Drug Utilization Review Board
January 26, 2017

Diane Schwilke: Good morning. This is Diane.

Lisa Chew: Hi. This is Lisa Chew here.

Jordan Storhaug: This is Jordan Storhaug.

Leta Evaskus: Yeah. We're waiting for three more people. There is somebody who is logging in but they haven't entered their name yet.

Donna Sullivan: Do we have a quorum yet?

Leta Evaskus: We do.

Donna Sullivan: Let's go ahead and get started then. So um thank you all for coming. I… There are a few members that are here in person and those of you on the phone. I just wanted to let you know that for this meeting it's just a DUR meeting and I did invite our managed care organization pharmacy directors to attend the meeting so that they could also participate in the discussion on the opiate policy. So I just wanted to introduce them. We have Yusuf Rashid and Frances McGaugh from Community Health Plan Washington. David Testerman from Amerigroup and Petra Eichelsdoerfer from United Healthcare and then possibly Piao Ching from Coordinated Care might be on the phone. So if you're on the phone and you can hear me can you just say hello?

Piao Ching: Hi Donna, I'm here. Thanks.

Donna Sullivan: Thank you. So I'm going to turn it over to you, Michael Johnson.

Michael Johnson: Welcome to the Washington State Drug Utilization Review Committee. Like Donna said this is only a Drug Utilization Review Board today. It's not a P&T Board. We can start off with other

introductions. I'll start off with Nancy here. Say your name and [inaudible].

Nancy Lee: Nancy Lee, clinical pharmacist and committee member [inaudible].

Dale Sanderson: Dale Sanderson, committee member.

Michael Johnson: Michael Johnson, committee member.

Susan Flatebo: Susan Flatebo, clinical pharmacist and committee member.

Donna Sullivan: Donna Sullivan, Health Care Authority.

Ryan Pistoresi: Ryan Pistoresi, Health Care Authority.

Ray Hanley: Ray Hanley, Health Care Authority.

Dan Lessler: Dan Lessler, Health Care Authority.

Charissa Fotinos: Charissa Fotinos, Health Care Authority.

April Phillips: April Phillips, Health Care Authority.

Jodie Arneson: Jodie Arneson, Health Care Authority.

Leta Evaskus: Leta Evaskus, Health Care Authority.

Michael Johnson: I'll call out names. Jordan Storhaug. If you can hear me say hello.

Jordan Storhaug: Hello.

Michael Johnson: Next is Diane Schwilke.

Diane Schwilke: I'm here. Hello.

Michael Johnson: Lisa Chew.

Lisa Chew: Here.

Michael Johnson: Po. Is he there? No? Catherine Brown.

Catherine Brown: Here.

Michael Johnson: And then Amber Figueroa.

Amber Figueroa: Yes, I'm here.

Donna Sullivan: Catherine can you come sit at the table?

Michael Johnson: Okay. Welcome to the new members. At this point I'm going to turn this over to Donna so we can go ahead and get started.

Donna Sullivan: In January we don't normally have meetings, but we wanted to have this special meeting to go over our opiate policy and because we had five new members that started this year I wanted to kind of go through an overview of our PDL process, P&T Committee, and what your responsibilities are. So that's what I'm going to go through now.

So in the first… or the next slide the roles and responsibilities, slide 2. For us here at this table I'm Donna. I'm the chief pharmacy officer. I oversee the Health Care Authority's prescription drug program for our Medicaid population, as well as our public employee benefits for most of the Uniform Medical Plan, which is our self-funded program that we have with the state and then we work with Group Health for the PEB [inaudible] as well and then I also work with the pharmacy directors that our Managed Care Medicaid program that are here today. Ryan Pistoresi is our assistant chief pharmacy officer sitting next to me. So he's really on point for our PEB program. He also helps as a representative on our drug effectiveness review project governing board. Next we have Ray Hanley who is the prescription drug program manager and his really role and responsibility is oversight and management of this committee process, our preferred drug selection process, our cost analysis, and really being on point for kind of like overall pharmacy, what's going on in the world of pharmacy. So he helps us out with that. Leta Evaskus is over in the corner. She is our program analyst. She is the brains and operations

behind this meeting and it wouldn't happen without her. She does all the scheduling with the committee members. She'll be your primary point of contact if you have any questions. She does all the reimbursement for your travel through the committee and then she helps us out with all the other program operations regarding either the cost analysis process or some other things that we do that aren't really PDL related.

In addition, we have April Phillips who is here. She is a clinical pharmacist. She does… she is kind of new to this role. Not new to HCA but new to this role. New to this role as far as coming up more and helping us develop our clinical policies, creating a lot of the slides that you see. Charles Agte, he's not here today. I excused him from coming, but he is our Medicaid pharmacy program specialist. He is a wealth of information about how the program works, rules and regulations that we have to follow as far as drug coverage and how we can operate within those rules. He's our subject matter expert on that. Allison Campbell who is here she's the supplemental rebate manager. So that's more important with the manufacturers. She's their primary point of contact when we have a P&T Committee process and we're asking for supplemental rebates, she manages that program. And then Jodie Arneson who is way down at the other end of this table is our Medicaid program specialist. She's the one that takes all of your recommendations from the DUR Board and from the P&T Committee and makes them operationalize in our fee-for-service [inaudible]. She does all of the system code, edits, all the communications to providers and [inaudible].

Labor and Industries typically participate in the pharmacy and therapeutics committee meetings. They are not here today because it is specific to Medicaid. Jaymie Mai is the pharmacy manager and Doug Tuman who is also a clinical pharmacist and then Christy Pham who is a third pharmacist that usually comes from Labor and Industries.

So I'm just going to kind of go through what kind of the process is for us doing drug evaluations and where we get our… where we get our evidence. So Washington State participates in a program that is

called the Drug Effectiveness Review Project. It's a collaborative of 13 states and at this point in time they are all Medicaid programs and then Washington participates with our public employees program, as well. And it is governed through the Oregon Health and Finance University down in Portland. And then they work with the Northwest Evidence Based Practice Center and they do the evidence reviews. So the governing board is, you know, one individual from each of the 13 states. We all meet on a monthly basis and it is that board who decides what the project is… which drugs or classes [inaudible] the project is going to review. And then OHSU and the Evidence Based Practice Center they go out and they gather up all of the evidence and do a very in depth systematic review. They grade the evidence and then they'll give us a [inaudible] pretty big report and then a summary of what is [inaudible] final outcome [inaudible]. So that's the DERP program.

The Washington Prescription Drug Program was created by legislature back in 2003 and it coordinated by Health Care Authority. The Uniform Medical Plan, Labor and Industries Program, and Medicaid Fee-for-Service all participate in this and it created really a preferred drug list… an evidence-based preferred drug list at the base of the prescription drug program and we now call it a formulary, but essentially the same thing. And really at the time the goal was to develop a state-wide evidence-based [inaudible] drug list and control prescription drug costs without [inaudible] quality.

So there were some other aspects of the program that went along with the preferred drug list. The preferred drug list was really the primary driver of the legislation, but the legislation also created the… established the pharmacy and therapeutics committee so all of those committee members that are here today. And in addition to the preferred drug list, in order to try to reduce provider burden of having to remember, you know, what's on formulary, what's not on formulary, they created something called the Therapeutic Interchange Program and the [inaudible] providers. And what that means is that for drugs that are preferred on the… drug classes that are [inaudible] on our PDL if a doctor has signed up to endorse the list he [inaudible]. They review the list and they agree with the list then

when a pharmacist gives a prescription for a non-preferred drug within a class, if the doctor has written "make substitute" then the pharmacist legally can substitute to that preferred drug even if it's a different brand without having to contact the doctor ahead of time. They are just required to notify the provider prescriber and what was the [inaudible]. So that was trying to allow, you know, when a doctor… you get a proton pump inhibitor they didn't care which one and, you know, they wrote for Nexium but we had generic omeprazole as preferred then the pharmacist could make that switch. If the doctor decided that they really needed a non-preferred drug then they could sign "dispensed as written" and then that would prevent the… the pharmacist would have to dispense with a non-preferred drug. So that's kind of the interchange program.

Now it will become clearer to the newer members when we're going through our P&T Committee motions because we include in our motion whether or not it is clinically appropriate to let the pharmacist make that decision of therapeutic interchange. So that was all of the next slide.

There are some refill extensions to the therapeutic interchange, to the antipsychotics, antidepressants, anti [inaudible], antiretroviral, [inaudible] drugs and hepatitis [inaudible] medications. To date when we made this slide there's about 7,200 endorsing practitioners. It's probably the majority of our prescribers, but we don't really know. There's over 15,000 [inaudible] prescribers in the state. We don't know how many of them are actively working and prescribing the [inaudible] though.

So the P&T Committee was established with 10 members. It is based… our makeup for our P&T Committee is based on the federal Medicaid requirements for the Drug Utilization Review Board which essentially says that you can't have more than 50% [inaudible] and more than 50% doctors. And so what we decided is to have the committee – four doctors, four physicians, a nurse practitioners, and a physician's assistant. We meet at least quarterly and we actually meet every two months on the third Wednesday. And during those meetings we'll review our [inaudible] that are prepared by the Drug

Effectiveness Review Project and then we'll determine based on what was presented what drugs are equally safe and effective, which might have [inaudible] in special populations, which might be less safe than others. And then really what you do is you make a recommendation and say, you know, all drugs needed in preferred, you know, you might say we don't care how many are preferred. They are all [inaudible] safe and effective. You might identify a particular drug and say we need this particular drug to be preferred and [inaudible] where this individual population is… might be more expensive than the alternatives, but it's the only one that works in a small [inaudible] patient. And then we will determine whether or not it is appropriate to interchange the package. And that's different than… and so the P&T Committee is establishing a preferred drug list for all three programs. So again the Medicaid Fee-for-Service, the L&I Program, and the Uniform Medical Plan. So the Drug Utilization Review Board, however, is specific to Medicaid and that's why, as we move forward in April [inaudible] it will be in the morning session we typically convene as the P&T Committee and then we adjourn and then we'll reconvene as the DUR Board. And we do that it's really more of a procedural thing more than anything because the DUR Board is really specific to Medicaid and it governs the Medicaid program whereas L&I and the Uniform Medical Plan could follow what we [inaudible] out of the DUR Board, but they're not required to look at the… follow those recommendations.

So the DUR Board was established in Title 19 of the Social Security Act. It is basically an extension of the P&T Committee and what the DUR Board is responsible for is making sure your [inaudible] are being used appropriately. So what we'll bring to you at times are policies like the opiate policy that we're going to present later and say, you know, is this clinically appropriate, you know, prior authorization requirements or a step therapy requirement and we'll have [inaudible] discussion about it and make changes as the committee feels should make changes and then we approve it or not approve it… those recommendations. What we also might bring to you sometimes is just an educational piece like there's [inaudible] times where we look at just the opiate utilization and across the Medicaid population or we've looked at the mental health utilization in kids

and looking to see if we needed to make some changes to those [inaudible]. And then we can engage in provider education activities, as well.

So specifically about the Washington preferred drug list is a list of preferred drugs and any of the Washington state agencies or anybody can use it. It's published online. It's currently probably more than 30 drug classes now, but not much more. So it's not a comfort sensitive formulary of all or preferred drug list of all drug classes that are available. It's small because [inaudible] we only, at this time, add drug classes to the PDL if they've gone through the Oregon Health Planning University that DERP reviewed.

So out of the Drug Effectiveness Review Project we get several different types of reports and I'm going to go through these and you'll understand more, but we have [inaudible]. There are many types of different reports. One is like a new class review, one is an update to an existing class review, and we have expanded scanning and we have a thing called drug addendum. So a new class review is when they'll do a very comprehensive study based on questions that are developed by the government board and create a report for that drug class. Then occasionally we will update that drug class when a new drug comes out or a new indication for something and we want them to look at the evidence around that and then the governing board might decide to update that class. Sometimes they don't update that class for many years. An expanded scan is like if there is one drug that has come out, but we don't feel that there is enough information… the single drug addendum… a new drug plan has come out, there might not be enough information to do a full update on that report and so what we might do is just kind of like an evidence review of that single drug and then try to marry it back to what was compared… what was done in the original report. And then we have expanded scans and typically we'll do an expanded scan when there is a drug class that is not really changing that much. There might be a lot of new drugs and we don't want to update the report because sometimes we [inaudible] class and we [inaudible] $100,000 or more for a full update. So we do it in a candid scan where they will really go in and they will evaluate the evidence and tell us whether or not

the studies have really provided any new information critical to the drug class that might change your decision. So in these types of reports, the new lines update the extended scan people are going to… this is what qualifies a drug to be eligible to be a preferred drug on… you have to go through some sort of critical evidence review.

The next type of report that we have is a scan. So once we have created a report then each year OHSU will gather the literature looking for new drugs, new indications, new safety issues, and they will give us a report back on that but what they report back is, you know, there was one new drug, there was two new indications. I'll tell you what the indications are and I'll tell you there are four more head-to-head trials. There's, you know, 12 more randomized, you know, RCWs or placebo-controlled trials. But they don't actually evaluate the evidence. They don't tell us anything about the trials. They just tell us that there is more information out there. For that reason drugs that are identified in a scan are not eligible to convert [inaudible]. So that's just [inaudible] when we go through the process when we start, but the categories of drugs on the PDL… so we have a preferred drug list, you know, it contains the preferred drugs and the non-preferred drugs, but we will [inaudible] just a list of everything preferred. So on the preferred drug list is the drug is preferred [inaudible] therapeutic interchange doesn't apply to the preferred drugs, but it might have other restrictions that the DUR Board has approved. So even though when we have a preferred drug it doesn't mean that there might not be prior authorization or requirements on it [inaudible]. And then there's non-preferred drugs, which are subject to therapeutic interchange and they are eligible… and they are subject to therapeutic interchange only if they've been included in one of those new class reports. So a new report, an updated report, summary or summary review an extended TM or a [inaudible]. And they are subject to therapeutic interchange when it's not a continuation of one of those drug classes that were from therapeutic interchange when a patient is already taking it and then it doesn't apply when the committee does not allow therapeutic interchange and it doesn't apply if the provider has indicated "dispensed as written" on a drug class where therapeutic interchange is allowed. So in a PDL class if the drug is in a preferred… in one of the classes that's

on our PDL that hasn't been included in the DERP report [inaudible] identified in the skew, but it wasn't… hasn't gone through that evidence review then it's not eligible. We don't do therapeutic interchange. We consider that not reviewed. So it's not preferred, it's not non-preferred, it's not reviewed. So therapeutic interchange doesn't apply to those drugs nor does dispensed as written. And then drug classes that are not on the preferred drug list, but each program manages those on their own. So those could be different according to the particular program.

And then at times we'll have a drug class, for example, with beta blockers when we first started this committee back in 2004, you know, [inaudible] XL and all of those, you know, branded beta blockers that were extended release were coming out. So we had beta blockers on the PDL. Now everything is generic. So it doesn't make a lot of sense for us to continue to pay for these reviews for drug classes that aren't changing very often. So we will archive some drug classes and the Health Care Authority will bring those drug classes to you to recommend archiving. And basically what we will do is we will review a final scan of the class. You will vote whether or not you feel it's appropriate to archive the class and then you'll determine whether or not, you know, therapeutic interchange, you know, should be continued with this drug class and then you might ask us to change a preferred status to [inaudible] costs. So what would happen is we wouldn't be bringing it to you for a clinical review, but the agency might notice that, you know, this generic was… the price went up and now it's twelve times more expensive than an alternative generic and we might make that not preferred and that you would be able to do that without having to come back to the committee because it's not a change based on a clinical [inaudible]. And then we would make sure that the preferred drugs position on the PDL still complied with the motion… the recommendation that you provided in the last [inaudible]. So if you said a particular drug had to be preferred then it would remain preferred until we can bring the class back and you might change that recommendation.

So there is kind of the… this is just the process slide. So before the meeting happens there's [inaudible] we sent out the agenda and then we send out a supplemental [inaudible] to manufacturers or let them know that the meeting is happening and invite them to [inaudible]. Those rebate [inaudible] are due the week before the meeting and then the committee meets and they make a recommendation, we conduct a cost analysis. We have the work [inaudible] between Labor & Industries and the Health Care Authority [inaudible] recommendations of which drugs we think should be preferred based on the committee's recommendations and the results of cost analysis and we make that recommendation to the agency directors who then approve or not the recommendation and then once we have a final decision we'll send that out to a stakeholder announcement setting [inaudible] folks know what was actually the final decision. So you're not making the final decision of what is preferred on the preferred drug list and the committee doesn't look at what types of drugs… in your deliberations on determining what your recommendations are. So that is the process in a nutshell. Are there any questions?

Dale Sanderson: What's the impact of what we do on the broader managed care…

Donna Sullivan: It really depends. So right now for the preferred drug list half of your work we require the managed care plan to follow our antipsychotic drug class. So any chance you make to the antipsychotic drug class we require the health plans to follow that. And then also like the age dose clinics that we have for kids on antidepressants and ADHD drugs or antipsychotics and so there is second opinion edits for therapeutic limitation or poly pharmacy we require the health to administer [inaudible]. From the DUR Board side there are times when we will ask them to follow the same policy that you guys recommend for the Fee-for-Service Program and again working with [inaudible] at the last meeting in December we removed [inaudible] prescriptions and requirements and so that is something that the managed care plans will be implementing and today this opiate policy that we are going to review is something that we are going to roll out across the managed care and that's why they are here today.

Dale Sanderson: Thank you.

Donna Sullivan: You're welcome. Any questions from anybody on the phone? Okay.

Ryan Pistoresi: So next on the agenda will be the opioid policy. So we'll get that.

Leta Evaskus: I have one announcement. We do record these meetings to be transcribed. So when you start speaking state your name so the transcriber knows who is speaking. Thank you.

Ryan Pistoresi: I'm the chief pharmacy officer here at Health Care Authority and I will be presenting the opiate policy. This one is specific for children and adolescents.

So I will get into that a little bit further, but to start I want to provide you with some background about the current landscape of the opioid epidemic in Washington State. As you can see not only are we as a state [inaudible] opioid epidemic, but the whole country is and specific to Washington state there are about 700 deaths annually from about 2011 to 2015 and while there has been a decrease in the amount of prescription opioid overdose deaths there have been a rise in deaths attributed to heroin particularly in young adults ages 18 to 29.

On October 7, 2016 Governor Jay Inslee signed an executive order 16-09, which directed state agencies to address equal [inaudible]. And the first goal of this executive order directed state agencies to prevent inappropriate opiate prescribing and to reduce opioid misuse and abuse for the general population, especially the adolescents.

On December 16, just a month ago, the CDC published in its weekly MMWR the need for continued prevention efforts around prescription opioids and in this MMWR they did site a study that looked at how preventing opioid… or reducing opioid prescribing, but not necessarily increased heroin overdoses, but might actually reduce the exposure to heroin of a population.

So some examples of other prevention efforts that are going on around the country. In 2012 Blue Cross Blue Shield of Massachusetts,

which is a [inaudible] of 2.8 million, went ahead and developed a policy to prevent opioids being prescribed as first line therapy for chronic pain and to limit the amount of opioids for acute prescribing. And the results of this were published in an NNWR by the [inaudible] and they found a 15% decrease in the average monthly prescribed rate and a 15% decrease was the average percentage of members with a prescription for [inaudible]. So we found that this implementation was successful in helping to reduce the amount of opioids in that population.

Other states around the country are also passing legislation and other health systems are looking at other opioid policies. Of note Maine has a state law that limits prescriptions to seven days [inaudible] acute pain. No more than 30 days of [inaudible] chronic pain and no more than 110 MMEs per day, which is the [inaudible] equivalent per day.

Rhode Island also passed a law last year, although this one was somewhat different. This one limited opiate prescription to 30 MMEs and a maximum number of 20 doses per prescription. Other states, particularly back east like Massachusetts [inaudible] are also developing and have passed opiate policies.

So to bring it back to Washington State and the purpose of this meeting the [inaudible] of this opiate policy is to [inaudible] health care authorities policies to be consistent with the 2015 state and EG guidelines and the 2016 national [inaudible] guidelines and to reduce the amount of unnecessary opioid [inaudible]. The policy is designed to allow for an appropriate opioid that's to provide clinically-meaningful improvement and function, also reducing the amount of unnecessary administrative burden for providers of health systems and to reduce the number of tablets… unnecessary tablet [inaudible].

So on this slide I have listed several of the sources that we used to develop this policy. We also had extensive [inaudible] engagement working with not only you as the DUR Board back in October and December, but also with external stakeholders and providers around the state just to get their feedback and to develop this policy further.

So the [inaudible] for this presentation will be to begin with the recommended criteria for the opiate prescriptions for opiate naïve children and then to review expedited authorization criteria for acute pain conditions and for chronic pain conditions and then for prescriptions outside of these criteria where that go beyond six weeks of continuous therapy the prior authorization criteria.

So for this first section the recommended criteria that [inaudible] is proposing today is that we would have a less than or equal to 18 tablets per prescription for patients ages 20 and younger and then two components of this would be a less than or equal to a three-day supply, and less than or equal to six tablets per day. And then for liquid dosages we proposed six dosages per day to be consistent. And then for the high strength opiates we are proposing a 90 to 80 limit, which is consistent with the CDC guidelines.

Lastly, the final component of this is that this is for intermediate release dosage form. We proposed long-acting opiate policy last month at the December DUR Board and that was approved. So this one is just focusing on the short-acting [inaudible].

If we go into our rationale for the recommended criteria the less than or equal to 18 tablets and a less than or equal to three-day supply is based off of CDC recommendation six in their most recent guideline, which states that increased length of therapy for treatment for acute pain is associated with an increased risk for opiate uses. And in the recommendation they recommend that a three-day supply or less will often be sufficient for most acute pain at this dose and more than a seven-day supply will rarely be needed. We believe that if we implement this policy for Health Care Authority that we can reduce the amount of unnecessary [inaudible]. So to provide some more background information [inaudible] the Washington Health Alliance is very collaborative. A few weeks ago released a call to action for health insurance plans to consider a three-day limit or 10 pills for youth opiate prescriptions. And when looking at data from the Washington State Department of Health we found that the median number of opiates… initial opiate prescriptions dispensed to youth

ages 14 to 19 was about 20 tablets or a three-day supply. And when examined in the data further of the known prescriber specialties for these prescriptions 58.2% were being prescribed by dentists.

When reviewing the primary literature we did find a few studies that help support [inaudible] initiative there's a recent study that found that 54% of the opiates that were prescribed following a dental surgery were unused after 21 days. And we feel that this caps about limiting the number of tablets per prescription and then helped reduce the number of opiates that have been prescribed and a secondary study that was released just a few weeks ago looking at surgery of patients found that of a mean 20 [inaudible] that were dispensed only a mean 10 were used and that a mean 19 were unused and the results of this study and the population of the 250 found that there were 4,639 leftover tablets just sitting out there.

The other component of this limit was the [inaudible] tablets per day and we found that the CDC and Canadian guidelines helped support this by recommending the most effective dose. The CDC specifically recommends no more than 50 mg morphine equivalence and the Canadian guideline found that populations with higher MEDs often have poor health outcomes.

So the less than or equal to six tablets is acting as a surrogate for this MED limit. We realized that an MED limit along would not adequately address [inaudible] dispensed. And the example below is looking at a 50 MED limit for Vicodin or hydrocodone 5 mg or hydrocodone 5 mg in that they limit it to a 50 MED per day. You can dispense up to 70 tablets for a seven-day supply or this population 30 tablets for a three-day supply. And if you went to an even lower dose the 2.5 mg would get you up to 140 for a seven-day supply or 50 tablets for a three-day supply. But we also realize that there are very high potency opiates that would be available and we are recommending a 90 MED limit for some of these higher potency opioids. And that is in line with the CDC guidelines. So to give you an example of what a 90 MED limit would be would be 10 mg of oxycodone [inaudible]. So we realize that, you know, 30 mg six times per day as an initial

prescription, you know, [inaudible] would be appropriate, especially in this population.

The last component of this is being the [inaudible] dosage form and we also found these through the CDC and Canadian guidelines. The CDC guidelines recommended that opiate trials being with immediate release opioid and the Canadian guidelines also found that recommending [inaudible] opioids have a less [inaudible] for opioid uses.

We also have some best practices [inaudible] courage and the way that we found these are that they were cited in multiple pain guidelines whether it be the CDC, AMDG, Canadian or American Pain Society guidelines. We have chosen not to enforce these with our initial prescription limits. However, we did want to make those clear that we found these and we're hoping to encourage their use in our population.

So you may be wondering, you know, there are certain conditions in which more than a three-day supply may be necessary and to address that we have developed some expedited authorization criteria. So the first ones that we'll be looking at are [inaudible] and the list at the bottom is not an exhaustive or inclusive list. We are still looking to develop a full list of conditions and we are encouraging you to help us in developing this list if you have any conditions that you would recommend that you think would be more than a three-day supply, but not be in the limited amounts. And what we are recommending for these acute conditions are up to a 14-day supply of opiates or up to 8. So we have provided two examples primarily from the last time that we talked about this in October, but we know that this was not an exhaustive list or an all-inclusive list that we are recommending that we [inaudible] developed this list for [inaudible].

For the chronic pain conditions, on the other side, so these are conditions that we realize are ongoing and not acute and that they be [inaudible] long duration of time. We are proposing that for these conditions that there be no limit. So they have a no [inaudible] supply limit or a no count [inaudible] on them. And for these

conditions we are recommending that maybe only reserved for active cancer treatment or Hospice.

So for opiate prescriptions that do not meet that recommended criteria or that are asked to be dispensed beyond that recommended criteria or that go beyond the six weeks of therapy or that go above the 90 day we are recommending that they meet this prior authorization criteria. And the purpose of this prior authorization criteria is [inaudible] opiates are medically necessary and show that clinically meaningful improvement and function.

On the next slide we have a list of all the prior authorization criteria that we are looking at and that this will go into detail with some of the [inaudible]. This is just a more comprehensive [inaudible]. So the first item would be trial and fail on opiate medications or non-pharmacologic therapy. And with each of these five… help provide some of the rationale that we found from the guidelines, as well as citations from the individual guidelines below.

The next one is in combination with non-opioid medications and non-pharmacologic therapies. That there be a baseline assessment of measureable, objective pain scores and function scores. That there have been a complete screening for mental health, substance abuse disorder, and naloxone. And to inform patients of the urine screens for continuing opiate treatment that develops long-term.

In checking the PDMP for concurrent use of benzodiazepines and for reporting the previous and new MEDs. And this is primarily for MEDs that are above 90, but help the physician or the prescriber understand how potent of an opioid they are prescribing for that patient.

And after comprehensive documentation of the pain condition of the patient's medical history. And below we have listed a few items to look out for that we identified in each of these guidelines that have higher risk for opiate use disorder or that have poor health outcomes.

For discussing the realistic goals of pain management history, such as what is reasonable and attainable for pain, function, adverse events and general “ups and downs” [inaudible].

[inaudible] control for discontinuation as an option and those are for if the medication is not producing the positive health outcomes, or if the patient can transition to a non-opiate therapy, or if the patient is showing signs of opiate use disorder or substance abuse disorder.

To report the anticipated length of treatment so the number of days that they anticipate with a condition to require and the number of tablets that they plan to dispense during this period and have a signed pain contract that shows that both the patient and provider understand all of the requirements that we are requesting.

So the next slide are various citations that we used to develop [inaudible]. So if you’re curious about any of the data that we provided or any of the itemized to research further we do have these citations here for you. And with that we are at the end of the criteria and we’re opening it up to discussion for the questions that you have.

Dale Sanderson: On slide 24 that I just… clarifying a complete screen for mental health, substance use disorder and naloxone use, this is a big issue. What qualifies it as a complete screening for mental health?

Ryan Pistoresi: The complete screening is to… so there are a few different instruments that are in the AMDG guidelines that provide [inaudible]. I believe it’s the THQ9.

Dale Sanderson: [inaudible] generalized anxiety disorder [inaudible].

Dale Sanderson: [inaudible] opens up a box here.

Ryan Pistoresi: Right. So we don’t actually have any types of screening or pain contracts or instruments that we are recommending, but the AMDG guideline in our appendage and throughout their guideline they provide tools that physicians and prescribers can use that we use to develop… all of these. So we can point to these as screening tools

[inaudible] contract [inaudible] list, as the score measures, but they are not [inaudible].

Michael Johnson: The question I have is looking at… if I have an acute pain… like today and I get a prescription for three days, let's say my acute pain doesn't go away. Is there any mechanism for [inaudible] a refill? To me the [inaudible] is very clear that it's that first refill that is the highest red flag indicator someone is going to get hooked on opiates. That's why we are trying to limit it. So if we give them a three-day supply and that's our limit are there any… how many can they get in six months or a year? Is there anything like that to obtain?

Ryan Pistoresi: Yes. So with this policy they can get a three-day supply, but there's no limit to how many times they can continue to refill it up to that six weeks, which is what the AMDG guidelines document. When you transfer throughout the acute phase then it is not [inaudible] phase and that's when you start to monitor more. So for conditions that we are looking at [inaudible] oral surgery that it would be a three-day supply and then if they need a little bit more the prescriber can send an electronic [inaudible] and they get a few more. But at that point is this trying to limit the amount of unnecessary 30-day supplies or 7-day supplies or 14-day supplies that they may only use one or two.

Donna Sullivan: And I want to clarify that three days is for kids. You know, 20 and younger. 21 and older they get a seven-day supply.

Michael Johnson: Will there be tracking for those people? I read somewhere it's like 4% of the country's population doing 80% of the opiates. [inaudible] refills are people that [inaudible].

Ryan Pistoresi: We think that since it is the prescriber or the physician that is issuing these refills it lets them see what's going on a little bit further. So if you are prescribing a 30-day supply you may not be able to monitor as well as someone that's continuously requesting more and more opiates [inaudible] see that they re-evaluate their pain a little bit first.

Michael Johnson: And then all the other mechanisms are in place. Like if they saw their dentist last week and now they are seeing me I'm going to know they had five prescriptions in the last month.

Donna Sullivan: [inaudible] then they will show up at the dentist, you know, that they had that prescription filled.

One of the things that is a component of this is we are also creating feedback reports to the prescribers for different measure and so we will probably bring that particular report to a different meeting to show to you. We don't have it ready, but we've been looking at, you know, the dose and all their pains that the prescribers use like high dose, [inaudible] that are taking chronic opiates and things like that. We'll bring that back.

Michael Johnson: One more thing. These are things that I see. As a physician, when I prescribe an opiate medication and it gets to a pharmacy and their insurance doesn't cover it then they offer to pay cash and I never know about those. I'd love some mechanism where I'd know if that patient offered to pay cash. Are we going to prevent any cash payment? If they run it through insurance we'd see it, but if they pay cash we don't see that.

Woman: [inaudible] cash it should be [inaudible].

Ryan Pistoresi: Rather than having a strict limit about how many they can continue to refill this. So they do have the opportunity to have a no copay. We feel that that no copay maybe [inaudible] through this process rather than to… people try to pay cash.

Woman: [inaudible] in terms of the [inaudible].

Ryan Pistoresi: [inaudible] updated so that it is [inaudible].

Woman: Now it's changed from like a two-week [inaudible].

Amber Figueroa: I'm on the phone. Can you guys repeat the question? I couldn't hear that.

Donna Sullivan: The question was is with the PDMPs whether or not there was still the delay from the time a prescription was dispensed to the time it actually showed up on the PDMP and the answer was that, I believe, now pharmacies are required to report daily and so there's only a 24-hour delay.

Lisa Chew: I share Michael's concern about the refills. Looking at the… I mean theoretically someone could get three-day supplies continuously up to six weeks and I'm wondering whether six weeks for the prior authorization is the right time or whether… it seems like a long time to me and whether we need to intervene early for a pre authorization. But I'd be interested in other people's thoughts.

Dan Lessler: Lisa, let me comment. I think, you know, we're sort of, you know, trying to move forward considering a number of different parameters around this policy. One has to do with, you know, clinically with trying to drive toward best practice on the one hand and on the other hand realizing that, you know, at any time we introduced, you know, a prior authorization process, especially with medications that are used, you know, across… half the Medicaid population is… or somewhere around half is kids. And so we have 1.8 million people. So, you know, you have close to a million people. The potential to impose an administrative [inaudible] and just on the community and then also on just whether it be the Health Care Authority or the plans who will be implementing this is a real consideration. So I would grant that it is theoretically possible that somebody could, for six weeks, you know, keep renewing. I think the fact that it would require a new prescription each time is, you know, is helpful to sort of making this front and center to the clinician. The… and I think as Ryan stated in his, you know, on slide 4, you know, what we're really trying to do is, you know, I would say it is pretty… the, you know, sort of the average, that medium doubt because we know… actually, it's not slide 4, but we know that there are, you know, half the prescriptions for people 20 and under are for 20 or more pills. So, you know, as a starting point if we can move that and do it in a way that, you know, doesn't overly burden the system and so forth at the first step that's what we're… that's what we're trying to do here hence the six-week

length is, you know, that's sort of the time period, the threshold where, you know, in publications and CDC guidelines and so forth typically have thought out that trend, you know, key transitioning point from acute to chronic. So I guess I just want to explain, you know, sort of the [inaudible] behind how we've gotten to where we are at.

Lisa Chew: I think that makes sense for a first step.

Dan Lessler: Thanks, Lisa. Your last comment I just want to say, and this is a first step. I mean I think we see this as, you know, very much an [inaudible] process where, you know, we'll do something here. We'll get data. We'll see how is it working or not? And then, you know, the plan would be to come back to you to both update you and then say, in light of what we're seeing, you know, here are some recommended modifications. So otherwise I think we have to enter this with, you know, in a continuous improvement kind of mindset.

Michael Johnson: So then if I wrote a prescription for let's say 36 tablets and the patient gets it at a pharmacy, [inaudible] twisted ankle from snowboarding or something. Does he or she get the three days' worth? I don't have to recall it?

Ryan Pistoresi: Right. At the pharmacy they would… the pharmacy would notify you saying you wrote for this many, but we were only allowed…

Donna Sullivan: And that's important because if they do need more they can't go back and get the remaining 18 off of that particular prescription. They will have to contact the pharmacist if they needed more and they came back and they said they need a refill. The pharmacist would have to contact you and say, you know, wrote for 36, but we only gave them 18 so that you would know that they only got 18. Or you could check their PDMP and you can see. There is some interesting federal legislations that allows, I think, the dispensing of that additional 18 on a single prescription, but our state laws haven't been updated to conform with that yet.

Man: We have positive [inaudible] and just let them know that with the comprehensive addition and recovery act last year that they will allow procedure prescriptions to be refillable now, but there's an RCW in Washington State that does not allow [inaudible].

Amber Figueroa: I think maybe going to the next step is, based on your information, over 50% of the prescriptions are from dentists. So do we have some kind of a mechanism to get the word out to the dentists or is just going to be… they are going to learn by trial and error?

Dan Lessler: That's a great question. The [inaudible] collaborative and the agency medical directors with the re-implementation group, which [inaudible] and I participate on, but the implementation of the pre recommendation around the AMDG cost savings guideline has a group that is working that in… and then we'd have an inner-agency group of medical directors that are working on this… in the direction of the governor in terms of [inaudible] where… we have… we have reached out to and have engaged the dental community both the Dental Quality Insurance Board and the Dental Society and we actually are convening them in March, early March. There's a half-day convening with the agency medical directors and some other leaders from the community in the pre-collaborative to talk about opiate prescribing and actually to come up with sort of an abbreviated agency medical director like set of recommendations that would be for dentists and are, you know, there will be plenty of opportunity in that conversation to bring whatever from this group to, you know, to that group. We also will take it… I mean we will take this out to the dental community. It is important to do and your point is well taken.

Amber Figueroa: Thank you.

Michael Johnson: Do we have questions from…

Yusuf Rashid: First of all I think this is great work not just a step forward, but a step in the right direction. I'm pretty sure that some things that stand out to me that we might want to be thinking about regarding the training component and the dependency on people doing the right thing not

just at the dentist level, but also the pharmacist. I see nothing in this process that would prevent say if the dentist wrote for six days and it should have been three, the pharmacist filling the three days through the insurance and then three days for cash and there's nothing except training to depend on to ensure that all the pharmacists know that the intent was to limit it because they had a prescription order. Secondly, in addition to the training dependency, prior authorization is a great tool for some of these things and for instance the quantity limitation that they supply, etc., but for others like the checking PDMP other than just asking, "Did you check?" And getting a yes/no. That is more of a dependency on the provider doing that than the PDM that implements the prior auths. Another thing like the comprehensive mental health, the ambiguity of that makes prior auth limited to and not necessarily reliable to it. It might be in an appeal process where we'd be able to actually implement that when there is sort of [inaudible]. So we want them to just call what those inter-operational and turns into [inaudible].

Donna Sullivan: Operationally, I think what we're trying to get out there is that this is the best practice. The question might be is we might not require, you know, chart notes or confirmation every single item that's on there before something is required. It might just be that the box is checked that they did it. So I think that, you know, that operationally we'll have to… we'll convene and figure out how we're going to implement it, but we're really rolling this out is this what the best practices are? And at least it gets the doctors, you know, thinking about what they are supposed to be doing.

Dale Sanderson: There's a number of challenges [inaudible] prescriber in terms of a wide variety of individual differences between pain tolerance, expectations of response, you know, all of those are [inaudible]. I don't know how that fits into what we're doing here, but in the trenches it's a real challenge to separate from abuse and diversion issues just trying to help a patient to be as comfortable as possible knowing that there is a wide variety of tolerated aid and what their expectations are. Do they want no discomfort at all or is it just a manageable discomfort? All of those issues, I think, play a role in how much of this is [inaudible].

Donna Sullivan: I want to throw out there that… remember, this is for acute pain. So a lot of those tolerance issues aren't necessarily going to be a factor. What we will be doing is identifying things they are currently doing on an opiate and we will make sure that they're not going to hit up against the three- or seven-day edit, because nobody will be happy if that happens. And so… that's a completely different approach that will have to be taken to, you know, deal with patients that are taking… on an opiate therapy that might not be appropriate and that are those of high doses. So we're going to manage that under a different process, but we will identify those patients and make sure that they're not… we'll try to the best of our ability to make sure that those people get their prescriptions disrupted by this policy.

Man: Thank you.

Michael Johnson: Anyone else have any questions? Comments?

Lisa Chew: I just want to say I really appreciate the effort that was put forward. I support this quantity limitation and the willingness to continue to look at how the medications are being used and to revise our policies accordingly. So thank you very much for that effort.

Man: Thank you.

Nancy Lee: I just had a question about clarification on the process for DUR. So after [inaudible] like and how much data you [inaudible].

Donna Sullivan: I'm sorry, but at this point in time we haven't decided yet. So we have… we had [inaudible] data on utilization of… based on age bracket. What we will probably do once the policy is implemented, which is probably going to be mid to late March, if not later, is set up, you know, a report [inaudible] a 90-day [inaudible] and the goal… we'll know right away if [inaudible] because the providers will be calling in. So I'm confident that I will know right away if this report… and so part of that… I think what we will look at is at least 90 days to figure out the impact utilization. I think part of what we find is, you know, doctors are habitual and they just, you know, they habitually

prescribe, you know, 15 or 20 or 30 when they write these and what will happen is that they will just re-adjust what their, you know, what their baseline is or what their [inaudible] is. I don't think that doctors that are, you know, only prescribe 5 or 10 at a time will increase to 18 just because we're making it limit reaching, but those ones that, you know, for… just because they pull 20 out of the air or 25 out of the air they will adjust their prescribing habit [inaudible]. I don't think it will be as bad as we are expecting it to be.

Michael Johnson: I think we'll certainly be limiting the exposure of opiates in the communities. I think we… we need to have a motion then?

Man: Stakeholders?

Michael Johnson: For the record there are no stakeholders.

[inaudible]

Michael Johnson: So no stakeholders. All right.

Woman: We didn't prepare a motion template for you. So just a motion to approve or deny or whatever.

Michael Johnson: I mean I would make the motion that we would approve the [inaudible] quantity limits and the duration for prior authorization also. All in favor say aye.

Group: Aye.

Michael Johnson: All opposed same sign. Okay. The motion passes. Thank you for all the hard work on that.

Dan Lessler: I really want to especially recognize Ryan Pistoresi because, you know, I think you all have commented on what an outstanding piece of work this is and I just want to acknowledge his work on this because he really has been the thought leader.

[Applause]

Michael Johnson: At this point we'll go ahead and adjourn. Thank you for coming.