MINUTES OF THE NOVEMBER 8, 2005 PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending: Michael O'Dell, M.D., Vice-Chairman; Myrna Alexander, M.D., Jennifer Gholson, M.D.; Jeff Jones, R.Ph.; Pearl Wales, Pharm.D.; Deborah King, F.N.P.; John Cook, M.D.; Steve Roark; Robert Smith, M.D., Todd Barrett, R.Ph.

Members Absent: Larry Calvert, R.Ph., Robert Lomenick R.Ph.

Also Present: DOM-Don Thompson, Deputy Administrator of Health Services; Judith Clark, R.Ph., Pharmacy Director; Philip Meredith, M.D., J.D., Medical Director; Terry Kirby, R.Ph., Pharmacist; Gay Gibson, R.N. Pharmacy Program Nurse; , Alecia Wasson, Pharmacy Technician; Rob DiBenedetto; Sam Warman, R.Ph., Dennis Smith, R.Ph., Pam DeRuiter, R.Ph., Lew Anne Snow, R.N., Kathleen Burns, R.N. – HID

Vice-Chairman Michael O'Dell called the meeting to order at 1:00 p.m.

Introductions: Judith Clark welcomed all committee members and guests present, and expressed appreciation to the committee members for volunteering their service and time. Ms. Clark then introduced members present from the MS Division of Medicaid. Ms. Clark reminded the committee of the Pharmacy Bureau's Mission Statement: "Working together we can provide optimal health care outcomes at reasonable costs for all beneficiaries."

Administrative Business: Judith Clark requested guests present please sign in on the attendance sheets. She explained that all documents referenced during the meeting could be found on the Division of Medicaid's website. Visitors were requested to silence electronic devices, limit leaving and entering the conference room to the break times, and that all conversations in the hallway outside the meeting room be kept to a minimum volume. Ms. Clark explained to the industry representatives present that there had been complaints from committee members regarding that the members were being confronted outside of their offices and she asked that the industry please limit interactions with the members to their offices and/or only where it was convenient for committee members. Ms. Clark stated that the meeting is taped, and a court reporter is transcribing the minutes at this meeting. Recording tapes are to be destroyed upon completion of transcription of the minutes. Votes will be taken by written ballot, and minutes will reflect each person's vote. Committee members are requested to sign and date their ballots, and place in manila envelope along with travel vouchers. To facilitate the recording of the minutes, the committee members are requested to use the microphones when speaking, and the chairman to please announce the name of the committee members making all recommendations or motions. Instructions were given regarding exit procedures from the building in the case of an emergency.

Approval of Minutes:

Todd Barrett made a motion to accept the minutes as written. The motion was seconded by Mr. Roark. All voted in favor and the minutes were approved.

Pharmacy Update

Ms. Clark referred the members to the information included in their packets regarding Medicare Part D and the changes effective January 1, 2006 as they relate to the MS Division of Medicaid. Ms. Clark presented the following information:

On January 1, 2006, Medicare's Drug benefit plan, otherwise known as Medicare Part D, will bring significant changes to Medicaid's prescription drug program. As federally mandated, Medicare becomes the primary source of drug reimbursement. This is a sweeping change for providers, beneficiaries, and Medicaid agencies nationwide. After 1-1-06, the Medicaid drug program focus will be for children, families and the newly disabled or those individuals whose disability precludes them from working.

- In FY 2005 there were approximately 748,000 Medicaid beneficiaries;
- Of the 748,000 Medicaid beneficiaries, in FY 2005, approximately 130,000 individuals have both Medicare and Medicaid
 - About 70,000 of the130,000 are dually eligible by federal definitions and will retain Medicaid coverage for necessary medical services and Medicare excluded drugs.
 - About 60,000 of the 130,000 beneficiaries will lose all Medicaid coverage for medical services. These individuals are commonly referred to as PLADs and Medicare will be their sole source of drug coverage. Medicaid will not pay for any medication; only cost sharing by payments of deductibles or premiums.
- Most, but not all, LTC beneficiaries are classified as dually eligible beneficiaries. There will be some beneficiaries, probably less than 5% of the total LTC population, who are Medicaid only.
- In FY 2005, there were approximately 100 dually eligible beneficiaries under the age of 21.
- After Part D implementation, over 70% of the Medicaid beneficiary pool will be under the age of 21.

Coordination of benefits between Medicare and Medicaid after January 1, 2006

Medicare's drug benefit will be comprehensive; however, all Part D plans will exclude 3 specific drug classes. Mississippi Medicaid has selected to provide coverage for these excluded categories. This will only impact the 70,000 dual eligible individuals. As of 1-1-06, Medicaid will cover the following drugs with limitations:

• Barbiturates – coverage of single-entity barbiturates will be limited to phenobarbital and mephobarbital (Mebaral) for <u>all</u> beneficiaries. Butabarbital, amobarbital, pentobarbital, secobarbital, and amobarbital/secobarbital combination product will not be covered for any Medicaid beneficiary. Note that butabarbital combination agents coverage will not change.

• Benzodiazepines – coverage will be limited to generic versions of these agents for <u>all</u> beneficiaries.

• Over-the-counter (OTC) drugs – Coverage will be limited to the Division of Medicaid's OTC Medicaid formulary for <u>all</u> beneficiaries. The exception to OTC coverage will be OTC insulin products, which will have coverage in Medicare's Part D plans and will not have coverage via Medicaid.

Therapeutic Category Reviews:

Pam DeRuiter, R.Ph. of Health Information Designs, Inc., (HID), moderated the therapeutic class reviews. After general discussion by the board, it was decided that Ms. DeRuiter would only review a summary of the recommendations and subsequent changes made by HID since the therapeutic category reviews.

NARCOTIC ANALGESICS

Ms. DeRuiter presented utilization data regarding opioid agonists utilization as requested at the previous P & T committee meeting. In order to analyze diagnosis trends associated with claims for sustained-release opioid products, all prior authorizations submitted year-to-date for these agents were analyzed to determine the most common diagnoses for which they were prescribed.

HID recommended all agents with a ranking of 1- generic codeine, fentanyl transdermal, hydrocodone, hydromorphone, levorphanol, tramadol, butorphanol and pentazocine.

Public comments in the Opiate Agonists and Partial Opiate Agonists category were presented by the following: Brian Barcellona; Panlab- Panlor SS; Brian Sansing; Teamm Pharmaceutical- Xodol; Kelly Englemann; Alpharma- Kadian; Ken Brier; Organon- Avinza

<u>Jeff Jones made a motion to accept HID's recommendation with the addition of Avinza and Kadian.</u> <u>Steve Roark seconded the motion.</u> The P & T committee requested that the DUR Board re-evaluate the limits currently imposed for controlled substances /analgesic products.

Ballot Results: 9 (nine) members present 9 (nine) votes for recommendation Alexander: votes against the motion

DOM selects Avinza and Kadian for Preferred Status.

ANTIDIABETIC AGENTS

HID recommended all agents with a rank of 1 for PDL inclusion- acarbose (Precose), acetohexamide, chlorpropamide, glimepiride, Lantus, glyburide/metformin, metformin (immediate release and extended release), Actos, Actos Plus, Prandin, Avandia, Avandamet, tolazamide, tolbutamide and vial insulin. Ms. DeRuiter stated that the current recommendations made by HID would remove Starlix as a preferred agent and add Actos Plus to the existing preferred anti-diabetic agents.

Public comments in the anti-diabetic agent category were presented by the following: Mari Chandler; GSK- Avandia/Avandamet ;Dr. Robbie Evans; Amylin- Byetta;Shellie Baugh; Novartis- Starlix; Tiffany Granderson; Takeda- Actos/Actos Plus Met; Todd Hobbs, M.D.; Novo-Nordisk- Novolog 70/30;Dr. Mark Haumschild, M.D.; Sanofi-Aventis- Lantus

Todd Barrett made a motion to accept the recommendation made by HID and it was seconded by Steve Roark.

Ballot Results: 9 (nine) members present for vote 8 (eight) votes for P & T's recommendation King: votes against the motion

DOM selects the following for Preferred Status: incretin mimetic- Byetta; insulin-all Novo products, and Lantus vials; oral agents-Actos, ACTOplus met, Avandamet, Avandaryl, Avandia, Prandin, and Starlix.

ANXIOLYTIC AGENTS

HID recommended there be no changes to the current preferred anxiolytic agents with alprazolam, buspirone, chlordiazepoxide, clonazepam, clonazepate, diazepam, hydroxyzine, lorazepam and oxazepam remaining preferred

There was no public comment on the anxiolytic agent category.

Todd Barrett made a motion to accept the HID recommendation and Jeff Jones seconded the motion.

Ballot Results:

9 (nine) members present for vote
7 (seven) votes for P & T's recommendation
Smith & Alexander: no vote

DOM's Decision:_Concur_

SEDATIVE/HYPNOTICS

HID recommended that estazolam, flurazepam, phenobarbital, lorazepam, temazepam and triazolam remain as the preferred agents and that Sonata and Ambien be removed as preferred agents.

Public comments in the Sedative/Hypnotic category were presented by the following: Joe Pyle; Mallinckrodt- Restoril 7.5;Dr. Daniel Garcia.; Takeda – Rozerem; Dr. Mark Haumschild; Sanofi-Aventis- Ambien CR;Dr. Howard Roffwarg; Sepracor – Lunesta

Committee member, Jennifer Gholson, M.D., joined the meeting during the public comment section.

Jeff Jones made a motion to accept the recommendation made by HID with the addition of Lunesta and Ambien CR. Pearl Wales seconded the motion.

Ballot Results: 10 (ten) members present for vote 10 (ten) votes for P & T's recommendation

DOM selects Ambien CR, Lunesta and Rozerem for Preferred Status.

INTERMITTENT CLAUDICATION AND PLATELET AGGREGATION INHIBITORS

HID recommended to retain aspirin and Plavix as preferred agents with the addition of Agrylin, cilostazol, and pentoxifylline

Public comments were presented in the intermittent claudication and platelet aggregation inhibitors categories by the following: Justin Graff, M.D.; BPI- Aggrenox; Tina Dancer, Pharm. D.; BMS-Plavix

Jeff Jones made a motion to accept the HID recommendation with the addition of Aggrenox. The motion was seconded by John Cook.

Ballot Results: 10 (ten) members present for vote 9 (nine) votes for P & T's recommendation Smith: no vote

DOM selects Clopidogrel and Aggrenox for Preferred Status.

Committee was adjourned for a brief recess at 3:00 p.m. The meeting reconvened at 3:15 p.m. Dr. Myrna Alexander was no longer in attendance.

INTRANASAL CORTICOSTEROIDS

HID recommended that agents presently considered preferred remain preferred- Flonase, Nasonex and flunisolide solution

Public comments were presented in the intranasal corticosteroid category by the following: William Webster, Pharm D; Schering – Nasonex; Dr. Mark Haumschild; Sanofi-Aventis – Nasacort AQ

Jeff Jones made a motion accept the HID recommendation and also to include Rhinocort AQ on the PDL. Deborah King seconded the motion.

Ballot Results: 9 (nine) members present for vote 8 (eight) votes for P & T's recommendation Odell: votes to accept HID's recommendation

DOM selects Flonase and Nasonex for Preferred Status.

SKELETAL MUSCLE RELAXANTS

HID recommends that agents presently considered preferred remain preferred-Baclofen, cyclobenzaprine and tizanidine.

There was no public comments were presented in the skeletal muscle relaxant category.

Jeff Jones made a motion to accept the HID recommendations. Pearl Wales seconded the motion.

Ballot Results: 9 (nine) members present for vote 9 (nine) votes to accept HID's recommendation

DOM's Decision: Concur

OSTEOPOROSIS AGENTS

HID recommended that all agents currently preferred remain on the PDL-Fosamax, Miacalcin, Evista and Actonel.

Public comments were presented in the osteoporosis agent category by the following: Thomas Wallace: Roche – Boniva;Russell Clayton, M.D.; Merck – Fosamax; Rhonda Sims; P & G-Actonel

Jeff Jones made a motion to accept the recommendation made by HID with the addition of Boniva. Deborah King seconded the motion.

Ballot Results: 9 (nine) members present for vote 8 (eight) votes for P & T's recommendation Odell: votes to accept HID's recommendations

DOM selects Actonel, Boniva, Evista, Fosamax, Micalcin for Preferred Status.

PROTON PUMP INHIBITORS

HID recommended that Prilosec OTC remain as the only preferred proton pump inhibitor.

There was no public comment presented in the proton pump inhibitor category.

Jeff Jones made a motion to accept the HID recommendation. The motion was seconded by Todd Barrett.

BALLOT RESULTS: 9 (nine) members present for vote 9 (nine) votes for HID's recommendation

DOM selects Zegrid and Prevacid for Preferred Status.

H2 ANTAGONISTS

HID recommended that cimetidine, famotidine, nizatidine, ranitidine and Zantac syrup for ages 12 and under remain as preferred H2A antagonists.

There were no public comments presented in the H2 antagonist category.

Pearl Wales made a motion to accept the HID recommendations. John Cook seconded the motion.

Ballot Results: 9 (nine) members present for vote 9 (nine) votes for P & T's recommendation

DOM selects Zantac syrup and Axid solution for Preferred Status .

ALZHEIMER AGENTS

HID recommended that there be no change and that Aricept, Namenda and Exelon remain preferred.

Public comment was presented in the Alzheimer agent category by the following: Drew Johnson; Novartis – Exelon Greg Johnson; Pfizer – Aricept Christine Sproles; Johnson & Johnson- Razadyne ER

<u>Jeff</u> Jones made a motion to accept the recommendations made by HID with the addition of all formulations of Razadyne. The motion was seconded by Jennifer Gholson.

Ballot Results: 9 (nine) members present for vote 9 (nine) votes for P & T's recommendation

DOM selects Aricept, Exelon, and Namenda for Preferred Status.

NSAIDS/COX-2 INHIBITORS

HID recommended no changes to the current PDL with only generic NSAID products as preferred agents.

Public comment was presented in the NSAID/ COX-2 Inhibitors category by the following: John Huntwork, M.D.; Celebrex

Robert Smith made a motion to accept the HID recommendation with the addition of Celebrex. Jeff Jones seconded the motion.

Ballot Results: 9 (nine) members present for vote 8 (eight) votes for P & T's recommendation Odell: votes to accept HID's recommendation

DOM's Decision:_Concur with HID's recommendation.

DUR Board Update:

Dennis Smith gave a brief update regarding the September 29, 2005 DUR Board meeting. Mr. Smith stated that the DUR board discussed the utilization by Medicaid beneficiaries of Zelnorm, all of the Triptans, as well as Zofran. The DUR board has also reviewed the utilization of hydroxyurea in patients with a diagnosis of sickle cell anemia. He stated that the board had recently focused retro-DUR activity in the area of the prevention of cardiovascular disease. Mr. Smith reported that the DUR also routinely reviews narcotic utilization.

Ms. Clark reminded committee members to place all ballots in the manila envelopes provided along with all travel vouchers and new member information. She stated that the next P & T meeting was scheduled for January 10, 2006.

There being no further business, Steve Roark made a motion to adjourn. Jeff Jones seconded the motion. Dr. O'Dell adjourned the meeting at 3:55 pm.

Robert L. Robinson, Executive Director Division of Medicaid State of Mississippi Date