MINUTES OF THE JANUARY 18, 2005
PHARMACY AND THERAPEUTICS (P & T) COMMITTEE MEETING

Members Attending: Myrna Alexander, M.D, Todd Barrett, R.Ph., Larry Calvert, R. Ph., , Gary Davis, M.D., Craig Dawkins, M.D., Jennifer Gholson, M.D., David Hudson, R.Ph., Jeff Jones, R. Ph., Michael O'Dell, M.D., Pearl Wales, Pharm.D.

Members Absent: Betsy Cummings, C.F.N.P., Raymond Wynn, M.D.

Also Present: Warren A. Jones, M.D., Sharon Barnett-Myers, Deputy Director of Health Services, Philip Merideth, M.D., J.D, Judith Clark, R.Ph., Terri Kirby, R.Ph., Gay Gipson, R.N.,– DOM, Rob DiBenedetto, Sam Warman, R.Ph., Dennis Smith, R. Ph., Lew Anne Snow, R.N., Pam DeRuiter, R.Ph.- HID.

Guests Present: Nicole Stofer- Governor's Office, Rob Reedy – ACS

Introductions:
Judith Clark welcomed all committee members present at the meeting and thanked them for their service. Ms. Clark introduced all members present from the MS Division of Medicaid. Dr. Warren A. Jones, Executive Director thanked the P & T members for their service and their guidance regarding the Preferred Drug List. Dr. Jones stated that the current deficit for this year is in excess of $268 million and the decisions made by the P & T committee were of utmost importance to the program. Dr. Jones also stated that 25% of the population, one out of every four Mississippians, was currently on the Medicaid rolls and by leveraging the guidance and counsel provided by the Committee members, MS Division of Medicaid could provide a program to meet the needs of all citizens of Mississippi.

Administrative Business
Judith Clark asked everyone in attendance to please sign in and to either turn off all cell phones and pagers or to place them on silent as to not disrupt the meeting. She gave instructions regarding exit procedures from the building in the case of an emergency. She also reminded everyone that the minutes of the meeting would be recorded, but the tapes would be destroyed upon completion of transcription of the minutes. In an effort to facilitate the recording of the minutes, she asked that all Committee members use the microphones provided when speaking. Ms. Clark asked that all members complete the travel vouchers which were in the packet provided to them. She also stated that a copy of the MS Division of Medicaid OTC Formulary was included in the packet for their information as some of the topical products currently on the list would be included in the reviews. Ms. Clark asked all members to please take a moment to review the paper ballots. She explained that each therapeutic class would have its own ballot and that voting would be for the motion, against the motion, or abstention. The ballots would not be tallied at the meeting. She reminded all members that in accordance with the Mississippi Open Meetings Act, the minutes would reflect each person's vote. Each ballot

should be signed, dated, placed in the manila envelope provided and then given to Terri Kirby, pharmacist with DOM. Ms. Clark explained that all ballots would be destroyed after the minutes of the meeting had been transcribed. Todd Barrett made a motion to accept the minutes of the October 14, 2004 P & T meeting as written. Pearl Wales seconded the motion. All voted in favor of the approval. Larry Calvert gave each member a copy of some suggestions regarding acceptance of public comments at future P & T Committee meetings. After much discussion, the following guidelines were selected:

P & T Committee Policy for Public Comment

A. Public comment during the P & T Committee Meeting is limited to representatives from the pharmaceutical industry and is not open to the general public, representatives of advocacy/special interest groups or members of academic organizations unless such individual is designated to speak on behalf of the industry by the industry.

B. Content is limited to drugs relevant to the drug classes on the agenda to be discussed during the meeting.

C. Speakers must sign in at least ten (10) minutes prior to the start of the meeting, otherwise the speaker will not be permitted to speak during the public comment period.

D. Presentations

(1) The Chair will recognize the speakers according to the order in which they are listed on the sign in sheet.

(2) Speakers may only provide oral presentations, no visual or audio aids may be used.

(3) Speakers shall limit their presentation to three (3) minutes per drug/per class/per manufacturer.

(4) The presentation should focus on the clinical advantages of the particular product and should refrain from criticizing the products from other competitors.

E. A one page summary of the speaker's presentation (per drug/per class/per manufacturer) may be submitted in advance to the Division of Medicaid's Bureau of Pharmacy for distribution to the members of the Committee. Twenty (20) copies of the summary must be submitted to the Bureau at least thirty (30) days prior to the meeting. Distribution of these materials by the Division of Medicaid is not a representation of the accuracy or reliability of the information, neither is it an endorsement of the particular product. The materials are provided for informational purposes only. No copies will be distributed at the meeting.

F. No questions or comments from the audience will be entertained unless approval is granted by two-thirds of the members present at the meeting.

G. The Committee reserves the right to suspend or eliminate the period for public comment if the privilege becomes abused or is deemed to be non-productive.

A motion was made by Jeff Jones to accept the guidelines as stated above to allow public comment at future P & T meetings. The motion was seconded by Dr. Dawkins. All voted in favor of the motion. Larry Calvert appointed Jeff Jones as the P & T committee parliamentarian.
A motion was made by Jeff Jones that the P & T committee return to the format once utilized in which a subcommittee meeting was held the morning of the regular P & T committee meeting. Following general discussion among the members, it was decided that the request would be taken to Dr. Jones. The motion was withdrawn by Jeff Jones.

Old Business:
At the October 14, 2004 P & T meeting, the committee tabled the review of Proton Pump Inhibitors. Pam DeRuiter, R.Ph with Health Information Designs, stated the proton pump inhibitor class of medication was placed on prior authorization with the criteria approved by the Mississippi Division of Medicaid and the P&T committee on June 1st, 2002. Included in the criteria was the requirement for testing as part of the medical justification for use. In the previous P&T meeting, this class was presented as a therapeutic class review for preferred or non-preferred status on the mandatory preferred drug list. One question arose during the discussion regarding whether the cost of testing outweighed the cost-savings benefit of the step-therapy edit. Subsequently, consideration of the class was tabled until the question was answered. Data presented from 6/1/2001 through 5/31/2004, included the numbers of endoscopic exams, the exam cost and PPI expenditures for this time period. The data presented showed a dramatic drop in the expenditures for this class, and that the cost savings from this edit were substantial. These results also indicated that the testing requirement did not adversely affect the cost savings. Additionally, an extensive search determined medical costs for recipients on PPIs before and after the implementation. A search was also sought to determine the medical cost of GI diagnoses in the same subset of patients which indicated that medical costs decreased on these patients. This validates the position that the step-therapy edit is not adversely affecting the medical costs or cost savings. Currently, Prilosec OTC is available without prior authorization. HID recommended Prilosec OTC as the sole preferred agent in this class. Jeff Jones asked if Zegerid, which had recently hit the market, and Prevacid Solutabs were included in this review. Ms. DeRuiter answered that only the PPIs that were used in the original review were included. Dr. Gholson asked that Prevacid Solutab be available for prior authorization for children without having the endoscopic testing requirement. Dr. Gholson made a motion to accept HID's recommendation and adding that Prevacid Solutab be available through PA for children under 18 years of age without requiring an endoscopic exam. Jeff Jones seconded the motion. All voted in favor of the motion by a show of hands.

Executive Director's Decision:_____

The P & T Committee also voted at the last meeting to table the review of the COX-2 Inhibitor therapeutic class due to recent problems with and subsequent removal of Vioxx from the market. A copy of the FDA's statement, dated January 14, 2005, indicated a special session to be held February 16, 17 and 18, 2005 to discuss non-steroidal anti-inflammatory drugs. The committee agreed to table the review for COX-2 Inhibitors pending the results of the FDA session.

THERAPEUTIC CATEGORY REVIEWS

Pam DeRuiter, R.Ph. with Health Information Designs (HID) moderated the therapeutic class reviews.

THYROID AND ANTI-THYROID AGENTS

Since thyroid agents have a narrow therapeutic index, HID recommended that all thyroid and anti-thyroid agents be included on the preferred drug list. Jeff Jones made a motion to accept the recommendation. Dr. O'Dell seconded the motion.

Ballot Results

ALL VOTED IN FAVOR OF THE MOTION

Executive Director's Decision:

5HT3 RECEPTOR ANTAGONISTS

HID recommended Zofran as the preferred 5HT3 antagonist agent because it is indicated for all three FDA-approved uses, prevention of nausea and vomiting associated with emetic cancer chemotherapy, prevention of nausea and vomiting associated with radiation treatment, and prevention of post-operative nausea and vomiting, and because Zofran is also available in an oral solution and oral disintegrating tablets for ease of administration. Jeff Jones motioned to accept HID's recommendation of ALL ZOFRAN as preferred. Dr. Davis seconded the motion.

Pearl Wales asked if there were currently quantity limits on Zofran. Judith Clark answered that currently the quantity was limited to the amount listed in Division of Medicaid drug reference file, but that the DUR board was looking at establishing quantity limits for all medications as this was a function of the DUR Board. Larry Calvert asked Judith Clark what would happen if upon receipt of the ballots, the majority of the ballots voted against the motion. Ms. Clark stated that all votes are reflected in the minutes. Dr. Jones reviews the minutes and as the executive director has the final say.

Ballot Results

ALL VOTED IN FAVOR OF THE MOTION

Executive Director's Decision:_____

ORAL ANTIFUNGAL AGENTS

HID recommended the generic oral antifungals, fluconazole, ketoconazole, nystatin, clotrimazole, and Brand griseofulvin microsize as the preferred agents. Jeff Jones presented prices he obtained from walgreens.com on the oral antifungal agents. Mr. Jones also stated that a study from a managed care group indicated that Lamisil (terbinafine) is cheaper in the long run, because the relapse rate is only 6.4 percent compared to 43 and 26 percent for the other drugs. Dr. O'Dell stated that when treating children, you can use terbinafine for a shorter length of time than griseofulvin. Dr. O'Dell also stated that terbinafine is his first choice in treatment of tinea capitis. Jeff Jones made a motion to accept the recommendation made by HID with the addition of Lamisil as a preferred product. Dr. Alexander seconded the motion.

Ballot Results

FOR motion = Alexander, Barrett, Davis, Dawkins, Gholson, Jones, O'Dell, Wales

AGAINST = Calvert, Hudson

Executive Director's Decision:_____

TOPICAL ANTIBACTERIAL AGENTS

Ms. DeRuiter indicated that of the topical antibacterial agents, currently, the only OTC formula that's been covered by the Mississippi Division of Medicaid pursuant to prescription, is Triple Antibiotic Ointment. HID recommended OTC triple antibiotic ointment, all generic legend agents which include gentamicin 0.1% cream , mupirocin 2% oint. and Cleocin Vaginal Ovules for inclusion on the preferred drug list. Dr. Alexander made a motion to accept the recommendation made by HID. Todd Barrett seconded. Committee members then discussed patient sensitivity to topical Neomycin contained in Triple Antibiotic Ointment. Jeff Jones asked to amend the original motion to also include OTC Bacitracin and Polysporin. Todd Barrett seconded the motion.

Ballot Results

ALL VOTED IN FAVOR OF THE AMENDED MOTION.

Executive Director's Decision:_____

TOPICAL ANTIFUNGALS

Ms. DeRuiter stated that currently, the Mississippi Division of Medicaid reimburses, pursuant to a prescription, OTC versions of miconazole 2% topical and vaginal cream; tolnaftate cream and powder; clotrimazole 1 % topical and vaginal cream; and clotrimazole 2 % vaginal cream. HID recommended that all generics and currently covered OTC topical/ vaginal products be considered preferred agents. Dr. O'Dell made a motion to accept the recommendations. Dr. Dawkins seconded the motion.

Ballot Results

ALL VOTED FOR THE MOTION

Executive Director's Decision: _____

TOPICAL ANTI-INFLAMMATORY AGENTS

HID recommended that only generic and generic combination topical anti-inflammatory agents be included on the preferred drug list. Dr. O'Dell made the motion to accept the recommendation. Jeff Jones seconded the motion.

Ballot Results

ALL VOTED FOR THE MOTION

Executive Director's Decision: _____

TOPICAL ANTIPRURITIC AGENTS

Ms. DeRuiter stated that the American Academy of Dermatology Association approved guidelines for care of atopic dermatitis recommends topical corticosteroids as the standard of care as well as the use of other topical therapies, such as emollients, pimecrolimus, tacrolimus, and tar. Ms. DeRuiter indicated that topical doxepin is addressed as useful for short-term adjunctive use to aid in the reduction of pruritus; however, the guidelines state that the development of side effects may limit the usefulness. Therefore, due to generic availability of other agents in other classes such as the topical corticosteroids and the effectiveness of these agents combined with recommendations of the American Academy of Dermatology Association, HID recommended no brand antipruritic agent as a preferred agent. Jeff Jones made a motion to accept the recommendation. Dr. Dawkins seconded the motion. Dr. O'Dell made an amendment to the motion to include doxepin. Dr. Gholson seconded the amendment. The amendment to the motion to include Prudoxin/Zonalon (doxepin) failed by a show of hands.

Ballot Results

ALL VOTED FOR THE MOTION

Executive Director's Decision:

TOPICAL ANTIVIRAL AGENTS

HID recommended that no product be included for preferred status because the Centers for Disease Control Sexually Transmitted Diseases, Genital Herpes Simplex Virus Infections Treatment Guidelines recommend the use of oral antivirals. Jeff Jones made a motion to accept recommendation. Dr. O'Dell seconded the motion.

Ballot Results

ALL VOTED FOR THE MOTION

Executive Director's Decision:

MISCELLANEOUS SKIN & MUCOUS MEMEBRANE AGENTS

HID recommended generic balsam peru/castor oil/trypsin combination, generic podofilox, and Aldara for PDL inclusion. Jeff Jones asked why Elidel for treatment of eczema was not recommended. Ms. DeRuiter replied Elidel is not first line therapy for treatment of eczema. She stated they should require prior authorization based on manufacturer's labeling. The labeling states it is indicated for those unable to tolerate first-line therapies or who have not responded to other therapies. Jeff Jones stated that it is difficult to treat children with the usual first-line therapies. Mr. Jones made the motion to accept the recommendation made by HID with the addition of Elidel. Dr. Gholson seconded the motion.

Ballot results

FOR = Alexander, Barrett, Dawkins, Gholson, Hudson, Jones, O'Dell, Wales

AGAINST = Calvert, Davis

Executive Director's Decision:

Other business

Judith Clark asked that all completed ballots along with the travel voucher be placed in the envelope provided, sealed and given to Terri Kirby.
Jeff Jones asked Division of Medicaid to consider reviewing narcotic analgesics before November 2005 as scheduled. Mr. Jones stated that he had done some research into what other states are doing about this particular class and some changes had been made which

resulted in millions of dollars. Judy Clark replied that she would give that request to Dr. Jones.

Dr. Gholson stated that she had received numerous letters regarding Xopenex. Dr. Gholson asked if MS DOM had an asthma disease state management program to which Ms. Clark replied that there was such a program. Dr. Gholson requested some data from DOM on the number of children below age 21 who are receiving Xopenex and who are stable on it.

Larry Calvert suggested to the members that it would be helpful if committee members would volunteer to attend their respective state association meetings in an effort to educate regarding the preferred drug list. Dr. Gholson volunteered to speak with MSMA and David Hudson volunteered to speak with the Independent Pharmacists Association. Dr. Gholson asked Judith Clark if the preferred drug list became effective December 1, 2004, and if so were we in the 90-day grace period granted to beneficiaries. Judith Clark stated that that information was correct and there would be a large mail-out to all prescribers and pharmacies around the first of February with information about the PDL.

Todd Barrett asked if the Division of Medicaid could provide not only a list of medication that are on the PDL, but also a list of the medication that were not preferred and would require prior authorization. MS. Clark stated that DOM would attempt to provide such a list if time allowed.

Larry Calvert explained to the members of the audience that Senator Nunalee, Chairman of Public Health, had asked him if the P & T members were having secret ballots. Mr. Calvert stated that he explained the P & T Committee meetings were held in accordance with the Mississippi Open Meetings Act and that all votes were reflected in the minutes.

Judith Clark told the members that the Division of Medicaid would soon begin an enhanced drug utilization review for mental health drugs. The review would look at appropriate drug utilization for antipsychotics, mood stabilizers, antidepressants, ADHD drugs, as well as opiates. Ms. Clark stated that looking at appropriate drug utilization along with prescriber education was being encouraged by NAMI and other mental health groups rather than requiring that those classes require prior authorization.

The drug expenditures for December 2004 were given to the committee members by Ms. Clark. Ms. Clark stated that in December 2004, there were 947,000 prescription claims with 45 % of those being for brand name drugs with an average cost of $110.14 per prescription. In comparison, in December 2003, there were 990,000 prescription claims with 42% being for brand name drugs at an average cost of $97.62 per prescription. In December 2004, generic drugs represented 46.6 % with at an average price of $ 25.50 per prescription. In December 2003 the average price of a generic drug was $23.24.

Judith Clark presented a recommendation from the DUR to the P & T committee for prior authorization and consideration regarding Neurontin. At the November 18th, 2004, DUR board meeting, drug utilization, including approved and off-label use of all strengths of

gabapentin was discussed. Matching the medical claim codes to the pharmacy claims, it was determined that only 0.16 %of all claims had an approved indication or even a documented indication for the drug utilization. Other states have started requesting an ICD9 code or prior authorization with this drug. The DUR board recommends to the P&T committee that Neurontin brand name would require prior authorization. The DUR Board recommends that prior authorization be granted for partial, partial complex seizures, post-herpetic neuralgia, diabetic neuropathy of the lower extremities, or treatment of ALS (as the drug does have orphan drug status for ALS). Corresponding clinical information must be in the beneficiary's chart and must be retrievable. Generic gabapentin is exempt from prior authorization. Dr. O'Dell made a motion to accept the DUR Board recommendation. Dr. Gholson seconded the motion. All voted in favor of the motion.

Ms. Clark presented the preferred drug list exception criteria as follows:

1) Beneficiary must have used 2 or more preferred agents for a thirty (30) day course of treatment per drug (as reflected in paid Medicaid claims) and failed trials, within six (6) months prior to requesting the PA
2) Documentation of therapeutic failure of preferred drugs
3) Documentation of stable therapy as reflected in ninety (90) days of paid Medicaid claims, not reflected in patient assistance programs or physician samples.

Criteria exceptions:

- Adverse event(s) reactions(s) to preferred agents
- Therapeutic failure(s) of preferred agents
- Contraindications to preferred agent(s) i.e. drug interaction, existing medical condition preventing the use of preferred agent(s).

A request was made by Judith Clark to move the March P & T meeting to March 29 due to holiday and school break schedules in an effort to assure a quorum be present for the meeting.

Jeff Jones asked if ACS could put an edit in their system to limit the quantity per prescription so that six separate PAs would not be required. Judy Clark stated that they were working on a solution to the problem.

Dr. Gholson asked if it would be possible to do prior authorizations on the computer. Ms. Clark replied that DOM had received a grant and were working on utilizing a handheld device where the physician could look at 60 – 90 days of paid claims for their patient, as well as determine what medications required prior authorization. Ms. Clark also stated that DOM was working on providing an electronic PA process at the pharmacy level.

Ms. Clark explained that all Medicaid programs must comply with very specific rules and regulations per the Centers for Medicare and Medicaid. If a drug manufacturer participates in the rebate program, Medicaid must cover all drugs for that manufacturer, with the exception of those drug classes not normally covered. Ms. Clark stated that the only venue a Medicaid agency has to not cover a drug or to put road blocks in the way is

with prior authorization. Currently, Ms. Clark explained, MS Division of Medicaid is at the max amount of co-payment allowed, $3 for a brand name, and $1 for a generic. The Division of Medicaid must comply with federally mandated CMS rules and regulations as well as State mandates for the agency.

There being no further business, Jeff Jones made a motion that the meeting be adjourned. Dr. O'Dell seconded the motion. The meeting was adjourned at 3:35 PM.