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DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
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DRUG USE REVIEW BOARD

Draft Meeting Minutes

Date of Meeting:	**Thursday, September 3, 2015 at 5:30 PM**
Name of Organization:	**The State of Nevada, Department of Health and Human Services, Division of Health Care Financing and Policy (DHCFP), Drug Use Review Board (DUR).**
Place of Meeting:	**Best Western Plus Airport Plaza Hotel** **1981 Terminal Way** **Reno, NV 89502** **Phone: (775) 348-6370**

Committee Members Present: James Marx, MD; Jeffrey Zollinger, DO; Michael Owens, MD; Paul Oesterman, Pharm.D.

Committee Members Absent: Chris Shea, Pharm.D.; David England, Pharm.D.

Others Present:
DHCFP: Coleen Lawrence, Chief, Program Services; Mary Griffith, RN, Pharmacy Services Specialist; Darrell Faircloth, Deputy Attorney General

HPES: Beth Slamowitz, Pharm.D.

OptumRx: Carl Jeffery, Pharm.D.; Kevin Whittington, R.Ph.

Others: Krystal Joy, Otsuka; Jennifer McKay, MD; Jeanette K Belz, NPA; Lisa Allen, Vertex; Gregg R, Vertex; Lisa May, Renown; Gregg Gittus, Alkermes; Thomas McCrory, MD, HCGP; Daniel Fry, HPES; Joe Haas, Washoe County Juvenal Services; Denis Rikalo, Renown; Sergio Gonzalez, Takeda; Kerry Kostman Bonilla, AZ; Kim Coppom, AZ; Tom O'Connor, Novartis; Corinne Glock, Relypsa; Samantha Min, Otsuka; Melissa Walsh, Novartis; Ryan Ley, MD; Marta Jensen, DHCFP; Matthew P; Katherine Thomas, UNR; Norton Roitman, MD

1. Call to Order and Roll Call

Meeting called to order 5:31PM – no quorum, start in the interest of time, without any voting.
Roll Call:
Carl Jeffery, OptumRx
James Marx, Pain Physician, Las Vegas
Jeff Zollinger, Pain Physician, Reno
Paul Oesterman, Pharmacist, Chairman, Reno
Darrell Faircloth, Deputy Attorney General's office
Kevin Whittington, OptumRx
Beth Slamowitz, HP
Mary Griffith, DHCFP
Coleen Lawrence, DHCFP

2. Public Comment on Any Matter on the Agenda

No comment.

3. Administrative

Coleen Lawrence: DHCFP now has a new administrator, Marta Jensen.

ICD-10, this has been a long project for us. October 1, 2015 is the implementation date. It will affect prior authorizations that can be bypassed at the pharmacy counter if the correct diagnosis is on the prescription. We have been working with prescribers and pharmacies to assure utilization of ICD-10. This is date of service based and will be only running ICD-10, not both.

We have a new reimbursement methodology. We are working with the pharmacy association. The new NADAC pricing and the new dispensing fee has been approved by CMS and will be effective November 1, 2015.

Dr. Owen joins the meeting at 5:37 PM providing a quorum.

Paul Oesterman, Chairman: I need a motion and second for approval of meeting minutes.

James Marx: I move to adopt the minutes as submitted.
Jeffrey Zollinger: Second.
Vote: Ayes across the Board, motion carries.

a. Review submitted Annual DUR Report submitted to CMS.

Carl Jeffery: There is the Annual DUR Board, submitted on June 30, 2015 in the binders. It reports standard information on the actions of the DUR Board. The questions in the report take into account the drug interactions, for example, the Pro-DUR edits. Toward the end of the

report there are on questions on initiatives taken by the Board. When it is available I will present the final report from CMS to the Board.

Paul Oesterman, Chairman: Are there any questions regarding the current report or next year's report.

Jeffrey Zollinger: How many other states actually require Board certification for pain management?

Carl Jeffery: It will be reported on the annual report next year when all the information from other states are rolled up, that information is not currently readily available.

James Marx: On question 80, paragraph C2, regarding checking prescriber DEA registrations prior to authorizing prescriptions. ..

Carl Jeffery: No, there are not any checks on DEA numbers in the system, the responsibility is up to the pharmacy, claims are processed with prescriber NPI.

2. Board Action

a. **For Possible Action**: Discussion on Psychotropics for Children and Adolescents prior authorization criteria and prior authorization form

Norton Roitman, MD: Child psychiatrist. The literature requirement will not accomplish what the intent is, which is to make psychiatrists more aware of what they are doing and that it is scientifically authorized. This will result in a certain number of articles that are found and will routinely be attached to prior authorizations, adding to the barrier and it will be a further disincentive to see Medicaid clients. I recognize this is problem. I suggest a public education campaign. If public was more informed about appropriate use, then the concenter would be armed and support the discussion they would have with the prescriber. Focusing on the provider won't affect the change.

Dr. Sorenson (via phone): I suggest a practice guidelines list. I have started one that is available if needed. There are no trials to support the use of these medications in children. The Board certified psychiatrists are aware of the dangers of the use of these medications. I believe in good intentions, but I want it to be instructive but not obstructive. I would rather spend time with the family rather than filling out a two page form. I have to spend time getting two extended release ADHD medications from the call center when the recipient has been stabilized for several years. I don't want to be pushed out of seeing children because of paperwork. I will put together a list of articles and practice parameters, but I don't want to spend 10 minutes filling out paperwork and on the phone with a pharmacist.

Jenny McKay: Child psychiatrist. FDA approval is supported by the manufacturer and there are not a lot of good randomized trials in children.
She read a consensus paper from Dr. Coffey from April 23, 2015.

Dr. Sorenson: There is peer-reviewed literature for just about everything that is commonly used in children, and that can be put together. But is this the same authorization required of nurse practitioners?

Paul Oesterman, Chairman: That question will be addressed shortly. One comment about cost containment, we are a drug use review Board, cost is not the primary focus.

Brian Ley: Child and adolescent psychiatrist. It is good to divide 0-5 and 6-18 and have approval for one medication is good. Literature errors and scandals about literature are becoming more common. The requirement to fail two medications independently, is difficult and not clinically good practice.

Coleen Lawrence: This policy began in 2009, it was modified in 2011, we've had active discussion in multiple meetings since then. After the April 23, 2015 DUR meeting, on May 1, 2015 we reverted back to the old form. On May 28, 2015 we held a workshop with practitioners and the industry. From that workshop, we drafted a new PA form and policy. Since then, we sent out two e-mail correspondences. The first on July 30, 2015 with draft policy and the PA form, the second August 25th with another version of policy with a few tweaks. The intent of the draft policy, is to modify classes to clarify classes, mood stabilizers, combine lithium preparations and anticonvulsants into one, not applying these for seizure disorders and also excluded ADD/ADHD drugs. Single therapy protocol was proposed, we removed PA criteria on single therapy for 6-18 year olds. We continue to PA 0-5 year olds with single therapy for psychotropic medications, that seemed to be the consensus. For the FDA indication and/or peer reviewed literature we will ask Dr. Sorenson to provide details, for an educational site on the web.

Dr. Sorenson: Who will decide what is relevant?

Coleen Lawrence: Dr. Nussbaum will help.

Dr Sorenson: Include me on future email communication.

Coleen Lawrence: We will go through an education route so everyone has the same information, and keep in mind it is only for 0-5 year olds. The second area was poly-pharmacy. The definition was discussed in detail and defined in the proposed policy as intra and inter-class poly-pharmacy. Intra-class is two or more drugs in the same therapeutic class, inter-class will be four or more in different classes. Allowing for cross-tapering, but we may need to work on some of the language. Continuity of care is a focus. We modified the language to make sure institutional and children already stabilized but new to FFS system do not have disruptions. We will continue the exceptions for anticonvulsants for seizure disorders and under the care of a neurologist and ADD/ADHD drugs are excluded at this time. Some states have separate forms for 0-5 and another for 6-18 and we also have one form for all children under 18, both draft forms were presented to the Board with the proposed policy.

Paul Oesterman, Chairman: Where does a five and a half year old fall?

Carl Jeffery: Should be less than six, they would be 0 – 5 year olds.

Paul Oesterman, Chairman: The Board has the proposed criteria. Do I have any comments from the Board.?

Jeffrey Zollinger: What about a limited supply while the recipient is going through the process?

Carl Jeffery: A 96 hour override is allowed to give time for the prescriber to get a PA submitted.

Coleen Lawrence: Recipients discharged from an institution will get a 6 month supply approval to give them time to follow up with a local provider.

Carl Jeffery: For the proposed criteria, the claims data from the last two months shows that 0-5 year olds will still always need PA, 97 recipients age 6 to 12 who have two or more agents in the same class. Recipients 13to 18 years old, 225 recipients will require PA. From the provider standpoint, this is a win.

Paul Oesterman, Chairman: The comments from the forums has been incorporated into the policy. One of the concerns presented is the documentation of the studies. Can we work with the medical schools to provide this so providers don't have to supply it every time, and the call center could retrieve it?

Jeffrey Zollinger: "When possible be prescribed or in consultation with psychiatrist?..."

Carl Jeffery: That was included to cover our rural areas with limited access to psychiatric providers.

Coleen Lawrence: The policy was created to allow a comprehensive plan, not just the treatment with medications. The DUR Board stated "if possible" to have a psychiatrist, but did not want to mandate it. Like other criteria, we use the word, "Encourage".

Jeffrey Zollinger: If there are enough child psychiatrists in Reno and Las Vegas, so that doesn't just mean rural areas, that means here in Reno and Las Vegas too?

Coleen Lawrence: Psychiatry should not be required because of access issues for some recipients.

Beth Slamowitz: Most claims are by psychiatrists, but if it is limited, you may have an access to care issue.

Paul Oesterman, Chairman: I need a motion to approve the policy for 0-5 years old.

Jeffrey Zollinger: Motion.

James Marx: Second.

Vote: Ayes across the Board, the motion carries.

Paul Oesterman, Chairman: I need a motion to approve proposed criteria for ages 6-18. There appears to be a difference from what is in the policy, section D # 5 – the recipient must fail a trial of

each individual agent alone, the reasons for failure must be documented in the medical record. The prior authorization has different verbiage and it says, "Multiple agents within the same class (intra-class), the recipient must have a trial of each individual agent alone, the recipient has inadequate response to monotherapy." The verbiage in the policy is a little more restrictive and I think we want to provide the option for the treatment failure.

James Marx: Motion.

Michael Owens: Second.

Jeffrey Zollinger: Poly pharmacy under D, should the exception be if one medication is used as a sleep agent as was mentioned before if they are taking two or more of say an antidepressant when one is being used as a sleep agent?

Beth Slamowitz: The form gives room to justify the additional agents, if two agents in the same class and one is being used for sleep, there is room to justify.

Jeffrey Zollinger: Where does it say that?

Carl Jeffery: The PA form, the policy should be close to the PA form, under B where it states the medication is used to augment the effects of another psychotropic agent.

Beth Slamowitz: The criteria states it as well under poly-pharmacy number four, it does talk about augmentation.

Coleen Lawrence: It is allowed.

Jeffrey Zollinger: It's not so much augmenting it, but using it for a different indication.

Beth Slamowitz: That falls under where each medication has to treat a separate indication and diagnosis and that is under the coverage and criteria. Under poly pharmacy it states each medication prescribed must be independently treating a specific symptom or diagnosis. On each PA form, it provides space to indicate which drug is being used for each indication.

Jeffrey Zollinger: So as long as the medication treats something individual, it is not considered poly pharmacy?

Beth Slamowitz: Treating a separate indication is justified.

Coleen Lawrence: The language on the PA form works, but it is more liberal than what is in the policy, there should not be a disconnect once we leave the meeting, it should be consistent.

Vote: Ayes across the Board, the motion carries, forms have been approved.

Paul Oesterman, Chairman: There is also the revised policy with the changes to make it easier for the single agent. Where it says each individual must fail a trial of each individual agent alone, that

has been amended to match the language on the prior authorization form. We need a motion to approve the policy that goes along with the prior authorization forms as amended.

James Marx: So moved.

Jeffrey Zollinger: Second.

Vote: Ayes across the Board, the amended policy is approved.

Question from audience: When will this be in effect?

Coleen Lawrence: Chapter 1200 must be modified, so another hearing will be scheduled.

b. **For Possible Action**: Discussion on Lock-in Program proposed changes to criteria

Item tabled due to time constraints.

3. Clinical Presentations

a. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria for Ivacaftor (Kalydeco®)

Lisa Allen, Vertex Medical Affairs: Requested Kalydeco be approved down to age 2 years old.

Proposed changes discussed.

Carl Jeffery: The only change is the age from 6 years old to 2 years old because it is a new FDA approved indication. The quantity limits are also included, 56 tabs per 28 days or 56 packets for 28 days.

Lisa May, social worker at Renown: I supports the age change to 2 years old.

Coleen Lawrence: There is a letter included in meeting material.

Jeffrey Zollinger: Is there a reason not to lower the age?

Coleen Lawrence: It is FDA approved down to that age.

James Marx: I move to approve revised PA criteria.

Jeffrey Zollinger: Second.

Vote: Ayes across the Board, the proposed criteria passes.

b. **For Possible Action:** Discussion and possible adoption of updated prior authorization criteria for medications for the treatment of onychomycosis.

Paul Oesterman, Chairman: Do we have public comment?
None.

Carl Jeffery: Pharmacy student Alex Zorn will present clinical information to the Board.

Alex Zorn: Provides background of onychomycosis and common treatment options.

Carl Jeffery: The criteria is being updated to include FDA approved indications. The requested length of therapy is appropriate. I added to itraconazole that they do not have heart disease, oral granules require clinical rationale vs. a solid tablet form, topical dosage forms require evidence of inadequate response or contraindication with ciclopiriox solution and the oral route.

Paul Oesterman, Chairman: The benefits of terbinifine outweigh the benefits of the topical, to use step therapy.

Carl Jeffery: To get any form of topical, they need to fail an oral form.

Coleen Lawrence: The Board can use step therapy as long as it is based on clinical decision, not cost. The Board does have the ability to consider cost, but when doing step therapy, it must be based on clinical rationale.

Paul Oesterman, Chairman: I have concerns with lack of efficacy with the newer topical agents.

Coleen Lawrence: Any clinical rationale you may have.

Carl Jeffery: The cure rates are so much better with the oral agents.

James Marx: What about drug interactions, they are pretty fierce.

Carl Jeffery: They are, and that would fall to the contraindication. Also consider compliance with the topicals, typical recipient won't be able to apply on their own.

Michael Owens: Does it make a difference if the toe nail is just removed? Removing the bed and then beginning treatment?

Alex Zorn: In some case studies, most nails removed had return of fungus if not treated. The fungus will come back in 100% of the cases, removing does help with pain and appearance. Oral treatment at the same time does help.

Jeffrey Zollinger: Is a positive stain and culture and necessary?

Michael Owens: I don't use anything, no time or inclination, I choose Lamisil.

Paul Oesterman, Chairman: Should we eliminate B out of the criteria?

Michael Owens: Yes, I don't see a lot of mistreatment.

James Marx: I don't think it is necessary and it isn't a requirement.

Jeffrey Zollinger: I suggest removing that whole statement about the testing.

Paul Oesterman, Chairman: So revised criteria with the removal of 1. B., everything else is the same.

Michael Owens: Moved.

James Marx: Second.

Vote: Ayes across the Board, the criteria passes.

c. **For Possible Action:** Discussion and possible adoption of prior authorization criteria for sedative/hypnotic medications.

Paul Oesterman, Chairman: Any public comment?
None.

Carl Jeffery: A few new products on the market prompted the review. Utilization trends are presented in the binders, broken down by age. I suspect alprazolam and diazepam for seizure. Adults use more of the zolpidem and there are just a few claims for Belsomra. The criteria calls out Heltioz because of a different indication. Quantity limits are also present on the criteria.

Mary Griffith: Under 2B, the injection, would be a NVPAD drug only. Should we make that a PA?

Carl Jeffery: Would midazolam ever be dispensed by an outpatient pharmacy? Should this be restricted for all point of sale?

Paul Oesterman, Chairman: Yes, I think so.

James Marx: Branded alprazolam is costly.

Carl Jeffery: They got the ok to get the brand name, they tried two different generics.

Coleen Lawrence: We will have to put it on the policy that injection is not allowed.

Paul Oesterman, Chairman: Can we take a look at those brand name products to see if it is the same patient or different patients? We have proposed criteria with agents listed and quantity limitations, with the midazolam injection being non-fillable at the community pharmacy.

James Marx: Could we get a report on the midazolam syrup as well? I move to accept as proposed.

Jeffrey Zollinger: Second.

Vote: Ayes across the Board, motion carries.

d. **For Possible Action:** Discussion and possible adoption of prior authorization criteria for Ivabradine (Corlanor®)

Paul Oesterman, Chairman: Public comment?
None.

Carl Jeffery: We have a new agent for heart failure with very specific rules. First of a couple that are being introduced. It was fast track approved because of such a demand. The proposed criteria follows FDA criteria.

Paul Oesterman, Chairman: The therapeutic class lists the name of the product, if there are more products coming out, can we make it for the therapeutic class assuming the new products will have the FDA indications, HCN class (hyperpolization-activated cyclic nucleotide-gated channel blockers). I need a motion to approve the proposed criteria for the HCN class?

James Marx: Moved.

Jeffrey Zollinger: Second.

Vote: Ayes across the Board, motion carries.

4. Public Comment on any DUR Board Requested Report

Paul Oesterman, Chairman: Any public comment?
None.

5. DUR Board Requested Reports

a. Report on diabetic patient compliance for blood glucose monitoring receiving insulin.

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

Carl Jeffery: This is the count of recipients on insulin without monitoring. I pulled out all the Medicare patients, and only included straight Fee for Service. 4500 patients are getting insulin without any test strip claims. The next section is the long-term care recipients. There is a good chance the facility is using their strips.

Paul Oesterman, Chairman: Is there a way to cross over the data to look at hospitalizations associated with hypo or hyper glycemic episodes? If that is the case, we have dropped the ball somewhere.

James Marx: One thing I have noticed is that patients are not aware that strips are a covered benefit, could there be better education?

Coleen Lawrence: We haven't done a campaign in a long time.

Kevin Whittington: We can work with the manufactures to get some education out.

Paul Oesterman, Chairman: I would also be interested in the U500 usage, that scares me in the outpatient setting

Carl Jeffery: A few new strengths are coming out, a new U200 and U300

Michael Owens: The price has gone up on the Lantus, so we are moving to Levemir, There is a price spike impact on the program as well.

Kevin Whittington: When the manufacturers move the price up that fast, they pay penalties and that works out well for the States. The vials net out to the State for very little money.

Coleen Lawrence: You can request information or reports between meetings.

8. Public Comment on any Standard DUR Report

6. Standard DUR Reports

Carl Jeffery: The usual reports, but high level, antivirals are holding the top spot, Hep C medications. There is a small drop in the second quarter, two more products on the market. Antipsychotics are always number two. Break down by drug cost, Abilify holds the top spot. By claim count, a lot for the opioids, anticonvulsants are up there, guess most are Neurontin.

Paul Oesterman, Chairman: Can we have a breakdown for the next meeting for the use of Neurontin vs. Lyrica to see how that is transitioning?

James Marx: There are also some new dosage forms.

Jeffrey Zollinger: Seems like opioid class is moving down, are the costs decreasing?

Carl Jeffery: They appear to be holding steady.

Paul Oesterman, Chairman: Can we have a breakdown of hydrocodone products?

Carl Jeffery: In the top 50 report, the fourth quarter 2014, 22,000 claims, almost 24 000 claims in Q1 2015. Gabapentin is number four.

Paul Oesterman, Chairman: Halfway down the report by cost is the blood glucose strips.

7. Closing Discussion

Paul Oesterman, Chairman: Can we start these meetings at 5:00 instead of 5:30.

Coleen Lawrence: October 22, 2015 is the Medicaid Conference. It conflicts with our next meeting. We will follow up with the Board members.

Jeffrey Zollinger: 5:15 may work better.

Meeting adjourned at 7:20 PM.