Minutes of the June 23, 2005
Drug Utilization Review (DUR) Board Meeting

Members Attending: Billy Brown, PharmD, Randy Calvert, RPh, Lee Anne Ross, PharmD, Rudy Runnels, M.D.

Members Absent: Tim Alford, M.D., Montez Carter, RPh, Clarence Dubose, RPh, John Mitchell, M.D., Lee Montgomery, M.D., Joe McGuffee, RPh, Andrea Phillips, M.D., Cynthia Undesser, M.D.

Also present: Judith Clark, RPh, Terri Kirby, RPh –DOM
Dennis Smith, RPH, Sam Warman, RPh, Lew Anne Snow, R.N., Kathleen Burns, R.N. – HID
Frankie Rutledge, Comprehensive Neuroscience, Inc

In the absence of the Board Chairman and Co-Chairman, Judith Clark requested that Dr. Ross chair the meeting at which time it was called to order at 2:15 p.m.

Also Ms. Clark noted that due to the number of absences, there would not be any voting. The Board agreed to continue the meeting without the option of approving any interventions.

Reports:

CNS Update
Ms. Rutledge presented to the Board a handout for the Mississippi Behavioral Pharmacy Management System implemented November 4, 2004. This informative material was dated November 4, 2004 thru March 2005. Included was the timeline for implementation and ongoing research to be distributed to physicians. To date, 3,455 letters were mailed to all providers who had prescribed a behavioral medication within the past twelve months. These mail- outs included an orientation letter of the program. The ongoing project oversight and account management will continue monitoring core areas as directed by the State.

Updates:
Antibiotic Utilization in Children
Dennis Smith, RPh presented the Antibiotic Utilization in Children Report as requested by the Board from the March meeting. The data was collected from a more recent 90-day period, October 2004 thru December 2004. Zithromax topped the list as the most duplicated antibiotic with 2,474 duplications as the first agent dispensed. These duplications were noted to be within a 72 hour timeframe. It was also noted that some of these agents were actually a 3rd or 4th agent prescribed within this 72 hour time. The top 10 prescribers were also noted with the actual name of the prescriber being deleted due to confidentiality. While central Mississippi seemed most implicated, it was also noted that traditionally it has the highest Medicaid participation by numbers. Conclusion indicated that over half of these duplications involved a hospital setting. Also the data seems to suggest that the same prescriber is involved in both prescriptions. Medicaid is working diligently to erase the use of the default physician numbers used by pharmacist which will eventually make data collection more accessible. The projected date by Medicaid for this default number to no longer be valid is August 1, 2005.

Hydroxyurea use in Sickle Cell Therapy
Information included in the manual showed that Sickle Cell recipients receiving at least one Rx for a narcotic analgesic, from January 2005 thru March 2005, were around 56.4%. The number of Sickle Cell recipients receiving at least one Rx for Hydroxyurea during that same time-frame was 8.9%.The study indicated that Hydroxyurea seems to be more useful in children but also is widely used in all age groups. Dr. Brown interjected many informative comments from his involvement with the Sickle Cell patients at UMC. Ms. Clark commented that we might research to identify if specialists are the physicians writing the Hydroxyurea. Also she noted that it might be helpful to know if there is a standard protocol at UMC to introduce Hydroxyurea into the care of these patients. The DUR board requested that HID look at identifying the specialties writing Hydroxyurea with regard to age and regional areas of the state. The Board also would like to have information pertinent to these patients being followed by a specialist while taking Hydroxyurea.

NSAID/Celebrex Utilization Analysis
Sam Warman, RPh presented the analysis as requested by the Board. The quantity limits set by First Data Bank are 150% of Maximum daily dose. The quantity limits reviewed included 90 days worth of data. The two diagnoses for Rxs exceeding maximum daily doses were Osteoarthritis and Rheumatoid Arthritis. The lesser diagnoses included; dysmenorrheal, fever, pain, ankylosing spondylitis. Medicaid has elected, as of July 1, 2005, to move to 100% maximum daily dose to ensure safety with these medications. Celebrex is still involved in the PA process which controls the overuse above the maximum daily requirements.

Cost Management Analysis
The top 15 Therapeutic classes by total cost of claims from January 1, 2005 thru March 31, 2005 are still led by Antipsychotic agents. The total for this time-frame of Rx claims was 2,714,835. The top Drug for this period was Synagis, which is a seasonal expenditure followed by Zyprexia.

Pharmacy Update
Ms. Judith Clark, RPh, Director of Medicaid Pharmacy Bureau, presented multiple changes to be implemented to comply with the state mandate as of July 1, 2005. The days supply will be changed to 31 days from the original 34 days. The Extension of Benefits authorization allowing up to 7 Rxs will cease to exist and beneficiaries will only be able to receive payment from Medicaid for (2) Brands and (3) generics. Medicaid has compiled a Maintenance Drug list which will allow the physician to write a 90 day supply from this list. This will change on a periodic basis as Medicaid updates this list. This is meant to facilitate the beneficiary in obtaining the needed monthly medications when the Extension of Benefits expires on June 30, 2004.
Medicaid is working with both UMC and The State health Department to help manage critical areas of care for HIV and Hemophilia patients. There will be a transition period for these patients as their management of care is moved to other areas to assist the Pharmacy program of Medicaid. Long Term Care facilities are the only "carve-outs" for the medication limits. Children with fall under the same guidelines as other beneficiaries with the addition of a Medically Necessary form to obtain more than five Rxs. The Co- pay for all beneficiaries will be $3.00 with the exception of children, LTC and pregnant patients. Their co-pay will remain unchanged. The Maintenance Drug List indicates generics only. The only exception being made is the newly posted list for Insulin's. Insulins designated as brand will be counted against brand name service limits. Insulins designated as OTC will not be counted against brand name service limits. Medicaid was able to include these OTC Insulins to afford some help for beneficiaries receiving more than (1) Brand Insulin.

New Business
DUR Intervention
Dennis Smith, RPh reviewed the DUR intervention process to the Board. The other areas of interventions and recommendations were briefly pointed out but due to lack of a quorum will be presented at the future Board meeting. Dr. Ross suggested in the presentation of Osteoporosis, that Osteopenia might be included in the future reviews. Dr. Ross continued stating that HID might look at the long term therapies instead of 30 day therapy used in these reviews. Dr. Ross then presented the Prevention of Cardiovascular Events as requested by HID. She continued with the fact that the JNC-7 report states that undiagnosed, untreated and uncontrolled hypertension places a strain on the health care delivery system. The encouragement of optimal treatment to goal could decrease this strain.Dr. Ross had several examples of known diagnoses that would benefit with additional JNC-7 pharmacological recommendations.

Black Boxed Warnings
Dennis Smith presented black box warnings issued by the FDA concerning the following:

- Trileptal- Novartis and FDA notified healthcare professionals about the revisions to the Warnings and Precautions sections of the prescribing information. The updated WARNINGS section describes serious dermatological reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) which has been reported in both children and adults. The PRECAUTIONS sections have been updated to include language regarding multi-organ hypersensitivity reactions with the use of Trileptal.
- FDA ALERT: Celebrex has been associated with an increased risk of serious adverse cardiovascular events in a long-term placebo controlled trial. FDA has requested that the package

insert for all NSAIDS including Celebrex be revised to include the potential increased risk of CV events and the well described risk of serious and potentially life threatening gastrointestinal bleeding. FDA has also requested the package insert for all NSAIDs be revised to include a contraindication for use in patients immediately post op from CABG surgery

- Prescription Non-selective NSAIDs: FDA requests for revising product labeling to include:
  1. A black box warning regarding potentially serious adverse CV events and the potentially life-threatening GI adverse events
  2. A contraindication for use in patients who have recently undergone CABG surgery
  3. A medication guide for patients regarding the potential for CV and GI adverse events Associated with the use of this class of drugs. The medication guide will be required to be given to patients at the time each prescription is dispensed.
- OTC Non-Selective NSAIDs
  FDA will ask manufacturers of all OTC products containing ibuprofen to revise their labeling to include:
  1. More specific information about the potential CV and GI risks
  2. Instructions about which patients should seek the advice of a physician before using these drugs
  3. Stronger reminders about limiting the dose and duration of treatment in accordance with package instructions, unless otherwise advised by a physician
  4. A warning about skin reactions
  5. It was also noted that Aspirin is a nonselective NSAID but due to other indications to reduce the risk of CV events, patients should remain under strict advice of their physicians in regard to this medication
- Novantrone prescribing information revisions regarding the increase risks of cardiotoxicity and secondary acute myelogenous leukemia (AML)
  May 24, 2005, Serona and FDA notified healthcare professional of revisions to the BOXED WARNINGS AND DOSAGE AND ADMINISTRATION sections indicated for the treatment of multiple sclerosis. This letter provided supplemental information regarding secondary acute myelogenous leukemia (AML) reported in MS patients with the use of Novantrone.It also included concerns regarding the risks of cardiotoxicity associated with Novantrone.

Dr. Ross then concluded the meeting asking for further comments. Ms. Clark reported that there will be (4) members on the Board rotating off. She also reminded the Board that one of the requirements to serve addresses attendance. A Board member must keep a 50% attendance record to be able to remain on the Board. She added that we must always be respective of those who have traveled and given up their appointments to attend these meetings. The new Board appointments are in process of approval.

The meeting was adjourned at 3:40 p.m.

Respectfully submitted:
Health Information Designs