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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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Administrator

DRUG USE REVIEW (DUR) BOARD

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

Meeting Minutes
January 25, 2007
Approved by the DUR Board on April 26, 2007

Committee Members Present:
David England, Pharm.D., Chairman
Keith Macdonald, R.Ph.
Marjorie Uhalde, MD
Steven Parker, MD
Steven Rubin, MD
Paul Osterman, R.Ph.

Others Present:
Coleen Lawrence DHCFP, Debbie Meyers DHCFP, Darrell Faircloth DAG, Jeff Monaghan FHSC, Dawn Daly FHSC, Shirley Hunting FHSC, Eric Rouse Eli Lilly, Bert Jones Glaxo SmithKline, Steve Farmer Amgen, Paul Voss Allergan, Johnna Nelson Eli Lilly, Craig Boody Eli Lilly, Joe Busby Eli Lilly, Ken Griffiths OMJ, Katherine Hollingsworth Takeda, C. Lepore J&J, Snady Sierawski Pfizer, Bret Parker Pfizer, Doug Powell Forest, Sabrina Avery BMS, Chris Almeida Purdue Pharma.

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 September 21, 2006 Minutes

MOTION: **Keith Macdonald motioned to accept the minutes as written.**
SECOND: **Steven Rubin**
VOTES: **Unanimous**
MOTION CARRIED

III. Status Update by DHCFP on the Federal Deficit Reduction Act of 2005.

Coleen Lawrence stated that regulations are being proposed by the federal government on Medicaid prescription drug provisions that were included in the Deficit Reduction Act of 2005. The proposed regulations will involve pricing algorithm changes from Average Wholesale Price (AWP) to Average Manufacturers' Price (AMP).

There are also new regulations requiring submission of the National Drug Code (NDC) when billing for outpatient physician-administered drugs in order to facilitate drug manufacturer rebates. This will impact physician administered drugs in offices, clinics and facility-based physicians. State Medicaids that do not comply with this regulation will not receive federal funding for drugs not reported at the NDC level.

Ms. Lawrence stated that a survey will be sent to providers to determine NDC knowledge, current reporting, etc., by physicians. DHCFP and First Health will be partnering with physician associations and pharmaceutical manufacturers focusing on provider education, outreach and training of NDC reporting. Targeted education will be provided to high-volume providers. There will also be structured mailings quarterly over the next year to notify and educate providers regarding this change. DHCFP and FHSC have been addressing programming requirements to ensure the system will be able to accept NDC reporting by physicians beginning January, 2008.

IV. As Requested by the Pharmacy and Therapeutics Committee, Presentation by First Health Services and Discussion by Board on Possible Changes to Clinical Prior Authorization Criteria for Drugs Used to Treat Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD) in Adults and Children

Jeff Monaghan stated that the Pharmacy and Therapeutics (P&T) Committee recently reviewed the ADHD drug class and recommended that the DUR Board reexamine the prior authorization requirements that are in place for this class of drugs. He presented the two types of prior authorization (PA) criteria that are in currently in place; one for children up to age 18 and one for adults 18 years and older. The Clinical Call Center receives approximately 200 requests per month for approval to place patients on ADHD drugs, the high 90th percentile of which are approved. He presented a cost and utilization analysis (average number of claims per member per month) of four states, including Nevada, and noted that Nevada's utilization is fairly low compared to the other states. The analysis also included a breakdown by age range which indicated highest utilization in the 5-11 age range followed by the 12-17 age range. In comparing PA criteria, Nevada has some of the more strict PA requirements in place for these drugs. Kentucky only requires a diagnosis for approval; Michigan requires a diagnosis of ADD/ADHD in the 3-5 age range with no PA required for the 6-17 age range.

Mr. Monaghan stated that the psychiatrist, Dr. Horne, on the P&T Committee felt very strongly that the requirement for an IQ test on the adult criteria was overkill and did not have validity and suggested that requirement be reexamined.

Dave England said that if a national standard exists, he felt the committee should abide by it and incorporate it or adjust the criteria for Nevada. He agreed that the requirement for an adult IQ test could be eliminated. He stated that the existing criteria seem rational and was not convoluted or vague. A report presented to the DUR Board a few months ago indicated that there was high drug utilization related to antipsychotics and these types of medications especially in youths, and his concern is possible over-diagnosing in this area.

Dr. Rubin stated that this is an opportunity to improve data collection and recommended increasing the information required and requested. He felt that ADD and ADHD diagnostics are grossly over-diagnosed and it's endemic in our state and nation. He would like to see efforts taken to reduce the over- or misdiagnosis of this syndrome and develop a databank of who's prescribing, the credentials of the prescriber and more clinical information; i.e., more ruled out specifics. This would help to eliminate the misdiagnosing of this disorder and the unnecessary prescribing. He recommended continuing requiring a PA and to improve the paperwork.

Mr. England said that the information he has reviewed indicates that most of these medications are not being prescribed by psychiatrists but other prescriber types. Are the DSM-IV criteria being followed to the point of where it's rationale and is it within the scope of their practice for other practitioner types to make these types of diagnoses?

Ms. Lawrence said that Dr. Horne suggested setting up the system to capture provider certification; i.e., if a provider is a psychiatrist, it would not be necessary to go through the PA steps.

Dr. Uhalde felt that pediatricians and family practitioners are prescribing these medications because that's who the kids go to. The problem is that psychological testing can take 6 to 8 months and if the child is in school, could flunk that grade. If it's too difficult to get the medications, kids that should be treated may not be treated. She agreed that most aren't properly

diagnosed. They are treated more on a symptomatic basis rather than actual psychological testing. Dr. Rubin added that nurse practitioners and physicians' assistants are prescribing these as well.

Dr. Parker agreed that he would like to see who is prescribing and also develop something computer-based for practitioners to access which provides criteria and information to make a proper diagnosis.

Ms. Lawrence stated that the system can provide prescriber specialty, regions of the state to determine if there is an urban versus rural issue, claims paid utilization on the recipient, diagnosis, and from the medical claim, can determine what other services were rendered.

Keith Macdonald said that he agrees with everyone's concern about who is prescribing and if it's correct. The Controlled Substance Abuse Task Force reports that stimulants are on a flat level and with the population rise in Nevada, there isn't an increase in stimulant prescriptions. He asked if these criteria are too difficult to get the medications for children who might need them as well as for children who may be prescribed inappropriately. He agreed with Dr. Rubin's idea of a study if it can be done.

Dave England suggested for Committee consideration that no changes be made to the existing criteria at this time. He requested a preliminary study be presented within the next three to six months to include data as suggested by Dr. Rubin. Based on the analysis, determine what adjustments may need to be made to the existing criteria.

Ms. Lawrence suggested a combination of a claims utilization report and conduct a provider survey for data collection. A group can be formed to determine the intent and information to be collected on the survey. Dr. Rubin volunteered to work with others to develop the survey.

Keith Macdonald reminded the Committee that it was suggested the adult IQ testing has no value and recommended removing this requirement from the criteria. Dr. Rubin agreed.

Public Comment

Johnna Nelson, Eli Lilly and Company, spoke in support of Strattera® being available on the Preferred Drug List (PDL) without restrictions. She stated that Strattera® is unique as it is a non-stimulant indicated and approved for the treatment of ADHD. 65% of children and adolescents will have at least one co-morbid condition. In pediatric trials, Strattera® was not contraindicated and did not exacerbate co-morbid conditions. Strattera® is not a controlled substance and has no liability with respect to addiction. Overall safety and tolerability have been demonstrated in clinical trials. There is a box warning regarding an increased risk of suicidal ideation, a warning regarding the risk of liver injury and rare allergic skin reaction. In 2006, the label was changed to include a warning for treatment of emergent psychotic and manic symptoms in children and adolescents and emergent agitation, aggression and hostility. The label was also changed for sudden death, stroke and myocardial infarction in adults and sudden death in children and adolescents with a pre-existing structural cardiac abnormality. Straterra® should not be used within two weeks of an MAOI.

Dr. Rubin asked who declared Strattera® as a non-stimulant. Ms. Nelson replied because of the mechanism of action (selective norepinephrine reuptake inhibitor), the package insert and according to the FDA, it is a non-stimulant. Dr. Rubin asked if she would classify norepinephrine as a sedative and she said that her classification would be a neurotransmitter. Dr. Rubin stated that his classification is "stimulant" and he would like the record to stand that Strattera® be regarded by the board as a stimulant.

Ms. Lawrence stated that when this class was reviewed in the past, even though this is not classified as a CNS stimulant by the FDA, we classified it in Nevada as a class of drugs that treat or are indicated for the treatment of ADD and ADHD so they are approved by State policy with the stimulants (regulations available on DHCFP website).
Ms. Lawrence stated that during the last P&T Committee, Dr. Johanna Fricke, developmental behavioral pediatrician and Dr. Ann Childress volunteered to assist the State in providing feedback for modifying the criteria.

Dr. Rubin offered the following points:
-An analogy would be that because a glass of beer is not nearly as potent as a glass of Everclear, we would not call beer non-alcoholic.
-The P&T Committee went through this with Rozerem® requesting it not be labeled as a sedative hypnotic and someone on the committee pointed out that if you do that, you could combine Rozerem® with, for example, Ambien®, and then you will have someone on two sleep agents which is dangerous. If we accept this initiative to declare a stimulating medication as a non-stimulant, we could develop the same problem of recipients who are on potent stimulants and combining this less potent stimulant could add to trouble.
-While appreciating physicians willing to participate with the Board, I am holding a monogram CME by Dr. Childress who is a consultant for several companies represented. That could be to our disadvantage if the criteria are in favor of the special interests and our special interest is in the health and welfare part.

Ms. Lawrence said committee members have on record disclosure statements. The State is aware that many programs are industry funded. In bringing forward information and/or issues to the board, funding sources are not taken into consideration. The purpose of the board is to provide clinical expertise and it is the board's decision on how they want to utilize the information provided.

V. *Action by Board Concerning Revisions to Clinical Prior Authorization Criteria for Drugs Used to Treat Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder(ADHD) in Adults and Children

MOTION: Keith Macdonald made a motion to remove from the criteria the requirement for an IQ test for adults (18 years and above).
SECOND: Marjorie Uhalde
Dr. Rubin made a friendly amendment that he favors the removal of the IQ test, however, this is not a finalized form.
VOTES: Unanimous
MOTION CARRIED

Mr. Faircloth asked Ms. Lawrence to inform the board on what the timeframe would be for amendment of the criteria. She stated that typically it is a minimum of 60-90 days after the vote for the new policy to take effect.

MOTION: Keith Macdonald motioned that the Chairman appoint three people to participate on a subcommittee to review data for criteria modification.
Ms. Lawrence stated for clarification because this is data collection and not policy making, it is not necessary to form a committee. Working together with DHCFP and FHSC, this can be accomplished administratively via email to the board members. A draft request will be sent to the board for review and comment.
Dr. Parker wanted to ensure that something is included about whether people would like to have education on the issue. He offered to second the motion with the number of appointments to the subcommittee not necessarily limited to three but at the chairman's discretion.
SECOND: Steven Parker
AYES: Dave England, Keith Macdonald, Marjorie Uhalde, Steven Parker
NAYES: Steven Rubin
MOTION CARRIED

VI. 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. He referred to the "Top 50 All Drugs Ranked by Payment Amount" for service period 1/1/2006 through 12/31/2006, noting that the antipsychotic drugs continue to dominate total payment amount.

He stated that a new system functionality now allows the capturing of compounded drugs. The reporting of these prescription type payment amounts is included in this report under "Compound Rx." FHSC is in the process of analyzing these prescriptions to see what types of drugs are being compounded and will report to the committee at the next meeting.

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

Jeff Monaghan reviewed the RetroDUR Summary Report for new profile reviews and re-reviews for report period 01/06 through 09/06. The focus during this period was acetaminophen dosing at the pharmacist and prescriber level. In September, 2006, statin inhibitor non-compliance was reviewed. The review indicated patients who were not getting statin prescriptions refilled on a regular basis. Prescribers were notified via letter alerting them that it appears that the drug may not be taken as prescribed.

Mr. Monaghan stated that he will review RetroDUR criteria for ADHD and present suggestions for review to the committee.

Dave England said that in terms of the acetaminophen review, prescribers have been notified and asked if anything can be done on a community basis to provide education to the patients and let them know that this is their concern and they should take responsibility for their care as well. He asked if information could be provided on the Medicaid website.

Dr. Parker suggested an informational flyer on acetaminophen be distributed to pharmacies as a handout to recipients.

Dr. Rubin felt another approach could be to incorporate the requirement of a certain amount of CE hours as determined by the State in order to renew pharmaceutical licenses.

Ms. Lawrence said that the State is not a proponent of recipient mailings due to the turnover of addresses. The healthcare professional is usually used as the mechanism for informing recipients. There is also the opportunity to distribute information directly to the recipient through care coordination offices and district welfare offices which are located throughout the state. Also, several agencies currently have a place for recipient information on the State's website.

VIII. Presentation by DHCFP and Discussion by Board Regarding the Formation of a Joint Subcommittee with the Pharmacy and Therapeutics Committee to Determine Quality and Outcome Indicators Related to the Preferred Drug List (PDL)

Ms. Lawrence stated that this item is being presented at the request of Dr. Carl Heard of the P&T Committee to discuss quality and outcome indicators as related to the PDL. It was decided that a subcommittee consisting of volunteer members from both the P&T and DUR Board could be created to develop quality reviews and outcome data related to the activities of these two committees. The subcommittee will not be a regulatory body and there will not be a quorum of either committee.

Mr. England asked that because the P&T Committee and DUR Board are set up as separate entities with responsibility for different duties, will there be a violation of statute if there is a subcommittee consisting of members from both committees?

Mr. Faircloth responded that he is not entirely clear what actions this subcommittee might take. Subcommittees are subject to open meeting laws. The P&T was anticipated to have subcommittees legislatively. He felt there would be no problem unless there was an attempt to meld the powers of the two committees at which point he would have to look at the specific circumstance to determine if there was a problem occurring. The DUR's statutory mandate is to assist Medicaid by recommending prior authorization criteria from a clinical standpoint. The P&T Committee's statutory mandate is to recommend drugs for inclusion to or exclusion from the Preferred Drug List. In the circumstance of the ADHD drugs today, the P&T Committee takes one tack as part of the PDL that the class of drugs has been established and there are prior

authorization criteria. However, the clinical aspect of the prior authorization criteria is this committee's function as opposed to creating and managing the PDL.

Dr. Parker questioned why another committee needed to be formed. If the P&T wants to see how the PDL has worked to cut costs, why can't they ask that question themselves?

Ms. Lawrence responded that P&T's intent was not to look at cost. Both of these boards are policy making boards. DUR makes policy on prior authorization, education and training and P&T is the policy board for the PDL. This initiative is not to make policy decisions but to utilize the experts we have to establish the parameters to measure what the recipient population is doing.

Mr. Monaghan said the main task will be agreeing on some type of indicators that make sense. To make the assumption that a certain outcome has been reached because of the PDL is a huge leap. There are so many other factors feeding into a clinical outcome. As long as that's understood and we don't think that we are going to either bless or condemn the PDL based on what is done here.

Dr. Parker suggested that once the specifics are determined by whatever internal mechanisms, questions can be presented to the board.

Keith Macdonald said when talking about quality and outcome indicators, there are so many other factors relative to access, reimbursement to practitioners and other things beyond our control. It would be difficult quantifying whether not putting a drug on the PDL or doing anything with any drug through these two committees is solely the result of these two committees' actions.

Mr. Monaghan said that if we go forward with any part of this, perhaps it should be quality and outcome indicators related to drug therapy as opposed to the Preferred Drug List.

Mr. England said that the board can continue to consider this and will be available as a resource.

IX. Status Report on Board's Educational Program Initiatives

Mr. Monaghan said that DHCFP and FHSC have been working with the University Of Nevada School Of Medicine's continuing education department to put together a program on the use of antipsychotic medications. The program is scheduled for spring 2007. The board will be informed once the program schedule is finalized.

X. Presentation on Asthma Education and Awareness Project

Ms. Lawrence stated that during previous DUR meetings, it was agreed that different educational initiatives should be developed. Bert Jones informed DUR at the last meeting that his company sponsors an asthma awareness project and is here today at the request of DHCFP to present information regarding the programs that are available.

Bert Jones, Director of Government Affairs, Glaxo SmithKline, stated that his company has developed asthma coalitions with other states and presented non-branded tools and programs available for consideration by DHCFP and DUR.

XI. Public Comment

No comment.

XII. *Adjourn

MOTION: Steven Parker motioned to adjourn the meeting
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED

Meeting adjourned at 3:00 p.m.