Nevada Medicaid
Pharmacy & Therapeutics Committee

Location of Meeting
401 South Carson Street, Room 2135, Carson City, NV

Teleconference
555 E. Washington, Room 4406 Las Vegas, NV

MEETING MINUTES OF
July 14, 2004, and August 12, 2004

July 14, 2004, 12 Noon

Committee Members Carson City:
Steven Phillips, MD, Chairman
Linda Flynn, RPh
Alan Greenberg, MD
Carl Heard, MD
Larry Pinson, PharmD
Susan Pintar, MD
Thomas Wiser, PharmD -Late

Committee Members in Las Vegas:
Diana Bond, RPh
Robert Horne, MD

Absent: Judy Britt, PharmD

Others Present:
Carson City:
Darrell Faircloth AGO,Coleen Lawrence DHFCP, Nancy Davis DHCFP, Jeff Monaghan PharmD First Health Services Corporation, Dawn Daly RPh First Health Services Corporation, Charles Duarte DHCFP, Joann Phillips, Bob McElderry Purdue, Bert Jones GSK , Jeanette Belz NV Psych Assn, Claude Lardinois MD, Myan Hawkins NDACA, Rachel Brooks, Jim Morgan Novartis, Tracy Davies Lilly, John Ostezan Lilly, Steve Schaerrer AZ, Tina Lin Shire, Bill Finnerery Shire, Pat Chimei NAMI, Bucnhi Tyler NAMI, Mark Burshell NAMI, Rod Muir P&G, Chris Lepore J&J, Slate Sparks Bertek, Tom Wood Wyeth, Scott Cullins Wyeth, Danielle Walters Sanofi, Kara Smith BIPI, Joe Duarte Cephalon, Barbara Colgin Ortho, Khollin Takedo, Jesse Deaver Aventis, Roland Baldwin Wyeth

Las Vegas:
Jamie Wyels RPh First Health Services, Paul Pereira TAP, Sedrick Spencer Roche, Patty Craddock NDA, Patty Miller DHCFP, Sherri Serrano Lilly, Chris Jensen Lilly, Kristin Kight Lilly.

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 1pm. Committee members present in Las Vegas: Diana Bond, RPh, Robert Horne, MD; Carson City: Linda Flynn, RPh, Alan Greenberg MD, Thomas Wiser, PharmD. (Late) Steven Phillips, MD, Carl Heard, MD, Larry Pinson, PharmD, and Susan Pintar, MD.

II. Approval of Minutes of June 17th, 2004 Meeting

Motion to Accept minutes: Dr. Pinson
Seconded: Ms. Flynn
Ayes: Unanimous (Dr. Horne & Dr. Wiser not present to vote)

Motion Carried

III. Public Comment:

Las Vegas: None

Carson City: None

IV. Histamine-Two Receptor Antagonists (H2RA's)
Public Comment: None
Dr. Horne arrived.

Dr. Monaghan, FHSC, stated the committee, after several months of review, will now be asked to make decisions for inclusion of specific drugs in the Nevada PDL. First Health Services and the state have taken the committee's motions and used them as the basis for the recommendations that will be made today. He stated this is a dynamic process and revisions can be expected. It is hoped that the committee can begin meeting on a quarterly basis. He stated the DUR Board had reviewed and acted upon the issues that the P&T Committee had referred to the DUR Board for review, e.g. PDL exception criteria.

Dr. Monaghan recommended the following drugs in this category for the preferred drug list: famotidine and ranitidine. He also recommended Zantac syrup for children under 12 years of age without prior authorization.

Dr. Pinson asked if over-the counter forms of these medications would be allowed. Dr. Monaghan replied they are covered but a prescription is required.

Motion: Ms. Bond motioned to accept this class as recommended from FHSC.
Seconded: Dr. Pinson

Vote: Ayes: Unanimous (Dr. Wiser not present)

Motion carried.

V. Proton Pump Inhibitors
Public Comment: None

Dr. Monaghan recommended to the committee the following drugs in this category for the preferred drug list: Nexium, Prevacid capsules and Prilosec OTC.

Discussion: Dr Pintar asked about using suspension for children. She stated there was a dosage difficulty for small children. Dawn Daly, FHSC stated for children less than 15kg the dose is 15mg. Dr. Pintar was concerned about the information getting to the parent regarding the opening of the capsule. Dr. Monaghan stated that non-preferred agents are available through prior authorization and the PA process could be utilized to obtain the suspension. Dr. Horne asked about the clinical edit prior authorization. Dr. Monaghan replied there are clinical edits on certain classes and clinical criteria would need to be met for the prescription to be paid even for a preferred agent. Dr. Phillips clarified that the task for the committee today involves selection of the drugs and does not involve decisions regarding the clinical edits. Dr. Heard inquired about the role of the DUR Board and the intent of the clinical edits. Dr. Phillips stated he had received, from Deputy Attorney General Faircloth, a statement from the congressional record. Dr. Phillips read the statement which allows the state to implement a prior authorization process on otherwise covered drugs to prevent unnecessary utilization. Ms. Bond asked that the PPI criteria be referred to DUR board for reconsideration, based on the availability of generics and over-the counter agents within this drug class. Dr. Phillips agreed to refer this issue to the DUR Board.

Motion: Dr. Heard motioned to accept this class as recommended. He asked that the DUR board review the current PPI edits and come back with recommendations for revision.
Seconded**: Ms.Bond**

Vote: Ayes: Unanimous (Dr. Wiser not presented)
Motion carried.

Charles Duarte, DCFHP wanted clarification that this could be implemented prior to going to the DUR board. Dr. Phillips stated this will be able to go live as stated in the motion.

VI. Bone Ossification Agents: Bisphosphonates

Dr. Monaghan, FHSC, recommended the following drug for inclusion in the PDL : Actonel.

Motion: Ms. Bond motioned to accept this class as recommended from FHSC.
Seconded: Dr. Horne
Vote: Ayes: Unanimous (Dr. Wiser not present)

Motion carried.

Dr. Horne asked about the provisions for grandfathering. Dr. Monaghan stated if there is not a formal decision to grandfather there will not be any grandfathering. He further stated there is an aggressive outreach and education process to minimize the need for grandfathering. Dr. Horne expressed concerns about the switch from one drug to another. Dr. Phillips stated that his concerns were duly noted. Dr. Horne stated he would not vote on any other class until this was clarified. Dr. Heard wanted the DUR to address the transition of patients to the preferred agent. Dr. Horne stated he wanted to add to the criteria for the non-preferred drugs that patients be allowed to continue to receive the non-preferred drug until they are seen by their provide Coleen Lawrence, DHCFP, provided further detail about the PDL outreach and education that had occurred. She stated FHSC had met with the Retail Association of Nevada, long term care association, DHCFP care coordinators, and large volume providers. She stated that FHSC has two pharmacists on staff to do the education/outreach and they have been very proactive. Dr. Phillips stated this is a work in progress and this effort will continue.

VII. Herpetic Antiviral Agents
Public Comments: Carson City: Bert Jones, GSK, asked how a patient would receive a non-preferred drug if the drug has a unique indication. Dr. Monaghan responded that prior authorization would be required. Mr. Jones commented that Coreg and Valtrex were tabled by the DUR board.

Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: acyclovir and Famvir. Dr. Monaghan concurred that the DUR board tabled the criteria but that should have no impact on the committee's action today.

Dr. Greenberg said the intent of the original motion with regard to herpes simplex was that there is no difference in efficacy within this class. He stated with regard to varicella zoster infections, there is evidence that Famvir and Valtrex result in a decreased incidence of post-herpetic neuralgia.

Motion: Ms. Bond motioned to accept this class as recommended from FHSC.
Seconded: Dr. Greenberg

Vote: Ayes: Unanimous (Dr. Wiser not present)

Motion carried.

VIII. Hepatitis C Agents
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Pegasys, Pegasys Convenience Pack and Copegus. He also recommended that current users be grandfathered through their course of therapy.

Coleen Lawrence, DHCFP, stated the committee has the authority to apply grandfathering and FHSC is simply recommending grandfathering when they believe it is appropriate.

Motion: Dr. Greenberg motioned to accept this class as recommended from FHSC.
Seconded: Dr. Pinson

Vote: Ayes: Unanimous (Dr. Wiser not present)

Motion carried.

Dr. Phillips clarified the motion to include the ribavirins.

IX. Cephalosporins Second Generation
Public Comment: None

Dr. Monaghan, FHSC, recommended thee following drugs for inclusion in the PDL: Ceftin suspension, cefuroxime, and Cefzil.

Motion: Dr. Pinson motioned to accept this class as recommended from FHSC.
Seconded: Dr. Greenberg

Vote: Ayes: Unanimous (Dr. Wiser not present)

Motion carried.

X. Cephalosporins Third Generation
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Cedax capsules and suspension, cefpodoxime, and Omnicef capsules and suspension.

Motion: Dr. Greenberg motioned to accept this class as recommended from FHSC.
Seconded: Ms. Flynn

Vote: Ayes: Unanimous (Dr. Wiser not present)

Motion carried.

XI. Macrolides
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Biaxin tablets and suspension, Biaxin XL, erythromycin base, erythromycin estolate, erythromycin ethylsuccinate, erythromycin stearate, and Zithromax tablets and suspension.

Motion: Dr. Pinson motioned to accept this class as recommended from FHSC.
Seconded: Dr. Greenberg

Vote: Ayes: Unanimous (Dr. Wiser not present)

Motion carried.

XII. Quinolones Second Generation
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Cipro, Cipro suspension and Cipro XR.

Dr. Pintar asked if the Otic suspension would be affected. Dr. Monaghan responded that it would not be affected.
Ms. Bond wanted confirmation that they are accepting the name brand instead of the generic. Dr. Monaghan stated it is the brand name. Ms. Flynn asked how this would affect new generics as they become available. Dr. Monaghan stated they would be non-preferred, but this would likely change as the price of the generics comes down. Ms. Flynn stated that they are required by Medicaid to dispense the generic unless the prescriber indicates name brand necessary. She asked if the pharmacy board had been consulted. Dr. Monaghan stated he would ask Keith Macdonald for an opinion.

Dr. Wiser joined the committee at 1:00pm
Motion: Dr. Greenberg motioned to accept this class as recommended from FHSC.
Seconded: Dr. Pinson
Vote: Ayes: Unanimous

Motion carried.

XIII. Quinolones Third Generation
Public Comment:
Dr. Monaghan recommended the following drugs for inclusion in the PDL: Avelox and Avelox ABC pack.
Dr. Monaghan referred the committee to the handout addressing adverse events in this drug class -Attachment. Dr. Greenberg complimented Dr. Monaghan, stating the information summary was state- of- the- art. Dr. Horne stated his concern is moving the market share. Dr. Monaghan stated the PDL along with a letter from Mr. Duarte will be sent to all providers. Dr. Phillips referred Dr. Horne to the educational tab in the packet for the rollout schedule.

Motion: Ms. Bond motioned to accept this class as recommended from FHSC.
Seconded: Dr Greenberg

Vote: Ayes: Unanimous

Motion carried.

XIV. Glaucoma Agents
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Alphagan P, brimodine, betaxolol, Betoptic S, carteolol, levobunolol, metipranolol, timolol solution and gel form, Azopt, Cosopt, Trusopt, Lumigan and Travatan.

Motion: Dr. Wiser motioned to accept this class as recommended from FHSC.
Seconded: Dr. Pinson

Vote: Ayes: Unanimous

Motion carried.

XIII. Onychomycosis Agents
Public Comment: None

Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Lamisil and Penlac. Dr. Monaghan informed the committee of the new clinical edits approved for this class by the DUR board on 6/24/04.

Motion: Dr. Pinson motioned to accept this class as recommended from FHSC.
Seconded: Dr. Heard

Dr. Greenberg asked for the DUR to consider another indication: recurrent cellulites, at least two or more occurrences of the lower extremities due to chronic fungal infection.
Vote: Ayes: Unanimous

Motion carried.

XVI. Low Sedating Antihistamines & Combinations
Public Comment: None

Dr. Monaghan, FHSC, recommended the following drugs in this class for inclusion in the PDL: loratadine OTC, loratadine OTC rapid disintegrating, loratadine OTC syrup, loratadine-D12 hr, loratadine-D 24 hr. He also recommended Zyrtec syrup for children less than 2 years without a prior authorization needed.
Dr. Wiser asked about the criteria of failure of 2 or medications within the therapeutic class when there is only one agent available. Dr. Monaghan stated the criteria should be changed to reflect that failure on one agent is appropriate when there is only one preferred agent.
Dr. Phillips asked Darrell Faircloth who has the authority to establish criteria exceptions. Mr Faircloth responded the division has the authority to establish criteria based on the recommendations of the DUR Board. Tom Wood, PhRMA, stated the language in AB384 is very clear on step therapy. He stated the DUR Board has no oversight over the PDL.
Dr. Phillips stated that in those cases where there is only one agent in a class, the criteria could be modified. Mr. Wood stated the committee does have the authority to change the criteria. Coleen Lawrence, DHCFP, stated there are opportunities to change the criteria on behalf of the state since the criteria are not policy yet. Dr. Horne asked to be able to get Zyrtec if there is failure on loratadine. Ms. Bond stated that Medicaid surely understands if there is only one agent available, and the patient fails, the patient would be able to get a non-preferred agent. Dr. Horne stated he wanted another preferred agent no matter what the agent is so the prescriber will not have to go through a prior authorization. Dr. Phillips emphasized that Coleen Lawrence is aware that if there is only one agent, there would only have to be failure on one agent to get to a preferred agent. Dr. Horne asked which agent FHSC would prefer if the patient failed on loratadine.

Motion: Dr. Horne motioned to accept as presented and add Zyrtec with no prior authorization.
Dr. Horne stated he would like to include the language "if the patient fails on loratadine".
Seconded: None
Motion did not carry.

Motion: Dr. Heard motioned to accept this class as recommended from FHSC and for FHSC to include an additional agent on the preferred list.
Seconded: Dr. Pinson

Vote: Ayes: Unanimous

Motion carried.

XVII. Short Acting Beta-Adrendergics (MDI & Nebulizers)
Public Comment: None

Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: albuterol inhaler and nebulizers, Combivent inhaler, DuoNebs nebulizers, metaproterenol nebulizers. He also informed the committee of the new clinical edits for Xopenex approved by the DUR board on 6/24/2004.
Dr. Heard asked about combination products. Dr. Monaghan asked if he was referring to Advair. Advair is not being addressed at this time so it will continue to be available without restriction.

Motion: Dr. Heard motioned to accept this class as recommended from FHSC.
Seconded: Dr. Pinson

Vote: Ayes: Unanimous

Motion carried.

XVIII. Long Acting Beta-Adrenergics
Dr. Monaghan, FHSC, recommended the following drug for inclusion in the PDL: Servent Diskus.

Motion: Dr. Pinson motioned to accept this class as recommended from FHSC.
Seconded: Dr. Wiser

Vote: Ayes: Unanimous

Motion carried.

XIX. Inhaled and Nebulized Corticosteroids
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Azmacort, Flovent and Qvar. He also recommended Pulmicort Inhaler and nebulizers for children less than 4 years without requiring a prior authorization.

Dr. Pintar asked if this would prevent children less than 12 months old from getting Pulmicort. She stated this medication is quite commonly used in children less than 12 months old. Dr. Monaghan stated these patients could receive the medication.

Motion: Ms. Bond motioned to accept this class as recommended from FHSC.
Seconded: Dr. Greenberg

Dr. Horne stated since Advair will still be available, can't it be placed on the PDL. Dr. Phillips stated since it was not reviewed it could not be placed on the PDL.

Vote: Ayes: Unanimous

Motion carried.

XX. Nasal Steroids
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: flunisolide, Nasalide and Nasonex.

Dr. Wiser asked about Flonase and its pediatric labeling. Dr. Monaghan stated the original motion called for a drug for the pediatric population. Flunisolide met this criterion.
Dr. Heard expressed the desire for an aqueous formulation.

Motion: Dr. Heard motioned to accept this class as recommended from FHSC and for FHSC to come back with an aqueous solution alternative at the next meeting.
Seconded: Dr. Horne

Vote: Ayes: Unanimous

Motion carried.

Recess 2:00pm.
Resumed at 2:10pm

XXI. Angiotensin Converting Enzyme Inhibitors and Diuretic Combinations
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL. benazepril, captopril, enalapril, lisinopril, benazepril/HCTZ, captopril /HCTZ, enalapril/HCTZ and lisinopirl/HCZT. Dr. Monaghan informed the committee of the Altace criteria the DUR board approved on 6/24/2004.

Motion: Dr. Greenberg motioned to accept this class as recommended from FHSC.
Seconded: Ms. Bond

Vote: Ayes: Unanimous

Motion carried.

XXII. Angiotensin II Receptor Blockers and Diuretic Combinations
Public Comment:
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Cozaar, Diovan, Diovan HCT and Hyzaar.

Motion: Ms. Bond motioned to accept this class as recommended from FHSC.
Seconded: Dr. Horne

Vote: Ayes: Unanimous

Motion carried.

XXIII. Calcium Channel Blockers: Dihydropyridine and Non-dihydropyridine
Public Comment: None
Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Dynacirc, Dynacirc CR, nicardipine, nifedipine immediate release, nifedipine extended release, Norvasc, Plendil, Sular, diltiazem, diltiazem extended release, verapamil, and verapamil extended release.

Dr. Heard stated the immediate release are falling so far out of favor, that the extended release are what they are leaning toward. Dr. Phillips stated it was the committee's intent to get away from the short acting. Dr. Greenberg stated the short-acting dihydropyridines do have safety issues but the non-dihydropyridines may have some indications for use as shorter acting agents. An example would be angina. Dr. Greenberg suggested leaving the short acting non-dihydropyridines on the preferred list.

Motion: Dr. Heard motioned to accept the dihydropyridines and non-dihydropyridines as recommended, and make nifedipine immediate release non-preferred.
Seconded: Ms. Bond

Vote: Ayes: Unanimous

Motion carried.

XXIV. Calcium Channel Blockers and Angiotensin Converting Enzyme Inhibitor Combinations
Public Comment:
Dr. Monaghan recommended the following drug for inclusion in the PDL: Lotrel.

Motion: Ms. Flynn motioned to accept this class as recommended.
Seconded: Dr. Greenberg

Vote: Ayes: Unanimous

Motion carried.

XXV. Beta-Blockers and Diuretic Combinations Oral
Public Comment: Bert Jones, GSK, pointed out the DUR Board tabled Coreg and First Health Services felt the product was being used correctly. He wanted to know how this committee would handle Coreg. Dr. Lardinois stepped forward and offered the following comments. He stated Coreg reduces insulin resistance, has a favorable lipid profile, and is one of the only beta blockers that reduces albuminuria. He stated that Coreg should be extended beyond heart failure**.** He wanted it for patients with high risk cardiovascular disease and that would include diabetes.

Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: acebutolol, atenolol, betaxolol, labetalol, metoprolol, nadolol, pindolol, propranolol, sotalol, timolol, atenolol/chlorthalidone, bisoprolol/HCTZ and propranolol/HCTZ. Dr. Monaghan informed the committee current recipients on Coreg would be grandfathered and future users would fall under the PDL criteria exception. Dr. Phillips asked which of the criteria Coreg would fall under. Dr. Monaghan stated it would be number five. Dr. Greenberg stated that Coreg and Toprol XL did have better outcomes for left ventricular dysfunction. He suggested making it a preferred agent with specific criteria. Dr. Pinson asked would it be possible to have Coreg available without a PA if it was written by a cardiologist. Dr. Monaghan stated it could probably be done but the program has not had any experience with this approach. Dr. Heard did not like the idea of having to refer to a cardiologist and asked if there could be a justifiable diagnosis written on the prescription. Dr. Monaghan stated he believed it could be done as it is being done with cancer patients. Coleen Lawrence confirmed it could be done, but it does fall upon the prescriber to indicate the diagnosis on the prescription. Ms. Flynn asked if this would be done by an ICD-9 code. Dr. Phillips stated the code was 428.0. He stated Coreg should not used for hypertension and is a drug that has to be titrated. Dr. Monaghan suggested having the prescriber write the ICD-9 code or the diagnosis on the prescription. Ms. Bond stated they need to be aware that retail pharmacies are not normal users of ICD-9 codes, they do not traditionally use them in their settings and they are not familiar with them. Ms. Bond stated there needs to be real clarification on the prescription so the pharmacy is not guessing what the ICD-9 should be. Dr. Pintar stated this is approach is not unique. She stated other insurance companies require the ICD-9 code and it also ensures confidentiality.

Motion: Dr. Heard motioned to accept this class as recommended from FHSC and add Coreg for the indication of Left Ventricular Systolic Dysfunction which would be written on the prescription using the ICD-9 code of 428.
Seconded: Ms. Flynn

Vote: Ayes: Unanimous

Motion carried.

XXVI. Lipotropics

Public Comment: Dr. Lardinois stated the safety issue with Crestor is still a concern. This class as a general rule reduces albuminuria. He stated in his opinion the PDL may be inadequate. Dr**.** Heard asked for his suggestion. He responded he would make Lipitor preferred. Dr. Heard asked if he found Crestor and Lipitor bioequivalent. He stated yes they are. Dr. Lardinois stated when he was at the VA Zocor was the first line agent and if the patient did not meet target then the patient was switched to Lipitor. Dr. Heard asked if they swapped Lipitor for Crestor would that compromise FHSC abilities to manage this. Dr. Monaghan responded yes because the recommendation was based on the assumption that these agents are therapeutic alternatives.

Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL: Advicor, Altocor, Crestor, Lescol, Lescol XL, lovastatin, and Zocor. Dr. Monaghan stated the problems with Crestor appear to be dose related. If the committee chose, they could put an upper dosing limit of 20mg daily. He also stated if the patient did not meet target then they could get a non-preferred agent. Dr. Phillips stated he uses Zocor and if the patient fails then changes to Lipitor. He referred back to Dr. Lardinois and the VA. Dr. Wiser asked what would happen if an agent comes out with a black box. Dr. Monaghan responded this is a dynamic process and can always be addressed. Dr. Lardinois stated he believed they should be on Zocor before going to Lipitor. Dr. Phillips stated one of the roles of the committee is to help the state so they can continue to provide services and medications. Dr. Pinson suggested they could grandfather Lipitor. Ms. Bond stated her concern is the HIV population and that lipid management is problematic in this population. She wondered it they could consider using the ICD-9 code for these patients and access Lipitor for initial treatment. Dr. Phillips asked if they were HIV positive or getting treatment. She responded those using protease inhibitors have many drug interactions and Lipitor is well-tolerated in these patients. Dr. Monaghan asked if this was anecdotal or were there any head to head studies available. Dr. Greenberg stated for patients on protease inhibitors being treated for hyperlipdemia, the recommendations are Pravastatin, low dose atorvastatin and fluvastatin. Dr. Phillips stated if goal is not reached then the exception criteria would fit.

Motion: Dr. Horne motioned to accept FHSC recommendation with the exceptions that Crestor be moved to non-preferred and Lipitor to preferred list.
No Second.
Motion did not carry.

Motion: Dr. Horne motioned to accept this class as recommended from FHSC with the addition of Lipitor to the preferred list and the maximum dose of Crestor to be 20mg daily.

Seconded: Dr. Heard

Vote: Ayes: Bond, Horne, Greenberg, Flynn, Pinson, Heard
Nays: Pintar, Phillips, Wiser
Motion carried.

XXVII. Long Acting Narcotics
Public Comment: None

Dr. Monaghan recommended the following drugs for inclusion in the PDL: Avinza, Kadian, morphine sulfate extended release, Oramorph SR, and Oxycontin. Dr. Phillips asked if Oxycontin has clinical edits or quantity edits. Dr. Monaghan stated there were quantity edits and there was an override for cancer patients.

Motion: Dr. Pinson motioned to accept this class as recommended from FHSC.
Seconded: Dr. Wiser

Vote: Ayes: Unanimous

Motion carried.

XXVIII. Sedative Hypnotics

Public Comment:

Dr. Monaghan recommended the following drugs for inclusion in the PDL: estazolam, flurazepam, temazepam and triazolam. Dr. Monaghan informed the committee of the quantity limit initiated by the DUR Board of 30 units per month of one strength only. Dr. Monaghan offered to put in age and gender edits for either Ambien or Sonata.

Motion: Dr. Horne motioned to accept this class as recommended from FHSC and add Sonata and Ambien for females between the ages of 15 and 50 years old.
Seconded: Ms Bond

Vote: Ayes: Unanimous

Motion carried.

XXIX. Serotonin Reuptake Inhibitors

Dr. Monaghan, FHSC, recommended the following drugs for inclusion in the PDL. fluoxetine, Lexapro, and fluvoxamine. He recommended 1 year grandfathering. He added that if after a year the patient is doing well, when the prescriber calls in for the PA they would not be required to change to a preferred agent. He also suggested a trial, i.e. unfavorable outcome, with one preferred agent versus two.

Dr. Horne stated he would like fluvoxamine moved to the non-preferred list. Dr. Horne stated there were no preferred agents for social anxiety disorder, panic disorder, many of the things Zoloft or Paxil have approval for. He stated he would like Zoloft on the preferred list with the ICD-9 code 300 indications. Dr. Heard asked about the geriatric population and anxiety disorders. Dr. Phillips stated Lexapro is a very clean drug and is increasing in use in his practice. It has very few drug-drug interactions. Dr. Phillips stated he felt it was a class effect regarding anxiety disorders. Dr. Heard suggested accepting the recommendations and come back with something with anxiolytic properties. Dr. Horne stated he wanted to use ICD-9 codes for the anxiety indications for Zoloft. Dr. Phillips suggested that paroxetine or sertraline could be used for these indications. Dr. Pintar stated that sertraline has the pediatric indication for OCD. Dr. Horne stated he wanted to add an age limit since Zoloft or Prozac has indications for children. Dr. Pintar stated that for OCD Zoloft is the first choice. Dr. Monaghan asked if Dr. Horne was trying to avoid the PA. Dr. Horne responded yes and that is why he wanted age edits and the use of ICD-9 codes. Dr. Monaghan asked if he was focusing on Zoloft or if he was open to discussion. Dr. Horne responded for age he was focusing on Zoloft and paroxetine as options for other anxiety disorders.

Motion: Dr. Horne motioned to approve the FHSC recommendations with the following changes, move fluvoxamine to non-preferred, Zoloft use in patients under 18 years without a prior authorization and indication for anxiety only for age greater than 18 years, and grandfather for one year.
Seconded: Dr. Greenberg
Dr. Heard asked for a friendly amendment to include Zoloft on the PDL without any restrictions.

Charles Duarte informed the committee that there was a wildfire on the west side of Carson City, and several homeowners were being evacuated.
Dr. Phillips called for a vote. Dr. Wiser stated he was uncomfortable making a decision without more discussion.

At 3:45 PM, Dr. Phillips declared there would be a continuance of the meeting with the date and time to be announced in the near future.

Continuance of meeting, August 12th, 2004, 1:00 PM

Dr. Phillips called the meeting to order. He resumed the meeting with agenda item XXXIX.
Las Vegas: Linda Flynn, R.Ph, Lynn Horne, MD, Diana Bond, R.Ph

Carson City: Steve Phillips, MD**,** Tom Wiser, PharmD**,** Larry Pinson, PharmD**,** Carl Heard, Judy Britt, PharmD**,** Susan Pintar, MD

Absent: Alan Greenberg, MD

Other Present:
Carson City: Jeff Monaghan PharmD, FHSC, Dawn Daly RPh, FHSC, Coleen Lawrence, DHCFP, Charles Duarte, DHCFP, Darrell Fairlcloth, OAG, Joe Duarte, Cephalon, Jim Goddard Shire, Roland Baldwin, Wyeth, Bill Sweet, Cephalon, Johnna Nelson, PharmD Lilly, Jim Morgan Novartis, Charlie Sperano, Novartis, Bert Jones, GSK, Rosetta Johnson, Human Potential Development, Slater Sparks Mylan, Joann Phillips, Mark Burchell, Chris Lepore J&J, Steve Caper, Pfizer, William Granger, John Ostezan Lilly, Tom Wood Wyeth, Turh Paxton NAMI, Rachel Paxton NAMI

Las Vegas:
Jamie Wyles, RPh, FHSC, Sherri Serrano, Lilly, Larry Mathies, Nevada State Medical Association, Dan Henry, PD3, Chris Jensen, Lilly.

Agenda Item XXIX. Serotonin Reuptake Inhibitors (continued)

The meeting continued with the discussion regarding the motion made on July 14th.
Dr. Phillips asked for a review of the motion made at the end of the meeting on July 14th. Dawn Daly, FHSC reviewed the motion. Dr. Britt stated she was in agreement with FHSC recommendations. She questioned making Zoloft a preferred agent and stated that she agreed with the grandfathering of these agents. Dr. Horne stated Lexapro is only indicated for depression. Dr. Horne stated there are multiple SSRI's that have multiple indications. He stated Zoloft is the only medication besides fluoxetine that is safe for children down to age 6. Dr. Britt asked if Zoloft was only approved for OCD in children. Dr. Horne stated yes, but there are some studies out there for major depressive disorder showing it to be safe for children. Dr. Monaghan stated recently two recent studies involving Zoloft and major depressive disorder in children showed no significant difference over placebo. When the results were pooled the difference was shown to be statistically significant. The FDA was critical of this tactic and stated this methodology did not meet their standards.
Dr. Phillips asked about the ICD codes and stated that 311 is the code for depression. He stated if you used the 311 code then the patient could get sertraline. Dr. Horne stated that the code for Premenstrual Dysphoric disorder is also 311. Dr. Phillips stated then the codes would not be acceptable. Dr. Pintar interjected that having only fluoxitene for children was too restrictive. She stated she would like to have Zoloft available for children with OCD. Dr. Heard stated if the medication has broad and general applications then it should be included on the preferred list. Dr. Phillips then reminded the committee of their purpose. He stated they were responsible for determining therapeutic alternatives, and working with the state and FHSC to then select safe and effective drugs for the PDL. He then referred back to the minutes in which Dr. Horne stated they are therapeutic alternatives. If the committee is to be true to the original motion, we should look at the recommendations. Dr. Heard stated he appreciated the chair's comments but wanted to temper the comments. Dr. Britt stated fluoxetine has the broadest range of indications and experience. Dr. Horne stated he thought paroxetine should be included since it is generic and fluoxetine has the longest half-life. Dr. Britt stated that the long half-life of fluoxetine is an advantage, especially for non-compliant patients. She asked Dr. Monaghan why paroxetine was not included. He responded the cost of generic paroxetine had not really moderated at this point

in time, but it would no doubt decrease within the next six months. Dr. Pinson stated the drug would be available through a prior authorization process. Dr. Heard stated he did not want to be burdened with the prior authorization process. Dr. Phillips asked about the PA process. Dr. Monaghan stated if you call in it is answered within one minute and the process itself can be completed in approximately two to five minutes. If faxed, the turnaround time in no greater than twenty-four hours. Dr. Britt asked for clarification on who can request a PA. Dr. Monaghan stated the prescriber or their designated representative must make the request.

Dr. Phillips called for a vote on the motion on the floor.

Vote: Ayes: Dr. Horne, Dr. Heard
Nays: Dr. Pintar, Dr. Britt, Dr. Phillips, Dr. Pinson, Dr. Wiser, Ms. Flynn, Ms. Bond
Motion did not carry.

Dr. Phillips called for a new motion.

Dr. Horne motioned that Symbyax needed to be removed from the non-preferred, remove fluvoxamine and move sertraline to the preferred list for children 6- 8, sertraline for adults with panic disorder with or without agrophobia, premenstrual dysphoric disorder, post traumatic stress disorder, OCD and grandfathering for this class be one year.

Dr. Phillips stated once an agent is removed from the non-preferred list it is available for use without any restrictions.
Motion did not get a second.
Dr. Phillips asked for another motion.

Dr. Britt moved to accept the recommendations from First Health with the following: Add paroxetine generic, allow sertraline in children between 6-17 if they had a prior history of a fluoxetine trial and a one year grandfathering for all of this class.
Dr. Horne made a friendly amendment to move fluvoxamine to non-preferred.
Dr. Britt accepted the friendly amendment.
Seconded: Dr. Horne.

Discussion: Dr. Pintar's concern was the initial trial of fluvoxamine for OCD in children when sertraline, in her opinion, is the preferred agent. Dr. Britt's concern was the use for sertraline in children for depression and all other disorders. Dr. Britt asked about the utilization of sertraline in children under eighteen. Dr. Monaghan responded he did not have the data available at the moment.
Dr. Pintar made a friendly amendment to accept sertraline for OCD in children.
Dr. Phillip reviewed the amendment in which sertraline would be a preferred agent in children ages 6-17 years with the ICD-9 code of 300.3 for OCD.

Dr. Britt accepted the friendly amendment.
Dr. Horne questioned if this would require the MD to write the ICD-9 code on the prescription. Dr. Pintar stated yes, in order to restrict its use to OCD in children, this would be required.

Votes: Ayes: unanimous.

Motion carried.

XXX. New Generation Antidepressants
Public Comment: Bert Jones asked about grandfathering. He asked if the physician changes the dose does that become a new prescription or would it fall under the grandfathering provision. Dr. Monaghan stated that would be a new prescription and would require a prior authorization if the agent was not preferred. Mr. Jones stated if the physician is making a dosage adjustment you would not want to have to call in for a prior authorization. Dr. Monaghan stated if the committee would like a dosage change not to require a prior authorization, that rule could be adopted. Dr.

Britt stated it is common with other companies to not require a PA for dosage changes. Dr. Monaghan stated this exception would not include a change in dosage formulations, e.g., going from a short- acting to a long- acting formulation.

Dr. Monaghan recommended bupropion, bupropion extended release, mirtazapine, mirtazapine rapidtabs and trazodone for inclusion in the PDL.

Dr. Horne stated there are no norepinephrine-raising agents and this could be resolved by moving Effexor XR to the preferred list. Dr. Monaghan stated that Effexor is a good drug but is not a first- line drug. The SSRI's are considered first line agents for depression. He stated the system could search claims history and if there was a trial of a preferred antidepressant, then the PA process could be bypassed.
Dr. Britt pointed out that mirtazapine is on the list of recommendations for preferred agents. She stated that mirtazapine does affect norepinephrine. She stated they did use a lot of Remeron in her psychiatric pharmacy practice with good results. Dr. Horne stated he felt that sedation and weight gain were an issue. Dr. Britt stated they found those issues to be dose-related, and not a major obstacle.

Motion: Dr. Pintar motioned to accept the FHSC recommendations as proposed with the addition of Effexor XR being available without prior authorization after therapeutic trial on one other preferred antidepressant in any class within the previous 90 days.
Seconded: Dr. Britt
Dr. Horne asked for a friendly amendment to grandfather for one year and change the PDL exception criteria to allow for a non-preferred agent after therapeutic trial on only one versus two preferred agents.
Dr. Phillips explained that if someone is prescribed a preferred agent in either antidepressant class and fails, a PA could then be submitted for a non-preferred agent.
Dr. Pintar accepted the amendment.

Votes: Ayes: Unanimous
Motion carried.

Darrell Faircloth stated if the committee is clear on their intent for grandfathering for this class, Medicaid will respect their decision and allow the motion to change the exception criteria for these classes.

Dr. Phillips stated there are only five drug classes that are affected by grandfathering. Mr. Faircloth stated they could not consider the other drug classes since they are not on the agenda. He stated the other drug classes would have to be place on a future agenda. Coleen Lawrence, DHCFP, stated the intent of grandfathering in this class is to allow titration of the same drug, and this can be allowed for by coding at the HICL level.

XXXI. Stimulants/ADHD drugs

Public Comment:
Ruth Paxton, RN, NAMI-She said the problem with restricted drug lists is that it increases hospitalization costs and administration cost. She stated it was poor medical practice to limit depression medications.
Mark Rochelle, NAMI-Stated changing medications midstream with the mentally ill is a serious problem and can cause increased hospitalization.
Dr. Johnna Nelson- Eli Lilly, gave an overview of Strattera
Rachel Paxton, NAMI-She stated that the drug lists are barbaric to people who have mental illness.
Joe Duarte-Cephalon-Gave an overview of Provigil

Dr. Monaghan, First Health Services, recommended that Adderall XR®, Amphetamine Salt Combination, Dextroamphetamine SA, Dextroampehtamine Tab, Dextrostat®, Focalin®, Metadate CD®, Metadate ER®, Methamphetamine, Methylin®, Methylin ER®, Methylphenidate, Methylphenidate Extended Release and Ritalin LA® for inclusion on the preferred drug list.

The clinical edits would still be in place and current agents would be grandfathered until their current PA's expire. Dr. Phillips asked if all the stimulants are under a clinical PA. Dr. Monaghan stated yes, but the edits do not apply to Strattera at this time. He stated the DUR Board will probably move in the direction of adding a clinical edit to Strattera. Ms. Bond asked if they accept the list as presented, how would a patient get a non-preferred agent? Dr. Monaghan stated failure with one versus two preferred agents could be applied, similar to the antidepressants. Ms. Bond asked about other exceptions, such as drug abuse. Dr. Monaghan stated this could not be automated but could be added to the clinical criteria. Coleen Lawrence, DHCFP, stated originally the clinical edit was only for the stimulants. Because Strattera is used in the treatment of ADHD, this should be considered for the same edits that apply to the stimulants used for ADHD. Dr. Heard stated he wanted a non-stimulant because you cannot write for a stimulant in advance. He stated this increases costs and administrative time. Dr. Monaghan deferred to Dr. Pinson, the President of the Nevada State Board of Pharmacy. Dr. Pinson stated the law was changed so you may write prescriptions in advance and just indicate on the prescription when it can be filled, this will allow you to write prescriptions in one visit. He stated this law has been in place for about six months. Dr. Heard asked why controlled substances are being recommended as the preferred agents. Dr. Monaghan stated after talking with Mojave clinic, other psychiatrists and Dr. Horne, stimulants are the gold standard in treating ADHD. Strattera does not seem to be as effective as the stimulants, but does have a place in therapy. He added that potential abuse of stimulants could be used as a criterion for approval of Strattera as a non-preferred agent. Dr. Horne stated in other states where FHSC is present, Strattera is a first line drug. He stated there has to be a non-stimulant available, but does agree with Dr. Monaghan if you did a double blind, placebo-controlled study stimulants would be more effective. He stated Strattera would be more effective than placebo.

Dr. Horne motioned to accept the recommendations from FHSC with the following revision: delete Provigil from the non-preferred drug list, put Strattera on the preferred list, and only have to fail one preferred agent to get a non-preferred agent.
Seconded: Ms Flynn

Dr. Heard stated they should keep Provigil on the non-preferred so it would not have open use.
Dr. Horne stated Provigil is not a stimulant and that is why he wants it deleted.
Dr. Monaghan stated the committee has in fact reviewed Provigil and the committee should not delete it from the non-preferred list. Mr. Duarte stated the drugs that are not covered by the PDL do fall under the DUR board if they feel it is necessary to place clinical edits on them.

Dr. Heard made a friendly amendment to leave Provigil on the non-preferred list.
Dr. Horne accepted.
Dr. Britt made another friendly amendment and recommended that the DUR Board consider clinical edits for Strattera and ADHD.
Dr. Horne declined the amendment and stated he would like that in another motion.

Votes: Ayes: Unanimous
Motion Carried.

Dr. Horne wanted to make a motion to place Provigil on the agenda for the next meeting. Dr. Phillips stated that the committee could not take action on this since it was not on the agenda. Dr. Heard asked the DUR board to review the criteria for all CNS stimulants and Strattera. Dr. Horne stated he does not do an IQ test before prescribing ADHD drugs and would like the DUR board to review this.

XXXII. Review of October 28th Meeting Location, Date and Time.

Location not determined at this time. Time will be 1:00pm

XXXIII. Public Comment

Charles Duarte, Administrator, DHCFP, stated this is not a closed formulary and access to drugs can be accomplished through a very workable PA process. He thanked the committee for the marvelous job they had done and added that this committee's actions constituted the best public policy discussion venue that he had seen.

Tom Wood, PhRMA, also commended the committee for their work. He stated he would like the attorney general to clarify the amount of DUR control and the DUR input into the PDL process. He stated the law states oversight of the PDL is the P&T Committee's responsibility and if the committee does not do it the state can do it. The other consideration he would like to see the committee review is the grandfathering process. Dr. Phillips stated all grandfathering had been for one year, with the exception of the PPI's and stimulants, where they were grandfathered for the remainder of the existing clinical PA. He stated the committee has adequately addressed the grandfathering issue. Joe Duarte, Cephalon, offered to bring in a sleep specialist to address the use of Provigil.

XXXIV. Adjournment

Ms. Bond motioned for adjournment.
Dr. Horne seconded.
Meeting adjourned at 3:10pm.