JIM GIBBONS
Governor

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

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Director

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DRUG USE REVIEW (DUR) BOARD

Las Vegas Chamber of Commerce
6671 Las Vegas Blvd. S., Suite 300
Las Vegas, NV

APPROVED
Meeting Minutes
April 10, 2008

Committee Members Present:
David England, Pharm.D., Chairman
Keith Macdonald, R.Ph.
Paul Oesterman, Pharm.D.
Marjorie Uhalde, M.D. (called in)
Steven Parker, M.D. (called in)

Absent:
Steven Rubin, M.D.

Others Present:
Mary Griffith-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, Mike Steelman-Pfizer, Sandy Sierawski-Pfizer, John Berry-Pfizer, Craig Boody-Lilly, Jane Stephen-Allergan, Ken Grant, MD,-University of Nevada School of Medicine, Lori Howarth-Bayer, Doug Powell-Forest, Doris Chavez-Assist Care, Blake Hennington-Merck, Stephen Andracki, MD.

I. Call to Order and Roll Call

Chairman David England called the meeting to order at 1:01 p.m.

II. Discussion and Approval of January 24, 2008 Minutes

MOTION: **Paul Oesterman motioned to accept the minutes as presented.**
SECOND: **Keith Macdonald**
VOTES: **Unanimous**
MOTION CARRIED

III. Status Update by DHCFP

Mary Griffith, Social Services Program Specialist II, DHCFP, provided the following update:

National Provider Identifier (NPI) Initiative and Timeline for Implementation
Effective May 23, 2008, NPI will be required for claims submitted to Medicaid. Medicaid will enforce the requirement of NPI submission on claims.

Pharmacy Lock-In Program
Procedures are being developed. DHCFP is working with FHSC to determine system requirements necessary to implement the program. An update will be presented at the next meeting.

E-Prescribing
E-prescribing will be offered to Medicaid providers. There will be an educational presentation for the Board at the next meeting.

Tamper-Resistant Prescriptions
Effective April 1, 2008, the CMS requirement of one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form will be mandatory to be considered tamper-resistant. Per CMS guidance, to be considered tamper-resistant, a prescription must contain at least one of the following three characteristics:

1. one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
2. one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; and/or
3. one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Effective October 1, 2008, a prescription pad must contain all of the foregoing three characteristics to be considered tamper-resistant.

The requirement applies to written prescriptions and will not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy or prescriptions communicated to the pharmacy via telephone by a prescriber.

Dave England asked if the Nevada State Board of Pharmacy or the Board of Medical Examiners have addressed this issue. In California, the board of pharmacy and department of health services have designated certain printers who are certified to print prescription blanks that are in compliance. Mr. Monaghan replied that the Nevada boards have made the decision not to be involved.

Mr. Macdonald stated that in his pharmacy practice, tamper-resistant prescriptions that are faxed are difficult to read. He asked who will enforce this requirement and will there be a penalty to the prescriber and/or pharmacies that do not comply. Ms. Griffith replied that the State will be responsible for conducting audits to ensure tamper-resistant prescription blanks are being utilized. Mr. Monaghan stated that per the Federal guidelines, funds could potentially be withdrawn from the pharmacy if a medication is written on a non-tamper-resistant prescription blank and dispensed to a Medicaid recipient.

National Drug Code (NDC) Billing Requirements for Outpatient-Administered Drugs
Medicaid is in compliance with the Deficit Reduction Act which requires the capturing of NDC numbers for physician-administered drugs.

Appointments/Reappointments to the Drug Use Review Board
Information on the deadline and documentation required for nominations for new members will be posted on the DHCFP website within the next few weeks. Current members interested in remaining on the Board should contact Coleen Lawrence or Mary Griffith.

IV. Status Update by FHSC

Determination of Generic and Brand Name Status for Claims Processing Purposes
Jeff Monaghan stated that First Data Bank (FDB) supplies the master drug file utilized by FHSC. The file contains all the drug claims data processing elements. FDB is changing the way generic drugs will be identified in the system. FDB is trying to get away from using AWP. Some of this is driven by lawsuits based on Average Wholesale Price (AWP). Prior to this, one of the indicators used to determine brand or generic status was the spread between AWP and wholesale acquisition. CMS and Medicare Part D recommended using the New Drug Application (NDA) for brand and Abbreviated New Drug Application (ANDA) for generic to determine whether a drug is generic or brand.

V. Proposal by First Health Services on the Feasibility of Requiring ICD-9 Codes and Claims History Edits versus the Current Prior Authorization Process for Patients Prescribed Gastrointestinal Agents

Jeff Monaghan stated that the Proton Pump Inhibitor (PPI) prior authorization (PA) edit was the first edit established by the Board several years ago when PPIs first became available. It was common at that time to place strict restrictions on the use of these drugs. Since that time, the marketplace for PPIs has grown; some are now available over-the-counter and some are available generically. Based on input from pharmacists and physicians, it was felt the requirements should be revisited and brought up-to-speed therapeutically and economically with the main focus on therapeutics. He ~~presented~~ proposed revisions to the current criteria as follows:

Gastric Esophageal Reflux Disease (GERD)
He referred to the updated practice guidelines for GERD published in the *American Journal of Gastroenterology*. The main change seen over the past 10-15 years for the treatment of GERD is the significant decrease in usage of antacids and H2 antagonists. The effective studies indicate that they clearly are not as effective. The article also points out that the benefit of lifestyle modifications has shown to be somewhat theoretical. He reviewed proposed changes to the existing PA criteria:

-A.1.a.1: Remove requirement for lifestyle modifications.
-A.l.a.2: Remove requirement for an antacid trial. Maintain documented requirement of one OTC H2A but remove the four week trial period.
-Inclusion on the transmitted prescription of ICD-9 code for GERD with a claims history of an H2A or a PPI in the last 30 days will bypass the PA requirement.

Mr. England stated that he is in favor of the inclusion of ICD-9 codes which speeds up the approval process and provides data on what these drugs are being utilized for.

Mr. Monaghan stated that utilizing an ICD-9 will allow the claim to process without further PA requirements but there is no way to limit duration of therapy. If the prescriber calls in the PA request, the Call Center can manually enter an end date. He recommended that because GERD is a chronic, long-term disease, eliminate the one year approval limitation requirement.

Mr. Macdonald said that the pharmacy will not know if the recipient has a claims history of an H2A or PPI in the past 30 days until the claim is processed. Reviewing the medication profile maintained by the pharmacy will not include any prescriptions of these agents dispensed by another pharmacy. If a DUR reject is received when the claim has been submitted, the pharmacy has to determine why. He requested the elimination of this requirement.

Mr. Oesterman suggested a trial of any H2A acid suppression trial versus a trial of an "OTC H2A." He asked what the difference is between payment authorization and prior authorization. Mr. Wuest responded that they are the same. The existing language was left in the proposed criteria and will be revised for consistency in the final document.

Peptic/Gastric Ulcer Disease (PUD)
Endoscopy or upper gastrointestinal (GI) series and H. pylori testing are required to confirm diagnosis. Proposed revision to the existing criteria:

-A.1.b.1: remove requirement for lifestyle modifications.

Mr. Oesterman said that the criteria require that testing has been done within the past two months and approval is for a 90-day time limit. Would it make sense to be consistent so there isn't a one month lapse? Mr. Monaghan clarified that the testing should have been accomplished within the previous two months then the recipient would be eligible for a 90 day duration of therapy following the testing.

Hypersecretory Conditions (Barrett's Esophagus, Zollinger-Ellison, etc.)
Mr. Monaghan stated that these are very serious and long-term hypersecretory conditions. Diagnosis must be confirmed with testing. Proposed revisions to the existing criteria:

-A.1.c.1: Eliminate the one year approval limitation requirement.
-A.1.c.2: Inclusion on the transmitted prescription of ICD-9 code for Barrett's Esophagus and Zollinger-Ellison will bypass the PA requirement.

Dave England felt review should continue on an annual basis. Mr. Monaghan stated that if the ICD-9 is transmitted, there is no way for the system to limit the duration of therapy; that is a manual entry. If duration of therapy is limited to a 12-month period, the Board will need to determine the specific questions to be asked of the prescriber by the Call Center for approval of continued therapy.

Mr. Macdonald stated that refills for prescriptions (non-controlled substances) are valid for a one-year period therefore an annual review of the PA requirements could take place if the prescription is renewed.

Steven Parker, MD, joined the meeting at 1:35 p.m.

Helicobacter pylori (H. pylori)
Mr. Monaghan stated that the diagnosis must be confirmed with testing and combination therapy must be documented. Proposed revisions to the current criteria:

A.1.d.2: Add: Regimen must combine one or more anti-infective agents.
Eliminate: Triple therapy (e.g., bismuth salt, metronidazole and tetracycline or amoxicillin) or other regimen that combines one or more anti-infective agents with a bismuth sale and/or an antisecretory agent should also be considered.

Dave England felt there could be confusion if the prescriber is required to include an ICD-9 on the prescription for some diagnoses and not others. Mr. Monaghan suggested that perhaps H. pylori disease and peptic ulcer disease could be combined into one criterion since prior approval must be obtained. The reason an ICD-9 was not proposed for either one is that testing is required and the PA request will need to go into the Call Center. If the testing requirement is removed, an ICD-9 could be applied. The proposal is to allow ICD-9s for the chronic conditions and require a PA on the more acute conditions. (It was noted that the ICD-9 can also be included on the faxed PA form to the Call Center to speed up the process as well as the prescription.)

Public Comment

Doris Chavez, Assist Care Pharmacy, stated that many of their Medicaid recipients are discharged from the hospital on a proton pump inhibitor (PPI) because it's on the hospital formulary. She requested consideration be given to allow an override for a 10 day supply for those recipients discharged into an assisted living or long-term care facility. This would allow time for the facility to contact the primary care physician to discuss an alternative drug, obtain a PA or determine if the recipient needs to be continued on the PPI. This is particularly an issue if the recipient is discharged on a Friday or weekend.

Ms. Griffith asked if the 72 hour emergency supply could be applied is this case. Ms. Chavez replied that it usually takes more than three days for someone to see a physician after discharge. She stated that Medicare allows a 5-7 day supply for hospital discharges so the patient has a reasonable period of time to see a physician. Mr. Monaghan asked if this is an issue primarily with PPIs and she replied PPIs and quinolones. She added that it's not usually difficult to have the ~~phsycian~~ physician ~~prescribed~~ prescribe an alternative medication within a drug class, but in the case of the PPIs, all require a PA.

Discussion and Action by Board Concerning Revisions to Clinical Prior Authorization Criteria for Gastrointestinal Agents

MOTION: **Keith Macdonald motioned to table this agenda item until the next meeting. The Board requested a "clean copy" of the proposed criteria be presented and options addressing the issue brought forth by Ms. Chavez be presented.**
SECOND: **Paul Oesterman**
VOTES: **Unanimous**
MOTION CARRIED

VI. Proposal by First Health Services on the Implementation of a Prior Authorization Process for Lyrica® (pregabalin)

Dave Wuest presented an overview of pregabalin (Lyrica®). FDA approved indications for use are epilepsy, diabetic peripheral neuropathy, post-herpetic neuralgia and Fibromyalgia. Lyrica® binds with high affinity to the alpha$_2$-delta site in central nervous system tissue. The mechanism of action is unknown. Animal studies suggest that the binding to this site may give its' ability to reduce sensitivity to painful stimuli and its' anti-seizure effect. Pain management is a complicated clinical endeavor and the purpose of this review is to ensure that Lyrica® usage is appropriate. Fibromyalgia Syndrome (FMS) is the most common cause of chronic widespread pain. Clinical experience leads the diagnosing of the disease. It should be appreciated that a number of treatable conditions may present with symptoms that resemble those of FMS and need to be excluded before diagnosing FMS. Lyrica® is a Schedule V controlled substance. In studies of recreational use of sedative hypnotic drugs including alcohol, Lyrica® received subjective ratings of good drug effects, high and likening to the degree that was similar with diazepam. He reviewed the proposed criteria:

Epilepsy and/or Seizure Disorder
Documented diagnosis of epilepsy and/or seizure disorder required. Prescriptions or prior authorization request forms transmitted with an ICD-9 code for epilepsy or convulsions will ~~the~~ be processed without prior authorization (PA). Mr. Wuest stated that the goal is to make it as easy as possible for the clinician to obtain the medication for their patients for these disease states.

Diabetic Peripheral Neuropathy (DPN) and Post-Herpetic Neuralgia (PHN)
For DPN, a 30-day trial or intolerance or contraindication to at least one of the following: tricyclic antidepressant (TCA) or gabapentin.
For PHN, a 30-day trial or intolerance or contraindication to at least two of the following: tricyclic antidepressant (TCA) or gabapentin or capsaicin 0.075% cream or lidocaine 5% patch.

Fibromyalgia
-Diagnosis of Fibromyalgia based on the American College of Rheumatology (ACR) classification criteria (pain present in 11 of 18 tender point sites).
-Documentation of widespread pain for at least 3 months.
-TSH (thyroid stimulating hormone) lab work performed and any abnormalities treated.

Public Comment

Stephen Andracki, MD, stated that he has been treating pain patients since 1991 in Las Vegas. He said he encourages the opportunity to cut costs and to do the appropriate testing but the prior authorization process creates roadblocks in the ability to supply a trial of medications to patients who are in need. Fibromyalgia and neuropathy patients are in pain. The alternatives are narcotics and opiates and avoiding the expensive medicines such as fentanyl. Putting roadblocks in for chronic pain patients is a problem that will not be resolved by using prior authorization. These people need to be treated appropriately and uniquely with medicines that seem to have effect. He has found tricyclics to be unfavorable due to the side effect profile. Amytriptyline is one of the highly prescribed medications for pain patients and it doesn't work well. Gabapentin is not well tolerated. Pregabalin in a certain set of sub-patients has value and is not an extremely high priced medication. He has not found abuse of this medication. To add additional steps in getting pain patients treatment is not favorable for the patient, physician or State.

Jeff Monaghan said that Dr. Andracki stated that in his experience, Lyrica® is better than gabapentin and asked what that is based on. Dr. Andracki replied that neurontin (gabapentin) is difficult to dose and titrate; side effects and dizziness are difficult to tolerate. He stated that he cannot explain why some precursor medications work differently in the body. Lyrica® is better tolerated, easier to dose and more acceptable for the patient. He said that he cannot produce any facts other than his own clinical experience.

Dr. Parker asked what percentage of patients has improved on Lyrica® and happy to the point that it's their final treatment versus the other medications where there is improvement and that's the final treatment. Dr. Andracki replied it's tough to find an end treatment for a chronic pain patient. This is a tough group of people. They want narcotics and something that takes them to another place. Dr. Parker felt that from Dr. Andracki's statements, there does not appear to be any difference between Lyrica® and neurontin. Success wise, they are both the same. Dr. Andracki said that in his clinical experience, he has found Lyrica® to be better tolerated, easier to adjust. He has found very few chronic pain patients who continue to stay on neurontin and found it to be a useful medication whereas Lyrica® has had a much higher success rate as the first and final medication. He currently has no Fibromyalgia patients on neurontin and ten on Lyrica®.

Dave Wuest stated that the recommendation is not for a step-therapy for Fibromyalgia. The recommendation is that the standard of diagnosis be confirmed by the Board which matches the current standard of care.

Dr. Parker stated that he has no problem with Lyrica® usage if it meets the criteria as outlined.

Kent Grant, MD, rheumatologist, University of Nevada School of Medicine, Las Vegas, said that Lyrica® is a seizure medicine and Nevada Revised Statutes state that seizure medications will not be limited. Fibromyalgia patients are very difficult to deal with. The American College of Rheumatology (ACR) has come up with criteria, but in most reviews, the criteria have weaknesses. The TSH test is not part of the criteria. He agreed that patients should have multiple trigger points but edits will slow down the process. Lyrica® does not work for everyone. According to the criteria, Fibromyalgia is not an exclusionary diagnosis. A patient can be examined fairly simply and the physician can see that they hurt all over. He felt the ACR criteria are vague. When edits are put in, they cause delays and the patient cannot be rescheduled for another appointment for three or four months.

Dave England stated that an edit is not being placed on neurological disorders. The prescription will process if the patient has been diagnosed with seizure disorder and the ICD-9 is transmitted. He asked Dr. Grant what edits he would propose to make Lyrica® available for the indications he is using it for. Dr. Grant suggested allowing patients to have a trial of the medication for a short period of time without prior authorization and justify continued use if there is improvement.

Dr. Parker said that if the patient has symptoms and meet the criteria, the medication is authorized for use. If a trial is allowed and there is improvement, there will be no documented criteria justifying initial use.

Dr. Grant suggested notifying the physician that the documentation will be required to continue use of the medication and improvement will need to be documented. He felt using products like Lyrica® will lessen use of narcotics and reduce emergency room visits.

Sandy Sierawski, Pfizer, spoke in support of Lyrica®. She provided a handout which included utilization and cost analysis for Board review. Lyrica® is not prescribed first line for seizure disorder because it is adjunct treatment for seizure control and should not be restricted. It would be the only anti-epileptic drug with the requirement to write the ICD-9 code on the prescription. This might conflict with Nevada Assembly Bill 384 as a restriction on an anticonvulsant. Putting PA criteria in place for Lyrica® may increase utilization of higher cost products. There are only a few drugs FDA approved for the treatment of Diabetic Peripheral Neuropathy (DPN) and Post-Herpetic Neuralgia (PHN). If restrictions are placed on Lyrica®, she felt there could be an increase in use of Cymbalta®. There are published guidelines that state Lyrica® and tricyclics are recommended as first line therapy but gabapentin is recommended as a second line agent. The

American Academy of Neurology Guidelines recommends Lyrica®, opioids and topical lidocaine as first line therapy in PHN. Capsaicin is effective but has a low magnitude of benefit. Lyrica® is the only FDA approved medication for the treatment of Fibromyaligia. Regarding the proposed requirement for TSH, she stated that there is no test for the diagnosis of Fibromyalgia. Doctors make a diagnosis through physical examination, evaluating symptoms and ruling out other conditions.

Dave England asked what her suggested proposal is. She replied that long-term, it would be ideal to see the diagnosis on every prescription to see how the drug is being utilized. To single out Lyrica® and require a PA is excessive as well as requiring a restriction on an anti-convulsant drug. Mr. England clarified that the requirement is not being placed for its anti-convulsant effect.

Darrell Faircloth, DAG, stated that there has been an issue raised as to whether this conflicts with some of the provisions of the statutes that relate to the creation of the Preferred Drug List (PDL). The purpose of this Board is not to create a PDL. If this is an anti-convulsant medication as contemplated by this statute, this is not the Pharmacy and Therapeutics Committee (P&T) which makes up the PDL. This is the Drug Utilization Review Board (DUR) which is charged to assist the Medicaid agency in creating prior authorization criteria that will ensure that medication is appropriate for the recipient. PA is a process that is used to impose certain restrictions on the utilization of medication. Utilizing the ICD-9 code to determine that the medication is being used to treat seizures or epilepsy simply allows the gate to swing open and the patient to access the drug. He felt this requirement seemed reasonable given that there are such a variety of uses for this product. By utilizing the ICD-9 code to identify whether the drug is being used to treat seizures, excludes it from any restrictions.

Discussion and Action by Board on Clinical Prior Authorization Criteria

Dave England stated that he would like the Board to consider the recommendation of a trial period as suggested by Dr. Grant. Mr. Monaghan stated that he is unsure if the system can be set up to allow for a trial period.

Dr. Parker said that in public testimony, it was stated that patients on Lyrica® may use less of other medications and go the emergency room less frequently. He asked if First Health can track drug utilization before and after Lyrica® usage of fibromyalgia patients or patients that receive Lyrica® for pain. Mr. Monaghan stated that he would consult with First Health's biostatistician to determine if this type of data can be collected.

Mr. Wuest stated that the criteria could delay the use of Lyrica® but as Dr. Grant said, the criteria are not onerous. It makes more sense to allow a trial for something that an outcome can clearly be defined. When dealing with pain, it's widespread and hard to define. He added that there has been an increase in Lyrica® usage.

Dr. Parker suggested tracking Lyrica® usage to determine proper therapy and cost-effectiveness. If another medication is being added to a myriad of other medications the patient is taking, there is no benefit and money is being wasted.

Mr. Monaghan stated that money is an underlying factor but the focus is good therapy. The pharmaceutical industry does not do head-to-head trials because the outcome is unsure in most cases and they do not want to show that their drug is not as effective as a less expensive generic. Their drug is simply compared to placebo; hopefully, showing superiority to placebo.

MOTION: **Paul Oesterman motioned to table this item until the next meeting at which time First Health can provide data on cost associated with pre-Lyrica® and post-Lyrica® usage and the impact in usage of other medications when the patient has been placed on Lyrica®.**

SECOND: **Steven Parker**

Darrell Faircloth stated that the Board is forbidden to consider cost of a particular therapy when they are promulgating step-therapy protocols. If this is a step-therapy protocol, the Board by statute cannot consider cost as a basis for formulation of policy. He urged the Board to focus on

the therapeutic effect of this because of their unique qualifications as practitioners but cost consideration is not forbidden if it's strictly a prior authorization issue.
Mr. England stated that the issue being made is that by using this medication, is it impacting utilization of other medications. It's not strictly a cost issue but is there a quality of care issue that's going to change because utilization of this drug may cause a decrease in utilization of other things.
Mr. Wuest stated the report can be structured to present utilization without cost.
Dr. Parker stated that he has always been under the impression that in medicine, it's physicians that are responsible for quality of care and being able to provide care and if the drug is not affordable, it's a cost issue. If cost is not an issue, the gates can be open for the use of a lot of drugs which will impact Medicaid's budget. He requested Mr. Faircloth discuss at the next meeting the Board's responsibility in terms of cost.
VOTES: Unanimous
MOTION CARRIED

VII. Presentation by First Health Services and Discussion by Board of Prospective Drug Utilization Review (Pro DUR) Reports
A. Top 50 Drugs Ranked by Payment Amount
B. Top 10 Therapeutic Classes by Payment Amount
C. Pro DUR Message Report

Jeff Monaghan presented drug utilization reports for the first quarter of 2008. He referred to the "Top 50 All Drugs Ranked by Payment Amount" and noted that palivizumab (Synagis®) dominated the total payment for the quarter. This is normally not the number one drug but is due to a seasonal issue as the drug is only given 3-6 months a year. The report otherwise remains somewhat consistent with anti-psychotics and narcotic agents taking up a large portion of the dollars. He stated that oxycodone is a non-preferred drug with high utilization. Utilization and proposed criteria will be reviewed and presented to the Board.

VIII. Presentation by First Health Services on Retrospective Drug Utilization Review Results

Jeff Monaghan presented the RetroDUR Summary Report for new profile reviews and re-reviews for the first quarter of 2008. He noted that the current focus for RetroDUR is poly-pharmacy. The poly-pharmacy initiative will improve therapy and provide cost-savings.

IX. Public Comment

No comment.

X. Date and Location of Next Meeting

The next meeting is scheduled for July 17, 2008, at the Meadow Wood Courtyard in Reno.

XI. Adjourn

MOTION: Steven Parker motioned to adjourn the meeting.
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED
Meeting adjourned at 3:04 p.m.