



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

**Meadow Wood Courtyard
5851 S. Virginia St.
Reno, NV**

**Meeting Minutes Board Approved
October 23, 2008**

Committee Members Present:

David England, Pharm.D., Chairman
Keith Macdonald, R.Ph.
Paul Oesterman Pharm.D.
Steven Rubin, MD
Marjorie Uhalde, MD (called-in)

Absent:

Steven Parker, MD

Others Present:

Coleen Lawrence-DHCFP, Mary Griffith-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, Colleen Boltman-FHSC, Annette Piccicilli-FHSC, Dr. Elizabeth Pritchett-Dr. Les Saltzberg and Gosia Sylwestrzata FHSC (called-in), M. Shefchyk-Novo Nordisk, Rafaele Villella-Alpharma, Arron Howe-Gilead, Robert Spivock-Gilead, Tim Hambacher-Abbott, Craig Boody-Lilly, Mike Steelman-Pfizer, Sheri Elpern-Saint Mary's Hospice, Dan Bay-Abbott, Tava Golden-BMS, Sandy Sierawski-Pfizer, Steve Cooper-Pfizer, Charles Price-Nevada Psychiatric Association, Isam Herndon-GSK, Doug Powell-Forest, Chase Freen-Pfizer.

I. Call to Order and Roll Call

Chairman England called the meeting to order at 1:05 p.m.

II. Discussion and Approval of July 17, 2008 Minutes

Paul Osterman noted that the last word on page 6, "She" can be deleted as it duplicates the first word on page 7.

MOTION: Paul Oesterman motioned to accept the minutes as presented with the correction as noted.

SECOND: Steven Rubin

VOTES: Unanimous

MOTION CARRIED

Chairman England reminded the public that public comment is limited to five minutes per individual, organization or agency.

III. Status Update by DHCFP

A. Nevada Medicaid Pharmacy Lock-In Program

Mary Griffith reported that Nevada Medicaid has recently instituted a program to lock-in recipients who meet specific over-utilization criteria for controlled substance prescriptions. Once a recipient has been identified, a claims check history and data analysis will be conducted to determine if the recipient meets the requirements. If the requirements are met, the recipient will be locked into a specific pharmacy for controlled substance prescriptions. Diagnoses will be taken into account which may justify high utilization. Recipients may change their locked-in pharmacy and also have the option to request a Fair Hearing to stop the lock-in process or file an appeal to be removed from the lock-in program. Nevada Medicaid will work with the Nevada State Board of Pharmacy Narcotic Task Force on recipients being considered for lock-in to determine if there is controlled substance behavior outside of the Medicaid program. Currently, six recipients are being considered for lock-in.

B. Tamper-Resistant Prescription Pad Requirement

Mary Griffith reported that as of October 1, 2008, a written prescription must contain all of the following three characteristics to be considered tamper-resistant:

1. One or more industry-recognized feature(s) designed to prevent unauthorized copying of a complete or blank prescription form;
2. One or more industry-recognized feature(s) designed to prevent the erasure or modification of information written on the prescription by the prescriber;
3. One or more industry-recognized feature(s) designed to prevent the use of counterfeit prescription forms.

She stated that Nevada Medicaid is requiring the prescriber to document the list of security features and descriptions on the prescription form to assist the dispensing pharmacists. This requirement applies to Medicaid fee-for-service prescriptions only and does not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy or prescriptions communicated to the pharmacy by telephone by a prescriber.

Keith Macdonald stated that the responsibility falls on the pharmacist for failure to use that pad. He asked why there was not an equal responsibility on the prescriber.

Coleen Lawrence reminded the Board that this is a federal not state requirement. The question has been posed to CMS as to why this has been enforced on the pharmacist but there has been no response to date. CMS does state that the onus is on the State to enforce the requirement.

Jeff Monaghan suggested that if the Pharmacy Board made this a requirement for all prescriptions, it would make the practice more consistent and the enforcement of the requirement would not be Medicaid's responsibility.

IV. Presentation by DHCFP and First Health Services on Clinical Prior Authorization Criteria for Psychotropic Medications in Children and Adolescents

Coleen Lawrence introduced First Health consultants Dr. Elizabeth Pritchett, child psychiatrist and Dr. Les Saltzberg, clinical psychologist and Director of Behavioral Health Services for First Health who will be participating via teleconference.

Ms. Lawrence stated that over the last year, DHCFP has been concentrating on reviewing the utilization of behavioral health services. This includes inpatient services, outpatient services, rehabilitative services and pharmacy services for behavioral health.

After reviewing the data, there was a concern regarding the utilization of psychotropic medications for children. Subsequently, there has been additional communication to the Director's office for the Department of Health and Human Services regarding the use of psychotropic medication for children who are in the child welfare system.

DHCFP is proposing a policy that monitors the appropriateness of these medications regardless of a child's eligibility group. The data will show a breakdown of child welfare versus all other Medicaid children that are in fee-for-service program. The policy is to address all children and the use of these medications.

One goal of the agency is to begin collecting more clinical information that supports the use of these drugs in this population, for example, specific diagnosis and symptoms of the children. As the Board has been faced with in the past, data is limited on the prescription form, what has been submitted on the PA or in the medical claims data. There is a sample prior authorization (PA) form in the meeting binder, however, the Board will not be acting upon that particular form. She requested input from the Board regarding what type of data they would like collected (diagnosis, symptoms, specific indications).

In preparation for this meeting and the development of this policy, DHCFP hosted a workgroup of Nevada Medicaid providers. The workgroup was presented a policy for review. The group consisted of four psychiatrists including child psychiatrists, a clinical psychologist and a Pharm.D. FHSC and the State took into consideration the group's recommendations and modified the policy accordingly. Those recommendations have been incorporated into the draft policy.

One item discussed within the group was "Well, that is not a reflection of my patient population". That outlook is appreciated especially from this group of well-respected providers. However, the data supports that it is happening "somewhere" within the Medicaid system. The goal is to support appropriate utilization on a statewide basis across all providers and recipients.

Ms. Lawrence thanked the professionals that volunteered their time by participating in this workgroup. She turned the presentation over to Drs. Pritchett and Saltzberg.

Dr. Saltzberg reviewed utilization data. The data collected and analyzed was derived from pharmacy and medical claims from calendar year 2007 of Medicaid recipients between the ages of 0-17 years to determine what percentage received an ADD drug, antidepressant, antipsychotic or anticonvulsant. The Welfare group (foster children) was separated from "other" because there currently is a national issue regarding the medication of foster children. He presented the following breakdown of Medicaid children on an antipsychotic during the reporting period:

Age Group	<u>0-5</u>	<u>6-12</u>	<u>13-17</u>
Welfare	3%	17%	21%
Other	<1%	5%	8%

He commented that the majority of the foster children in age group 0-5 (35%) had a diagnosis of reactive attachment disorder; 23% had the diagnosis of ADHD; 5% had a diagnosis of conduct disorder. Diagnosis is not usually associated with antipsychotics. The three highest prescribers of antipsychotics across this age group were psychiatrists. 50% of the diagnoses were ADHD and it was the only diagnosis in the medical claims. There could be secondary diagnoses that were not coded but it's unusual if someone is using an antipsychotic to not code the most severe diagnosis.

He presented a breakdown of Medicaid recipients with concurrent use of different drugs (2 or more antipsychotics; 2 or more antidepressants; 2 or more antipsychotics with 1 or more antidepressants; 1 or more antidepressants with 1 or more ADD agents). In the 0-5 year old group of foster care children, 1% was on 2 or more antipsychotics; 6-12 years 4%; 13-17 years 6%; which, overall, is a 3:1 ratio prescribed to foster children compared to other children.

Comparing data to other states, Nevada rates higher for antipsychotics in children ages 0-17; 52 per 1,000 children are prescribed antipsychotics. Of the welfare children, 135 per 1,000 are prescribed an antipsychotic. There are a series of states that have published a fair amount of data

regarding foster children on antipsychotics and all states have discussed that too many children are getting medications. In Nevada, 23% of foster children are on psychiatric medications and the range is in 25% to 29% from other states that have taken some action to begin some controls. He turned the presentation over to Dr. Elizabeth Pritchett.

Dr. Pritchett discussed the comparison of the use of psychotropic medications in the 0-17 year old welfare (in state custody) population and 0-17 year old non-welfare population in Nevada which indicates the following:

1. Significant increases in psychotropic prescriptions among the welfare populations in all age categories as compared to the non-welfare population.
2. The increase in psychotropic prescriptions is across medication classes.
3. Increased psychotropic polypharmacy among the welfare population in age groups 6-17 years. While polypharmacy in the 0-5 year group does not appear to be significantly increased, as compared to the non-welfare population, the documentation of 17 children under five years on 2 or more antipsychotics is concerning.

The fact that the population of children in state custody (Welfare) has a higher rate of psychotropic medication prescribing is not surprising. The children are in state custody due to familial disruption, neglect, abuse, behavioral dyscontrol, substance abuse and psychiatric disorders combined with parental insufficiency. In short, the population represents more severely affected juveniles. Additionally, the multiple disruptions that these children have in home placements, caretaker, communities and schools may also give rise to or exacerbate mental disorders such as Reactive Attachment Disorder (RAD). For children ages 0-5 in the welfare population, RAD diagnosis was the most highly represented. This is contrasted to its 7th place listing among the non-welfare population of children on Medicaid. Due to placement in custody, foster care, group homes, residential settings, they are more likely to have a mental health assessment and contact with mental health providers. The prescribing mental health provider is more likely to prescribe a psychotropic medication and be more comfortable in prescribing more than one psychotropic than a non-mental health prescribing practitioner.

Just as children in custody, by virtue of being in custody are more likely to be exposed to mental health services, we see the flip side of this with the children who are not in custody. These children who may experience behavioral disruptions or other mood disturbance are more likely to be seen and treated by the family doctor and pediatricians for such complaints as attention deficits, depressive episodes, anxiety and panic. The Nevada statistics reflect this with 700 children on psychotropic medications but not receiving behavioral health services captured by CPT codes.

This raises the question of quality care, as all treatment protocols associated with childhood mental health disorders indicate at least adjunctive therapies and education as part of the best practices. However, it is a question that is a Pandora's Box, as given the State's shortage of psychiatrists, who is there to treat them?

The most striking and unexpected data in this area is the high number of children with ADHD diagnoses who are on antipsychotic medication (presumably in addition to their stimulant medication). The available information does not indicate whether there are secondary diagnoses more consistent with use of an antipsychotic. In the absence of information documenting secondary diagnoses which would require an antipsychotic, it is likely that psychotropics are being used for symptomatic behavioral control.

The data may reflect the practice of prescribing to symptoms rather than conditions. This is particularly likely in the under age 5 population, where these medications are used for sleep, aggression. Specific chart review would be necessary to further identify underlying rationale for these medications.

It is not uncommon to find antipsychotics in use for the other conditions. They are being used for "off-label" treatments. For instance bi-polar disorder is commonly treated with multiple psychotropic medications and medications are often state dependent. So within the same fiscal

year, an individual might be moved around on meds depending on the disease state to achieve optimum remission.

She suggested the following actions for consideration:

1. Age related edits for certain classes of medication
 - a. Under five, all psychotropic medications should require prior authorization. Prior authorization requirements should include psychiatric evaluation or specific diagnostic criteria citation.
 - b. Six and over all antipsychotics should require prior authorization.
 - c. Polypharmacy (more than one medication from same class or more than three psychotropics prescribed at the same time) triggers TCM referral.
2. Comprehensive, independent psychiatric evaluation for all children entering treatment homes.

Prior to the Board's consideration and discussion of the proposed policy, Jeff Monaghan presented a brief summary of the indications, warnings and experience with these agents.

He stated that although generally considered to be useful agents when used appropriately, recommendations on psychotropic drug use in children are based on limited research, adult literature and clinical experience. For our purposes, the drug classes of anti-anxiety agents, anticonvulsants, antidepressants, lithium preparations, sedatives and antipsychotics are included in the psychotropic drug category. The ADHD drug class was not included as this drug class has been addressed in detail in an existing policy.

Ms. Lawrence summarized the proposed PA criteria for psychotropics for children:

Children Ages 5 and Younger

- Psychotropic medications:
 - should be administered by or in consultation with a child psychiatrist.
 - therapy must be a part of a comprehensive treatment plan that addresses education, behavioral management and psychotherapy.
- Physician monitoring is required while the recipient is utilizing the medication.
- Diagnosis of a unique condition must be made for each psychotropic agent.
- Drug categories and medications subject to PA are:
 - anti-anxiety agents
 - anticonvulsants
 - antidepressants
 - lithium preparations
 - sedatives
 - antipsychotics
- Exceptions to this policy are:
 - treatment of seizure disorders with diagnoses codes beginning 345 (Epilepsy), 780.3 (convulsions) and 779.0 (convulsions in newborn). The diagnosis code included on the prescription and entered into the pharmacy point-of-sale system will bypass the PA requirement.
- Treatment of ADD/ADHD is not covered under this policy. The current policy for the treatment of ADD/ADHD will be followed. (Ms. Lawrence noted that the medications in the ADD/ADHD class will be monitored. Data will be reviewed to determine if this class of drugs should be considered in the future for inclusion to the psychotropic policy.)

Paul Oesterman asked if lithium preparations are ever used in children under the age of five. Dr. Pritchett responded that it's rare. He also stated that polypharmacy has two different meanings and asked if polypharmacy, in this case, is referring to therapeutic duplication or of a patient who is seeking multiple pharmacies. Dr. Pritchett replied that it's defined as the use of more than one drug from the same class of medications or the use of more than three psychotropic medications in different classes. Ms. Lawrence stated that the proposed policy will be modified to include the definition.

Dave England asked if this policy is supported by and follows the guidelines of best practices from child, adolescent and/or adult psychology groups. Dr. Pritchett replied that these policies are based on practice parameters. Best practices are usually tied to an individual diagnosis such as best practice treatment for attention deficit hyperactivity disorder, the best practice treatment for depression, and within these there are medications. Those are best practices tied to individual diagnoses. Then there are practice parameters. For instance, practice parameters recently released for monitoring of antipsychotic medications or monitoring of antidepressant medications. As we developed this policy, we looked at best practices by the American Academy of Child and Adolescent Psychiatry, the American Academy of Pediatrics and also the practice parameters.

Mr. England stated that as new information and data becomes available, the policy should be updated to include current information. Dr. Pritchett agreed particularly in the area of child and adolescent psychiatry. The National Institute of Mental Health is continuing research in these areas monitoring the affects that these medications have on a growing developing brain. She added that as more information becomes available, these policies will be modified.

Dr. Rubin requested that the second sentence of section 4, which addresses polypharmacy, be modified to include “and the documentation of medication side effects”. He stated that it’s very common for a child on a psycho-stimulant to develop insomnia and need a sleep agent. He would not want to see a diagnosis of insomnia skirt the fact that polypharmacy is being done to compensate a drug side effect.

Recipients Ages 6-17

Ms. Lawrence summarized the proposed criteria stating that the policy for this age group focuses further on polypharmacy which is more than one medication prescribed within the same psychotropic therapeutic class within a thirty day look-back period or if there are three or more psychotropic medications regardless of therapeutic class within the last thirty days. The same therapeutic classes, exception for seizure disorders and ADD/ADHD policy documented in the criteria for ages 5 years and under, apply to ages 6-17.

In addition to the above conditions, the PA requirements include:

- Diagnosis of a unique condition must be made for each psychotropic agent.
- For multiple drug therapy for one diagnosis, treatment of unique symptoms must be documented.
- Failure of a trial of a single medication within the same class before treatment with multiple agents will be considered. Ms. Lawrence stated that the policy is not defining how long the length of treatment is before the physician determines it’s a failed attempt.
- Physician monitoring is required while the recipient is utilizing the medication.
- Comprehensive treatment plan that addresses the medication education, behavioral management and psychotherapy. Ms. Lawrence added that the policy will be modified to address living/home environment conditions.

Jeff Monaghan commented that on the anticonvulsant prescriptions if the ICD-9 code is included on the prescription and transmitted, it will bypass the PA requirement. If it’s not included, there are concerns that denials will be created for drugs that are being used routinely for seizures. One solution is to not include the anticonvulsants in this discussion. The child getting a prescription for phenobarbital or Dilantin® potentially will be impacted by this.

Paul Oesterman said that one of the requirements of the pharmacist on a new prescription is to counsel the patient. One of the things that should be counseled for is what did the physician order this medication for. That information should come back to the pharmacist at the point-of-sale and the ICD-9 code could be entered into the pharmacy system.

Mr. Wuest stated that the data indicates that more than 50% of PA requests for children in the 0-5 year range are for anticonvulsants and most of those children do not have a behavioral disease.

Ms. Lawrence suggested a look back in claims history. If the drug is in history, the prescription processes without a PA and/or an override given at the pharmacy level if the medication is for seizure disorder. Mr. Monaghan stated that the override could be the ICD-9 code. The Board

agreed that the ICD-9 could be applied to override the rejection at the pharmacy level, however, the ICD-9 must be written on the prescription by the prescriber. If the ICD-9 is not included and the patient states the medication is for seizure disorder, the pharmacy will be required to verify the diagnosis with the prescriber and document on the prescription. Mr. Macdonald commented that it is very time consuming for the pharmacy to contact the prescriber. Dr. Rubin felt that the burden of calling the physician does not have to fall on the pharmacy. Inform the recipient that the prescription cannot be filled and to contact their doctor. Prescribers will then become trained to put the diagnosis code on the prescription which will promote efficiency.

Mr. Monaghan stated that the options appear to be to 1) exclude anticonvulsants until it could be automated, 2) require the ICD-9, or 3) grandfathering (claims history look back). If the anticonvulsants are included, he recommended grandfathering which will allow time for provider communication and education and prevent a large volume of calls to the Call Center. In terms of the ICD-9 bypass for seizure disorder, Ms. Lawrence reminded the Board of the 92-hour emergency fill override which the pharmacy can request through the Call Center until they are able to communicate with the prescriber.

Dr. Rubin recommended a look back and to encourage the practitioners to provide a diagnosis code and Mr. Macdonald added provider training.

Mr. Monaghan stated that the high volume prescribers and pharmacies can be identified for targeted training. Ms. Lawrence said in addition to the training, a web announcement can be posted as well as a message on the providers' remittance advice.

Public Comment

No comment.

Discussion and Action by Board Concerning the Adoption of Clinical Prior Authorization Criteria for Psychotropic Medications

MOTION: Keith Macdonald motioned to adopt the clinical prior authorization criteria for psychotropic medications for children five years of age and younger. The proposed policy will be modified to include the definition of polypharmacy and section 4 will be modified to include "the documentation of medication side effects."

SECOND: Paul Oesterman

VOTES: Unanimous

MOTION CARRIED

MOTION: Paul Oesterman motioned to adopt the clinical prior authorization criteria for psychotropic medications for recipients ages six through seventeen years of age.

SECOND: Keith Macdonald

Dave England summarized the Board's recommendations for anticonvulsant prescriptions:

- 1) A look back in claims history – previous history will bypass the PA process.
- 2) ICD-9 code – inclusion of the ICD-9 code for seizure disorder on the prescription by the prescriber or verified with the prescriber by the pharmacy will allow the pharmacy to transmit the ICD-9 and bypass the PA process.
- 3) Prescriber and pharmacy provider education.

Paul Oesterman added that in section 4.a. "initiative" be changed to "initial".

VOTES: Unanimous

MOTION CARRIED

V. Presentation by First Health Services on the Implementation of a Clinical Prior Authorization Edit Process for Lyrica® (pregabalin)

Dave Wuest stated that his item has been discussed at the previous two Board meetings. He presented the proposed criteria which are based on FDA indications and utilization data as requested by the Board.

A total of 1,217 Medicaid recipients received Lyrica® in FY2008. He referred to the chart which breaks out diagnosis by number of recipients. He noted that the first four diagnoses (Post Herpetic Neuropathy [PHN], Seizure Disorder, Diabetic Peripheral Neuropathy [DPN], Fibromyalgia) were allowed duplication of diagnoses; i.e., if a recipient had seizure disorder in addition to DPN, they would count twice but would not count twice in the “Other Diagnosis (not listed above)” category. The majority of recipients receiving Lyrica® during the reporting period did not receive it for an FDA indication.

A review of the 206 recipients receiving Lyrica® for Fibromyalgia was completed. Narcotic utilization was compiled for 90 days prior and 90 days after each recipient received Lyrica®. On average, these recipients received 4.5 doses of a narcotic per day prior to and after the inclusion of Lyrica®. Mr. Wuest noted that this is an average and that an individual recipient’s narcotic usage per day may have increased or decreased when Lyrica® was added. Mr. Monaghan added that the reason for the analysis, as requested by the Board, was that it was stated or implied that Lyrica® would reduce narcotic usage.

Mr. Wuest noted that Fibromyalgia is now considered a medical condition as defined by the American College of Rheumatology (ACR) 1990 Criteria for the Classification of Fibromyalgia and that Lyrica® has an FDA indication for Fibromyalgia. He reviewed the proposed criteria for PA approval:

-For the diagnosis of epilepsy and/or seizure disorder, DPN and PHN, prescriptions transmitted with the applicable ICD-9 will bypass the PA process.

-Fibromyalgia:

- Diagnosis of fibromyalgia based on ACR classification criteria
- Documentation of widespread pain for at least 3 months
- TSH (thyroid stimulating hormone) lab work was performed and any abnormalities treated

Paul Oesterman stated that based on the different diagnoses, the maximum daily dosage recommendations are different and asked if there is a way to determine if they are falling within the realm of where they should be. Mr. Wuest replied that utilization reports can be generated. Mr. Monaghan pointed out that First Data Bank through the pharmacy system will flag minimum/maximum dosages back to pharmacists.

Dr. Rubin asked what the research data shows comparing Lyrica® to Neurontin® and Gabitril®. Mr. Monaghan stated that there are no head-to-head studies; the studies were against placebo. Mr. England asked regarding best practices for treating Fibromyalgia. Mr. Monaghan responded that there are guidelines that do include Lyrica®. The proposal is not suggesting that Lyrica® not be used for Fibromyalgia but suggesting that it be prior authorized with documentation that Fibromyalgia exists.

Public Comment

Sheri Elpern, volunteer with Saint Mary’s Hospice, spoke on behalf of Kelle Brogan, MD, director of the hospice program. She read a letter from Dr. Brogan supporting Lyrica®. The letter states that “...Lyrica® has long been an important part of Saint Mary’s hospice formulary because it controls nerve pain in patients who cannot tolerate opioids. In other patients, Lyrica® helps reduce patients’ opioid requirements. Gabapentin, Lyrica’s earlier generation drug, triggers sedation and dizziness. With Lyrica® these side-effects are milder and often absent. Lyrica® clinically has a faster onset of action than Gabapentin. Further, Lyrica® can be dosed once or twice a day versus the usually required four times a day dosing for Gabapentin thereby enhancing

patient compliance. I have found that the overall cost of Lyrica® is no greater than that of Gabapentin in the long run...”

Sandy Sierawski, Pfizer, spoke in support of Lyrica®. She thanked the Board and First Health for reevaluating the initial criteria that came forward based on discussions at the April meeting. She stated that not having a clean ICD-9 process for every prescription could result in a delay in epilepsy medication for some patients. Regarding the proposed criteria for Fibromyalgia, criteria 1 and 2 seem clear cut but unclear on where the TSH lab work has clinical evidence. Mr. Wuest responded that it's part of the ACR guidelines. Ms. Sierawski said that the ACR criteria for the classification of Fibromyalgia states that no exclusions are made for the presence of concomitant radiography or laboratory abnormalities. Mr. Wuest responded that the rationale for the testing is that sometimes thyroid disease presents with similar symptoms so the criterion is there to ensure that the thyroid is normal before diagnosing Fibromyalgia.

Mr. England spoke to Ms. Sierawski's comment that the process might delay patients getting medications stating that Ms. Lawrence addressed that earlier with the 92 hour emergency fill.

Ms. Sierawski recommended that provider training be provided to high prescribers of Lyrica® so they know an ICD-9 code is needed. Ms. Lawrence responded that typically there has not been a problem with physicians not having information that comes from the DUR Board. Manufacturers are partnered with to assist in providing that information to physicians. There is the public hearing process and policy changes will be reflected in Chapter 1200 of the Medicaid Services Manual. Web postings and remittance advice messages may also be used to announce policy changes.

Dr. Charles Price, psychiatrist, stated that the diagnosing of Fibromyalgia is still in the practicing physician world. People with Fibromyalgia often have psychiatric disorders that come along with any pain syndrome. He summarized letters that he has received from twelve practitioners who treat Fibromyalgia in a non-psychiatric setting. The basic message from the letters state that Fibromyalgia is a controversial diagnosis but the people with Fibromyalgia do not see it that way. They see themselves as being discriminated against. He stated that it's difficult to get colleagues to accept the diagnosis and when it's accepted, getting the proper treatment. The physicians state that treating Medicaid patients is getting more onerous all the time and the more pressure on the practitioners, the more will opt out of the program. For Fibromyalgia, the physician's integrity is not trusted in that they have correctly diagnosed the disorder by asking for several different requirements. For example, the criteria do not include an EEG to prove the diagnosis of epilepsy correctly. He suggested that for the patients, practitioners and society, the diagnosis code of 729.1 allow a prescription to go through. He referred to the data presented by FHSC which showed 1,217 patients were prescribed Lyrica® and only 206 had Fibromyalgia so it's not a big pool. He requested the Board consider use of the diagnosis code for Fibromyalgia as with the other disease states and if it becomes an issue in the future, put something else in place.

Mr. England asked Dr. Price what other criteria he could suggest to ensure a clean diagnosis; pain is subjective. Dr. Price replied that's where psychiatrists are different from other physician in a sense that how do you prove that someone has depression; how do you prove that someone has anxiety. There are no lab tests to prove those conditions whereas in a lot of other medicine there is. It's a clinical diagnosis and it's not based on labs.

Discussion and Action by the Board on Clinical Prior Authorization Criteria

Dr. Rubin stated that his argument is not the controversy of the diagnosis but if approval is given for expensive, me too drugs like Lyrica® and Pristiq® and we see this money being spent by the millions of dollars, there will be no practitioners left to prescribe these drugs. Practitioners need to be scrutinized more closely. This diagnosis has become an epidemic in this country and it's time that the decade of the big pharmacy be told no. He felt no convincing, valid statistical data has been presented to indicate that this drug is unique other than its price versus what is on the formulary now.

Due to another commitment, Dr. Rubin was excused from the meeting at 2:58 p.m.

Mr. Macdonald suggested that if it's not objectionable to the Board, add the ICD.9 code for Fibromyalgia to section 1.d. of the proposed criteria.

MOTION: Paul Oesterman motioned to accept the proposed criteria for Lyrica® as presented adding the diagnosis code of Fibromyalgia to section 1.d. In six months, usage data regarding the dose pertaining to each of the respective diagnoses to be presented.

SECOND: Keith Macdonald

VOTES: Unanimous

MOTION CARRIED

VI. Presentation by First Health Services on the Implementation of a Clinical Prior Authorization Edit for Topical Lidocaine Patches

Deferred until the next meeting.

Public Comment

Discussion and Action by Board on the Adoption of Clinical Prior Authorization Criteria for Treatment with Topical Lidocaine Patches

VII. Presentation by First Health Services on the Clinical Prior Authorization Process for Cox-2 Inhibitors

Deferred until the next meeting.

Public Comment

Discussion and Action by Board on the Revision to Current Clinical Prior Authorization Criteria for Cox-2 Inhibitors

VIII. 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

Deferred until the next meeting.

IX. Presentation by First Health Services of Retrospective Drug Utilization Review Results

Deferred until the next meeting.

X. Public Comment

No comment.

XI. Date and Location of Next Meeting

The next meeting is scheduled for January 29, 2009, in Las Vegas.

XII. Adjourn

MOTION: Keith Macdonald motioned to adjourn the meeting.

SECOND: Paul Oesterman

VOTES: Unanimous

MOTION CARRIED

Meeting adjourned at 3:02 p.m.