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Governor

STATE OF NEVADA
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**Nevada Medicaid
Drug Use Review (DUR) Board
Draft Meeting Minutes**

The Division of Health Care Financing and Policy (DHCFP) Drug Use Review (DUR) Board conducted a public meeting on January 22, 2015 beginning at 5:30 pm at the following location:

**Silver Legacy
Silver/Gold Room
407 N Virginia St
Reno, Nevada 89501**

Board Members Present:

Paul Oesterman, Pharm.D., Chairman; Dave England, Pharm.D.; James Marx, M.D; Jeff Zollinger, DO; Michael Owens, MD

Board Member Absent:

Chris Shea, Pharm.D.

Others Present:

DHCFP:

Coleen Lawrence, Chief, Program Services; Mary Griffith, RN, Pharmacy Services Specialist; Darrell Faircloth, Senior Deputy Attorney General;

HPES:

Beth Slamowitz, Pharm.D.

Catamaran:

Carl Jeffery, Pharm.D. Account Manager

Public:

Brandon Shaffer, Celgene; Betty Chan, Gilead; Charlie Collin, Gilead; Sergio Gonzalez, Takeda; Brian Hueston; Patrick Moby, Supenus; David Melikhan, Mallinckrodt; Lovell Robinson, Abbvie; Brett Ferguson, Pfizer; Sandy Sierawski, Pfizer; Scott Larson, BMS; Marykay Queener, J&J; Charissa Anne, J&J; Ryan Ley, NV Health Care Guidance; Jane Stephen, Allergan; Jeanette Belz, NV Psychiatric Assn.; Kim Jacoby, Lundbeck.

MINUTES

1. Call to Order and Roll Call

Meeting called to order at 5:30 PM

Roll Call:

Carl Jeffery – Catamaran
James Marx – Las Vegas Pain Management Physician
Michael Owens – Reno Family Physician
Dave England – Pharmacist Las Vegas
Paul Oesterman – Pharmacist Reno
Darrell Faircloth – Senior Deputy Attorney General
Jeff Zollinger – Physician Reno
Beth Slamowitz – HPES
Mary Griffith – Nevada Medicaid
Coleen Lawrence – Nevada Medicaid

2. Public Comment on Any Matter on the Agenda

No Comments.

3. Administrative

a. Review and Approve Meeting Minutes from July 24, 2014

Movement and second to approve the minutes from July 24, 2014.

Dave England: Move to accept the minutes.

James Marx: Second.

Voted: Ayes across the Board.

Approved.

b. Status Update by DHCFP

i. Public Comment – No public comment

ii. Medicaid's overview of the upcoming legislative session – Coleen Lawrence
The Governor gave his State of the State address and released the government's recommendations for the budget to the public. There were no specifics for pharmacy. There is one position in there for pharmacy that we are looking to fill. Everyone works together on the Nevada Medicaid team, but if there are upcoming bills that affect Medicaid, let DHCFP know about them to give us plenty of time to review.

iii. Introduction of new member, Dr. Michael Owens

I'm originally from California. I did my residency in Casper Wyoming. I've recently moved to Reno and am a family practice doctor at the Community Health Center (CHC). I'm married, my wife is a family practice at CHC also. We have 2 children. I've been in Reno for about 4 months.

4. Presentation and Discussion of Nevada's Prescription Monitoring Program

- a. Jenine M. Davis, Pre-Criminal Intervention Officer, Controlled Substance Abuse Prevention Task Force

Everybody knows that prescription drug abuse is a huge problem. I just want to give you an idea of where we stand. Americans comprise about 6% of the world's population, yet we consume 80% of the world's supply of opioids, 75% of the world's oxycodone, and 99% of the world's hydrocodone. In the nation's ranking, Nevada is second in the consumption of hydrocodone, second in the consumption of oxycodone, fourth in the consumption of methadone, and third in the prescription overdose deaths. With a population of 2.7 million people, in one year, 81 million doses of hydrocodone were dispensed. 51 million of oxycodone and 25 million of alprazolam. Everyday youths, aged between 12 and 17 abuse an opioid for the first time. 2,700 use each day. There are more men than women and many more white and Native Americans than other races. Middle aged adults are the highest percent of opioid overdose deaths. People in rural counties are twice as likely to overdose as are people in the cities. In Nevada, this equates to 19.6 deaths per 100,000 people.

These are some of the reasons that we have the prescription monitoring program. So what is it? It is a database that collects information on the controlled substance prescriptions filled in the state of Nevada. The purpose of it is to help identify individuals abusing controlled substances, so they can get help. It was not set up for law enforcement purposes, but to help individuals.

In 1995 and 1996, legislation was passed NRS 453.1545 mandating the Board of Pharmacy and the Nevada Division of Investigation to develop a computerized program to track controlled substances. These regulations made data collection compliance effective in 1997.

We collect, through the prescription monitoring program, data from pharmacies, as well as dispensing practitioners, regarding schedules 2-4, dispensed in the state of Nevada. In the beginning the pharmacies were required to report once a month and now it's required weekly. However, most of the chain pharmacies are reporting every day, just so we have the most accurate, current information. Healthcare providers (er's, urgent care, pharmacies, family practice) can access this information online, 24-hours a day, 7 days a week.

The reports show the patient's name, where they are picking up the medication, the drug name, the date it was filled, the date it was written, and the type of payment. If it was Medicare, cash, or insurance, that is also on the report.

Currently it is not a requirement, or a statute, that each practitioner has to run a report. It says that they shall, under certain circumstances, if there's suspicion, but there is nothing requiring a practitioner to run a patient when they are prescribing.

Questions:

Paul Oesterman, Chairman: I'm very familiar with the program as a practicing pharmacist. Nevada is recognized for this program as one of the leaders in the country. It's great. My concern is what are we doing with the data? We've got great data and lots of it, but obviously

it's not working or we wouldn't be number 2 in the country. So what can be done to make it more effective?

Davis: Currently we have 4,900 users registered to use the system online. We get about 2,000 actively using the system. What needs to be done is the practitioners and the pharmacists need to use the system. The information is there. It just needs to be accessed and looked at.

Paul Oesterman, Chairman: It's not working in a community setting, I'm sure I'll be extremely unpopular with my colleagues, if I were to say what would it take to make it a statute, to make it mandatory that the data be looked at by the prescriber before they prescribe, the pharmacy before they fill, or the emergency department when a patient walks in.

Davis: Currently there is a statute saying basically that if you have any concerns that this patient is doctor seeking, or abusing the controlled substances – I think that is actually going to be brought up in legislature this year. I don't know that it will pass, but I think it is going to be brought up.

James Marx: I think the statute says in the event that you suspect abuse, you are to access the database. There is no requirement before you dispense. It's just when certain behavior presents itself. What's happening now, for example, Walgreen's is using it for every single fill. It goes through a call center and every prescription takes three days to be dispensed, which is a major disadvantage. Collecting data does not stop the abuse potential. The fact that we have so much data is the fact that we do such a good job recording it. On the other hand, we have a lot of opioid overdose deaths, a lot of those coming from Las Vegas, where a lot of those deaths are mischaracterized. The Medical Examiner's office in Las Vegas typically does over 1,000 forensic autopsies a year. The National Association of Forensic Pathologists says that they should do no more than 250. They are not adequately researching the manner, or cause of death as well as it should be done. So there's a lot of issues that really need to be addressed. But I think the one thing that the task force has done very well is provided a way that we can identify doctor shopping, where patients are going to multiply doctors and filing prescriptions, perhaps multiple times in a day, or a week. Now that ERs have access to this, I think that has helped a lot. It has cut down over the last 10-12 years tremendously and we have figures to show that.

One of the other issues is that when we started out, we had filter criteria. We have a lot of data and what happens is, if you didn't set the filter criteria incredibly high, literally 1,000s of people were falling out. It takes 48-hours to follow up on those sifted type of responses. So it's physically impossible, with the meager resources that the pharmacies, Board, and even law enforcement has to follow up on all of these indexed cases.

It's really going to come down to the prescriber community, the dispenser community, to really get a handle on this. The database is not going to go out and nab people.

Davis: No. It's a tool for the prescribers and dispensers to use.

Coleen Lawrence: It's kind of interesting because one of the best practices that we've been noted for is actually the collaboration we've had with the Board of Pharmacy and with Nevada Medicaid. Because it is very restricted on how the data can be utilized, for protection reasons, obviously. We use it in our Lock-In program. We do our own filters on the data. When we find somebody, we send our data over and match it with the Board of Pharmacy and that's how we lock people in to specific pharmacies and specific providers. Maybe looking at enhancing it that way, but allowing different providers the data in a different manner, same as we do. What are our numbers? Our numbers have grown. We don't have enough resources honestly to keep up with our Lock-In program. There's about 777 people in our Lock-In program and that started at about 100. And that is only because we don't have enough resources to keep up with the data mining to put people on the Lock-In program.

James Marx: I have one patient on the Lock-In program who has never been a problem. I don't understand why she's in the Lock-In program because there has never been an issue in 15 years.

Coleen Lawrence: But it might be because of other claims history, other than yours. Because it has to be multiple providers.

Dave England: In essence, this started about 10 years ago and the idea was to get a handle on this. By collecting the data and not doing anything with the reporting, other than through Medicaid – Does the Board of Pharmacy, or the Nevada Department of Investigation look at this data and then send out a letter? If the physician goes online to check a patient, but then continues writing prescriptions for that patient, knowing they are going elsewhere, is there any follow up?

Davis: We do unsolicited reports, which I think Dr. Marx referred to. What happens is that we may get a call from a provider who is concerned. We may get a call from a pharmacy. I do some reports for Northern Nevada. If somebody hits a certain criteria for picking up multiple pharmacies, multiple practitioners, we'll send out a letter to the practitioners and pharmacies within a certain time period to let them know that this person has seen 6 doctors, been to 4 pharmacies, just to make them aware.

We don't monitor prescribers. It's not in our jurisdiction. If someone is having surgery, the doctors are aware of it. We may have someone with mental health medications, as well as pain medications.

Dave England: Have any arrests taken places of either patients, or prescribers, or dispensers, through the data collected in this program?

Davis: I don't know. I know interventions have been done.

Dave England: Ok, not arrests, but interventions. Has anything been done as a result of this data to help the patients.

Davis: Yes. We have a program in the North. I'd have to look at my numbers, but I've done 60-80 interventions, where I meet with people who are doctor shopping and I try to get them help. We are at about 80% success rate. It makes the doctor aware that the patient is doctor shopping. It is up to the doctor whether he/she continues prescribing or not.

James Marx: I've worked with Jenine in the past. I try to get a report every time I have a patient I encounter, so I know if they fill a prescription somewhere else, or if I see something fishy, I make multiple calls to Jenine. She will make a phone call to the patient. That seems to work pretty well.

Jeff Zollinger: You mentioned that pharmacies now can access the database. What is the percentage of pharmacists actually checking the report? You mentioned that the physicians are actually a very small percent that are registered to access the reports. Do all pharmacists have access; are they registered?

Davis: I believe it's about 85% of pharmacies are registered. Some pharmacies have more than one account, some have just one, so it's hard to say.

Jeff Zollinger: I still get phone calls from pharmacists that say "I think this patient has gotten this filled at a different pharmacy." It seems like they would be able to check the report. They would be able to find that out for themselves.

Davis: They should be able to, yes. They should be able to get the same information you are.

Paul Oesterman, Chairman: Unfortunately, I think much of the management of chain pharmacies are saying volume, volume, volume. To do this, takes time. And the pharmacists are caught in that.

Jeff Zollinger: I know it takes time, but I've got a medical assistant who could prep a report within a couple minutes. So it's not that time consuming.

Davis: It's pretty quick. I don't know if anybody here has used the system. It takes a minute or two.

James Marx: A big issue is that they don't want to allow point of sale pharmacies access to the internet, because they don't want them on Facebook, so they have to go through some sort of call center to filter out that non-professional use of access. But yes, you're right, you could probably access it on a smartphone. They just don't want that access because they don't want techs, or the pharmacists checking their email, or whatever. I think that's really been a barrier to adoption in the retail environment.

Jeff Zollinger: I would agree. It seems that right now we don't have enough providers registered, so we're not really checking these reports. I would support an idea where we may get a bit more mandatory where physicians who are going to be prescribing opioids on a long term basis, there should be language in there that says if you're going to provide narcotics on a long-term basis, you need to be registered.

Davis: I believe that would be up to the Boards. We have jurisdiction over the controlled substances.

Mary Griffith: Is there any possibility of getting this information linked? We have a lot of people who go from here to California and back. It would be nice to have.

Carl Jeffery: Especially Vegas, we've got 4 states within an hour's drive.

Davis: We are currently working on linking 17 states right now. California does not have the ability to link their data with ours yet. It's probably going to be a ways off.

Coleen Lawrence: I think what the Board is saying is – This is a federally mandated Board for Nevada Medicaid. The Board has a very strong interest in promoting the use of this registry. As the session proceeds and as you have any type of active analysis that comes on any BDRs, let me know. Directly contact me to find out what is going on. That way I can find out what the stance is from behind the scenes from the Board. That way, from the Division standpoint, we can put what the Board's statement is and what their stance may be – in support, opposition, or neutrality on your analysis, so we can support the Board of Pharmacy on issues you may have with the registry. Because if it's sharing of data, or the drug task force, you'll come across a lot stronger if you have a report from the DUR Board.

Jeff Zollinger: Another way to utilize the information is for each physician to print out their own prescribing record. There are quite a few physicians that don't ever prescribe narcotics, but somehow people have gotten a hold of their numbers and have called in a prescription and they are totally unaware. It's prudent that physicians are aware that people can call in prescriptions, or try to fill medications using their DEA number for prescriptions. So checking your own report, or your own prescription history, is pretty important.

Davis: For the Dental Board, it is now regulation that they check theirs annually just for that reason.

Coleen Lawrence: Doesn't the Dental Board require all of the dentists to enroll in the registry, or participate? Isn't that why they have such a high participation?

Davis: Yes.

James Marx: All physicians were required to enroll. Enrolling doesn't mean you'll use it.

Davis: Correct.

Dave England: Would it be possible, and I don't know that we have the technological ability, or not, but a lot of prescriptions can't be hand written anymore. Is there any way, when a drug is being e-prescribed, that that drug is automatically linked in and then you can follow it back to the dispenser, or the pharmacist?

Davis: At this point, I don't think so. The way the system is set up, it would require every doctor's office be linked up. But I could ask about that.

Paul Oesterman, Chairman: Is there a way to look at those patients that get prescriptions under Medicaid that are also paying cash for large quantity prescriptions? We know it happens.

Davis: At this point, we don't have that ability. We are getting some new reports coming in. I don't know that that is one that we can pull, but if you were to ask me again in a month, I would know.

5. Clinical Presentations

Chairman Oesterman recuses himself from voting and leading the discussion due to possible conflict of interest. David England stands in as temporary chairman.

- a. **For Possible Action:** Discussion and proposed adoption of updated clinical prior authorization criteria for sofosbuvir (Sovaldi®).
 - i. Public comment on proposed clinical prior authorization criteria. – No comment.
 - ii. Presentation of utilization and clinical information.

Carl Jeffery – There has been a spike in Sovaldi that you can see (in presentation). We have the criteria that we approved at the April 24, 2014 meeting. We are not proposing any changes, but I think we are getting some pressure from the administration to bring this back up before the Board to maybe add some additional criteria because there are some other states with pretty strict criteria. For example, Oregon has criteria that has a once-in-a-lifetime treatment option. So if they're re-infected, they are just out of luck. They also have a requirement that they are almost to the end stage with liver disease before getting treatment. They also have requirements for drug testing and alcohol testing to make sure these patients are clean while they are on therapy. My personal feeling is that I don't think these are a benefit to our recipients or the State. No changes proposed. To be honest, these are expensive agents. They have PA criteria, so we are verifying that they are being used appropriately according to the current Chapter 1200 criteria.

Coleen Lawrence: As you can imagine, this drug has hit every press article possible. What's happened is that it has hit everybody's list serve within our Division, within our Department. We turn on the nightly news and it's on there. It's propaganda at its best right now. So we've been asked to bring it back to the DUR Board to assure that we are clinically, appropriately reviewing this criteria, in the most quality and cost effective and efficient manner. Obviously we had the World Health Organization document that came out the same month that we first reviewed, which I believe was April, 2014. They released their recommendations based upon best practices on how to treat the recipients with Hep-C. We know the pipeline drugs are going to come out. This is going to be a continual discussion that we're going to have for years to come. We've known this was going to hit us. This is not the last discussion we're going to have. We're just asking you to review it, look at the total picture.

Dave England, Chairman: The recommendations that we are following are the recommendations by the AASLD. If we are following that criteria, I don't know how much more scrutiny we would want to give it. I can see the rational for the "once in a lifetime" dose. If we get someone cleaned up, so to speak, and they go back and get re-infected due to lifestyle, or whatever the case may be, we might want to consider that limitation on it.

Coleen Lawrence: So some of the states have done things like the "once in a lifetime". That is more of an ethical, social issue that you'll have to cross that bridge when you come to it and make that decision. There's also duration treatments. Do you want to, instead of giving all of the treatment, and allowing for one year prior authorization, and I'm saying this hypothetically, do we want to allow a 14-day trial and try it from a compliance standpoint. That is one approach that some of the states have looked at. Do we want to make sure that there is adherence to the treatment first, versus allowing a check back with the physician? That's one approach that some of the states have taken. Instead of being a more social type approach, it's more of a compliance to medication type of issue.

iii. Discussion by the Board and review of utilization data.

Dave England: In essence, we're probably not going to have the answer tonight.

Carl: I don't know that we necessarily need that decision tonight. It's just for the Board to review.

Coleen Lawrence: Well, you could do the quantity, absolutely, if you guys want to more of the compliance type route.

Carl Jeffery: It's hard to mandate compliance with these patients. Because even though they claim they are tolerating it ok, we can't force them to take it every day.

Dave England: At the same time they keep coming back because they are getting worse, but they aren't compliant. What's the rational for continuing to provide medication when the medication's there, but it's not being utilized properly? Why continue with it?

Carl: Especially if we have some patients, I think we've seen these, were they are prescribed Sovaldi and the ribavirin. Well the ribavirin, apparently gives them horrible side effects. So they are just taking Sovaldi, which is setting them up for failure. We certainly don't want to see that, but I think that is where they are going. So maybe there needs to be rules put in place where they have to renew every month, or in 20 days, so that the call center can check and say yes they picked it up. But even though they are picking it up at the pharmacy, we can't guarantee they are taking it.

Beth Slamowitz: Just to give you guys the big picture view, for the month of December alone, the three Hep-C drugs that are out there constituted 13% of the pharmaceutical expenditure for that entire month. That constitutes roughly 100 patients.

Carl: And we haven't seen the new (Hep-C drug on the market) yet.

Beth: Which would be a fourth.

Dave England: I'll put the spotlight on Dr. Owen. Having seen some of these patients in your practice, what would you feel about recommendations to require compliance? Would that be beneficial for your practice?

Owen: Just in the 4 months that I've been here, I have 10 patients with Hep-C. You're probably looking at 200 patients in our entire population that are Hep-C positive. You have to weigh several things. Here is a disease that was very difficult to treat where the cure was more deadly than the disease in the past, and now all of the sudden these medications have come out that have little to no side effects, but the price tag is so great. You will break the system. It kind of becomes an argument of what is the percentage of these patients that are going to progress to end-stage liver disease or hepatocellular carcinoma? What is the risk of passing this disease and how is that going to grow? It's not an easy argument.

Dave England: My recommendation is to continue with our criteria that we have right now and then have another look at the data and then try to differentiate which patients are going to show improvement and which ones aren't and which ones are going to comply.

iv. Proposed adoption of updated prior authorization criteria.

James Marx: Motion to accept 2 week initial fill for this class of drugs.

Michael Owens: Seconded.

Voted: 4 Ayes.

1 Abstain.

Motion Passes.

b. **For Possible Action:** Discussion and proposed adoption of prior authorization criteria for ledipasvir-sofosbuvir (Harvoni®)

i. Public Comment on proposed clinical prior authorization criteria.

Betty Chan – Gilead Sciences – Commented about a quantity limit for consideration. We saw quantity limits with the VA criteria. The goal was to look at adherence and compliance, but ultimately the VA took that out because it caused some adherence issues due to delaying treatment by getting the lab test and then getting the drug dispensed and PA criteria issues. But outside of that, how do you test for adherence? You can do pill counts. In clinical trials we do pill counts. There's no drug level testing that is commercially available. In clinical trials, we

test to see if patients have the drug level in their system. There is no commercially available way to do that. The only way to see is to check if their viral load has become undetectable in two weeks. If it's not undetectable, you could say maybe they are not taking their drug, but depending upon how high you start, it might take you longer to get there. Aside from that, the AASLD came out with guidance on who to treat first if you are budget constrained, but it also said to check the viral load at week 4, but a decision regarding whether or not to stop treatment should not be based on that. No severe side effects for this drug. The label also suggests to not split the bottle. Stability testing was not done for the drug outside the bottle. So you need to dispense one whole bottle at a time. That is why a lot of payers did go back on that.

Carl Jeffery: Is there something special about the bottle?

BC: No, it is just the testing wasn't done to make sure it was stable in other bottles. The label states to not split the bottle.

Dave England, Chairman: But we really have no idea how that medication is going to be stored at home.

BC: Also with getting levels, many payers are taking that out of the criteria because it does not impact duration of treatment. The AASLD recommends getting a viral load at 4 weeks, but they say to not alter treatment based on that level.

Paul Oesterman: The expiration dates are based on the bottle stored in controlled conditions.

BC: For the clarification of the Harvoni criteria, under 1D, it states there is a clinically appropriate reason why the recipient cannot or should not use the preferred alternative.

Jeff Zollinger: What are the side effects with this medication?

BC: They are nonspecific, and very low.

ii. Presentation of utilization and clinical information.

Carl: In the first three months, the claims we have sky rocketed. We're seeing a lot of utilization. It has only been approved for type 1 which is the most common in the United States.

Dave England: If it has only been approved for type 1, is it also being used for types 2-4, and if so, how are we rationalizing coverage?

Carl: The call center handles these questions and uses this criteria. The call center hasn't reported any issues with the drug only being utilized for type 1. Other than the Claims data, there is no way for us to know for sure.

- iii. Discussion by the Board and review of utilization data.

Board Member: For utilization, would we want to put the same two-week requirement on this as we did on Sovaldi?

Carl: I would recommend on the criteria item 1d, that the Board strike that criteria for preferred agent.

- iv. Proposed adoption of updated prior authorization criteria

Motion to accept 2 week initial fill for this class of drugs.

Seconded.

Voted: 3 Ayes, 2 abstain.

Motion Passes.

Paul Oesterman is reinstated as Chairman for the remaining of the meeting.

- c. **For Possible Action:** Discussion and proposed adoption of updated clinical prior authorization criteria for simeprevir (Olysio®).

- i. Public comment on proposed clinical prior authorization criteria.

Mary Kay Queener – Scientific liaison with Johnson & Johnson

The most recent guidelines don't recommend combining with peg/riba. The recent label update to Olysio is to approve the combination of sofosbuvir and simeprevir based on a Phase II clinical trial. This combination is now in the PI – 1 tablet of each product, once daily for 12 weeks – non cirrhotic / 24 weeks for cirrhotic.

The other two protease inhibitors in the PA criteria are no longer on the market, so that should probably be addressed.

- ii. Presentation of utilization and clinical information.

Carl: We have a utilization spike. We were asked to bring this back up before the Board to make sure that we are keeping on target with appropriate criteria. No proposal for changes.

- iii. Discussion by Board and review of utilization data.

Paul Oesterman, Chairman: Since the other two drugs have been taken off the market, should we remove them?

Carl: It almost makes sense to leave them in because it doesn't hurt to have them there in case of drug resistance.

Paul Oesterman, Chairman: We have no new criteria to approve.

- iv. Proposed adoption of updated prior authorization criteria.

Dave England: Motion to accept 2 week initial fill for this drug combination with Peg Intron and Ribavirin.

Michael Owens: Seconded.
Voted: Aye across the Board.
Motion Passes.

d. **For Possible Action:** Discussion and proposed adoption of updated prior authorization criteria for Oxycodone w/acetaminophen tab CR (Xartemis XR®)

i. Public Comment on proposed clinical prior authorization criteria.

David Malicky – Director of Medical Affairs for Mallinckrodt Pharmaceuticals
This is a unique product – immediate release component and an extended release component. One tablet has 7.5 mg oxycodone and 325mg acetaminophen. When the drug is taken, 25% of the oxycodone and 50% of the acetaminophen is released and then over the next 11 hours, you get 75% of the oxycodone and the remaining 50% of the acetaminophen. The dosing is every 12 hours. There is an abuse deterrent in the formula. We're working with the FDA to get it on the label. Post-operative administration is the goal.

Paul Oesterman, Chairman: One question, does crushing lead to immediate release?
DM: If they crush it, it mixes and still has a slow absorption over two hours.
Alcohol actually slows the release of the product as well.

Dave England: Question about combo with OxyContin. Is it recommended to be given before a procedure?

DM: This has a fast acting product, so this can be used immediately post operatively.

ii. Presentation of utilization and clinical information.

Carl: For recipients 18 years and older and current diagnosis of acute pain. The quantity does not exceed 20 tablets for a 5 day supply, one 5 day supply per 6 months.

iii. Discussion by the Board and review of utilization data.

James Marx: Suggests this may not be long enough treatment for some surgeries.

Paul Oesterman, Chairman: Current proposal:

1. Recipient is 18years old or over
2. Current diagnosis of acute pain
3. Quantity does not exceed 60 tablets for 15 days supply, one 15 day supply is allowed every 6 months with one refill. More than two fills of a quantity of 60 each requires prior authorization within 6 months. PA is good for 6 months.
- 4.

iv. Proposed adoption of updated prior authorization criteria.

Jeff Zollinger: Motion to approve the 3 criteria for Xartemis XR.

James Marx: Seconded.

Voted: Ayes across the Board.

Motion Passed.

- e. **For Possible Action:** Discussion and proposed adoption of updated prior authorization criteria for apixaban (Eliquis®)

- i. Public Comment on proposed clinical prior authorization criteria.

Sandy Sorofsky – Pfizer Medical Division – requested the prior authorization criteria be reviewed due to new FDA approved indications. FDA approved this drug for treatment of DVT and PE and for the reduction of recurrent DVT and PE following initial therapy and also for prophylaxis of DVT and PE in patients who have gone through hip replacement surgery.

Paul Oesterman, Chairman: How does Eliquis compare in indications with Xarelto and Pradaxa?

SS: I don't have the others indications at my fingertips, but they are similar. All are good for Afib and treatment of DVT/PE, but I'm not sure about the prophylaxis. We do not recommend use with prosthetic valves because it has not been studied.

- ii. Presentation of utilization and clinical information.

- iii. Discussion by the Board and review of utilization data.

- iv. Proposed adoption of updated prior authorization criteria.

James Marx: Motion: For all of the new oral anticoagulants approval will be given to the following criteria: Diagnosis code transmitted on the pharmacy claim is associated with the FDA approved indication and there are no contraindications to the medication.

Dave England: Seconded.

Voted: Ayes across the Board.

Motion carries.

- f. **For Possible Action:** Discussion and proposed adoption of updated clinical prior authorization criteria for the immunomodulator class of medication.

- i. Public comment on proposed clinical prior authorization criteria. – None

- ii. Presentation of utilization and clinical information.

Carl: Two preferred agents are on the top of the list. What brought this before the Board is the addition of the Entyvio.

iii. Discussion by Board and review of utilization data.

iv. Proposed adoption of updated prior authorization criteria.

Dave England: Motion: Approve the addition of vedolizumab to the list of immunomodulator in our current format.

James Marx: Seconded.

Voted: Ayes across the Board.

Motion carries.

g. **For Possible Action:** Discussion and proposed adoption of updated clinical prior authorization criteria for transdermal fentanyl.

i. Public comment on proposed clinical prior authorization criteria. – None.

ii. Presentation of utilization and clinical information.

Carl: We're adding criteria to make this a bit easier to use. The criteria on these are so strict, that it might be pushing people over to drugs with more potential of abuse.

iii. Discussion by Board and review of utilization data.

Board Member: If we stick with the black box criteria, we should be covered.

Board Member: In the interest of time, we have the proposed criteria in front of us, the black box warning, we encourage prescribers check with the Board of Pharmacy PMP system. Then if transitioning, we have the recommended dosage guidelines. And then we are eliminating the addition of 1-C.

Carl: I updated it to make it a 12 month approval instead of a 6 month approval.

iv. Proposed adoption of updated prior authorization criteria.

Dave England: Motion: To approve the updated criteria

James Marx: Seconded.

Voted: Ayes across the Board.

Motion carries.

h. **For Possible Action:** Discussion and proposed adoption of updated clinical prior authorization criteria for palivizumab (Synagis®).

i. Public comment on proposed clinical prior authorization criteria.

Public comment from Dr. Nakamura – Infants born after 32 weeks, may not require prophylaxis. Previously we were able to treat babies born between 32 weeks and 35 weeks, but now due to a change in criteria, we are no longer able to treat these patients. Infants born between 29 weeks and 31 weeks are still at very high risk. The data shows similar hospitalization for these infants. The proposal is to treat babies under 6 months of age at the start of RSV season, namely babies in the category born after 05/01/14. The letter goes on to state that due to the higher elevation,

babies born between 32 and 35 weeks that do develop lung disease and who do go home on oxygen should be prophylaxed. They agree with the AAP guidelines for babies with lung disease and congenital abnormalities.

ii. Presentation of utilization and clinical information.

Coleen Lawrence: To remind the Board and public, with Synagis season starting, we've had an interim emergency Board meeting to catch the RSV season prior to starting, where we adopted the new AAP guidelines. The Synagis policy has a one-liner that reads prior authorization may also be submitted with supporting medical documentation. It was a safety net clause for the criteria.

After the last interim emergency Board meeting, we received the public comment from Dr. Nakamura. (Read aloud)

We will keep the overrides to those guidelines in our office and so far for the season, we've had 19 overrides. That is for the whole Fee For Service population.

Carl: We brought this back up because at the time there was concern from the public to review the guidelines. No proposed changes just discussion.

iii. Discussion by Board and review of utilization data.

iv. Proposed adoption of updated prior authorization criteria.

6. DUR Board Requested Reports

a. Report on Top 10 Black Box warning medications:

i. Public comment on Black Box warnings.

ii. Discussion by the Board and review of utilization data.

Board reviewed and made comments on interesting trends seen on the list.

Carl: Next DUR Board meeting there will be a report that breaks the data down by age.

b. Report on controlled substance utilization and trends.

i. Public comment on controlled substance utilization and trends.

Carl: No big shift of agents.

ii. Discussion by the Board and review of the utilization data.

c. Report on psychotropic drug use in children.

i. Public comment on psychotropic drug use in children. – Dr. Leyr from Westhills – There has never been a single study done that linked causality of suicide with antidepressants. Several studies show that when people are in treatment and taking

medication, they are far less likely to commit suicide or self-harm. Over prescribing of psychotropic drugs in children is a huge problem.

- ii. Discussion by the Board and review of utilization data.

A request was made from the Board to drill down into the details of the report to see if these drugs are being given long term.

Also requested off label use.

We're looking at what other states are doing for assuring that these drugs are being used appropriately. If they are using the drugs as an off label, why?

- d. Report on buprenorphine and buprenorphine/naloxone use.

- i. Public comment on buprenorphine and buprenorphine/naloxone use.

- ii. Discussion by the Board and review of utilization data.

Nothing to add here.

- e. Report on Nevada Medicaid Lock-in Program

- i. Public comment on Lock-in Program.

- ii. Discussion by the Board and review of utilization data.

Before we lock-in a recipient, we'll take a snapshot of their medications and what we are spending on them and then every month after that, we'll see how much they are utilizing. There is more than enough ability to add more recipients into the Lock-In program. 15-20 people being added a month.

- f. Report on Asthma treatment utilization.

- i. Public comment on asthma treatment utilization.

- ii. Discussion by the Board and review of utilization data.

We identified recipients that have been admitted to the hospital and have asthma. Then we took a look at their medications. We're not sure if the hospitalization is due to asthma attack, so this could be skewed. Some on the list have no asthma medications.

Board: Can we run a report for next time on outpatient asthma medication use to see if patients are using just one time, or if they are getting them on a regular basis.

- g. Report on Tussionex Utilization.

- i. Public comment on Tussionex Utilization.

- ii. Discussion by the Board and review of utilization data.

Carl: Not too many claims on here for Tussionex.

7. Standard DUR Reports

- a. Review of Prescribing/Program Trends.

- i. Top 10 Therapeutic Classes for Q2 2014, Q3 2014, and Q4 2014 (by Payment and by Claims).
 - ii. Top 50 Drugs of Q2 2014, Q3 2014, and Q4 2014 (by Payment and by Claims).
- b. Concurrent Drug Utilization Review (ProDUR).
- i. Review of Q2 2014, Q3 2014, and Q4 2014.
 - ii. Review of Top Encounters by Problem Type.
- c. Retrospective Drug Utilization Review (RetroDUR)
- i. Public comment on Retro DUR.
 - ii. Status of previous quarter.
 - iii. Status of current quarter.
 - iv. Review and discussion of responses.

8. Closing Discussion

- a. Public comments on any subject.
None.
- b. Date and location of the next meeting.
April 23, 2015. Location TBA.
 - i. Discussion of the time of the next meeting.
- c. Adjournment.

Meeting adjourned at 8:46 PM.