Minutes of the February 23, 2006
Drug Utilization Review (DUR) Board Meeting

Members Attending: Harold Blakely, RPh, Billy Brown, PharmD, Randy Calvert, RPh, Frank Marascalco, RPh, John Mitchell, M.D., Lee Montgomery, M.D., Rudy Runnels, M.D., Wallace Strickland

Members Absent: Montez Carter, RPh, Andrea Phillips, M.D., Troy Griffin

Also Present: Judith Clark, RPh, Terri Kirby, RPh,- DOM, Dennis Smith, RPh, Samuel Warman, RPh, Lew Anne Snow, R.N., Kathleen Burns, R.N. -HID

Dr. John Mitchell called the meeting to order at 2:10 p.m.

Approval of the minutes for the November 17, 2005 meeting:
Approval of the November 17, 2005 DUR Board meeting minutes was tabled until May 18, 2006 due to incomplete information in the minutes.

Updates:
Cost Management Analysis
Dennis Smith presented a brief cost management analysis report. According to the top fifteen (15) therapeutic classes based on total cost of claims from 11/01/2005 thru 11/30/2005, the antipsychotic agents led with 23,496 prescriptions at a total cost of $5,868,424.74 or 2.98% of total claims. The antipsychotic agents also led from 12/01/2005 thru 12/31/2005 with 23,972 prescriptions at a cost of $6,003,338.90 or 3.0% of total claims.

DUR Activity Report:
Dennis Smith gave a report on RDUR activities from October 2005 thru January 2006. Mr. Smith stated that HID is awaiting responses within the 120 days post-intervention period. With proper responses, solid trends can be identified post-intervention

Bo Bowen from Information and Quality Healthcare (IQH) was introduced to the Board by Ms. Clark. Mr. Bowen presented a brief overview of IQH regarding Medicare patients and their Prescription Drug Plans.

Pharmacy Program Updates

Ms. Clark introduced Mr. Frank Marascalco, RPh as a new DUR Board member. Ms. Clark presented information regarding a new Hospice edit which became effective February 2006. Ms. Clark stated that additional information regarding this may be found on the Division of Medicaid website. Ms. Clark gave the board members a copy of products with quantity limits and explained that these limits help in the over-utilization of many classes of drugs. In October 2005, a new handheld device was distributed to 225 physicians throughout the state. Ms. Clark announced that Mississippi was only the second state to receive these devices and that with these devices the physician is able to pull up all paid pharmacy claims for their Medicaid

beneficiaries. These PDAs also allow the physician to view the Division of Medicaid preferred drug list as well as submit prescriptions electronically to many pharmacies.

New Business

DUR Interventions:
With 70% of the Medicaid population being children, Dennis Smith presented several interventions pertinent to pediatric patients.

Childhood Onset of Type 2 Diabetes
Mr. Smith reported that it is estimated that as many as 8-45% of new onset childhood diabetes cases in the United States may be Type 2 diabetes. Using the above percentages, it is thought that between 380 and 2,137 of children covered by Mississippi Medicaid have Type 2 diabetes. Two important factors in the development of Type 2 diabetes in children are puberty and obesity. MS leads the nation with the largest number of obese children. Mr. Smith explained that while experience to date in dealing with the treatment of type 2 diabetes in children is limited, some general guidelines have been published to guide providers in the management of this disorder. The American Diabetes Association (ADA) issued a consensus statement on Type 2 Diabetes in Children and Adolescents. According to the ADA, at the time of diagnosis it can be very difficult to determine the correct classification of diabetes in children (Type 1 verses Type2) due to the similarity of symptoms and findings.

Recommendations:
As pointed out by Dr. Montgomery, it would be a monumental task to try to do any interventions at this time for this childhood disease. No recommendations were made at this time.

Topical Corticosteroid Utilization in Children
Mr. Smith reported that the use of topical corticosteroid agents in children is a common and necessary mode of treatment in various dermatoses. Due to the risks and warnings associated with these agents, the appropriate use of highly potent topical corticosteroids is very important.

Recommendations:
After much discussion, Dr. Montgomery suggested placing POS system edits on the super-potent agents. Dr. Mitchell suggested that DOM also impose an edit that is age specific. Dr. Montgomery also agreed that an age edit would useful on these agents. Dr. Montgomery made a motion that the DUR review criteria regarding the use of high potency topical corticosteroids be implemented immediately. Dr. Mitchell seconded the motion. All voted in favor of approval. The board also requested that HID work in conjunction with DOM to create a list of topical corticosteroids agents appropriate for use in children 0 to 2 years of age that could be used as a reference for physicians.

Retrospective DUR Criteria Recommendations:
Dennis Smith presented the following retrospective DUR criteria recommendations:

- Long-acting Beta Agonists/therapeutic appropriateness- Even though long-acting beta-2 agonists (LABA) decrease the frequency of asthmatic episodes, these medications may make the episodes more severe when they do occur. LABAs should not be the first medicine used to treat asthma. They should be added to the asthma treatment plan only if other medications do not control asthma.

- Rosiglitazone/therapeutic appropriateness- Post-marketing reports suggest that Avandia/Avandamet/Avandaryl (rosiglitazone-containing products) may cause new onset and worsening of diabetic macular edema. Concurrent peripheral edema may also occur in these patients. Macular edema resolved or improved, in some cases, following discontinuation of the drug or dose reduction.

- Avinza/therpeutic appropriateness- Patients must not consume alcoholic beverages while on Avinza (morphine extended-release) therapy. Additionally, patients must not use prescription or non-prescription medications containing alcohol while on Avinza therapy. Consumption of alcohol while taking Avinza may result in the rapid release and absorption of a potentially fatal dose of morphine.

- Lindane/therapeutic appropriateness- Lindane can be poisonous if not used properly. Seizures and death have been reported following use with repeat or prolonged application, but also in rare cases following a single application. The medication should only be used by patients who cannot tolerate or have failed first-line treatment with safer medications. Infants, children, the elderly, patients with other skin conditions and those who weigh less than 110 lbs (50 kg) may be at greater risk for serious neurotoxicity.

- Beta Blockers/therapeutic appropriateness- Non-selective beta-blockers should be used with caution in patients with diabetes. These agents may mask the signs and symptoms of hypoglycemia and delay recovery time. Beta blockade also reduces the release of insulin in response to hyperglycemia; it may be necessary to adjust the dose of antidiabetic drugs. Cardioselective beta-blockers are preferred due to the decreased risk of adverse effects on glucose regulation.

Dr. Mitchell made a motion to accept these criteria recommendations with the exception of rosiglitazone/therapeutic appropriateness. The motion was seconded by Dr. Montgomery. All voted in favor of the motion.

Boxed Warning Updates

Ketek (telithromycin)
Audience: Infectious Disease, Hepatology and other healthcare professionals
[Posted 01/20/2006] Annals of Internal Medicine published an article reporting three patients who experienced serious liver toxicity following administration of Ketek (telithromycin). These cases were also reported to FDA MedWatch. Telithromycin is marketed and used extensively in many other countries, including countries in Europe and Japan. While it is difficult to determine the actual frequency of adverse events from voluntary reporting systems such as the MedWatch program, the FDA is continuing to evaluate the issue of liver problems in association with use of telithromycin in order to determine if labeling changes or other actions are warranted. As a part of this, FDA is continuing to work to understand better the frequency of liver-related adverse events reported for approved antibiotics, including telithromycin.

Elidel Cream (pimecrolimus)
Protopic Ointment (tacrolimus)
Audience: Dermatological and other healthcare professionals
[Posted 01/20/2006] The Food and Drug Administration announced the approval of updated labeling for two topical eczema drugs, Elidel Cream (pimecrolimus) and Protopic Ointment (tacrolimus). The labeling will be updated with a boxed warning about a possible risk of cancer and a Medication Guide (FDA-approved patient labeling) will be distributed to help ensure that patients using these prescription medicines are aware of this concern. The new labeling also clarifies that these drugs are recommended for use as second-line treatments. This means that other prescription topical medicines should be tried first. Use of these drugs in children under 2 years of age is not recommended.

Clozaril (clozapine) tablets
Audience: Neuropsychiatric healthcare professionals and patients
[Posted 01/13/2006] Novartis and FDA notified healthcare professionals of revisions to the BOXED WARNING, WARNINGS, CONTRAINDICATIONS, PRECAUTIONS (Information for Patients and Pharmacokinetic-Related Interactions subsections), and ADVERSE REACTIONS (Postmarketing Clinical Experience subsection) sections of the prescribing information for Clozaril (clozapine) tablets. Recommendations from the FDA's Psychopharmacological Drugs Advisory Committee regarding the white blood cell monitoring schedule, required for all clozapine users, has resulted in modification in the monitoring schedule. Additional labeling changes address safety issues related to dementia-related psychosis, paralytic ileus, hypercholesterolemia and pharmacokinetic interaction with citalopram.

Avandia (rosiglitazone maleate)
Avandamet (rosiglitazone maleate/metformin HCl)
Audience: Endocrinologists, other healthcare professionals and patients
[Posted 01/05/2006] GlaxoSmithKline and FDA notified healthcare professionals about post-marketing reports of new onset and worsening diabetic macular edema for patients receiving rosiglitazone. In the majority of these cases, the patients also reported concurrent peripheral

edema. In some cases, the macular edema resolved or improved following discontinuation of therapy and in one case, macular edema resolved after dose reduction.

Long-acting Beta2-Adrenergic Agonists:
Advair Diskus (fluticasone propionate & salmeterol inhalation powder)
Foradil Aerolizer (formoterol fumarate inhalation powder)
Serevent Diskus (salmeterol xinafoate inhalation powder)
Audience: Pulmonologists, other healthcare professionals and consumers
[Posted 11/18/2005] FDA notified manufacturers of Advair Diskus, Foradil Aerolizer, and Serevent Diskus to update their existing product labels with new warnings and a Medication Guide for patients to alert health care professionals and patients that these medicines may increase the chance of severe asthma episodes, and death when those episodes occur. All of these products contain long-acting beta2-adrenergic agonists (LABA). Even though LABAs decrease the frequency of asthma episodes, these medicines may make asthma episodes more severe when they occur. A Medication Guide with information about these risks will be given to patients when a prescription for a LABA is filled or refilled.

Paroxetine HCl - Paxil and generic paroxetine
Audience: Neuropsychiatric and other healthcare professionals
[Posted 12/08/2005] The FDA has determined that exposure to paroxetine in the first trimester of pregnancy may increase the risk for congenital malformations, particularly cardiac malformations. At the FDA's request, the manufacturer has changed paroxetine pregnancy category from C to D and added new data and recommendations to the WARNINGS section of paroxetine prescribing information. FDA is awaiting the final results of the recent studies and accruing additional data related to the use of paroxetine in pregnancy in order to better characterize the risk for congenital malformations associated with paroxetine.

Physicians who are caring for women receiving paroxetine should alert them to the potential risk to the fetus if they plan to become pregnant or are currently in their first trimester of pregnancy. Discontinuing paroxetine therapy should be considered for these patients. Women who are pregnant, or planning a pregnancy, and currently taking paroxetine should consult with their physician about whether to continue taking it. Women should not stop the drug without discussing the best way to do that with their physician.

Dr. Mitchell then asked for intervention suggestions for the next 90 days. No suggestions were made by the Board at this time, but Ms. Clark requested that board members submit any suggestions to either HID or DOM at a later date. Dr. Mitchell asked if hypnotics had a quantity limit set by DOM. Ms. Clark responded that currently the quantity limit for hypnotics was set at 31 per 31 days. After much discussion, Mr. Strickland made a motion that a limit of 15 per month be set on all hypnotics. Dr. Montgomery seconded the motion. All voted in favor of the motion

Dr. Mitchell adjourned the meeting at 4:05 p.m.

Respectfully submitted:
Health Information Designs