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

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DRUG USE REVIEW (DUR) BOARD

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

Approved
Meeting Minutes
August 2, 2007

Committee Members Present:

David England, Pharm.D., Chairman
Keith Macdonald, R.Ph.
Marjorie Uhalde, MD
Steven Rubin, MD
Steven Parker, MD (called-in 1:06 p.m.; phone connection lost 1:45 p.m.)

Absent:

Paul Oesterman, Pharm.D.

Others Present:

Coleen Lawrence-DHCFP, Debbie Meyers-DHCFP, Mary Griffith-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Shirley Hunting-FHSC, Joseph Tyler-NAMI, Doug Powell-Forest, Bobby White-UCB, Lisa Durette-Child and Adolescent Psychiatrist, John Stockton-Genentech, Chad Patel-Eli Lilly, David Bruhn-Lilly, Craig Boody-Lilly, Sabrina Aery-BMS, Lori Howarth-Bayer, Kara Smith-Cephalon, Dave Wuest, Jeanette Belz-Nevada Psychiatric Association, Chris Almeda-Purdue, Victor Torrence-Al Pharma, Sandy Sierawski-Pfizer, Bret Parker-Pfizer.

I. Call to Order and Roll Call

Chairman David England called the meeting to order at 1:04 p.m.

II. Discussion and Approval of April 26, 2007 Minutes

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

III. Status Update by DHCFP on the Federal Deficit Reduction Act of 2005 and the National Provider Identifier (NPI) Initiative

Coleen Lawrence presented an overview of the Deficit Reduction Act of 2005 (DRA). The Centers for Medicare and Medicaid (CMS) have enacted changes which significantly impact payment for prescription drugs by the Medicaid Program. The proposed regulations were released in December 2006. DHCFP submitted public comment within the allotted time period. The final regulations were made public on July 6, 2007, printed in the Federal Register on July 17, 2007, and can be accessed through the CMS website.

She provided a handout (attached) and highlighted the changes:

Average Manufacturer Price (AMP)

The regulations define what prices should be included and excluded from the determination of AMP. This affects the collection of rebates and such issues as what can be considered in a rebate amount. Parameters on the reporting requirements for the drug manufacturers to CMS have also been redefined.

Federal Upper Limit (FUL)

CMS has changed the reimbursement methodology of the FUL (FUL is the maximum allowable cost for multi-source drugs as determined by CMS). CMS has redefined the reimbursement methodology which will be dependent on AMP and has released a pilot pricing list. However, due to many errors in the database, DHCFP has chosen not to use it. DHCFP will analyze the new rates to determine the impact on Nevada's reimbursement. The impact may be minimal as there currently is a State maximum allowable cost (MAC) on multi-source drugs.

Physician-Administered Drugs

CMS will be requiring states to collect the National Drug Code (NDC) on providers' claims to enable the collection of rebates on rebatable physician-administered drugs. Physicians currently bill using the Healthcare Common Procedure Coding System (HCPCS) codes and HCPCS units. Effective January 1, 2008, physicians will be required to submit the NDC on physician-administered drug claims utilizing NCPDP units. DHCFP and First Health are working on system enhancements to accept the NDC on the CMS 1500 and UB-04 claim forms. Pharmacy Point-of-Sale (POS) edits will be strictly enforced. She recommended that manufacturers who do not currently participate in the drug rebate program consider doing so by January 1, 2008, as non-rebatable drugs will not be covered. Ms. Lawrence stated that First Health will be conducting targeted provider training with high utilizers and the State will also be reliant on the representatives of drug manufacturers in the field to assist with education.

National Provider Identifier (NPI)

CMS was to make publicly available the National Provider Identifiers by August 1, 2007, but it has not been released on the CMS website to date. The file will provide prescriber NPIs for submission on claims. Once the NPI file is available, use of the "dummy number" will be discontinued in the POS system.

Mr. Macdonald asked if use of the prescriber "dummy" number has decreased with NPI. Mr. Monaghan replied that the major chains have not yet made that conversion in their systems as they are awaiting the release of the CMS NPI downloadable file. Pharmacy submission of NPI is currently at 95%.

IV. Presentation by DHCFP and Discussion by Board of Requirement to use Tamper-Resistant Prescription Pads for non-electronic Medicaid Prescriptions

Ms. Lawrence stated that Section 7002(b) of the U.S. Troop Readiness, Veteran's Health Care, Katrina Recovery and Iraq Accountability Appropriations Act 2007 requires the use of tamper-resistant prescription pads for all prescriptions written for Medicaid recipients. CMS has not yet provided the guidelines or definition of tamper-resistant pads, but has informed states that the guidelines will be available before the effective date of October 1, 2007. Several states have appealed this action requesting an amendment, an extended timeframe and/or require use of these pads for controlled substances only.

Dave England stated that APhA has gone to Congress requesting a delay of the October 1, 2007, date. Some states have implemented tamper-resistant prescription pads for Schedule II prescriptions and it has taken up to eighteen months to have the prescription blanks prepared. In California where the triplicate prescriptions have been eliminated and tamper-resistant blanks for Schedule II's has been implemented, printers are required to be approved by the state board of pharmacy and the Department of Justice Bureau of Narcotic Enforcement.

Ms. Lawrence said that Nevada Medicaid has partnered with APhSA, the National Association of State Medicaid Directors and the Governor's Association. Under the same letterhead, all three agencies have sent information to Congress requesting delay of the implementation date. Until the law is changed, states will be required to comply with the October 1, 2007, effective date. Until CMS provides further guidance, DHCFP will put a general policy in place stating that effective October 1, 2007, tamper-resistant prescription pads will be required for Medicaid recipients. This will begin the required public process for policy implementation. The policy can be pulled and/or modified once CMS provides guidance.

Dr. Rubin asked what the consequence of non-compliance is. Ms. Lawrence stated that the prescription payment can be recouped for outpatient prescriptions and added that enforcement has not been clarified by CMS. CMS' premise for instituting this act is controlling fraud and abuse for Medicaid recipients.

Mr. Monaghan stated that if this truly does serve the public interest, the pharmacy board should take this on for all patients as opposed to enforcing this with just a small Medicaid population. That is how California has approached this.

The board discussed several potential problems; e.g., an increase in phoned-in prescriptions, physicians discontinuing the prescribing of pain medications, tamper-resistant prescription pads not available by effective date, increase in emergency room visits, delays in patients receiving medications, etc.

Ms. Lawrence stated that the top advocacy groups are involved in this issue and until the law is appealed or amended, the State must comply. DHCFP has participated on all of the CMS calls and has responded to CMS requesting guidance. To keep the providers and public informed, notifications and updates will be posted on the DHCFP website. The state will conduct a public hearing on this regulation which can be changed/postponed depending on the issuance of the CMS guidance.

It was agreed that the DUR Board cannot make recommendations or take action until clarification is received from CMS.

V. Presentation of Report by First Health Services on Prescriber Specialty and Drugs Prescribed for Patients with Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD) in Children

Jeff Monaghan stated that the Pharmacy and Therapeutics Committee (P&T) has asked the DUR Board to review prior authorization (PA) criteria and relax the current practice of requiring a PA on all ADHD drugs. This was discussed at the last DUR Board meeting and the board requested additional data be presented at this meeting. Mr. Monaghan presented utilization data for CY 2006. Included in the report are the most prevalent types of drugs prescribed, the prescription volume by specialty and the most common drugs prescribed by specialty. He stated that three specialty groups, Pediatrics, Child Psychiatry and Psychiatry comprise 75% of the ADHD prescriptions. Drug type by age indicates that the majority of usage is in the seven to fifteen year old age group. He referred to the June, 2007, Clinical Prior Authorization Report. Based on the current criteria, 96% of requests for CNS stimulants (ADHD requests) are approved. He noted that written public testimony has been submitted by Ann Childress, M.D., Child and Adolescent Psychiatrist and distributed to the board.

Ms. Lawrence reminded the board that the current prior authorization for ADHD drugs is for a one year period. The board has the latitude of doing things based on diagnosis, age, history look back, polypharmacy, and prescriber specialty. If prescriber specialty is considered, the prescriber's NPI must be submitted on the prescription; i.e., the dummy number will not describe specialty and the claim will deny.

Mr. Macdonald offered for discussion, consideration be given to removing the PA requirement for the high volume specialty groups as noted in the utilization report (Pediatrics, Child Psychiatry and Psychiatry). Mr. England suggested considering setting a benchmark that if the standards are

being met and PAs are approved 96% of the time, consider relaxing or releasing the requirements. He recommended a review period of three to five years.

Mr. Monaghan stated that the approval rate has been consistently high for the past four years.

Mr. England asked if DHCFP has audited information given in approved PA requests against the patient charts and Ms. Lawrence replied no. Dr. Parker felt that if the information provided cannot be confirmed, suggesting change to the current criteria would be based on no information.

Mr. Macdonald suggested that if the PA requirement is relaxed and utilization suddenly increases inappropriately to the population numbers or the percentage rate significantly increases over the current rate, reinstitute the current PA requirement.

Dr. Rubin recommended continuing to scrutinize the requests and make it less easy to put a developing child's brain on a psychostimulant. Rather than abolish any data collection and controls, it's more important to reinforce this and continue to monitor. He said he believes there will be a sharp increase in Parkinson's Disease in the next 10-20 years relative to the prescribing of these medications.

Mr. England felt when it involves the psychotropic class, there needs to be more than a pharmacological fix. If medications are given for depression or ADHD, there is an environmental effect as well as internal effect. With drugs, the internal milieu can be affected but not the external milieu. He suggested with the psychotropic class, the PA include a counseling component.

Mr. Macdonald asked if the percentage of utilization of these drugs has decreased. Dr. Rubin stated that it's going up and is the number one class of drugs abused on college campuses.

Ms. Lawrence reminded the Board that counseling requirements were applied to PAs for erectile dysfunction drugs and PPIs. She stated that First Health can do claims history searches which indicate if a recipient is receiving more than one medication within the timeframes for more than a thirty day transitional time period. This may help to see if the criteria are being adhered to.

VI. Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD) Agents

Public Comment

Lisa Durette, M.D., Child and Adolescent Psychiatrist, spoke in support of reducing the restriction of access to ADHD medications. She stated that she has no affiliation with pharmaceutical companies. She offered the following comments:

-A Preferred Drug List (PDL) is in place, but a PA is required on all ADHD agents both on the PDL and those not on the PDL.

-PA is required for amphetamines, methylphenidate and pemoline as well as Strattera®, which is not a stimulant, not considered a drug with the potential for abuse, and is not a controlled substance.

-There are several studies demonstrating the lack of negative effects of treating ADHD later in life. There is no data that demonstrates that utilization of the stimulants early on predisposes patients to a mood disorder or that there is a predilection to a mood disorder.

-ADHD is a psychiatric illness which affects 4-5% of youth.

-The diagnosis is a clinical diagnosis determined by criteria as outlined in the DSM IV-TR; there are no psychological tests.

-The American Academy of Child and Adolescent Psychiatry, the American Academy of Pediatrics and the Academy of Family Physicians recognize the key to treatment is medication.

-The MTA Trial demonstrated that the medications were the most effective in treatment. In the study, psychotherapy alone did not provide benefit. Psychotherapy with medication provided temporary benefit but when the psychotherapy was removed, the benefit continued with medication alone.

-2005 data gathered by the DEA demonstrates that Nevada ranked between the 45th and 50th among the states for cumulative distribution of stimulants.

-Long-acting agents (Daytrana®, Concerta®, Vyvanse®) have less abuse potential due to the manufacturing and packaging of the products and Strattera® has zero abuse potential.
-Studies demonstrate that in children treated for ADHD, there is a decrease in substance abuse disorders, motor vehicle accidents, school failures and entrances to juvenile detention centers.
-The PA process is time consuming. She cited case examples. In one case, it took three days to obtain a PA. In another, a PA was required for dosage change of the same medication which had a PA in place.

She offered the following solutions:

Remove the PA restriction:

- for non-controlled substances used to treat ADHD
- that does not allow the prescribing of more than one agent in the same class for ADHD; e.g., stimulant in the morning and Strattera® in the afternoon. Monotherapy is rare in psychiatry and all fields.
- for dosage changes

Mr. Monaghan referred to her case examples whereby she stated that someone in her office was informed that PA requests could not be phoned in. He stated that the Call Center receives and accepts all calls for prior authorization requests. He requested she provide specific examples to him for follow-up. He also stated that the PA requirement for dosage change had been addressed previously and will follow-up to ensure that a new PA is not being required for dosage changes of ADHD medications.

Mr. England stated that there is rationality for using polypharmacy. The purpose of the DUR Board is not to make it difficult to obtain medications, but to ensure that treatment is appropriate. He asked Dr. Durette her suggestion on preparing a more practical and appropriate PA. She responded that when the clinician has made the diagnosis of ADHD and included the diagnosis on the prescription, the questions included on the PA form have been addressed. In terms of polypharmacy, because there is not a check-box answer, make a PA form with a one line explanation of why; e.g., patient stable on long-acting substance, needs immediate acting in the morning to help with symptoms.

Dr. Durette asked what the purpose of a PDL is. Ms. Lawrence clarified that the DUR Board and P&T Committee have specific functions which are defined by statute. There are other mechanisms that fall behind the PDL not just whether a PA is required or not. Nevada participates in the National Medicaid Pooling Initiative through First Health which secures additional rebates for the drugs that are reimbursed in our system. The P&T has the authority to develop the PDL and the DUR Board has the authority to implement prior authorization criteria. In terms of Strattera®, the policy (Chapter 1200 Medicaid Services Manual) states agents for the treatment of ADHD whether it's a stimulant or non-stimulant. When Strattera® was released, this board made the decision to include all agents that treatment ADHD.

Dr. Durette asked the board to consider Wellbutrin® stating that it is well documented and included in the Texas Algorithm Study to be utilized for the treatment of ADHD. It is no more abuse able than Strattera® and there is no PA requirement.

Mr. Monaghan asked Dr. Durette if she felt that psychiatric specialists and child and adolescent specialists should get a free pass on PA criteria and she replied that they do in other states.

Presentation by First Health Services on Possible Revisions to Current Clinical Prior Authorization for Drugs Used to Treat Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD) in Adults and Children

It was noted by Chairman England, that the presentations and discussion for Agenda Items V and VI were merged.

Discussion and 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 motioned for no changes to the current PA criteria at this time; review the existing criteria and consider modification based on evidence-based medicine; FHSC to review procedural issues (dosage change, phone-in PAs).

SECOND: Steven Rubin

VOTES: Unanimous

MOTION CARRIED

Ms. Lawrence asked for clarification that the request is for DHCFP and FHSC to bring to the board evidence-based criteria to use polypharmacy for these specific medications. Mr. England stated not just polypharmacy but anything dealing with the pharmacologic treatment of ADHD.

VII. Pseudoephedrine

Public Comment

No comment.

Presentation by First Health Services on Proposed Quantity Limits on Pseudoephedrine

Jeff Monaghan stated that this item is being presented in order to fall in line with the state law that limits the sale of pseudoephedrine-containing products to 3.6gm per day or 9gm per month. Pharmacies are required to keep the drugs behind the counter, require identification and keep track of how much is sold. The law is flawed in that a person can go to several pharmacies and purchase the maximum quantity at each pharmacy. DHCFP and First Health are recommending quantity limits be implemented. The quantity edit would apply to over-the-counter (OTC) products. There currently is a two prescription limit within the same therapeutic class per month for OTCs and a prescription is required.

Ms. Lawrence said that this issue is being presented to the board for opinion because it (methamphetamine abuse) is an issue in this state.

Board Discussion and Action to Approve Proposed Quantity Limits on Pseudoephedrine.

Mr. Macdonald stated that with the current quantity limitations in place, he did not feel there was a potential for abuse and Mr. England agreed.

Ms. Lawrence said that OTCs have a two prescription per therapeutic class per month limit. The drug can also be obtained through a prescription but the two do not edit against each other and asked if that makes a difference for utilization?

Mr. Monaghan stated that he is not aware of legend pseudoephedrine being used in a divisionary way. Mr. England said that most of the prescription items are combination products and it would be difficult to use it for that purpose. The abuse is coming from the OTC side. Mr. Macdonald added that he has not seen any abuse in legend pseudoephedrine.

The board agreed that the current limitations are adequate and no action was taken.

VIII. Presentation by First Health Services and Discussion by Board of Nevada Medicaid Drug Utilization Review Annual Report

Jeff Monaghan presented the Nevada Medicaid Drug Utilization Review Report for Federal Fiscal Year 2006. The annual report is a summarization of drug utilization review, outcomes, cost savings, number of prospective drug utilization alerts experienced, retrospective drug utilization review intervention statistics and DUR Board activity.

The report is prepared by First Health and submitted to DHCFP for review, approval and submission to CMS. States are required by the federal government to submit this report annually.

The report includes a summary of all ProDUR alerts; therapeutic duplication was the most common. Cost avoidance for the past year was approximately \$30 million (the number of claims reversed or not resubmitted based on ProDUR alerts). Due to the implementation of Part D last year, overall expenditures decreased by 31% with a 43% decrease in recipients. The average payment per user per month decreased by 9.4%, which is a good indicator of the program's cost-savings initiatives. The largest utilizing group with the aged going to Part D is the 40-65 age group which comprise 50% of the program dollars. The age group 0-12 years had the highest average cost per claim. These are the children on antihemophilia products as well as antivirals such as Synagis®.

Examples of RetroDUR criteria were distributed. Mr. Monaghan explained that RetroDUR criteria is selected and screened against the drug utilization base, exceptions fall out and a medication profile is generated. Clinical pharmacists review the profiles to determine if there is a potential problem. (He noted that to maintain independence and credibility, the pharmacists are contracted and not First Health employees.) If so, a letter is generated specific to the criteria and sent to the prescriber. Included with the letter is a fax back response form that requests the prescriber complete and return to First Health. The annual report lists the therapeutic categories and criteria that were applied in FFY06. Mr. Monaghan stated compliance is one area that has not been strongly reviewed. The P&T Committee has brought up the issue of treatment outcomes. By reviewing compliance with beta blockers, statins, and antihypertensive agents, a quality issue can be folded in. Another area of review could be polypharmacy; looking at patients receiving several drugs, seeing several physicians and pharmacies. FDA alerts could be another area of focus. Patient profiles containing drugs with an FDA alert can be generated and a letter sent to the prescriber highlighting the FDA alert.

Dr. Uhalde stated that retrospective drug review notifications are a nuisance and that her office has no central way of knowing what patients are on what medications. She felt a notification from Medicaid regarding FDA alerts would be helpful.

Mr. England noted that in the past, the response rate from the prescriber has been 20-30%. Since the response is voluntary, what can Medicaid do to improve that rate? Mr. Monaghan noted that the rate is comparable to other states.

Ms. Lawrence stated that the drug use review annual report is part of a federal regulation and sent to CMS. In terms of the profiles, do they give the information the prescriber wants to see? If the profiles aren't meaningful to them, the prescriber will not respond. She recommended a reevaluation of the criteria and profile to determine the focus for next year. There has been discussion of trying other ways to have the response letters returned; e.g., email, web responses.

Dr. Uhalde stated the type of criteria being reviewed is very important. Being made aware that a patient is going to several pharmacies and getting narcotics, that's valuable information versus being notified that a patient is taking, for example, 29 Zocor® rather than 30.

Ms. Lawrence proposed presenting additional criteria at a future meeting. An example is black box warnings. If someone is utilizing a drug and the FDA issues an alert within the last thirty days, a letter could be sent stating that this prescription was filled for this drug and a warning has been released since the medication was last prescribed. Another example would be sending a notification to the prescriber if there is non-compliance resulting in an increase in ER utilization. The board agreed that these types of criteria would be useful.

Dr. Rubin felt that the letters are out of context and reflect a narrow view of the entire situation. He suggested that those who are reviewing or making recommendations need to look at the entity and not just the drug or black box.

MOTION: Keith Macdonald motioned that DHCFP and FHSC present recommendations particularly related to multiple practitioners, multiple institutions, multiple drug overlap, ER utilization, black box warnings, FDA alerts that pertain to specific patients, and other criteria that will be effective.

SECOND: Steven Rubin

VOTES: Unanimous

MOTION CARRIED

IX. Presentation of Compounded Drug Utilization Report by First Health Services

Jeff Monaghan stated that as reported at the last meeting, there is a new system functionality in place, Multi-Ingredient Compound (MIC), which allows the capturing of compounded drugs. Total dollars in this class have been increasing in terms of total dollars and the board requested an analysis of these prescriptions to see what types of drugs are being compounded. Mr. Monaghan presented a report on compounded drugs which includes the ingredients contained in the compound and the payment amount. He stated that with the new MIC functionality, pharmacies are now able to bill these prescriptions as a compounded drug which will shift dollars from other categories into this category. For example, some of the antihemophilic factors and antivirals have fallen into this category.

X. Follow-up report by DHCFP on Anti-Psychotic Drug CE Program

Ms. Lawrence reported that the Anti-Psychotic Drug CE Program conducted in May was well attended in both northern and southern Nevada (150 total attendees) and there was very positive feedback on the surveys for neutrality, content, and material.

XI. Public Comment

No comment.

XII. Date and Location of Next Meeting: October 18, 2007- Las Vegas

XIII. *Adjourn

MOTION: Marjorie Uhalde motioned to adjourn the meeting

SECOND: Keith Macdonald

VOTES: Unanimous

MOTION CARRIED

Meeting adjourned at 2:53 p.m.