatically. We published a paper where we looked at gastric cancer. The cheapest regimen for gastric cancer was \$800. The most expensive regimen was \$57,000. The difference in survival between those regimens was one month. So there's a lot of room for narrowing things down, you know, we talk about building within class and focusing on value. That can absolutely be done in my opinion in oncology and we really need to get there. We're all about transparency. I'd love to have you help me weigh in... our goal ultimately is to make this information available, you know, even to the public, but certainly to payers, patients, and practitioners. When we get the state data and Medicare I think we'll have a pretty comprehensive picture of cancer. But that kind of stuff needs to be highlighted so that we can get that variability down and then actually let patients know. Most patients have no idea that there is that much variation in the costs.

Ray Hanley:

Do we have another question right over here?

Man:

My question is just around some of the new [inaudible] that's been happening like the oncology care model from CMS and things like that. Do you guys have any plans in integrating that and understanding, you know, at least in terms of some of the analyses and some of the data that you collected through those things and the payment models and...

Scott Ramsey:

Yeah, the oncology care model is an experimental model of alternative payment model for oncology care and I don't actually know how many clinics in Washington are participating. I think it's a couple. So we won't have much data on our state and we really are focused on this state. The other one, the big one, I don't know... are you talking about Macra at this... that's the big change in Medicare payment. And that one we are going to track and actually there's a lot of outcomes measures as part of Macra that we're actually going to build into this so hopefully the oncology practices we can help them track those outcomes as well.

Ray Hanley: We have one more.

Man: Thanks for your presentation. I know we focused on today mainly the price per unit of the drugs, but your presentation is highlighting. It's not just the unit price, it's actually how you prescribe and utilize the drug. Now as my hair has gotten grayer and thinner I've heard repeatedly about, particularly with oncology, about the sometimes fruitless interventions that are done at the end-of-life. So this is not new news, you're just demonstrating it perhaps in a little bit of a different way. So what new interventions do you... have you thought about that we can employ to mitigate this?

Scott Ramsey: Are you talking about the end-of-life?

Man: The end-of-life, yeah.

Scott Ramsey: This actually is one of those... it's not good news, but it's hopeful news that there seems to be a coalescence of opinions that we are not serving patients well at the end of life in oncology. We're treating them too aggressively. And the patients agree on this. The health plans do and the oncology clinics. The question is how do you attack that problem? That variation I showed, I mean that was shocking to me. I mean there just shouldn't be that kind of variation. But there actually are a number of initiatives. Premera is involved. Regence and Premera actually are among the leaders in trying to develop approaches to get oncologists to have end-of-life discussions with their patients so they are actually paying to have that done, which hadn't been done before. There are some commercial vendors that can come in and do goals of care discussion that hopefully will be transmitted. Our institute actually has a whole group of volunteers focused on identifying ways to talk to patients. I can tell you one thing that is a big part of the problem here, is the patient's perception of what they are going to get from chemotherapy when they are diagnosed as advanced disease. There is a famous paper published a couple of years ago that showed among patients who have advanced colon and lung cancer, people with those diseases at that stage are going to die of that disease. 80% of them thought the chemotherapy

they were getting was going to cure them and that's just... I mean whether the doctor's not saying it or the patient's not hearing it, I don't know, but we've got to communicate better with patients about their goals. There also was a famous study that was published in the New England Journal about three years ago that showed that patients who were referred to palliative medicine specialists at the start of their treatment versus those who had usual care actually lived longer in the palliative care. They got less chemo, less radiation, they lived longer, and their costs were lower. That experiment was replicated in other cancers. We need more palliative medicine, I think, in my opinion consults for patients with advanced cancer. So those are a few things I think we can do to get that trend and that variability down.

Ray Hanley:

I'm going to exercise my moderator skills and ask you one more question. There's been a lot of discussion over the years about spending at end-of-life. And as a data analyst and non-clinician I tend to see the end-of-life as really... it's pretty easy to find in the data. My question to you is, how much of this discussion about savings at end-of-life... I will hark back to one other thing. There was a Milbank article where they tried to look prospectively at people going into hospitals and whether or not they thought they would live. I'm curious about, with cancer in particular, how well do they know that this person is... they will die of cancer, but when?

Scott Ramsey:

That's an excellent question. I mean, you know, we can all be... it's easy to be Monday morning quarterback for something like this. But, you know, the short answer is we don't know precisely but as the time grows nearer multiple oncologists have told me, you know, I can tell you when a patient is within a month of dying. I get a pretty good idea of when they're two months of dying and then 90 days is a little harder. That said, I mean let me just show one slide here. So... oh, I don't have the hospice. So, I'm sorry I didn't show that. But, you know, hospice benefits are usually for the last six months of life and we found that, you know, less than 30% of patients are in hospice even at 30 days. So, you know, that doesn't mean you end care. You can get people into comfort situations in hospice even when you're treating. But, you know, oncologists, the reason the six-month period

was chosen is because it is pretty easy to know within six months. Getting more precise than that is much harder. I challenge anyone though for patients within... who have an advanced cancer diagnosis who have failed their initial therapy for the solid tumors... that second, third, fourth line is not adding much. And I don't know that that conversation is being had in a way that patients understand that at most they might be getting two or three months and those are toxic treatments that are also financially toxic. Those are the discussions that we're trying to promote so those patients have the information. If you want to get hardcore therapy right up to the end I think that should be your right, but you need to know what you're getting into.

Ray Hanley: Thank you. Let's have a...

[applause]

Ray Hanley: Thank you. Our next speaker is Kai Yeung who is going to be talking about long-term outcomes on value-based pharmacy. Kai earned his PhD from the Pharmaceutical Outcomes Research and Policy Program at the University of Washington in December 2016. How'd he do that? His dissertation was entitled, Does Cost-Effectiveness Analysis Have a Role in the U.S. Managed Care Drug Formularies? An Empirical Study of Utilization Costs, Outcomes and Elasticity in Value-Based Formulary. Related to his work Kai has co-authored a paper published in the Journal for Managed Care and Specialty Pharmacy presented at a student podium presentation. He was awarded dissertation funding from NIH, National Center for Advanced Translational Sciences and the Agency for HRQ. Prior to the University of Washington Kai was at the university at USC where he completed a PharmD. At USC Kai has cultivated a keen interest in expanded use of evidence and analytics and decision-making. He's worked for Kaiser's Drug Information Services, HRQ, Tufts University, the CEA Registry and NICE in the UK. Thank you.

[applause]

Kai Yeung:

Thanks, Ray. My talk today is on the application of cost effectiveness logic to U.S. managed care drug formularies, long-term outcomes of a value-based formulary.

So in the past decade and a half there has been tremendous growth in the use of prescription drug copays as a method of cost sharing in employer-sponsored plans. In the graph on the left you see that the percent of workers that are covered by plans with high copayment tiers, which are tier 3 or tier 4 or greater copayment tiers has increased dramatically. Not only so the graph on the right you see that the average copays within those copayment tiers has also largely outpaced the growth of inflation. The problem with this is that these copay increases are based on the cost of these drugs rather than the clinical and economic value provided by these drugs. And so the question is, is there a way that we can cost share more intelligently? One approach to this is a value-based formulary designed by Premera Blue Cross back in 2010 which explicitly uses a cost-effectiveness analysis to determine copayment tiers. How this works is essentially cost-effectiveness analysis, if you're not familiar, in very broad strokes is a way... an economic method to estimate the value of interventions, in this case drugs, by looking at a ratio of both the incremental cost relative to the incremental health benefit. And so this plan from Premera Blue Cross utilized cost effectiveness analysis to just estimate the value of each individual drugs. Drugs that had higher values, which are drugs with lower incremental cost effectiveness ratios are placed in lower copayment tiers to incentivize their use. And drugs with higher incremental cost effectiveness ratios, which are lower value drugs are placed in higher copayment tiers to disincentive their use. Concurrently the number of copayment tiers were increased from 3 in the pre value-based formulary setting to 5 tiers in the post setting to increase the range of tiers available.

Further details regarding the design of this value-based formulary was published in the April issue of the Journal for Managed Care and Specialty Pharmacy. But I would just present to you just one slide on... in terms of implementation.

So basically the implementation of this value-based formulary occurs via two decisions. The first one is the [inaudible] one I think that many of you in audience are probably familiar with. So the first process is a formulary pharmacist will gather information regarding a drugs' safety and effectiveness via all the published sources and then communicate that via a formulary monograph to a P&T committee, which then evaluates that drug based on safety and effectiveness and makes a determination of coverage. But then in addition with the value-based formulary, an additional step is taken. Once that drug is determined to be covered that formulary pharmacist, which is trained in economic evaluation will actually gather evidence with regard to the economic value of that drug. Right? It can come from published sources. It could come from other health technology and assessment organizations. In cases where this evidence is insufficiently clear applicable to the Premera population, Premera will actually conduct their own economic analyses. That information is then synthesized via a value monograph and communicated to a value assessment community similar to a P&T committee, but this time composed of clinicians, economists, [inaudible] and members of [inaudible] public. Then that committee then using that evidence makes a determination of the value of that drug and then determines which copayment tier that drug belongs in.

So given that this value-based formulary is a novel approach to using cost-effectiveness analysis to determine copayment tiers, it merits evaluation. However, we don't know what the impact of this is without evaluation for a number of reasons, one of which is that even though cost-effectiveness analysis is one of the most commonly used approaches to evaluating the value of pharmaceuticals, in many cases there is still limited evidence.

In terms of study design we used a retrospective cohort study with interrupted time series analysis, which is called the strongest quasi-experimental research design. The reason why is that it provides for strong control for confounding and that's combined with a two-part generalized estimating equation model. I'm happy to talk more about it, but I'm sure you'd like to focus on other things for this presentation.

So here's some... just some illustrations of how this approach works. Right? Some graphical illustrations instead of Greek letters. Right? So here is the hypothetical member out-of-pocket medication expenditure. This is... so the red dots are for the VBF group, the value-based formulary group. The blue x's are the control group. The X axis represents time. This line here represents the policy implementation date and the dots, again, are the average per member, per month expenditure in the two groups. So you see here qualitatively that after the policy [inaudible] you have a decrease in the intervention group in terms of expenditures. To that you fit your regression based models and then using your regression model you then also create this orange line or yellow here which represents what would be the spending in the VBF group had they not implemented the policy. And so this difference here represents the policy effect. Here in this case it's a savings. Right? So this is the hypothetical example.

Let me show you the results now. This is a typical, you know, in a research study it's a typical sort of demographics table of representing the two different groups. We have about 5,000 members in the intervention group, about 11,000 members in the control group. And what you see is that, you know, you will notice that some of these differences, or a number of them are statistically significantly different. But it's largely I would say driven more by sample size than anything else. For example, let's see here, percent of African Americans in these populations, you know, it's like 1% difference. Right? But regardless, you know, some of the differences that may be important that are different are, for example, income or perhaps age. And we control for these and other demographic factors in our models.

Here's the first slide on the results. The first thing that we looked at is, well, what is the impact given that you've changed these copays for these medications? What is the impact of those value-based formulary on people's medication utilization? Right? And so here we broke it down by where the drugs ended up in the value-based formulary from the lowest year, the preventive tier up top, to the



highest tier on the bottom. And here are the observed utilization in terms of days apply per member, per month in the whole population and here is the expected numbers. And here is the difference between the two. So for here what we see is that there's about an 18% actual increase in day's supply of medication for those drugs that were placed in the lowest copayment tier. So individuals for incentivized increased utilization of those medication. There's also a trend of decreasing utilization across as you go higher and higher in the copayment tiers, but those aren't, unfortunately, those are not statistically significant, but this difference actually represents about a 30% decrease in utilization in the highest copayment tier.

Our primary outcome though was to look at what is the impact of shifting to a value-based formulary on people's medication expenditures. Here what I'm showing is expenditures for both the member plus the health plan. Right? So the net of the two. So here is our observe expenditures. To that we fit our reduction trends and then using the regression model we then predict what is the expenditure had there not been an implementation of the value-based formulary. So again the difference between these two represents the policy and effect and here it's a savings. Right? Like here if you hadn't implemented the value-based formulary the expending would be higher than had you implemented the formulary. And this difference actually represents an \$8.00 member per month decrease in expenditures or a 9% decrease in total medication expenditures, which for this patient population of about \$5,000 over a three-year time period actually represents a \$1.1 million decrease in expenditures. Okay?

So here is the effect for total non-medication expenditures. So this is for the medical claim side for member plus health plan. And there was no statistically significant impact in expenditures on this side. But if anything there was perhaps a slight savings, but again not statistically significant. Okay?

So if you combine the two medical plus... sorry, medication plus non-medication that becomes a \$9.00 decrease per member per month or

2% decrease in expenditures, which is not statistically significant. Okay?

So this table then breaks down all of those expenditures that I showed you from... into the member out-of-pocket expenditures and the health plan expenditures and then total expenditures for both the medical and the non-med... sorry, the medication and non-medication expenditures. What you see here is that the member expenditure goes up by \$2.00 per member per month and the health plan goes down by \$10.00. So the net of the two is actually the \$8.00 decrease that I showed you before. On the non-medication side you see essentially these numbers are much smaller in magnitude than on the medication side and those, again, are not statistically significant. And then if you look at the grand total it's what I showed you earlier. That's a \$9.00 decrease in expenditures.

The other thing we wanted to know is given that, you know, you've... what I've showed you so far is that this value-based formulary does indeed shift patients towards, you know, "higher value" drugs, and it also decreases medication expenditures without [inaudible] impacts on the non-medication side. What's the impact on essentially health outcomes? Right? And so we tried to look at that using this... the available claims data by looking at proxies for health outcomes in terms of ER visits or emergency department visits, hospitals, as well as office visits and we looked at both the probability that a member would be... would visit the ED and the number of ED visits and then the probability of being hospitalized... the number... the days within the hospital, the probability of an office visit, and the number of office visits is on a per member, per month basis. Essentially the finding here is that we have... there was no deleterious impact on any of these outcomes that we could find.

What we found with this study is that the value-based formulary was associated with a shift in utilization towards our medications with lower copayment tiers. There was decreased total medication costs with savings primarily accrued through the health plan, and there was no significant reduction in overall medication utilization. That's a slide I didn't show you, but in bulk there was no impact there. If

anything, member medication utilization increased slightly. And there was no significant impact in terms of deleterious impacts on non-medication costs, office visits, ED visits, or hospitalizations. So future work in this area would like to explore, you know, the true impact of this value-based formulary on actual outcomes on different populations. This formulary was implemented within the Premera employee's independence. So working age on commercially-insured population, which... and you might find different outcomes if you were to look at the poor or the elderly.

Also of note the Center for Medicare and Medicaid Innovation is attempting pilot programs to test something very much similar to the value-based formulary called the value-based insurance design in the Medicare advantage plans, I believe in Oregon is one of the near states. And so the results from this value-based formulary can potentially inform that work. Okay?

Just like to acknowledge my contributors in terms of number of researchers at the University of Washington, as well as collaborators at Premera Blue Cross and the value assessment committee and also funding from the NIH, as well as the Agency for Healthcare Research and Quality. I'll take questions.

[applause]

Dan Lessler: Great piece of work, Kai.

Kai Yeung: Thanks.

Dan Lessler: I actually have two questions. The second might be a bit more of a comment. I was wondering, did you do anything to evaluate patient experience? I mean how did patients, you know, what do they think of this?

Kai Yeung: So that's question number 1? Yeah. Okay. So there were some qualitative focus groups that were done by Premera internally, not by myself, to evaluate their member experiences and I think for those who are sort of working with, you know, health plans and claims and

so on it's not surprising to us that the vast majority of their members did not realize that if they had, you know, taken part in this value-based formulary and the shift in benefits, right? So that's not surprising. For those who did and once they were educated in the focus group with regards to what the value-based formulary was, I think they were generally for it. Right? Because the concept is to maximize health benefit with regards to expenditures.

Dan Lessler:

So my second question... first a comment with Oregon friends here. This strikes me almost, you know, Oregon did this years ago, but at a population level where they had a line and if you were below the line then it wasn't covered. It was done based on cost-effectiveness analysis. This sort of is each individual drawing their own line because they decide whether or not they want to pay the extra for the tier 4, you know, the more expensive, less cost-effective drug. With respect to the health outcomes would it be right to hypothesize that... and I know you said you need to evaluate that. But to the extent that you are driving people... more people to use more cost-effectiveness drugs, that that would overall have a positive benefit on population help. I mean is that... would that be a correct assumption?

Kai Yeung:

There's a lot of comments there. I think there's actually at least three things I could comment on there. First is, you know, with regards to the use of an explicit threshold. Right? One of the nice things about this implementation, as I mentioned earlier, is that there is... let's see if I can show you the slide here. If you go to slide 5. Okay. Well, anyway, so there's the use of the value assessment committee. Right? So on the one hand, you know, we showed you the slide early on on these ICER ranges or incremental cost effectiveness ratio ranges that are associated with the copayments, but what happens is then this information is fed to a value assessment committee where it is composed of clinicians and economists who then evaluate the evidence. So it gives it a little bit more... there's additional information that might not be captured within the ICER that... with regard to uncertainty or with regards to other factors that might play a role in estimating value. So I think that gives it a little bit more of a nuance instead of just having one... perhaps one threshold [inaudible]

and one line. The second thing is... yeah, so the nice thing about having tiers instead of one... perhaps one threshold is that it does give individuals choices, as you mentioned. Right? So if individuals did want to use an “on average” population average lower value drug they still can, they just have to pay a higher copayment. And then the copayment also signals to them that, hey, there might be a lower... sort of higher value alternative. And then in terms of what the impact of this... true impact of this formulary on health outcomes I would actually say that it depends. Right? Like a good researcher, it depends. And the reason why is that value has two components. Right? It’s a ratio of cost and benefit and so if you move a population or individual towards a higher value drug it could mean that you save money. Right? And you have poorer health outcomes. It could mean that you have, as was said earlier I think by yourself actually... it could mean that you have better health outcomes and you spend more money or it could be both. Right? You could have better outcomes and you reduce expenditures, as well. So it could be any of those. So it depends, I think, on the particular implementation.

Ray Hanley:

We have a question in the back there.

Emily [inaudible]:

I was a medical student at Dartmouth where we trained to think critically about the value of prevention, in addition to everything else. So I’m interested in your preventive tier and sort of what you fit within that and if you look at things like cholesterol medications, which are preventive on some level and treatment on some level and have a wide variation in value. Sort of what did you put in that preventative tier and what didn’t you?

Kai Yeung:

Yeah. A number of cholesterol medications and things like that have anti-hypertensives and so on. We’re in the preventive tier. I think Kathy Brown who is sitting next to you at the table she might also be able to comment more specifically about the items that were in there, but it’s things like, you know, a number of the medications that you use to treat chronic conditions were in there.

Emily: I guess I would say you might get more effect from this if you did include some questions around value even within what we consider prevention.

Kai Yeung: All right.

Eileen Cody: So on your control group were they then paying the pre-value based copays?

Kai Yeung: No.

Eileen Cody: Where were they at?

Kai Yeung: Yeah, okay. So they had... this is... so I should mention a little bit more about the methods. These control groups were chosen because they had similar sort of classifications in terms of industrial work classifications. They were like sort of also white collar people. In fact, one of them was in also an actuarial group. So at Premera there are a number of... they are an insurance company so they have actuaries. So we tried to match on that, as well as on demographics and then also we chose them because they had no changes in their pharmacy benefits over the seven-year period of study. And so what matters in this case in terms of the methods is actually... it's not where they start in terms of their expenditures, but it's whether or not there was a change in their benefits. Right? I can go into a lot more in terms of why in terms of methods, but...

Eileen Cody: I'm just trying to figure out what... on the comparison between the value-based formulary versus what the control group was on, if the... I mean depending on what that control was on you might have actually better because... I was just trying to figure out like what tier 4 was because sometimes tier 4 is 50% and hardly anybody can afford that. So whether you have... would get better outcomes or worse outcomes depending on what the control group is paying.

Kai Yeung: Yeah. So you're kind of forcing me to talk about the methods. So...

Eileen Cody: Yeah, I am.

Kai Yeung: Yeah. So even, you know, in essence you could say that it... for the purposes of the evaluation of the intervention group it doesn't matter so much about whether or not the copay... the coinsurance or copayments for specialty drugs were very high for the control group as long as they did not change. Because what we used the control group for is to control for secular changes in copayment. So this is... in introductory times there's an analysis or difference in differences in analysis. We're actually... we're using information from the intervention group in the pre period to control for expenditures in terms of the start. So we're not using the pre policy expenditures in the control group to control for the post policy expenditures in the intervention group. Happy to collaborate more.

Man: Thanks for this. So the intervention began in June of...

Kai Yeung: July of 2010. Yeah.

Man: And you measured out to 2013.

Kai Yeung: Yeah.

Man: We've got another three years of experience now. So my question for our colleagues from Premera, or maybe you know, number one, are they still doing it? Number two, is it still just for their employees? Or have they implemented this for other insured groups as well? And how is it going?

Kai Yeung: So I think what I... what I can say is that it is still going. Right? They continue to do... add, you know, new drugs as they come along to this value-based formulary. In terms of expansion I know there is interest internally, but I don't think... I don't know how that sort of marketing is going on. I think Kathy could probably comment more about that.

Kathy: Yeah, happy to comment a little more. We haven't, you know, Kai was trying to... is publishing... is going to publish this as a paper so we haven't created sales collateral or things like that that publish the PMPM difference, yet. But what I would say is yes we're still doing it

and yes we have more groups that have signed on to the value-based formulary. It's funny because we were really excited to collaborate with the University of Washington with Kai on this research because it's kind of a hard concept to sell from a... to benefits managers and producers and people that... because it's a little bit different than the general health plan formularies. So I would say it's probably not as... it's, you know, Premera employees are on this, for example, we probably have four or five big groups on it. But the big question is, well, you're going to disrupt members. It's not as explainable as the standard three-tier formulary with generic brand and specialty. So what are... is the juice worth the squeeze? And so now I think we're getting more data that shows there's actual value in a value-based formulary. I think it will be easier to sell. Does that make sense?

Man: Great presentation by the way. I'm just wondering... so you expect that there are certain drugs that have maybe move down tiers because they are less value. Do you remember any drugs that might have been typically like a tier 3, tier 4 actually moving up to like a tier 2 because maybe they show a very high clinical benefit even with a high cost or something like that?

Kai Yeung: Yeah, there were definitely drugs that moved down just as there were drugs that moved up. So some of the cases, I believe, are actually some of the biologics where there was evidence of both clinical effect in the inflammatory conditions, as well as value and so even though the traditional way in terms of budget and... or acquisition cost is high and therefore placed in traditional formularies in high coping in tiers in the value-based formularies they were moved down for that reason.

Man: So it's almost like an opportunity to provide access to these very high value, even though they might be expensive, they are still... the access there is still good for these patients because they show a... I guess the other part of this is, you know, at least in the traditional formulary, tier placement is really based off of contracting and rebating and things like [inaudible], non-preferred. So how do you accommodate both things or is it something you can accommodate? Is it one or the other? I guess... did you have to accommodate for that? I mean were



there products that got automatically tier placement because of contracts and rebates and things like that?

Kai Yeung: I believe that all of the products essentially were placed on tiers based on the value system and committees evaluation.

Ray Hanley: We talked about Oregon and the Oregon experiment in 1990 actually found that one of the difficulties with cost benefit is the high cost, high benefit, and low cost, low benefit actually come out with the same ratio. And I'm wondering if those kinds of consideration actually weigh into a value-based formulary?

Kai Yeung: That's a great question. So, yeah, the question was how do you evaluate or compare drugs that are high cost, high benefit relative to drugs that are low cost and low benefit? Right? In the technical sense that they might have similar cost effectiveness or similar incremental cost effectiveness ratios. Right? I think in that case that's why you don't make, you know, in this case you don't just use a decision rule. Right? Like given a certain ICER range you place a drug on a certain tier. But there is a value assessment committee then that actually looks at additional values.

Ray Hanley: And then my follow-up question would be with regard to life years, did you guys have to choose any... I mean when you're doing the cost-effectiveness what did you value your life year at?

Kai Yeung: Right. Okay. So in terms of... how do I answer this? So if you look at the sort of overall literature on what a quality adjusted life year would be, what people are willing to pay for a quality adjusted life year, you find a huge variability. Right? Somewhere between \$50,000 to \$150,000 or something like that. Right? And... so it's actually very hard to pin down like an actual threshold, but in this case, right, you actually don't need to. Right? If you go to slide 3 in essence what you have is four or five different thresholds or ranges. Right? So you don't have to have that debate, which is actually very, very nebulous of what a quality adjusted life year is worth. Right? But you signal to individuals that there are higher value drugs and that there are lower value drugs and these ranges, you know, can be

in a sense somewhat arbitrary as long as there is a gradient. And that's sort of the beauty of this. And so as drugs come along and there are... and they are of higher value, hopefully newer innovations hopefully are higher value then you can displace lower value drugs into higher copayment tiers and over time actually increase the value that is provided by this formulary without actually explicitly setting a threshold as you mentioned.

Ray Hanley: Thank you. Any other questions? Thank you.

[applause]

Ray Hanley: We have come to a break time and so we're going to take a 15-minute break and that will bring us back into the room at five minutes to 3. Thank you. Coffee in the back. Restrooms to your right.

So our last formal presentation today is from Josh Carlson and it's on outcome-based risk-sharing agreements, which is one of the newest things around. Josh Carlson graduated with his PhD from the Institute of Public Health Genetics at the School of Public Health and Community at the University of Washington in 2007. He received his masters of public health in the same department in 2004. Mr. Carlson is an assisted professor at the Pharmaceutical Outcomes Research and Policy Program and a faculty member at the Fred Hutch Cancer Center. Dr. Carlson conducted his post-doc training in Pharmacoeconomics at the UW 2007 to 2009 and his current research interests and work to date are primarily focused on the intersection of three different areas—genomics and emerging technologies in the field of personalized medicine, uncertainty in both our decision-making process as the concept applies to the application of medical technologies in the real world setting, that is outside of clinical trials including comparative effectiveness research and the economic and policy options to address these uncertainties as we seek to improve our health care system and the health of our population. Dr. Carlson?

[applause]

Josh Carlson:

I haven't even started yet. Thank you. So thanks for being here. I have the enviable position of being the last speaker of the day. So there's only one person between you and beginning to head home. But, you know, I think this will hopefully touch on a lot of what we've talked about already today. Certainly with regard to the SMART-D program, some of this stuff was already brought up. So I'm going to talk today about outcomes-based risk-sharing agreements.

First, some acknowledgements. This is based on a long line of research. This actually began during my post-doc time back in 2007 and so we've been actually tracking this since that time. Quick disclosures – so I do some work via healthcare consultancy and some of this original work was sponsored by manufacturers. We have a corporate advisory board and this was something that was mutually of interest to them so they put some money together and that essentially funded some of the work that I did during that post doc period. Subsequent to then we've developed and gone our way in developing this work further.

So just agenda – I'm going to do some background stuff and then we're going to look at a review of some performance-based risk-sharing agreements and then we'll also try and touch on some informative case examples.

These agreements have been referred to in a lot of different ways. So I just a number of the different terms that are used. Some of these are completely interchangeable. Some of them have a little bit of a nuance difference to them, but these are a non-exhaustive list of terms that are typically thrown out when people talk about performance-based risk-sharing agreements. I call them performance-based risk-sharing agreements, some people just throw out different stuff. I'll try and be consistent about how I talk about them.

As I said, this work, our work, began essentially in about 2007 and it first came on our radar with some publications and this one was from the New York Times that basically detailed some of these agreements and this one was covering some stuff out of the UK. So the first

example was one on a drug called Velcade, which was used in multiple myeloma where essentially they followed patients and if they responded after four treatments they could get more and if they didn't respond after four cycles of treatment there was a rebate, they got refunded that amount. And so this detailed that and it kind of caught our attention and began some of the work we've done in the space. And so this is kind of what that example... that Velcade example I just spoke of translated into when it was implemented in the Italian system. So essentially what we have is an initial session... an initial set of cycles... basically an initial set of cycles and then there's an evaluation period and this is a clinical... an evaluation on the clinical outcome. There's non-responders, there's treatment is stopped, and there's a discount that can either be... basically there's a rebate or a full refund and that's a negotiable part. For responders they can continue treatment and that treatment is essentially continued on. And so this is kind of traditional outcomes-based agreement, and they implement this for almost all new cancer drugs and they have developed an entire separate system for doing this in Italy and Italy is one of the most frequent users of these types of agreements.

So we've talked about some of the stuff that relates to the impetus for why these agreements have come about. And I think we've talked a lot today about medical expenditures and the rise in medical expenditures. Something that I think I wanted to underscore is just the amount to which uncertainty plays a role in this type of thing. I list a lot of sources of uncertainty here, but the concept is when new medical products come, you know, for consideration for coverage reimbursement they come with a lot of uncertainty and so that's coupled with the cost pressures, but also, you know, there's a lot of uncertainty when we translate clinical trial evidence to real-world environments and we don't know that and we won't know what the impact is or how this product will perform unless we actually observe those outcomes. And we won't know the realized value unless we actually track and track that... we might know the cost, but we actually... we know even less about how... the realized values in those patients across these populations. So I just want to underscore that uncertainty is a key part of this, as well.

And so we've also talked about a number of mechanisms that payers have implemented classically. This also has... can I skip that? So there's a larger... I think part of this slide got cut off. Oh no, I changed it and then I didn't update my slides. That's what it was. So basically this is something that... a response by the National Association of Medicaid Directors to the hep C case that we all are very familiar with where they just basically called out the fact that this was creating a lot of problems for them. I'm not going to read this whole slide, but they detail a lot of the issues that came up during that timeframe. What they did was they actually put out some suggestions, some policy suggestions that they thought needed to be put on the table for consideration. And so they cover really big ones and I'm sure that this list was really scary for a lot of manufacturers. But I did want to call out the fact that, and we've already touched on a couple of these, this last one here does call out this innovative payment example and outcomes-based agreements, as well as things like monopsony payments and things like that. But as I said probably pretty scary for manufacturers at the time.

This is sort of the current conversation, I think. Hep C has pushed this into a higher level of consideration and we've seen some of the repercussions that have been happening over time.

So now, what are performance-based risk-sharing agreements? So essentially there are five key characteristics. One is that there is a program of data collection and this is basically as part of an agreement between a manufacturer and a payer. The data collection is typically initiated during the time period following regulatory approval, so right when the drug is coming on the market. And the key is that the price reimbursement and/or revenue for the product is linked to an outcome of this program of data collection and it's basically by formula and it might be linked to whether or not a product is covered, it might be linked to price, it might be linked to rebates, but essentially it is linked to some outcome-related coverage or reimbursement. It's typically the data collection is linked to issues around uncertainty as I mentioned. And where it gets the risk-sharing thing is essentially this leads to a different distribution of risk for the

parties involved. That's why they call it risk-sharing. A lot of manufacturers like to call it risk shifting because they don't feel like it ever benefits them. But regardless it's called risk sharing in the classical [inaudible].

That's a little bit of a set up for this. I'm going to move into some work that we've done over the years trying to basically characterize these types of agreements and talk about some of the characteristics and some observations we have. So we started off this work by just basically surveying the landscape. We hit all the normal sources, as well as a number of government sources to try and find as many agreements as we could and then basically work backwards to try and do some categorization around them so we could understand what types were out there. And so in that process we came up with a definition. Here it is – an agreement between a payer and a pharmaceutical, device, or diagnostic manufacturer where the price level or the nature of reimbursement is related to the actual future performance of the product in either the research or the real world environment. And so the key here is that it is the future. It's not based on historical evidence or anything like that. It is based on what we observe to happen after we come to an agreement about what we are going to do. We've created a database that we maintain over time at the University of Washington and I'll show you some results from that database as well.

So here's the taxonomy that we came up with and I'll just sort of orient you a little bit to it and then I'll dive into some of these areas a little deeper. So essentially we initially separated it out into what are called health outcomes-based agreements and non-outcomes-based agreements. So over here these are basically only related to financial or utilization-related measures and over here it has to do with health outcomes, clinical outcomes. On the health outcomes side we have what's called conditional coverage. Those are agreements that are only about whether a product is covered or not. It doesn't have to do with the amount of money that's changing hands. It's just whether it's actually covered or not. Under that we have what's called coverage with evidence development. This is the... in the U.S. CMS has a big thing around coverage with evidence development that

exists external to the U.S. as well and there's two varieties, one is basically only when patients are involved in research and the other is basically when a subset of the patient population is involved in research, but the implications apply to the whole population. So that's a little bit of a nuance, but essentially in the CMS version it's only when patients are actually in a registry or in a trial will they be covered, but it's part of a research aim. It's not about the amount of money that's changing hands.

Conditional treatment continuation is a subset of that where basically you have a short-term measure of effectiveness and it's assessed and only patients who are benefiting from treatment continue to get coverage. If they are not benefiting and demonstrating... they're not demonstrated benefit they don't get additional coverage. It's a [inaudible] to a stopping rule that clinicians may use, but this is at the coverage of reimbursement level.

And then we have... most of what we have been talking about are people are interested in, which is performance-linked reimbursement. That is the outcomes guarantee or the Velcade example that I gave and that's where we link the amount of money that changes hands, and that can thought of a few ways—rebates or discounts ahead of time, etc., to tracking of clinical endpoints. The key there is that it is actual health outcome.

Over on the non outcomes-based side there are some interesting ones—utilization caps. For example, there's a couple where the manufacturer gets covered for, in the UK for example, they will cover 22 infusions of Lucentis and then they won't pay anymore. So they kind of cap that. So there's some unique ones over here, but most of the work that's of interest is over on the outcomes based side.

The main dimensions that are sort of... people have boiled this down to are that these agreements can take place at the patient level or at the population level. That is for the Velcade example the reimbursement happens at an individual level. That patient responds or they don't. There's a reimbursement for that if there's not. It's a patient level interaction. In the U.S. we tend to see population level

because there are issues with, for example, Medicaid best price. Right? So if you give a drug away for free or you give a hyper discount for one person there may be repercussions and I think the landscape is changing and there's hopefully some legal work that's going to come out to inform that a little bit, but certainly manufacturers are afraid of dealing at the patient level because of issues around that. So typically what we see is a population will be followed and then there will be an adjudication for the... at a population level maybe quarterly or every year or something like that.

And then the other distinction is whether they are health outcomes-based or, you know, financial or utilization-based. And you can sort of map the different groups to this 2x2 table.

So we're going to break them down a little bit. So with coverage of evidence development, you know, what problems are being addressed? Essentially the problem is the lack of evidence. When new products come to the market they don't have sufficient evidence. So this is basically a middle ground between saying, "Yes, we'll cover it," and "no, we won't". It's sort of a maybe, yes, but. And so this creates a mechanism for allowing access, but collecting additional evidence to support a future coverage and reimbursement decision. And so payers benefit because they get additional data to support their coverage and reimbursement decisions and manufacturers get access. Now it's reduced access, they would prefer just blanket access, but they do get some access and they might also get reduced coverage of data collection and for drug manufacturer's that's less of an issue. For devices and things like that that may be a little bit of a better incentive there.

Conditional treatment continuation – this is essentially continuation of coverage for individual patients conditioned upon meeting short-term treatment goals. So the problem is that medical products can be used in inappropriate patient populations. And so by conditioning coverage on short-term treatment you can help ensure that only patients who are actually benefitting from treatment are the ones who continue to receive that treatment. A lot of benefits to the



payer in this one. So it can minimize long-term treatment exposure or cost exposures, it can improve cost effectiveness, it can replace the need for prior authorization. So if you're actually going to check up on a patient shortly after initiating on them and there's a measure of treatment effectiveness then only the people who are benefiting on drug are going to be the ones who continue on that drug. So it decreases the need for prior authorization, at least theoretically. There may be concerns about patients and providers who continue treating patients when there's not good benefit, but there are good alternatives out there. So there are some conditions out there where there aren't very many good alternatives and there's an impetus to try and keep patients on drug just because there's no other good alternatives and that's not actually a very efficient way or a good way to... for medical care. And again the benefits to the manufacturer relate to access.

So performance-linked reimbursement – there's actually two kind of primary rationales here. One is that payers may desire more evidence to support a manufacturer's claim. So when a manufacturer comes and they make their arguments about their value proposition they may say a lot of really nice things about their product. Some of those things might have a nice amount of evidence to support, some may not, and a payer may desire more evidence around certain aspects of that. So the manufacturer... the generation of that evidence actually can be very expensive. Right? They are going to have to go connect on other clinical trials and it can be expensive in terms of actually paying for that trial, but also lost time in the market. So instead of actually going and shoring up that evidence with data collection you can just guarantee that outcome with some sort of mechanism, a contract and we've seen some, and I'll show you an example of this in a little bit, where the contract that was put in place was directly related to the uncertainty that existed in the clinical trial data that came out. But essentially it's a way of supporting your claims but not with additional evidence collection, just with financial or some sort of contract that guarantees that outcome. And the other one is around price transparency. So this is a big one, for example, in the UK when these first came out was that if a manufacturer gave a discount in the UK that price would ripple all the

way through Europe because of external reference pricing. And you still may see some of that in markets where there's any sort of price transparency. So this is actually a mechanism for providing a local discount without actually changing a list price, which is kind of a big one and one that may be useful in terms of what the negotiations actually wind up being. But I just show a little example here. I know the writing is small. You have this in your handbooks, but essentially in the UK with the Velcade example the list price was £760 and after a rebate for non-responders the effective price paid was about £540 per unit and yet the list price remained the same so they didn't experience that... the negative consequences of that external reference pricing that they would have seen throughout Europe. That was a big impetus early on. And so benefits to payer – the provide access to patients at a discounted price and they decreased their financial exposure for under-performing products. For manufacturer's they get access at or near launch and it can be used to provide this local discount, which is actually a very efficient way of pricing. If you're a manufacturer you want to price to your local market as much as you possibly can. It's a very efficient way of doing your pricing.

So by summary these are addressing both uncertainty... you can address residual uncertainty with coverage with evidence development or you can sort of mitigate the negative consequences of uncertainty. Those negative consequences might be a bad buy if you're a payer, and manufacturers it might be a loss of access. That's a negative consequence of the uncertainty. And then it also can address issues with inefficient pricing.

So now I'm going to show you a couple trends that we've observed from our data. So this is basically us tracking the number of these cases over time. The gray bars are the aggregate cases and then the purple are year on year and you can see that there was sort of a spike in 2007 and it's varied a little bit here and there and we don't have that much data on 2016 yet, although we have seen some increases... we've observed some increases recently.

In terms of the manufacturers who are engaging in this you see pretty much all of the big names are engaging with some more than others. Novartis is probably one of the more engaged among the manufacturers out there, but certainly many are doing it.

In terms of the product areas there's a big spike there on the left. It's oncology and there's pretty good reasons why oncology is an area why we see a lot of these. Obviously price is a major issue. Uncertainty is still a pretty major issue, especially when you're just coming into market. There's also a mechanism for doing this. That is you have response measures and those response measures are usually near term so they can kind of be evaluated within the timeframe of a contract. They are agreed upon clinically among communities so there's not a lot of disagreement about whether, you know, the clinical measure of response is actually a good measure of benefit or not. It may not be perfectly translatable into overall survival, but it is still a pretty good measure of short-term outcome. So there's a lot of reasons why oncology is a big target there or we see a lot of agreements there. There's also been a lot of products that have come out in that timeframe that we are looking look.

So some examples. And these are U.S. examples. There's a lot of examples throughout the world, but I just picked two U.S. examples, which I think are interesting to think through. So this one is Junuvia and Janumet and this was an agreement between Merck and CIGNA. So this has actually three components. One is that CIGNA is going to assess blood sugar levels for any patients on any anti-diabetic medication. So not theirs, but on any. And if the A1c values improve there's a bigger discount. So that means if patients do better then CIGNA gets a bigger discount from the manufacturer. They are incentivizing patients to do better. CIGNA will use claims data to make sure that everybody is being adherent. So there is an adherence component and you'll see that part of this is that they want to make sure that that the patients and the patients who might be eligible for larger discounts are being adherent on their drugs. And for that they get better placement on CIGNAs formulary, including a lower copayment versus other branded drugs. So they get a better placement and they get access.

This is a really interesting one because it's a little bit different because there are deeper discounts if patients do better. Right? And so this can actually benefit all the parties. Right? If there's diabetes patients who are more adherent have better outcomes. So they have an adherence incentive. Patients with better adherence tend to utilize other... fewer other resources so the payer could actually get advantages there plus deeper discount, and the manufacturer can actually make up some of the discount-related losses by increasing sales and volume... sales volume related to adherence and CIGNA has an incentive to push people towards that manufacturer. Right? Because they are getting deeper discounts there. They are also... Merck is also betting that their drug is the best. If CIGNA gets a deeper discount if patients do better then Merck is sort of saying, "We believe our drug is the best. We are going to incentivize you to push people on our drug and you're going to see savings because of it." And so basically it said in the New York Times it said that Merck is betting not only that their drugs prove superior, but that CIGNA's incentives help them realize some of those benefits.

And here's another really interesting one. This is Risedronate. This was an agreement with Proctor & Gamble and Sanofi-Aventis and Health Alliance, which is a payer. So these companies agreed to reimburse the insurer of the cost of treating non-spinal fractures suffered by patients who consistently take their medications. So the first... this is the first published example in the U.S. where the manufacturer agreed to cover the cost of disease-related sequela. So this isn't related... they're not giving a rebate on the drug cost. They are covering the cost of non-spinal fractures for patients who take their drug. So it's different. They are separated out and it's actually an interesting mechanism because then you don't have to get into drug pricing issues. Right? This is covering something else. They use hip and wrist fractures. They can cost about \$30,000 to \$6,000 respectively. So it's a decent amount of money. And the benefit to the manufacturer is they get to keep patients from switching to a generic version and it also maintained a lower copayment level than their competitor, ibandronate.

This is the one that I was kind of commenting on that's related directly to uncertainty. So the clinical trials of risedronate failed to show a statistically significant reduction in non-spinal fractures, whereas some of the competitors actually were able to show that in their clinical trial programs. So instead of doing another trial or addressing that uncertainty by collecting additional evidence they just guaranteed that outcome financially as opposed to doing that. So this is one of those really nice examples where theory kind of lined up without the agreement that we wound up seeing. And so, again, benefit to the payers that there's an outcome guarantee related to this uncertain clinical end point and the makers of risedronate are betting that the product's going to actually reduce non-spinal fractures in real... and maybe it was just smaller samples size or something like that, but... or that the cost of treating them will be offset by maintaining or even expanding their marketshare because of the incentives for the payer. Those are two really interesting U.S. examples and I usually find that people like to dive into the examples when I have these. So there's lots of examples, but those are two that I think line up well.

There's also one related to tests. I know we don't... this is mostly on drug pricing so I won't dive too deep into this but basically this is an example where Palmetto... they have something called coverage with data development, I think. It's a new little unique [inaudible] that they have, but they are trying to incentivize the collection of data to support the coverage of diagnostics in their MDx program. And so under this scheme essentially if the drug in a registry is shown to perform better than they... or as well or better than they are expected to they are going to expand access to providers who can then use this test in the network. So their sales volumes will go up if their drug does better. If it doesn't do better then they keep the amount... they cap the amount of providers who can actually prescribe or use this test. And so it actually... this is both the coverage with evidence development, but also has this outcomes guarantee so they are tracking how well patients are actually doing and there's a revenue... potentially revenue-generating element for the manufacturer if they participate.

So people often want to know about the results of these like how well have these done? What are drivers of success, etc.? And there's just almost nothing that is written on this. There's a little bit, but these are often [inaudible] agreements and so sometimes we see the agreements, not always, and much less we actually see the results of the agreement. Although there is some out there, but at a high level we do understand that the payers have been engaging in these. So there's incentive and so they are likely getting some cost savings and uncertainty reduction. And the manufacturers... a form of success is that they are getting access. So if they are willing to go into this then what they are getting is access. So that's one form of success from their perspective.

Here's what we've seen in the U.S. Again, the green is the aggregate and the red is the year upon year. So we have seen a fair amount of activity here. And just some results from this... so from the coverage with evidence development it's been used to inform at least two specific policy decisions. That is there has been an uptake to the coverage decision based on the data that came from a CED agreement. There were other problems with actually implementing the CED agreement at all. So some of them went to length of creating a coverage with evidence development agreement with specific trials, etc. and then no one was enrolled or the registry was never formed. So that happens as well. There's been some follow-up on each of the two examples that I spoke about. So with the CIGNA and Junuvia example in what they observed was that the blood glucose levels improved by more than 5%. So CIGNA did get this deeper discounts and adherence was sufficiently high, about 87% on these populations. So there were good outcomes related to that one.

With Health Alliance the reimbursement rate was high and it was basically within the parameters of the agreement so parties were generally thought to be happy with how that agreement came together.

In terms of recent U.S. activity there has been the CMS proposed rule and this actually covers potential pilot programs related to risk-sharing agreements. And so I think this is actually going, you know,

part of what has brought this again to a higher level of awareness and it's yet to be seen how this actually plays out. There's been a good amount of commentary so far but I think this is at least pushing the envelope and pushing the discussion to areas where that discussion needs to happen. So I was obviously happy to see that, also happy to see that the database was listed in there. So it's nice to get a little federal recognition.

So in terms of some more recent U.S. activities also, there's been a couple cases this year which are really interesting. So Entresto and CIGNA have come up with a performance-based agreement linking the use of Entresto to hospitalizations for heart failure. So they are covering the cost of heart failure. Again, that separation between a rebate or a discount, but actually covering the cost of that disease-related sequela and that's around heart failure.

A really interesting one, AstraZeneca and Express Scripts. And I like this one for a few reasons. Basically AstraZeneca will reimburse the cost of lung cancer drug Iressa if patients stop treatment before the third prescription fill. So in cancer often times it's a treat to progression disease. Right? And so what we care about, for example, is its response measure. However, tracking individual patients' response, getting clinical data is really difficult. You have to set up entire new systems. However, because it's treat to progression you can just use the actual prescription as a proxy for essentially progression. If they stop getting prescriptions then the assumption is that they progress. Now there's some noise around that, but it's actually, for a contract like this, it's not a bad way of going about it and the key thing is you can leverage existing information systems, which is a really useful way of doing it. Any time you can leverage existing information systems and don't have to recreate the entire system for each contract then that's going to be an efficient way of doing it. This is actually borrows from one that they did in the UK, which was similar in nature. So they just used a utilization as a proxy for essentially progression.

I mentioned the diagnostic test stuff with Palmetto and they did this for a number of different tests and I think will continue to do so.

There's also been a lot more activity with devices. This is an interesting one and they are very interested in it. They don't have a lot of data when they come to market and so they are going to be at a competitive advantage if they guarantee certain outcomes that they are trying to guarantee. So a lot more activity in the device space over the last couple years.

So we did some work where we were focusing on the U.S. and we asked both payers and manufacturers about their opinions about a wide range of things, but I thought this was one of the more telling things, because essentially what are the potential barriers in the U.S. to use of these types of agreements? And so on the left we have our basically top 11 and on the right we actually get this sort of strength or the ranking of which ones were sort of thought of as being the biggest barriers. And so I'll just mention sort of a couple on the top, but basically the amount of effort... so, you know, these are... essentially can be thought... I mean sometimes they are one off. So doing a whole new contract where you have to actually leverage and analyze claims systems and collect clinical data sometimes and then have, you know, sort of the money change hands with these period times it can be a lot of work and from the payer perspective that can be really challenging. Part of the lesson there is that trying to come up with reproducible agreements is going to be a really efficient way of doing this. That's why in Italy they created a whole system that they could uniformly apply to a number of agreements. It took a little while to ramp that up, but now whenever they have a new agreement they can come in and they can track all of those outcomes through that single registry. And so that's part of what that barrier is sort of telling us is that the more that you can create consistent reproducible systems the better it's going to be. And again data infrastructure is a key piece. Data systems that you can easily track that's why integrated systems may be in a better position to do this than other systems because they will have, you know, better access to those types of data. We often saw Medicaid best price that came up for a lot of manufacturers in terms of their concerns. I think especially their legal departments' concerns about setting these type of agreements up. And then you can see a number of other ones, but this is sort of telling in what are some of the key things that are



holding us back in the U.S. I think another thing that is holding us back in the U.S. is also just the lack of a big stick from the payer's perspective. So in the UK they can say, "No, we're not going to give you access." That's a pretty big stick. In the U.S., as we saw, that's primarily around, "Well, we'll put you in tier 4." There's less that they can do in that regard. So the manufacturer has less of an incentive to sit down and negotiate even if they might be willing to think about it, they are less willing to get to an agreement that's actually going to work for both parties.

And so just sort of thinking about how we develop these types of agreements, it's useful to think first about just understanding interventions. So where is the uncertainty related to this intervention? What are their available short-term efficacy and safety measures? And what schemes might address those two elements? It's important to understand the market factors. So if there is a competitive landscape, as we saw with the CIGNA and Merck example, that company was willing to bet on itself and so that may put products... might lead one to certain types of agreements versus the other example where they didn't have as good clinical evidence so they wanted to guarantee an outcome so that they would be on par or compete with... in a market where maybe they weren't the leader. So the type of agreement is going to be related to the nature of the intervention, but also the market factor. So we are thinking about it. Also when you think about situations where additional investment and evidence generation might be beneficial or may be the driving element that needs to happen.

And you can always use, you know, cost effectiveness and revenue models to try and understand the potential implications of any of these agreements. But I always recommend doing that.

I'm a little early, but we'll have plenty of time for discussion. In conclusion, essentially these performance-based agreements are in line with healthcare trends trying to address cost issues, trying to address uncertainty, moving towards more considerations of value. They are intrinsically appealing because they can align incentives. There are substantial barriers to implementation and it's going to

take a lot of work to actually reduce those barriers. We do see some of them, but if this is going to continue to be increasingly useful and used then there's going to have to be a more concerted effort to address those barriers. But they are a viable option for coverage and reimbursement for new medical products in many health systems. So I think they are now, at least, sufficiently part of the conversation that we can begin to make movement.

I'll just end by... people often talk about these being new, innovative, brand new ideas, and the general concept has been around for a long time so this is just an article from a long time ago where it says that all headaches are instantly cured or your money refunded. So the concept has been around for quite a while. So with that we can move on to questions, etc. Thanks.

[applause]

Ray Hanley:

Do we have any questions?

Thank you. I appreciate that. My question is really related to when you might use this tool and you talked a little bit about the advantages it has. I'm thinking both last... to your last cartoon where how many people actually got their refund. Right? And was it the pill or something else that instantly cured their headache? So translating that to our current hep C issues... the viral load clearances aren't really the issue. So that wouldn't help us in terms of an outcome that we wanted to look for. And in some cases where there's... it's unclear whether it's a placebo effect for instance or something else. I'm not sure that this would be an appropriate tool. So it seems like there are some places where it would be a really great tool and I'm wondering if you've done any work around where it really can't separate out either effect, which seems like, you know, we're starting to substitute maybe what should be additional due diligence on a manufacturer's part for pay or reimbursement at a very early stage.

Josh Carlson:

Sure. I mean that's a lot of pieces to that question. But I think at the outset you still, for example, have essentially an estimate of what, you know, the proportion of people who are going to meet that viral

loud. Right? It's like 96% in one genotype and that varied a little bit between genotype. And you might have revenue models that are around... or cost-effective models that are driven by that percentage. You still don't know how that's going to translate to the real-world population. You don't actually know. So you might be negotiating on a value of 96% and that might be what's driving the conversation, but what you actually experience in your population may be different. So I actually think this is really useful right when a product is coming into the market to try and... to probably just try and inform perhaps a subsequent negotiation two years from now. I think it's actually probably one of the better ways it might be thought of as using as trying to get to the right rebate, even if that's what you're trying to get to because you... if you just take the manufacturer's evidence at face value then the negotiation... that's your evidence packet. Right? But if you are... if the evidence that you see in your population is different that's going to be a different sort of evidence packet that you can then move towards a negotiation.

Man:

I guess the true quandaries at least from my perspective that assumes that the price points that they were at or even any rebate that you can negotiate is actually going to be sustainable for us over the long term. Many of us think that that's not true. So it's not getting at that... it's like nibbling around the edges versus a core issue and again I think it could be a really great tool for certain issues, but for hep C it's not really about if it's 97% response rate versus 80% response rate when only 15% of the population goes on to develop long-term very poor consequences.

Josh Carlson:

Yeah. This is not going to address affordability at a major level. Right? So this is, again, this is a mechanism within current stuff that can be used to address uncertainties and it's not going to just deal with all issues around affordability. So, you know, it doesn't solve affordability. It does... it can get you a discount whereas you may not have been able to get a discount before. So it helps, but it's not going to take that way. So it doesn't get at that larger element. However, in... I think it deals with both... there's a short-term effect of getting maybe a larger discount, but also it's a good signal for the system. That is that you will... that what matters is value in the long-term and

we're going to reward products that demonstrate value and there's going to be a refund for products that don't. So that sends a signal to manufacturers around that, at least in a dynamic sense, as well. But it doesn't get it, you know, sort of just the general high cost of drugs that are coming as they come out necessarily.

Eileen Cody:

So the quest... alarms go off in my head from all the fights we had just implementing the preferred drug list in the state and all I can think about is on this example of the drug that was not as effective, but they got a better price that you're not using evidence on that. The evidence would be that you should use the other drug. And so that... basically who saves the money is the plan or the purchaser, not the patient, and does the patient even know that they are taking a drug that's less effective? It seems like there should be a... that's a trial. Is there any human subjects review, you know, on this?

Josh Carlson:

Sure, sure. I get what you're getting at. But both of these drugs were on the formulary already. So they've already gone through and they are probably considered pretty equivalent. It met its primary endpoint, which was spinal fractures. This was a secondary outcome so the drug probably wasn't powered for that. It's not totally clear that you're leaving benefit or that one is clearly better than the other. Now this is just one example and so, you know, at the end of the day that... some doctors would be using this drug and some would be using the other anyways and I don't know if patients would know the difference in that case either. Doctors are still, you know, free to prescribe what they want. So they are still the ones who are... the bridge to what patients should get in terms of, you know, that's not necessarily on the plan. On the plan side, you know, this has gone through a normal P&T. So it's on their formulary, they are already considered equivalent. So this is just basically around preferred list and so how would this be different if those two drugs were on there and one drug... one company gave a larger rebate and the other didn't? And they had different evidence bases? So the plan may still incentivize something because they are getting a larger rebate and so, you know, in that case you have the exact same issue. If they are both on the formulary they have already gone through P&T, they are already considered safe and effective by enlarge, you haven't had a

head-to-trial between them, and the manufacturer who has slightly worse data on a secondary endpoint gave you a larger rebate. They very well may end up in a better tier than another drug. So it's essentially the same situation as that.

Man: Great presentation. Great examples. So, you know, I go back to Oregon. I'm a payer at Oregon Health Authority. I want to start negotiating with drug companies. Any advice or thoughts on, you know, starting that and how to think about which drugs to start with? Is it the really high cost breakthrough drugs or is it ones that have a lot of volume? Or is it the ones where there's maybe not so great evidence and we're not sure the outcomes? Which class should I start thinking about first?

Josh Carlson: Yeah, that's a good question. Certainly you want ones that are high cost either because of high unit cost or a high volume because it has to be actually worth it for you to go to the effort of establishing this in the first place. So that's a clear signal. And then newer drugs... so there's less evidence out there are probably where to start. So the recent examples with Entresto and the PCSK9s, for example, you know, knew... there's pretty clear uncertainty about long-term outcomes. And so... and they are trying to be in a situation where they are getting, you know, on formularies and increased usage. So they are probably going to be in a position where they're more willing to negotiate in high cost and a good amount of uncertainty. So, you know, you had three things, I think. Anytime you get all three of those happening at once is where you want to go. But at a minimum it certainly needs to be worth your effort. There needs to be enough on the table in terms of potential cost savings that it is worth the effort that it goes to establishments.

Ray Hanley: We have another question back in that corner. Could you please state your name and turn on your mic?

Woman: Question about the Junuvia/Janumet. I was intrigued by the word deeper discounts. And the reason I was intrigued by that was because typically in the value-based arrangements that I'm familiar with the money comes back in the form of a rebate. Is this money

coming back actually in a deeper discount? And how does that work? Because to Eileen's point earlier the problem with higher drug prices, high rebates, which is what we've seen, the person that really doesn't get any of the benefit of those rebates typically is the member at the counter. So I am just curious about how... so when I saw that I was curious about how that actually works with the discounts.

Josh Carlson: Yeah, it's a good question. I don't have the exact details. I don't... but it is termed deeper discount so essentially my sense is that they looked at it over a defined period of time and then for whatever the next period of time was that there was probably a deeper discount. So that was some...

Woman: [inaudible] quarter?

Josh Carlson: I think it was initially a two-year agreement so I would imagine they probably looked over one year, but then maybe the second year, but I actually don't know. I would assume they would have said bigger rebates if that's what they meant. That's what I was able to observe.

Ray Hanley: Question over here.

Torel Foreke(?): Hi. I'm a graduate student at UW and I'm question is how do you prove that the patient consistently took the medication? I imagine that is difficult to prove.

Josh Carlson: Yeah. So there's basically a few ways you can measure adherence, but that's in a claims-based environment so you basically look at days filled as a proportion of the time since they initiated treatment over a period of time. I believe it's usually around 80% of the amount of time. So they basically have some thresholds for if the patient consistently got their refills over the time period that they defined as a treatment period within like 80% of the days that define the period then they would be determined adherent. There's a few different ways there are nuance there, but basically you observe in claims the number of pills they have over a defined period of time and if it's above a certain threshold then they determine adherence. So they actually, you know, do anything more detailed than that.

Ray Hanley: Let's take one on this side. One up front here. We have time.

Robert Judge: Thank you. I'm from Moda. Really an interesting discussion and I'm trying to think of its applicability in a broader sense given the fact that roughly 85% of our drugs go through PBMs that are sitting outside of... where all the clinical data gets assembled. What do you think the long-term implications are for being able to do this more broadly or is it going to be really refined to health plans that own their own pharmacy benefits inside or [inaudible]?

Josh Carlson: It's a little bit unique for each and every one, but you did see the PBM involved in one of these. Right? That doesn't preclude multiple party agreements and things like that, which gets pretty complex. The early work will probably be in the more simplified settings like that, but, you know, the U.S. is always particularly challenging in the way that it is fragmenting that way. There are... I think you're right in thinking about that there are very complex situations which it's going to be less applicable and then some that are a little cleaner. That's another reason why the integrative systems may be a more common first place where we see them.

Ray Hanley: Got one right over here.

Petra Eichelsdoerfer: United Health Care. Two questions really. The first one is that you kind of eluded to the fact that a lot of these agreements are confidential or at least are kept quiet. What's your sense of how widespread they really are in the United States?

Josh Carlson: Yeah. So we don't know what we don't know, according to Donald Rumsfeld, which I always like to do. That was part of our survey work that we did where we asked payers and we asked manufacturers. My guess is we're seeing a good number of them. We see the fewest in the U.S., but I don't think we're missing that many in the U.S. yet. That is I think there is enthusiasm, but not that many agreements that have actually been out there. So most of what we heard was they have had discussions about them, they've started conversations, but they haven't actually realized agreements. But we have seen some.

We've seen CIGNA do it twice. So there are a few parties that are kind of... seem like they may be a little bit more willing to go that route. All we have is a little bit of a glimpse from what we've been told from these payers and these manufacturers and I think right now we're in a position where the enthusiasm is outpacing the number of agreements that are actually in existence.

Petra Eichelsdoerfer: So then the second question, again, you kind of eluded to this in your talk about agreement on what are the proper outcome measures and the question here is the clinicians and the company they have an agreement on what is effective. What happens when the patient disagrees?

Josh Carlson: When the patient disagrees.

Petra Eichelsdoerfer: So the patient thinks they are getting a clinical improvement, but the clinician doesn't necessarily agree with them and the payer or the manufacturer doesn't necessarily agree with them. Does that ever taken into account?

Josh Carlson: Not in these agreements. The agreements are, you know, at the level. Typically the U.S. though we also don't see these at a patient level very much... as much. For example that's why we say they mostly happened at the population level. So let's look at response rates for the whole group and if they improved it. So then the patient is a little bit not quite as involved in that specific decision. But... and so... it's interesting because the Velcade example there was a little bit of negotiation over what was considered a response to the drugs. And so basically, without getting into too much detail, essentially it had to do with the measure of a blood... a blood measure and the proportion that was considered a response versus not was actually negotiated and it was a little bit different than what the clinical community thought. So the threshold was a little bit higher in the agreement than the clinical community might have been considered a response. In that way there might be some benefit left on the table. It's theoretically possible. Right? And so at the individual level you can see that there might be some patient pushback on that one, for sure. But that wouldn't be new with these types of... but in the U.S.



we don't see it as much, again, because of the population level outcomes.

Ray Hanley: We have time for one more question. Anymore questions? Up front here.

Gary Franklin: One thing I'm interested in is the difference between clinically meaningful improvements from these drugs versus kind of minimal improvement that they might have shown in a randomized trial. I'm wondering if that difference has been addressed in any of these sort of pilots?

Josh Carlson: It probably goes... I mean it goes down to the selection of the short-term measure of effectiveness. So insofar as that's a negotiation between the payer and the manufacturer then it theoretically could move from their endpoint that they showed in a trial versus what the expectation is in terms of the agreement. But I can't think of any specific examples where I've seen that specifically called out.

Ray Hanley: Great presentation.

[applause]

Ray Hanley: We've come to the end of the day and I'm going to turn things over to Dan and Donna. Before I do I just want to make sure that you understand that we passed out a little sheet that actually asks you to address some of the questions that we put forth at the beginning. So we'd like to at least give you at least five minutes before they launch in to fill out the little questionnaire and the questions are really, what's the most important lesson you'll take away, what can we take away from it, what topics should we be investigating? At the conclusion of that I'd like to open it up to Dan and Donna, though, and they will wind this thing down. So my job is done. But I just wanted to thank you all for coming today and I hope we get an opportunity to do this again. So, with that, thank you.

[applause]

Dan Lessler: If you would, just take like two or three minutes and answer those three questions. Top of mind. We would really welcome your thoughts. I think there's some more sheets if people need them. We really want to get your best thinking. Remember, we're thinking outside the box here today.

Donna Sullivan: And I just want to put in, the last question... people... I don't know if you've noticed, but Pharma is obviously not in the room today and that was done with a purpose. We wanted to focus on purchasers. So you as purchasers and stakeholders it would be really helpful for us because we are going to engage Pharma in a similar convening, but what would you ask them? What are your questions to them that we can help try to come to a compromise or some sort of meaningful arrangement as we try to tackle the high cost of drugs? So keep that in mind and maybe that's one of the last things you put down about what else... what other questions should we be asking and who should we be asking them to?

Dan Lessler: All right. Well, thank you very much for taking that time. I'm reminded of sort of standing and taking an SAT or something like that watching people write here, but appreciate people's comments.

A few brief closing comments and I think really, you know, mostly those of thanks. First of all I want to thank everybody who is here today for taking the time to come and participate in this conversation. I think it has been, you know, really a very robust conversation with... and we've covered a lot of ground. I dare say that I would bet that everybody here has learned at least something today. I know different people, different backgrounds, different levels of knowledge, but we... from regression analyses to sort of more policy-oriented commentary we have really covered the ground. And your comments and questions have just really been excellent and helped us to learn and I think it will help us as we think about how we move forward as a state in terms of informing our pharmacy purchasing. So thank you all.

I want to thank then, of course, especially our speakers who really have been likewise very generous in their time and putting together

these... putting together PowerPoint presentations that you all have to take with you. I should mention that everything we're doing here we are going to make public. We will put it on the ACA website so that everyone who might not have participated today or might not have been invited will have access to all the information here.

And finally I want to thank the folks who just put so much work into making this a successful day—Ray, Leta, Rachel, Judy in back, and Donna, just could never have pulled this off without all of their tremendous help.

[applause]

My closing comment... it's interesting, the conversation that we had and I want to go back to Bill Ely's slide. He was the actuary from Kaiser and Senator Parlette's comment that... which I would tend to agree with that fundamentally there is a very broken market here and, you know, so you look at that and it's a very steep hill to climb in terms of, you know, when things are so fundamentally broken, what do you do? But I think Yohan's point is also really well taken. We just sort of have to start somewhere, take the bull by the horns, and go to work and figure this out. I think, as is often the case, out of adversity and really difficult kinds of challenges come ideas that can lead us to places that we never thought we could ever get to, you know, better than if we just waited for the market to fix itself so to speak. So we've had I think a lot of great discussion around what we're doing currently, what the as-is state is, what the fundamental issues are what drives the cost of pharmaceuticals in terms of specialty costs, and then a deep dive into oncologic drugs, which are really probably one of the fastest growing portions of that specialty cost spend and then we've also had an opportunity then to turn and look at some really innovative approaches potentially in terms of value-based formularies and, I think Kai's presentation was just fascinating in terms of that notion and sort of the experiment at Premera. And then Josh's last... the last presentation we had on alternative-related... sort of alternative payment models for pharmaceuticals. So, you know, we've got big challenges in front of us, but I think there's a lot of out-of-the-box thinking and opportunities to try and improve on

how we purchase pharmaceuticals so that we continue to spur the innovation that we need on the one hand and on the other hand that we get the value that we're looking for and we don't break the bank. So with that, again, thank you all for coming today and thanks for your comments. You can just leave your papers, you know, what you just filled out on the table. We'll pick those up. Remember to get a validation if you haven't because your... today there is free parking. With that I hope everybody travels safely and take care.

[applause]