



JIM GIBBONS  
Governor

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

MICHAEL J. WILLDEN  
Director

CHARLES DUARTE  
Administrator

**DRUG USE REVIEW (DUR) BOARD**

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

**Meeting Minutes  
January 24, 2008**

**Committee Members Present:**

David England, Pharm.D., Chairman  
Keith Macdonald, R.Ph.  
Paul Oesterman, Pharm.D.  
Marjorie Uhalde, M.D.  
Steven Rubin, M.D.

**Absent:**

Steven Parker, M.D.

**Others Present:**

Coleen Lawrence-DHCFP, Mary Griffith-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, Gosia Sylwestrzak-FHSC, Bert Jones-GSK, Rajiv Dass-Sepracor, Craig Boody-Lilly, Joe Busby-Lilly, Chris Almeda-Purdue

**I. Call to Order and Roll Call**

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

**II. Discussion and Approval of October 18, 2007 Minutes**

**MOTION:** Steven Rubin motioned to accept the minutes as presented.  
**SECOND:** Marjorie Uhalde  
**VOTES:** Unanimous  
**MOTION CARRIED**

**III. Status Update by DHCFP**

**The Deficit Reduction Act of 2005 as it Relates to the Average Manufacturer Price (AMP) for Drugs and Physician-Administered Drugs**

Coleen Lawrence stated that due to litigation at the federal level, implementation of AMP into the State's system is currently on hold. When implemented, AMP will be loaded in First DataBank which is the drug database used by the Point of Sale pharmacy claims processing system. The lesser of logic will apply for reimbursement.

Effective January 1, 2008, physicians will be required to submit the National Drug Code (NDC) for physician-administered drugs utilizing the National Council for Prescription Drug Programs (NCPDP) billing units. The NDC will be required on the CMS 1500 and UB-04 claim forms for physician and outpatient facility drug claims. The Healthcare Common Procedure Coding System (HCPCS) codes and Current Procedural Terminology (CPT) codes (with the exception of immunizations) for physician-administered drugs will no longer be utilized for billing Medicaid the drug portion of these claims.

## **National Provider Identifier (NPI) Initiative and the Timeline for Implementation**

Ms. Lawrence reported that CMS will lift its NPI contingency plan, meaning that only the NPI will be accepted, effective May, 2008. DHCFP will go into full NPI operational mode at that time.

## **Nevada Medicaid Pharmacy Lock-In Program**

Ms. Lawrence stated that Governor Gibbons has mandated budget cuts for each state agency. Part of DHCFP's budget cut for Nevada Medicaid is the implementation of a polypharmacy initiative for the pharmacy program. Implementation is required by June, 2008. More information will be presented to the Board at the next meeting.

Mary Griffith reminded the Board that at the October, 2007 meeting, there was discussion and approval by this Board to pursue the pharmacy lock-in program based on the criteria and procedures presented. The program is designed to lock-in a recipient to a specific pharmacy due to the inappropriate over-utilization of Medicaid resources. Other agencies within Medicaid will be involved in this process. Recipients identified for lock-in will be referred to the Surveillance and Utilization Review Section (SURS) unit. The recipient has a right to request a hearing before placement in the pharmacy lock-in program. The request for a hearing will be referred to the Hearings Unit for processing. Care Coordination will also be involved. There is a provision for emergencies in case there is a need for the recipient to use another pharmacy. Provider training will be conducted once the process is approved and implemented.

Dave England asked if inappropriate use occurs often enough to require implementation of this program and will this help with the budget cuts. Ms. Griffith replied that it depends on how strictly the criteria is set. If the criteria are tailored to target the more abusive recipients, the number of cases will be low. Ms. Lawrence added that part of the criteria will include utilizing the Board of Pharmacy's controlled substance data for information on any cash payments to pharmacies for controlled substances by Medicaid recipients.

Paul Oesterman asked what the specific criteria are. Ms. Lawrence stated that the criteria includes provider "shopping" (seeking services at three or more pharmacies and/or prescribers within 60 days), recipients receiving 10 or more targeted medications within 60 days, recipients receiving three or more different types of opiates, other observed and documented behavior (as reported by case coordination offices). Mr. Wuest added that the number of pharmacies recipients are utilizing appears to be a key identifier for whether or not the system is being abused. Mr. Oesterman agreed based on what he's seen in his practice.

Mr. England asked if a waiver signed by the patient is required in order to review their pharmacy records. Ms. Lawrence replied that when recipients are enrolled in to Medicaid, the application includes a HIPPA release.

## **IV. Presentation by First Health Services on the Feasibility of Requiring ICD-9 Codes and the Initiation of an Audit Plan Versus the Current Prior Authorization Process for Patients with Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD)**

Jeff Monaghan introduced Gosia Sylwestrzak. Gosia has recently joined First Health in the role of biostatistician. She is attending the meeting today to get a flavor for the type of reporting that is being done and the issues being faced.

Mr. Monaghan stated that this item has been on the agenda for the last four meetings. In reviewing the data, 75% of these drugs are prescribed by psychiatrists, child psychiatrists and pediatricians. The majority of usage of these agents is in the 7-15 year old age group. 97% of the prior authorization (PA) requests are currently being approved. At the last meeting, there was discussion regarding the use of an ICD-9 code as approval criteria for these agents and the issue of an audit was also discussed. DHCFP and First Health feel the ICD-9 approach is valid and viable. The auditing piece is an issue in terms of resources, however, reports can be generated and utilization tracked for significant increases or decreases.

Ms. Lawrence said that the Board's options are to decide to modify the requirements by implementing age limits, practitioner, ICD-9 codes, quantities, etc., or not to modify the existing criteria at all.

### **Public Comment**

No comment.

### **Discussion and Action by Board Concerning Revisions to Clinical Prior Authorization Criteria for Drugs Used to Treat Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder in Adults and Children**

Mr. England suggested that medications in this class written by a psychiatrist for children 5 years old to 18 years of age can submit the ICD-9 code and bypass the PA process. Prescriptions for children 4 years and under or 19 and above will require prior authorization applying the current criteria regardless of who prescribed the medication. He recommended authorization implementation for one year at which time the Board will review to determine the impact on the utilization of these medications.

Steven Rubin stated that he is opposed to any easing of the PA criteria. Making it easier for psychiatrists, especially, who are quite vulnerable to the influence of the pharmaceutical industry, is an ethical mistake.

Mr. Macdonald suggested setting a benchmark that if there is a 5% or 10% increase within the next 90 days, the policy be discontinued. Mr. Monaghan stated that there is a baseline and the utilization rate can be tracked and reported back to the Board. Considering the time for coding the system and provider notification, data could be available by the July meeting. Overall utilization can be tracked as well as utilization by age range.

Ms. Lawrence suggested reviewing national statistics on the number of children in a population that might be utilizing these types of medications and compare our data to that to ensure we are within those benchmarks.

Mr. Macdonald stated that though Dr. Rubin's ethical concept makes sense, there is frustration from a pharmacy standpoint with the prior authorization process. The prescription gets to the pharmacy counter and it rejects for PA; the pharmacy has to engage the practitioner, the practitioner contacts the Medicaid program, the pharmacy is in turn engaged again and the claim is resubmitted. It's a very convoluted and discouraging process on a day-to-day basis.

Dr. Rubin felt that making it easier and less accountable to prescribe stimulants to children without any measures and without a databank is a great mistake. There will be more violence as a result and a lot of medical problems. He asked the pharmacists how many patients receiving these amphetamine drugs are on single psychotropic agents as opposed to a little antipsychotic or a little sedative to go to sleep. The doors are being opened for polypharmacy without accountability.

Mr. Oesterman stated that he does not see a lot of other prescriptions being filled for kids on ADD and ADHD medications. Generally, it tends to be the one product. As they get older, 17-18 years and beyond, he sees other medications being added.

Mr. England asked if there is a progression being seen. If a 5 or 6 year old child is being treated for ADHD or ADD, is their risk higher for development of schizophrenia or any other mental health issues by the time they reach their teens as opposed to if they weren't on medications.

Dr. Rubin replied that the problem is the information to answer that question is like the information for all the drugs, it's selective. Objective information is released selectively. He stated that he has witnessed amongst his colleagues that misdiagnosis is an epidemic. The majority of children diagnosed with ADD are not. He felt easing the requirement will result in more fabrication of ICD-9 codes in order to obtain reimbursement from insurance. There is polypharmacy in 5 year olds. We don't want them on cold medications, but there are no restrictions if you want to put them on methamphetamine. The PA process is one thread for some

kind of databank accountability because there will be retrospective review. He recommended voting the proposed motion down and creating a new motion that the current process stands as is.

**MOTION:** Steven Rubin motioned that the prior authorization process remains as it currently is and this issue be revisited in one year.

**SECOND:** None

**MOTION:** Paul Oesterman motioned that prescriptions for ADD/ADHD medications will not require prior authorization for patients between the ages of 5 and 18 years of age if the medication is prescribed by a psychiatrist and an ICD-9 code for ADD/ADHD (ICD-9 314.0 – 314.9) be documented on the prescription. Implementation will be for one year and evaluated at the end of the one year time period.

**SECOND:** Keith Macdonald

Darrell Faircloth asked for clarification if the intent is from the 5<sup>th</sup> birthday to the 18<sup>th</sup> birthday.

Mr. Oesterman replied from the 5<sup>th</sup> birthday up until their 19<sup>th</sup> birthday.

**VOTES:** Macdonald, Oesterman, England

**NAYES:** Rubin

**ABSTAIN:** Uhalde

**MOTION CARRIED**

Mr. Oesterman referred to the written criteria and pointed out that section C.1.a.2 is stated under the general criteria for children and adults and restated in section C.1.b.3 under the children's' general criteria. He recommended removing section C.1.b.3 since it is stated within the general criteria.

Mr. England said that section C.1.b.2.a. states the TOVA achievement test *or* DMS-IV. TOVA in and of itself is not a criteria and he recommended changing the requirement to TOVA achievement test *and* DMS-IV.

Mr. Faircloth said that section C.1.b. states for children up to age 18 years and the previous motion was for children through 18 years.

Ms. Lawrence felt that the age did not need to be changed since this is the clinical criteria that if they weren't going through the parameters of the first motion, this policy would still apply for general practitioners.

Mr. Monaghan said the current policy is up to age 18 and should the motion made be consistent with the policy. Ms. Lawrence suggested that since this policy has been in place, the motion be modified to reflect the policy (up to age 18).

**MOTION:** Paul Oesterman motioned to modify the age range in the previous motion to the age of 5 years up to age 18 years of age.

**SECOND:** Keith Macdonald

**VOTES:** Oesterman, Macdonald, England, Uhalde

**ABSTAIN:** Rubin

**MOTION CARRIED**

Mr. England affirmed that on the PA criteria, section C.1.b.3 be omitted; under section C.1.b.2.a., remove "or" between 2.a. and 2.b. and replace with "and". Dr. Rubin recommended including 2.c as a requirement and changing "or" between 2.b and 2.c to "and".

**MOTION:** Paul Oesterman motioned to modify the criteria for ADD/ADHD: section C.1.b.3 be omitted; section C.1.b, between b.1 and b.2 add "and all of the following"; C.1.b.2.a., remove "or" between 2.a. and 2.b. and replace with "and"; remove "or" between 2.b and 2.c and replace with "and".

**SECOND:** Keith Macdonald

**VOTES:** Unanimous

**MOTION CARRIED**

Mr. Macdonald requested reports be provided prior to the end of the one year trial period for Board review.

**V. Proposal by First Health Services on Suggested Changes to Clinical Prior Authorization Criteria for Growth Hormone**

Jeff Monaghan presented proposed revisions to the criteria for growth hormone. He stated that the appeals for the use of growth hormone in children have increased over the last year. Pediatric endocrinologists have been challenging the criteria, specifically the requirement for growth hormone stimulation testing in all cases. The Lawson Wilkins Pediatric Endocrinology Society is an international group that focuses on pediatric endocrinology and he presented their guidelines for use of growth hormone. Based on these guidelines and feedback from local practitioners, the proposed criteria were modified to indicate when a growth hormone stimulation test is needed and required and when it's not. In all cases, specialty consultation is required, all other causes for short stature have been ruled out, and replacement therapy for other pituitary deficiencies has been addressed. If that's been accomplished, there are other indications that the patient would qualify for growth hormone; e.g., Turner's Syndrome, Prader-Willi Syndrome, chronic renal insufficiency, trauma to the cranium which brings about a decrease in pituitary release, hypoglycemia, intrauterine growth restriction (small for gestational age [SGA]). There is a consensus that growth hormone stimulation testing may be close to the standard, but if you tie in other clinical criteria, growth hormone stimulation testing may not be needed in all cases. That's what the proposed criteria attempts to do. The proposed criteria for Idiopathic Short Stature requires that bone age be  $>2$  SD below the mean for the age (epiphyses open), height  $>2.25$  SD below the mean for the age, or growth velocity  $<25^{\text{th}}$  percentile for bone age. If the patients meets these criteria and has had a growth hormone stimulation test which is less than the threshold, they would qualify for growth hormone replacement. The exception being proposed, which is based on input from literature and practitioners, is to allow consideration of the insulin-like growth hormone factor test (IGF-1). It is a less traumatic test (a simple blood-draw versus repeated blood-draws over a period of time to obtain a growth stimulation test). For patients meeting these metrics, a growth hormone stimulation test would not be required if the insulin-like growth factor or insulin-like growth factor binding protein 3 (IGFBP3) is below normal. These requirements tie in with the consensus guidelines contained in the Lawson Wilkins' review.

**Public Comment**

No comment.

**Action by Board on Suggested Changes to Clinical Prior Authorization Criteria for Growth Hormone**

Mr. Oesterman requested clarification on the definition of children. The previous item defined children up to age 18; these criteria state children up to age 21. Would it be beneficial to be consistent across the board?

Ms. Lawrence responded that the reason that this criteria is up to age 21, is because of the EPSDT rule, which is the healthy kids rule. Typically, the age of children qualified to receive benefits is under the age of 21 years which is different when establishing age for PA criteria.

Mr. Oesterman pointed out that the section B. Adults (age 21 and older), states that "Agents selected for treatment must have an FDA-approved indication for the diagnosis being treated as stated in the package insert." That statement does not appear under section A for children.

Ms. Lawrence reminded the Board that for Medicaid coverage, there must be an FDA-approved indication. For consistency, it can be added to section A. Mr. England said that although there's an FDA-approved indication for these medications, there is literature support for medications to be used off-label. Ms. Lawrence replied that the Social Security Act allows use based upon peer reviewed literature.

Mr. Monaghan stated that section B should apply to both adults and children and recommended including the statement in section A.

Mr. Oesterman referred to section B.2.a and asked for clarification on the definition of “stable”. Ms. Lawrence replied that it is not defined in the pharmacy chapter but is the determination of the clinician. Mr. Oesterman referred to B.2.b.2 and asked if there are criteria as to how long a patient might have been tried on appetite-stimulating drugs and anabolic steroids to be deemed to have failed to respond. Mr. Monaghan replied that there is no clear definition but that the PA request becomes a review of the criteria with dialogue between the Clinical Call Center pharmacist and the clinician on the phone. Mr. England stated that in certain situations, there should be a clinical discussion and the clinical picture is what the determination is based upon and not just the verbiage in the criteria. Ms. Lawrence added that a peer-to-peer review is conducted for determination of denial of the request. Mr. England stated that changes to the verbiage are not necessary since there is the understanding that the clinical picture is taken into account.

Mr. Faircloth stated that the existing regulations in the Medicaid Services Manual indicate separate criteria for the continuation of therapy versus initial prior authorization of therapy. Do the proposed criteria address the elimination of continued therapy under Appendix A, page 8 or is that to remain in place. There are instances whereby patients come from other pay sources and try to obtain authorization for Medicaid payment of continued therapy such as this. When that occurs, these tests set forth in the old policy and perhaps in the new policy, may not be valid. It may be difficult to document that the patient met the initial criteria. What different set of criteria would be appropriate to authorize continued therapy as opposed to initial therapy? Mr. Monaghan stated that section 1.A.2 addresses continuation for therapy in children. If the patient is on existing therapy and they become Medicaid eligible, if their bone age is >2 SD and if their epiphyses are open, and the documented growth rate is less than the 25<sup>th</sup> percentile, the patient would meet the criteria and the drug would be approved. If the patient is not >2 SD, there is a chance that it would not be approved.

Mr. England said that by accepting this criteria, if there is a deviation to the Medicaid criteria, there would be a clinical review; i.e., peer-to-peer review. Ms. Lawrence stated that every service evaluated in Nevada Medicaid is also required to be evaluated based upon medical necessity. For children under the age of 21, there are the EPSDT rules that also apply.

Mr. Monaghan reviewed the proposed changes to the criteria:

- 1.A.g is an expansion of the trauma piece;
- 1.A.h and i are new based on the consensus guidelines;
- 1.A.j has been revised to not require the provocative stimuli test in all cases and to allow the IGF-1 if the other conditions have been met.

**MOTION:** Paul Oesterman motioned to accept the proposed criteria for growth hormone as presented with the exception that the statement in section B requiring an FDA-approved indication for the diagnosis being treated be included as a general statement and moved to the section above “Coverage and Limitations.”

**SECOND:** Keith Macdonald

**VOTES:** Unanimous

**MOTION CARRIED**

## **VI. Proposal by First Health Services on Suggested Changes to Clinical Prior Authorization Criteria for Hematopoietic Agents - Epogen® and Procrit® (Erythropoietin) and Aranesp® (Darbepoetin)**

Dave Wuest presented the proposed revisions to the criteria for hematopoietic agents. He stated that he will be referring to this class as ESAs. On April 30, 2007, the FDA released an alert stating that the use of these drugs over what is recommended in the package insert can be detrimental to the patient. Subsequently, a black box warning was issued for all three agents stating that the agents should only be used for the approved FDA indications. The proposed criteria changes are based directly from the FDA indications.

He reviewed modifications to the criteria noting that sections 1 a and b are direct FDA indications:

- Section 1.a includes maintaining the hemoglobin levels within the range of 10 to 12 g/Dl for most cases;

- Section 1.b states that for transfusion patients if significant blood loss is anticipated, epoetin alpha (Epogen®) may be used to achieve and maintain hemoglobin levels within the range of 10 to 13 g/Dl. Darbepoetin alfa (Aranesp®) does not have this indication;
- Section 1.c: Based on CMS guidelines for use of drugs in class, section c lists conditions that these agents will not be a covered benefit for Nevada Medicaid recipients as findings indicate a decrease in survival rate.

Mr. Wuest said that the literature suggests that the guidelines be applied for pediatric, adolescent and adult patients.

Ms. Lawrence stated that the proper use and billing for these medications has been an issue and the medically unbelievable edit (MUE) is currently being applied in the claims adjudication system. She proposed that additional language be added to the criteria stating that this policy applies to the use of this drug in all settings with the exception of inpatient facility settings. Mr. England suggested adding the statement at the beginning of the document.

Mr. Wuest said that billing errors are very common with these drugs and referred to the section added to the proposed criteria which states: “The medically unbelievable edit (MUE) threshold for epoetin alfa Epogen®/Procrit® claims is 400,000 units and 1200 micrograms for darbepoetin alfa (Aranesp®) claims per rolling 30 days. Claims reporting doses exceeding this threshold are assumed to have typographical errors and will be denied.” He added that these thresholds are based on CMS guidelines.

Mr. Wuest stated that prior approval will continue to be for one month. The proposed criteria include a new condition that “Recent laboratory results are required for prior authorization; i.e., serum hemoglobin within seven (7) days of prior authorization request.”

Mr. Oesterman requested a report on the utilization of drugs in this class.

**Public Comment**

No comment.

**Action by Board on Suggested Changes to Clinical Prior Authorization Criteria for Hematopoietic Agents - Epogen® and Procrit® (Erythropoietin) and Aranesp® (Darbepoetin)**

Mr. Monaghan suggested that perhaps the motion could give DHCFP the flexibility to adjust the MUE threshold based on future CMS recommendations as opposed to bringing recommended changes to the Board each time adding that CMS may currently be considering increasing the thresholds to 500,000 units and 1500 micrograms.

Ms. Lawrence cautioned that stating the thresholds are based on current CMS guidelines will require that the system be changed based on when the CMS change occurs. She suggested a more general statement that the MUE is applied but do not include the thresholds. The policy is that the MUE is applied and the billing thresholds go into the billing manual not into policy.

**MOTION:** Paul Oesterman motioned that the proposed criteria for hematopoietic agents be accepted as presented with the addition of the statement “This policy applies in all settings with the exception of inpatient facility settings” (statement to be placed at the beginning of the criteria). The medically unbelievable edit (MUE) will be applied. MUE thresholds can be adjusted by DHCFP as needed.

**SECOND:** Keith Macdonald

**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**

Mr. Monaghan presented drug utilization reports for calendar year 2007.

Mr. Oesterman asked what the utilization impact is with the release of over-the-counter Zyrtec®. Mr. Monaghan replied that is addressed within the current Preferred Drug List (PDL). Zyrtec® is currently a non-preferred medication with the exception of Zyrtec® syrup for children less than 2 years of age; the preferred agent is loratadine. Consideration for addition to the PDL would need to be addressed by the Pharmacy & Therapeutics Committee.

Ms. Lawrence added that the over-the-counter (OTC) policy (two prescriptions per month per Standard Therapeutic Class) also applies to OTC drugs on the PDL.

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

Mr. Monaghan presented a summary of RetroDUR results for service period 01/07 through 09/07. He stated that the major focus of RetroDUR in the future will be polypharmacy.

**IX. Public Comment**

No comment.

**X. Date and Location of Next Meeting**

The next meeting is scheduled for April 10, 2008, in Las Vegas at the Chamber of Commerce.

Ms. Lawrence said that meeting locations have been alternated between northern and southern Nevada. Currently, the majority of Board members reside in northern Nevada. Alternating locations is not a requirement.

Mr. Oesterman stated that he had no objection to traveling if the meetings are located in northern Nevada. In consideration of the public, he recommended having one meeting in southern Nevada. Mr. England agreed that at least one meeting should be conducted in Las Vegas.

Mr. Macdonald said that at the last meeting in Las Vegas, there were public members of the audience that did not represent the pharmaceutical industry. Mr. Monaghan stated that in general there is greater attendance in Las Vegas. Ms. Lawrence added that more practitioners attend the meetings in Las Vegas.

After discussion, the Board agreed to have three meetings in northern Nevada and one meeting in southern Nevada this year. Mr. Monaghan stated that a location for the April meeting in Las Vegas has been reserved with a deposit. Mr. England said the April meeting will be in Las Vegas as scheduled.

**XI. Adjourn**

**MOTION: Steven Rubin**  
**SECOND: Paul Oesterman**  
**VOTES: Unanimous**  
**MOTION CARRIED**

The meeting was adjourned at 2:31 p.m.