Mississippi Division of Medicaid
Drug Utilization Review (DUR) Board
Minutes of the May 17, 2007 Meeting

Members Attending: Billy Brown, Pharm.D.; Harold Blakely, R.Ph.; Laura Gray, M. D.; Frank Marascalco, R.Ph., Chair; Wallace Strickland; Lee Voulters, M.D.; John Wallace, M.D.

Members Absent: Roy Arnold, R.Ph.; Randy Calvert, R.Ph.; Lee Montgomery, M.D.; Andrea Phillips, M.D.; Troy Griffin.

Also Present:
DOM Staff: Judith Clark, R.Ph., Director of the Medicaid Pharmacy Bureau; Terri Kirby, R.Ph.; Paige Clayton, Pharm.D.

HID Staff: Dennis Smith, R.Ph., Project Manager; Ashleigh Holeman, Pharm.D.; Kathleen Burns, R.N.; Gail Franks, R.N.

Call to Order:
Frank Marascalco,R.Ph.,Chairman of the Board, called the meeting to order at 2:05 p.m.

Ms. Clark asked that the Board proceed with business that would not require a vote while awaiting arrival of enough members to constitute a quorum.

Updates:
Cost Management Analysis
Mr. Smith began by presenting a report reflecting pharmacy costs during the month of February 2007. The analysis began with the top 15 therapeutic classes by total costs in claims. The top therapeutic class by cost was the antipsychotic agents followed by monoclonal antibodies. The top 25 drugs based on the total number of claims were led by azithromycin. Mr. Smith continued the report with the top 25 drugs based on total claims cost, led by Synagis. It was pointed out that Synagis is a seasonal pharmaceutical with most utilization ending in March.

Approval of the Minutes:
With the arrival of a seventh Board member, Wallace Strickland made a motion to accept as submitted the minutes for the February 15, 2007 meeting. Dr. Voulters seconded the motion. All voted in favor of the approval.

DUR Activity Report:
Mr. Smith continued with a discussion of the role of the retrospective DUR program in encouraging proper utilization of medications. Dr. Voulters brought to the Board his input on the proper utilization of stimulants in both children and adults. It was suggested that HID develop criteria to alert the system of the use of stimulants, as well as Strattera. These initial retrospective reports will be presented at the next Board meeting.

Pharmacy Program Update:
Ms. Clark began her update by reviewing a handout concerning the removal of Zelnorm from the market by the FDA. In addition, she alerted the Board of the revised PDL that will be in place starting July 1, 2007. The new PDL will be published in the June Medicaid Bulletin.

New Business:
Ophthalmic Antibiotics
Mr. Smith began by presenting an extensive report on bacterial conjunctivitis and the appropriate use of ophthalmic antibiotics. Appropriate use of these agents has become a concern of many managed care organizations. As a result, many health insurers have limited access to these agents through prior authorization step-therapy requirements. These agents will be reviewed by the Mississippi Medicaid Pharmacy and Therapeutics Committee at the July meeting for the inclusion on the Preferred Drug List.

HID recommended distribution of a Medicaid Prescribing Update for this drug category. This is to be delivered to prescribers by the Academic Detailing staff of HID. This document should also be available by link from the Division of Medicaid's Website. In addition, HID recommended retrospective DUR criteria to focus on appropriate length of therapy and use in appropriate age patients. The motion was made by Harold Blakely and seconded by Dr. Laura Gray to accept these recommendations. All voted in favor of this motion.

HIV Therapy
Mr. Smith continued with a report based on the most recent NIH treatment guidelines for the treatment of HIV, updated in October 2006. He presented criteria based on these guidelines. After extensive discussions ranging from the total cost of the medications to the appropriate treatment for HIV patients, the criteria were brought to the Board for a vote. Dr. Voulters motioned that the criteria presented with requested changes be accepted. Mr. Strickland seconded the motion. All voted in favor of accepting the 83 criteria as presented by HID.

Other Criteria Recommendations
Continuing with a review of the remaining 31 criteria pertaining to several new drugs, Dr. Voulters made a motion to accept the criteria as presented with a second by Dr. Laura Gray. All voted in favor of the motion.

Mr. Smith asked the Board for input on developing a response to prescribers related to the removal of Zelnorm® from the market. The board recommended developing a Medicaid Prescribing Update (one pager) with the input of a gastroenterologist to help inform physicians of the appropriate approach to treatment of chronic idiopathic constipation and irritable bowel syndrome (IBS).

Mr. Smith introduced an off-the-agenda discussion of the antiplatelet class of medications. These medications were reviewed at the April meeting by the P& T Committee. It was noted that from April 2006 through April 2007, approximately 10,000

claims had been processed at a total of 1.4 million dollars. He continued that a Medicaid Prescribing Update (one pager) could be delivered to the physicians to educate them on the comparison studies available for this class of drugs. It is believed that the utilization of this class is appropriate but should be addressed educationally. All members supported the distribution of such a document by the Academic Detailers.

Boxed Warnings Update:
Mr. Smith presented black box warnings, other warnings, and labeling changes issued by the FDA concerning the following:

Actiq (fentanyl citrate) Oral Transmucosal Lozenge:
WARNINGS: IMPORTANCE OF PROPER PATIENT SELECTION
and POTENTIAL FOR ABUSE
See full prescribing information for complete boxed warning.

- Must not be used in opioid non-tolerant patients.
- Contains fentanyl, a Schedule II controlled substance with abuse liability similar to other opioid analgesics.
- Life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates.
- Contraindicated in management of acute or postoperative pain.
- Contains medicine in an amount that can be fatal to a child. Keep out of reach of children and discard opened units properly.
- Use with strong and moderate CYP450 3A4 inhibitors may result in potentially fatal respiratory depression.

Femring (estradiol acetate vaginal ring):
BOXED WARNING: Cardiovascular and Other Risks
.....The estrogen-alone substudy of the Women's Health Initiative (WHI) reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 6.8 years and 7.1 years, respectively, of treatment with oral conjugated estrogens (CE 0.625 mg) per day relative to placebo. The estrogen-plus-progestin substudy of WHI reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis in postmenopausal women (50 to 79 years of age) during 5.6 years of treatment with oral conjugated estrogens (CE 0.625 mg) combined with medroxyprogesterone acetate (MPA 2.5 mg) per day, relative to placebo. The Women's Health Initiative Memory Study (WHIMS), a substudy of WHI, reported increased risk of developing probable dementia in postmenopausal women 65 years of age or older during 5.2 years of treatment with CE 0.625 mg alone and during 4 years of treatment with CE 0.625 mg combined with MPA 2.5 mg, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women.....

Humira (adalimumab) Solution for Subcutaneous Injection:
BOXED WARNING
.....Patients should be evaluated for tuberculosis risk factors and be tested for latent tuberculosis infection prior to initiating Humira and during therapy.....

Ketek (telithromycin) Tablets:
BOXED WARNING
Ketek is contraindicated in patients with myasthenia gravis. There have been reports of fatal and life-threatening respiratory failure in patients with myasthenia gravis associated with the use of Ketek.

Benazepril-containing products (Lotensin, Lotensin HCT, Lotrel):
BOXED WARNING**:** Use in Pregnancy
When used in pregnancy, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, Lotensin should be discontinued as soon as possible.....

Next Meeting Information:
Ms. Clark announced that the next meeting would be on August 16, 2007. She continued with the information that there would be new additions to the Board at the next meeting.

Special recognition:
Billy Brown, Pharm.D., was complimented for his service on this Board as his term will end prior to the next meeting.

Frank Marascalco called for the meeting to be adjourned. Dr. Lee Voulters made the motion to adjourn and Harold Blakely seconded the motion. All voted in favor of the motion to adjourn.

Respectfully Submitted:
Health Information Designs