Mississippi Division of Medicaid
Drug Utilization Review (DUR) Board
Minutes of the May 15, 2008 Meeting

Members Attending: Frank Marascalco, R.Ph., Chair; and Lee Voulters, M.D.

Members Absent: Roy Arnold, R.Ph.; Harold Blakely. R.Ph., Laura Gray, M.D.; Wallace Strickland; John Wallace, M.D.

Also Present:
DOM Staff: Judith Clark, R.Ph., DOM Pharmacy Bureau Director; Paige Clayton, Pharm D, DOM DUR Coordinator; Terri Kirby, R.Ph., Andrea McNeal, Ella Holmes.

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

Call to Order:
Frank Marascalco, Chairman of the Board, called the meeting to order at 2:15 p.m.

Ms. Clark offered that the Board may choose to delay the meeting until June in light of the lack of quorum or continue with the present meeting. The Board members in attendance agreed to proceed, acknowledging that no voting would be possible.

Updates:

Cost Management Analysis:
Mr. Smith presented an overview of data covering several months, including top therapeutic classes by total cost of claims, top drugs based on the number of claims, and top drugs based on total cost of claims. Mr. Smith pointed out seasonal trends, such as increases in antibiotic use and Synagis.

Pharmacy Program Update:
Dr. Clayton reminded the Board that the new PDL will be available on the DOM website on or about June 1, 2008 with an effective date of July 1, 2008.

New Business:

FDA Updates:
Mr. Smith presented recent FDA labeling updates and other FDA healthcare provider communications. In past DUR Board meetings, this presentation was referred to as Box Warning Updates, but has been renamed and moved up in the agenda. This information is provided to assist in identifying drug products with potential for concern surrounding safety and appropriate utilization. He stated that while many of the alerts included are not Black Box Warning additions or updates, they are labeling changes or updates with relevance worthy of action by the FDA.

CellCept (mycophenolate mofetil)
Myfortic (mycophenolate acid)
4/10/2008: FDA informed healthcare professionals that the Agency is investigating a potential association between the use of CellCept and Myfortic, medicines used to prevent organ rejection, and the development of progressive multifocal leukoencephalopathy (PML), a life-threatening disease. PML is a rare disorder that affects the central nervous system usually occurring in patients with immune systems suppressed by disease or medicines. FDA is reviewing data submitted by Roche, including postmarketing reports it has received of PML in patients who took CellCept or Myfortic, and the proposed revisions to the CellCept prescribing information. FDA has asked Novartis, the maker of Myfortic, for data on PML cases and to revise the Myfortic prescribing information to include the same information about PML included in the CellCept prescribing information. FDA anticipates it may take about 2 months to complete its review of the postmarketing reports and the proposed revisions to the prescribing information. As soon as the review is completed, FDA will communicate the conclusions and recommendations to the public.
Until further information is available, patients and healthcare professionals should be aware of the possibility of PML, such as localized neurologic signs and symptoms in the setting of a suppressed immune system, including during therapy with CellCept and Myfortic.

Neupro (rotigotine transdermal system)
4/09/2008: Schwarz Pharma informed healthcare professionals and patients of the recall of Neupro, a transdermal delivery system worn on the skin and used to treat early stage Parkinson's disease, at the end of April 2008, because of the formation of rotigotine crystals in the patches. When the drug crystallizes, less drug is available to be absorbed through the skin and the efficacy of the product may vary. Healthcare professionals should not initiate any new patients on Neupro and should begin to down-titrate all patients currently using the product per the guidelines in the product labeling. Patients should NOT abruptly discontinue therapy. Abrupt withdrawal of dopamine agonists has been associated with a syndrome resembling neuroleptic malignant syndrome or akinetic crises.

Exubera (insulin human rDNA origin) Inhalation Powder
4/09/2008: Pfizer informed healthcare professionals and patients of updated safety information in the WARNINGS section of prescribing information for Exubera, a short-acting insulin you breathe in through your mouth using the Exubera inhaler that helps to control high blood sugar in adults with diabetes. There have been 6 newly diagnosed cases of primary lung malignancies in clinical trials among Exubera-treated patients, and 1 newly diagnosed case among comparator treated patients. There has also been 1 post-marketing report of a primary lung malignancy in an Exubera-treated patient. There were too few cases to determine whether the emergence of these events is related to Exubera. All patients who were diagnosed with lung cancer had a prior history of cigarette smoking. Because of limited availability of Exubera, healthcare professionals should seek alternative treatment options to maintain patients' glycemic control.

Relenza (zanamivir)
4/01/2008: GlaxoSmithKline informed healthcare professionals of changes to the WARNINGS AND PRECAUTIONS sections of prescribing information for Relenza regarding information from postmarketing reports (mostly from Japan) of delirium and abnormal behavior leading to injury in patients with influenza who are receiving neuraminidase inhibitors, including Relenza. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of Relenza to these events has not been established. Influenza can be associated with a variety of neurologic and behavioral symptoms which can include seizures, hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease.

Patients with influenza should be closely monitored for signs of abnormal behavior. If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient.

Ziagen (abacavir)
Videx (didanosine)
3/27/2008: The FDA issued an Early Communication about recent findings of The Data Collection on Adverse Events of Anti-HIV Drugs Study. Data analyses from this study indicate a higher risk of heart attack in patients infected with HIV-1 who were taking Ziagen (abacavir) or Videx (didanosine) as part of their drug therapy. The study is a large observational study of 33,347 HIV-1 infected patients living in North America, Europe and Australia. Patients in this study are being followed to evaluate the short and long term adverse effects of treatment with anti-HIV drugs. FDA continues to evaluate the overall risks and benefits of abacavir and didanosine. This evaluation may result in the need to revise labeling for the products. Until the FDA's review is complete, health care professionals should evaluate the potential risks and benefits of each HIV-1 antiretroviral drug their patients are taking.

Regranex (becaplermin) Gel
3/27/2008: The FDA is conducting a safety review based on study data suggesting there may be an increased risk of death from cancer in diabetic patients using Regranex (becaplermin) Gel, a skin product used to heal leg and foot ulcers. While the review is ongoing, the FDA recommends health care professionals discuss the potential risks and benefits of using Regranex with their patients.

Singulair (montelukast)
3/27/2008: FDA informed healthcare professionals and patients of the Agency's investigation of the possible association between the use of Singulair and behavior/mood changes, suicidality (suicidal thinking and behavior) and suicide. Singulair is a leukotriene receptor antagonist used to treat asthma and the symptoms of allergic rhinitis, and to prevent exercise-induced asthma. Patients should not stop taking Singulair before talking to their doctor if they have questions about the new information. Healthcare professionals and caregivers should monitor patients taking Singulair for suicidality

(suicidal thinking and behavior) and changes in behavior and mood.

Tiotropium (marketed as Spiriva HandiHaler)
3/18/2008: Boehringer Ingelheim and FDA notified healthcare professionals that ongoing safety monitoring has identified a possible increased risk of stroke in patients who take Spiriva. This product contains tiotropium bromide and is used to treat bronchospasm associated with chronic obstructive pulmonary disease. Boehringer Ingelheim reported to the FDA that it has conducted an analysis of the safety data from 29 placebo controlled clinical studies ("pooled analysis"). Based on data from these studies, the preliminary estimates of the risk of stroke are 8 patients per 1000 patients treated for one year with Spiriva, and 6 patients per 1000 patients treated for one year with placebo. This means that the estimated excess risk of any type of stroke due to Spiriva is 2 patients for each 1000 patients using Spiriva over a one year period.

It is important to interpret these preliminary results with caution. FDA is working with Boehringer Ingelheim to further evaluate the potential association between Spiriva and stroke. FDA has not confirmed these analyses and while pooled analyses can provide early information about potential safety issues, these analyses have inherent limitations and uncertainty that require further investigation using other data sources. Patients should not stop taking Spiriva HandiHaler before talking to their doctor, if they have questions about this new information. This early communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews of drugs.

Erythropoiesis Stimulating Agents: Aranesp (darbepoetin alfa), Epogen (epoetin alfa), and Procrit (epoetin alfa)
3/12/2008: Amgen and FDA notified healthcare professionals of changes to the Boxed Warnings/WARNINGS: Increased Mortality and/or Tumor Progression section of the Aranesp and EPOGEN/PROCRIT labeling to update information describing the results of two additional studies showing increased mortality and more rapid tumor progression in patients with cancer receiving ESAs. Based on the results of these studies, the prescribing information has been revised as follows: ESAs shortened overall survival and/or time to tumor progression in clinical studies in patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers when dosed to target a hemoglobin of $\geq$ 12 g/dL.

Prezista (darunavir)

3/21/2008: FDA issued a new "Information for Healthcare Professionals" sheet highlighting the addition of hepatotoxicity information to the WARNINGS section of prescribing information for Prezista.

3/12/2008: FDA and Tibotec Therapeutics notified healthcare professionals of changes to the WARNINGS section of the prescribing information for Prezista (darunavir) tablets regarding the risk of hepatotoxicity. In clinical trials and postmarketing experience, drug induced hepatitis has been reported in patients receiving combination therapy with Prezista/ritonavir. Appropriate laboratory testing should be conducted prior to initiating therapy with Prezista/ritonavir and patients should be monitored during treatment.

Increased AST/ALT monitoring should be considered in patients with underlying chronic hepatitis, cirrhosis, or in patients who have pretreatment elevations of transaminases, especially during the first several months of Prezista/ritonavir treatment.

Long-Acting Hydrocodone-Containing Cough Product (marketed as Tussionex Pennkinetic Extended-Release Suspension)
3/11/2008: FDA informed healthcare professionals of life-threatening adverse events and death in patients, including children, who have received Tussionex Pennkinetic Extended-Release Suspension (Tussionex). The reports indicate that healthcare professionals have prescribed Tussionex for patients younger than the approved age group of 6 years old and older, and more frequently than the labeled dosing interval of every 12 hours. Tussionex is contraindicated for use in patients less than 6 years of age because of their susceptibility to life-threatening and fatal respiratory depression.

Patients have administered the incorrect dose due to misinterpretation of the dosing directions, and have used inappropriate devices to measure the suspension. Overdose of Tussionex in older children, adolescents, and adults has also been associated with life-threatening and fatal respiratory depression. Prescribers should be familiar with the dosing recommendations of Tussionex before prescribing. In addition, patients and caregivers should use a properly marked measuring device to measure Tussionex to prevent overdose.

Tamiflu (oseltamivir phosphate)
3/04/2008, updated 3/04/2008: Roche and FDA informed healthcare professionals of neuropsychiatric events associated with the use of Tamiflu, in patients with influenza. The label has been revised as follows: Influenza can be associated with a variety of neurologic and behavioral symptoms which can include events such as hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease. There have been postmarketing reports (mostly from Japan) of delirium and abnormal behavior leading to injury, and in some cases resulting in fatal outcomes, in patients with influenza who were receiving Tamiflu. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made but they appear to be uncommon based on Tamiflu usage data. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of Tamiflu to these events has not been established. Patients with influenza should be closely monitored for signs of abnormal behavior. If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient.

Spiriva (tiotropium bromide inhalation powder) Capsules
Foradil (formoterol fumarate inhalation powder) Capsules
2/29/2008: FDA informed healthcare professionals and consumers of the correct way to use Spiriva and Foradil inhalation powder capsules. FDA and the American Association of Poison Control Center's (AAPCC) National Poison Data System have received many reports of patients swallowing Spiriva and Foradil capsules rather than placing the

capsules in the inhalation devices. Both products are to be used in the HandiHaler (Spiriva) and Aerolizer (Foradil) devices to deliver the medicine to the lungs to improve breathing in patients with asthma, and in individuals affected by chronic obstructive lung disease and bronchitis. Both products will not treat a patient's breathing condition if the contents of a capsule are swallowed rather than inhaled. Healthcare professionals should discuss with patients how to correctly use the Spiriva HandiHaler or Foradil Aerolizer. See the Public Health Advisory for important information on the correct use of both products.

Tysabri (natalizumab)
2/27/2008: Biogen Idec, Elan and FDA notified healthcare professionals of reports of clinically significant liver injury, including markedly elevated serum hepatic enzymes and elevated total bilirubin, occurred as early as six days after the first dose of Tysabri. The combination of transaminase elevations and elevated bilirubin without evidence of obstruction is recognized as an important predictor of severe liver injury that may lead to death or the need for a liver transplant in some patients. Tysabri should be discontinued in patients with jaundice or other evidence of significant liver injury. Physicians should inform patients that Tysabri may cause liver injury.

Avandia (rosiglitazone maleate)
2/26/2008: FDA and GlaxoSmithKline notified pharmacists and physicians of a new Medication Guide for Avandia (rosiglitazone maleate). The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern. A list of currently approved Medication Guides are available at http://www.fda.gov/cder/Offices/ODS/medication_guides.htm. The Medication Guide and current Prescribing Information for Avandia are provided below.

Fentanyl transdermal system CII Patches
3/03/2008: Actavis Inc. has voluntarily recalled of all lots of Fentanyl Transdermal System CII patches sold in the United States.

2/19/2008: Actavis Inc. announced a nationwide recall of certain lots of Fentanyl transdermal system CII Patches sold in the United States and labelled with an Abrika or Actavis label. The product may have a fold-over defect which can cause the patch to leak and expose patients or caregivers directly to the fentanyl gel. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal. The lots covered by this recall include doses of 25, 50, 75, and 100 mcg/hr and are listed in the firm's press release.

Duragesic 25 mcg/hr (fentanyl transdermal system) CII Pain Patches
2/15/2008: PriCara and Sandoz Inc. announced a nationwide recall of all lots of 25 mcg/hr Duragesic Patches sold in the United States. The product is being recalled because the patches may have a cut along one side of the drug reservoir within the patch which may result in the possible release of fentanyl gel that may expose patients or caregivers directly to fentanyl gel on the skin. Fentanyl is a potent Schedule II opioid

medication and exposure to the gel may lead to serious adverse events, including respiratory depression and possible overdose, that may be fatal. Patches with a cut edge should not be used. These recalled patches have expiration dates on or before December 2009 and are all manufactured by ALZA Corporation.

Heparin Sodium Injection (Baxter)
2/28/2008: Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection, and their heparin lock flush solutions.
2/11/2008: FDA informed healthcare professionals of important warnings and instructions for Heparin Sodium Injection use. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension. Most events developed within minutes of heparin initiation although the possibility for a delayed response has not been excluded. The reports have largely involved use of multiple-dose vials. However, there have been several cases in which product from multiple, single-dose vials have been combined to administer a bolus dose. Heparin sodium is an anticoagulant (blood thinner) that is used in patients undergoing kidney dialysis, certain types of cardiac surgery, and treatment or prevention of other serious medical conditions, including deep venous thrombosis and pulmonary emboli. Heparin treatment is initiated using high doses (5000-50,000 units) given directly into the blood stream (intravenously) as a bolus. Serious adverse events have recently been reported in patients who received these higher bolus doses.

The manufacture of multiple-dose vials of heparin sodium has been suspended pending the completion of an extensive ongoing investigation to determine the root cause of the problem. Because heparin sodium is a medically necessary product and serious public health consequences would result if there were a sudden shortage of the drug, the multiple-dose vials of heparin sodium manufactured by Baxter that are currently in distribution will not be recalled. See the FDA Public Health Advisory for Agency recommendations to healthcare professionals on the use of heparin sodium for injection.

Botox, Botox Cosmetic (Botulinum toxin Type A), Myobloc (Botulinum toxin Type B)
2/07/2008: FDA issued an early communication about an ongoing safety review regarding Botox and Botox Cosmetic. FDA has received reports of systemic adverse reactions including respiratory compromise and death following the use of botulinum toxins types A and B for both FDA-approved and unapproved uses. The reactions reported are suggestive of botulism, which occurs when botulinum toxin spreads in the body beyond the site where it was injected. The most serious cases had outcomes that included hospitalization and death, and occurred mostly in children treated for cerebral palsy-associated limb spasticity. Use of botulinum toxins for treatment of limb spasticity (severe arm and leg muscle spasms) in children or adults is not an approved use in the U.S. See the FDA's "Early Communication about an Ongoing Safety Review" for Agency recommendations and additional information for healthcare professionals.

Injectable Colchicine (including drugs containing colchicine)
2/06/2008: FDA announced its intention to take enforcement action against companies marketing unapproved, injectable colchicine, a drug used to treat gout. Colchicine is a highly toxic drug that can easily be administered in excessive doses, especially when given intravenously. There is a narrow margin between an effective dose of the drug and a toxic dose that can result in serious health risks, including death. The FDA is aware of 50 reports of adverse events associated with the use of intravenous colchicine, including 23 deaths. Potentially fatal effects include low blood cell counts, cardiac events, and organ failure. This action does not affect colchicine products that are dispensed in tablet form.

Individuals and companies must stop making these products within 30 days and stop shipping the product within 180 days or face regulatory action. After these dates, all injectable colchicine drug products must have FDA approval to be manufactured or shipped interstate.

Varenicline (marketed as Chantix)
2/01/2008: FDA informed healthcare professionals and consumers of important revisions to the WARNINGS and PRECAUTIONS sections of the prescribing information for Chantix regarding serious neuropsychiatric symptoms experienced in patients taking Chantix. These symptoms include changes in behavior, agitation, depressed mood, suicidal ideation, and attempted and completed suicide. While some patients may have experienced these types of symptoms and events as a result of nicotine withdrawal, some patients taking Chantix who experienced serious neuropsychiatric symptoms and events had not yet discontinued smoking. In most cases, neuropsychiatric symptoms developed during Chantix treatment, but in others, symptoms developed following withdrawal of Chantix therapy. See the FDA Information for Healthcare Professionals Sheet for recommendations and considerations for healthcare professionals on using Chantix therapy for patients.

Antiepileptic Drugs
1/31/2008: FDA informed healthcare professionals that the Agency has analyzed reports of suicidality (suicidal behavior or ideation) from placebo-controlled clinical studies of eleven drugs used to treat epilepsy as well as psychiatric disorders, and other conditions. In the FDA's analysis, patients receiving antiepileptic drugs had approximately twice the risk of suicidal behavior or ideation (0.43%) compared to patients receiving placebo (0.22%). The increased risk of suicidal behavior and suicidal ideation was observed as early as one week after starting the antiepileptic drug and continued through 24 weeks. The results were generally consistent among the eleven drugs. The relative risk for suicidality was higher in patients with epilepsy compared to patients who were given one of the drugs in the class for psychiatric or other conditions.

Healthcare professionals should closely monitor all patients currently taking or starting any antiepileptic drug for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.

The drugs included in the analyses include (some of these drugs are also available in generic form):
Carbamazepine (marketed as Carbatrol, Equetro, Tegretol, Tegretol XR)
Felbamate (marketed as Felbatol)
Gabapentin (marketed as Neurontin)
Lamotrigine (marketed as Lamictal)
Levetiracetam (marketed as Keppra)
Oxcarbazepine (marketed as Trileptal)
Pregabalin (marketed as Lyrica)
Tiagabine (marketed as Gabitril)
Topiramate (marketed as Topamax)
Valproate (marketed as Depakote, Depakote ER, Depakene, Depacon)
Zonisamide (marketed as Zonegran)

Although the 11 drugs listed above were the ones included in the analysis, FDA expects that the increased risk of suicidality is shared by all antiepileptic drugs and anticipates that the class labeling changes will be applied broadly.

NuCel Labs Eye Drops and Eye/Ear Wash Products
1/31/2008: NuCel Labs and FDA informed consumers and healthcare professionals of a voluntary nationwide recall of all Eye Drops and Eye/Ear Wash Products. The products were recalled after testing indicated the presence of bacteria and particulate matter, deeming these products non-sterile. Non-sterile eye drops pose an unacceptable risk of causing eye infections, which in rare cases could lead to blindness. No illnesses or injuries have been reported to date. There are no lot numbers or expiration dates on the products. Consumers who have the product should discontinue use of the product and return it to NuCel Labs. See the manufacturer's press release for return shipping information.

Ezetimibe/Simvastatin (marketed as Vytorin), Ezetimibe (marketed as Zetia), and Simvastatin (marketed as Zocor): Early Communication about an Ongoing Data Review
1/25/2008: FDA provided healthcare professionals with an early communication about an ongoing data review for Ezetimibe/Simvastatin (marketed as Vytorin), Ezetimibe (marketed as Zetia), and Simvastatin (marketed as Zocor). This early communication is in keeping with FDA's commitment to inform the public about ongoing postmarketing drug issues.

Merck/Schering Plough Pharmaceuticals reported preliminary results from the Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia (ENHANCE) trial. This trial was designed to evaluate the amount of atherosclerotic plaque in blood vessels located in the neck based on images obtained through ultrasound in patients treated with Vytorin (ezetimibe plus simvastatin) or simvastatin alone. Merck/Schering Plough stated that there was no significant difference between Vytorin and simvastatin in the amount of atherosclerotic plaque in the inner walls of the carotid

(neck) arteries despite greater lowering of LDL-cholesterol (bad cholesterol) with Vytorin compared to simvastatin. Once Merck/Schering Plough completes the analysis of the unblinded data from ENHANCE, it will submit a final study report to FDA. Once FDA receives the final study report, FDA estimates it will take approximately 6 months to fully evaluate the data. After reviewing the data from the ENHANCE study, and considering all other available information about the link between LDL lowering and reduction of cardiovascular events, FDA will determine whether any further regulatory action is warranted with regard to Zetia and Vytorin and also whether any changes to FDA's current approach to drugs that lower LDL cholesterol are warranted.

Patients should talk to their doctors if they have any questions about the information from the ENHANCE trial.

Leukine (sargramostim)
1/24/2008 Bayer and FDA informed healthcare professionals of the market withdrawal of the current liquid formulation of Leukine, a growth factor that helps fight infection and disease in appropriate patients by enhancing immune cell function. The product was withdrawn because of an upward trend in spontaneous reports of adverse reactions, including syncope (fainting), which are temporally correlated with a change in the formulation of liquid Leukine to include edetate disodium (EDTA). The upward trend in adverse reaction reporting rates has not been observed with the use of lyophilized Leukine. Healthcare professionals should immediately stop using liquid Leukine and return unused vials to the manufacturer.

Review of 1st Quarter Meeting Materials:
The members present were briefed on the prior meeting information and agreed to continue with other business.

Carisoprodol Prior Authorization Update:
Mr. Smith began by reporting that the P& T Committee concurred with the recommendation of the DUR Board to require a PA for all carisoprodol products. He continued by pointing out that with quantity limits and distribution of the prescribing information update and tapering schedule to physicians, this medication continues to show high utilization. Dr. Clayton interjected that she had requested input from several states and heard similar concerns and approaches throughout the country. The new carisoprodol prior authorization form to be implemented July 1, 2008 was presented for review.

Off-label Use of Atypical Antipsychotics for Children with ADHD/ODD:
Dr. Holeman noted that HID receives prior authorization requests regularly for atypical antipsychotics in pediatric patients with the only diagnosis provided being ADHD or ODD, neither of which is an approved indication. The youngest age for which any of the atypical antipsychotics is approved is five years. This indication is approved for Risperdal® in children with irritability associated with autistic disorder. Abilify ® is approved for adolescents from 13 years of age for Schizophrenia. The remaining atypical antipsychotics (Geodon®, Invega®, Zyprexa®, and Seroquel®) are not approved for use

in children or adolescents under the age of 18. This information, coupled with the large number of prior authorization requests seen for these medications in the pediatric population, raised concerns about the off-label use of these medications in children with ADHD and/or ODD. Dr. Holeman presented a chart depicting the use of these medications in pediatric Medicaid beneficiaries. While the largest number of beneficiaries range between the ages of 13 and 16 years, the chart also showed substantial use of atypical antipsychotics in children as young as six for ADHD and/or ODD.
In an effort to encourage appropriate use of these agents among this young population, a retrospective DUR criterion is recommended to identify these beneficiaries who do not have an FDA-approved diagnosis. The criterion will be presented at the next meeting due to the lack of a quorum at this meeting.

Synagis® trending Report:
HID has compiled seasonal information on Synagis utilization with emphasis on year-to-year trending of this costly medication. The intent of DOM policies regarding this agent is to ensure that the medication is available to all children who meet the criteria and that the medication is delivered to the appropriate beneficiary. The information presented illustrates that, while maintaining and encouraging appropriate utilization of this medication, the criteria and dose limits have resulted in a leveling of the average number of claims per beneficiary over the past three seasons. The outcome of the trending study showed that although 2007-2008 had more approved beneficiaries and the cost of the medication had increased, significant cost avoidance can be attributed to the policies implemented by DOM and HID.

Generalized Anxiety Disorder (GAD):
Dr. Holeman reviewed the prevalence of GAD, stating that it affects about 6.8million adult Americans and about twice as many women as men. With SSRI antidepressants being the preferred class for the treatment of GAD, once treatment at optimal dosing with one or more of the SSRIs has been tried and failed, second line treatment with Effexor XR® or Cymbalta® should be considered. Dr. Holeman mentioned that while benzodiazepines do have a place in the treatment of GAD, treatment guidelines recommend that their use be short-term, not to exceed two to four weeks. Due to apparent inappropriate use of benzodiazepines, the DUR Board has recommended that DOM distribute information to prescribers to encourage appropriate use. As a result, a Medicaid Prescribing Update was created by HID highlighting current GAD treatment guidelines. This update will be distributed by the Academic Detailers to all prescribers and will also be available by a link from the Division of Medicaid website.

Risperdal Consta:
Mr. Smith and Dr. Holeman presented a review of the impact of subjecting Risperdal Consta® to the prior authorization process. Risperdal Consta® is well-suited for patients for whom medication compliance is a challenge. According to the FDA-approved prescribing information, tolerability to oral risperidone should be established prior to initiating therapy with Risperdal Consta®. The labeling also states that oral risperidone or another antipsychotic medication should be given with the first injection of Risperdal Consta®, continued for three weeks, then discontinued to ensure that effective

therapeutic plasma concentrations are reached and maintained prior to the main release phase of risperidone from the injection site. In October 2007, HID was given the responsibility for supervising the prior authorization of Risperdal Consta®. Utilization data was gathered by searching the paid claims submitted to HID by the fiscal agent. The six month period prior to HID involvement in this PA saw 138 beneficiaries on duplicate therapy with Risperdal Consta® and an oral atypical antipsychotic, compared to 124 beneficiaries during the subsequent six month period. In this analysis, indicating a ten percent decrease in duplicate therapy, DOM realized a decrease of approximately $900,000 in oral atypical antipsychotic expenditures in this short time. Based on the information presented, this effort has been successful. Dr. Holeman mentioned HID's efforts to educate prescribers on the Risperdal Consta® prescribing information, monitoring claims data and following up with those patients who are supposed to be tapered off oral medication. Dr Voulters suggested that HID contact the American Psychiatric Association for guidelines or treatment recommendations for the above mentioned disease states reviewed today.

Criteria Recommendations:
Unable to present at this time due to a lack of quorum

Frank Marascalco reminded the Board of the next meeting August 21, 2008 and adjourned the meeting at 3:15 p.m.