MENTAL HEALTH DRUG ADVISORY GROUP
Meeting Summary
August 30, 2006

Opening Remarks/Introductions

The Mental Health Drug Advisory Group met to review and respond to the Prior Authorization Committee's recommendations regarding Antidepressants – SSRIs, Stimulants and Related Agents, Alzheimer's Agents, and Antiparkinson's Agents.

Helene Nelson, Secretary of the Department of Health and Family Services, opened the meeting by introducing Kevin Hayden, Administrator of the Division of Health Care Financing. The following members were present: Joyce Allen, Barry Blackwell, Clarence Chou, Molly Cisco, Ted Collins, Kay Cram, Ron Diamond, John Easterday, Dianne Greenley, Shel Gross, Harold Harsch, Jenny Lowenberg, Linda Oakley, Ken Robbins, Molli Rolli, Susanne Seeger, and Michael Witkovsky.

Secretary Helene Nelson's Review of her Decisions regarding Atypical Antipsychotics

Secretary Nelson summarized the June 8, 2006 letter to the Mental Health Drug Advisors which stated her decisions on Atypical Antipsychotics.

Overview of Prior Authorization Process Meeting

- Jim Vavra summarized the PA Process meeting attended by Ted Collins, Ron Diamond, John Easterday, Carrie Gray, Shel Gross, Cathy Kunze, Jenny Lowenberg, and Jim Vavra.
  - ✓ He reported that they did a demonstration of the pharmacy process.
  - ✓ They revised the physician PA using simplified language and including the hotline.
  - ✓ They simplified the Emergency Supply Form. They also published the availability of a fourteen day supply use for emergency situations.
  - ✓ They sent a letter to all prescribers of antipsychotics regarding the process.
  - ✓ Mark Moody presented to NAMI.
  - ✓ Ron Diamond and Carrie Gray published articles in the Medical Society Newsletter and the Wisconsin Psychiatric Association Newsletter regarding the process.
  - ✓ A suggestion was made to simplify the PDL list which led to the development of a Quick Reference Guide. This is listed on the pharmacy web site and has been disseminated to physicians.
  - ✓ The Senior Care Advisory Committee meets quarterly and receives an update of what the PA Advisory Committee and Mental Health Advisory Group are doing.
  - ✓ Medicaid receives a weekly report from the EDS customer service hotlines. He reports that they have had very few calls on Mental Health Classes.

In order to obtain PA, the physician completes the form for fee-for-service Medicaid recipients and sends it to the pharmacy. The Medicaid HMOs do not use this form. The pharmacies are live electronically with the system. Jim invites anyone with suggestions on how to disseminate the information regarding the PA process to submit them. Secretary Nelson advises to add this issue of the HMOs to the next agenda. She indicates that she and Kevin Hayden will discuss how to dialogue with the HMOs prior to the next meeting.

Comments from the group regarding the Secretary's Decisions regarding Atypical Antipsychotics

Harold Harsh asked Abilify and Seroquel were made non-preferred when no one at the previous meeting discussed making them non-preferred. It was noted that Seroquel is preferred. Secretary Nelson responded that State Statutes call for the Secretary to make decisions regarding PDL and call for an advisory committee. The Medicaid PA Advisory Committee is that committee. The committee is a voting committee but the votes are advisory. Secretary Nelson felt that there wasn't enough expertise in the area of mental health so she convened a Mental Health Drug Advisory Group. She intended for this to be an advisory group as well. She indicates that she additionally looks at what the scientific advisors and staff recommend. Secretary Nelson reports that with the last review she was struck by the science regarding efficacy. Various factors led to her decision including the discussion of cost, efficacy, the split vote by the PA committee, and the scientists' recommendations to not include Abilify. She concluded that Abilify was expensive without obvious superiority.

Clarence Chou noted that follow-up with data on things such as hurdles and usage patterns may be more important than the initial decision. Ron Diamond stated that we are talking about where to start and not what is available. Secretary Nelson stated that when science is not clear we need to create a system that has flexibility. Barry Blackwell stated that it is important to consider other costs such as hospitalizations, in addition to the drug costs. He questioned whether the state is collecting that data. Secretary Nelson responded that the Department looks at the entire Medicaid budget. She recommended adding the issue of hospitalization trends and drug utilization trends to the next agenda.

Clarence Chou stated that psychiatrists only prescribe some of the psychotropic medications and recommended looking at who the prescribers are. Mike Mergener responds that for Atypicals the vast majority are prescribed by psychiatrists at least initially and this issue is class dependent. They have looked at selected services pre and post policy change but indicate that at this time it is too close to the implementation to get valid data. Jenny Lowenberg agreed that it is important to measure ramifications. Secretary Nelson directed that performance review be put on the next agenda in addition to the HMO discussion and data management.

Molly Cisco asks what happens to a recipient when they are put on a medication in an inpatient unit and then discharged. Molli Rolli responds that the inpatient doctor fills out the paperwork for PA. She reports that she hasn't had any problems with the Medicaid system. Mike Witkovsky recommended comparing inpatient versus outpatient prescribing practices.

Secretary Nelson noted the example of Zyprexa being used for an aggressive inpatient. She stated that Medicaid does not want a disruption of care. Clarence Chou states that PA is so important with data. He states that in the ER anything and everything might be used so PA is much more important.

Molly Cisco questioned whether a 30 day sample would be considered for grandfathering. Jim Vavra responded that this would not be appropriate because drug companies could circumvent the system by providing samples. A discussion occurred outlining how often people are on samples prior to receiving Medicaid eligibility. Ron Diamond stated that it is important to be reasonable without gaming the system. Jim Vavra stated that in these situations the system wouldn't deny prior authorization. Mike Mergener states that doctors are less likely to provide samples to MA recipients because they have low co-pays. Secretary Nelson stated that we need to look at the transfer from inpatient to outpatient. Jim Vavra stated that they will continue to look at the PA process and talk to groups of people about it. Kevin Hayden states that coming from a private insurer; he sees that the PA process in the state system is done well. He is impressed by how automated the PA system is. He stated that he is very interested in listening to feedback regarding the operational process. He indicated that the fiscal issues around PA are real. He feels that there is a need to minimize time for physicians completing the PA process.

Overview of Prior Authorization Committee's Recommendations from the August 16, 2006 Meeting

Jim Vavra reviewed the summary of the PA Committee's recommendations. He noted that there was a general recommendation to always grandfather non-preferred drugs in the mental health categories.

Alzheimer's Agents:

- ✓ Harold Harsch questions why there was a recommendation to change Razadyne ER to no. Jim Vavra answers that the company changed the rebate and there are clinical alternatives.
- ✓ Molli Rolli questions how you prove one of the agents failed. Mike Witkovsky indicates that there was testimony at the PA Committee that an early start and no changes once a recipient is doing well are particularly important for this class.
- ✓ Harold Harsch notes that in the VA system everyone is on Razadyne because it is the cheapest.
- ✓ Barry Blackwell questioned whether there was a legal reason not to state the reason the recommendation was made was based on cost. He indicated that it is otherwise impossible to tell why the decision was made.
- ✓ Jim Vavra questioned whether psychiatrists prescribe this class of medications. Molli Rolli states that it is mostly gerontologists and neurologists. Mike Mergener questioned whether this class should be considered mental health. Harold Harsch responded that there are psychiatrists, such as him, who specialize in this area. Ken Robbins responded that these drugs have mental health benefits in addition to cognitive benefits.

Antiparkinson's Agents: Barry Blackwell asked why there are so many name brands if generics are available. Mike Mergener responded that the newer drugs have a unique action and are different therapeutic classes of drugs. Ken Robbins commented that it is a little quirky to have it as a mental health drug class because psychiatrists only prescribe the first two. Secretary Nelson indicated that utilization will be monitored.

Antidepressants – SSRIs:

- ✓ Dianne Greenley stated that it would be useful to have a list of generic and brand names available.
- ✓ Harold Harsch stated that Lexapro is the only SSRI shown to be superior to Celexa and should therefore be on the PDL. Mike Mergener responded that those studies were funded by Forest Laboratories when Celexa was going generic.
- ✓ Barry Blackwell asked whether there was a cost differential. Ted Collins responded there is a significant cost differential.
- ✓ Harold Harsch stated there were three patients in his clinical practice who were switched off of Lexapro and they all relapsed. He emphasized that Lexapro is a better drug than Celexa.
- ✓ Shel Gross asked what was discussed at the PA committee. Jim Vavra responded that it is non-preferred now and would stay non-preferred.
- ✓ Barry Blackwell stated that there is a need to look at other costs such as hospitalizations and suicide noting the example given of the three patients being switched off.
- ✓ Shel Gross asks if there was any data on changes in market share. Mike Mergener responds that it is hard to get clear data in the mental health classes due to the grandfathering.
- ✓ Shel Gross asked why the generic was blocked with Zoloft. Jim Vavra responded that the company is offering a rebate that is better than the generic price. Secretary Nelson responds that the general policy of the state is to use generic when available. Ken Robbins questioned how it is to the advantage of the drug company to reduce the price lower than the generic. Mike Mergener responded they are able to make money by selling at a reduced price.
- ✓ Molli Rolli asked if the pharmacies would know to use name brand. Secretary Nelson responded that the pharmacy system is automated.
- ✓ Jenny Lowenberg asked how this would affect consumers. Secretary Nelson responded that after six months there would be a generic substitution.
- ✓ Molly Cisco asked whether the doctor or the pharmacist would explain the change to the consumer. Molli Rolli responded that the pharmacist does.
- ✓ Barry Blackwell asked why we are only looking at SSRIs. Jim Vavra responded that the TOP$ reviews are scheduled by Provider Synergies, not the Medicaid program.

Ken Robbins states that there is a new class of drugs for substance abuse and asked whether the Mental Health Drug Advisors should review this group. Mike Mergener responded that this is not a class scheduled for review by Provider Synergies. Medicaid policy states that if the manufacturer has signed a rebate agreement with CMS and reported the drug to First Data Bank, it is a covered drug.

Stimulants and Related Agents:

- ✓ Pemoline is off because it has a black box warning.
- ✓ Harold Harsch stated that Strattera is not a stimulant, not addicting, and not diverted like the others in this class so it should be encouraged not discouraged. Barry Blackwell stated that he is in agreement and continues by stating that stimulants have been around forever and lead to meth abuse because of diversion.
- ✓ Mike Witkovsky responds that Strattera has a large dose range and a therapeutic response may take 6-8 weeks whereas methylphenidate can provide a response in ten minutes. He argues that treatment with methylphenidate stops drug addiction. One example provided indicated that Concerta is not diverted because of packaging.
- ✓ Barry Blackwell questioned why waiting a few weeks for a response for a life-long illness is an issue. Clarence Chou stated that the standard is to start with stimulants and then if they are not tolerated try something else. He stated that he is working with adults and sees many untreated cases of ADD or ADHD with major costs to society. He stated that Strattera has a black box warning for kids due to liver problems.
- ✓ Molli Rolli stated that the issue is why Medicaid requires PA for Strattera and not whether Ritalin is a good treatment for ADD or ADHD. She added that Strattera may be preferable for many of those untreated adults including those with substance abuse issues.
- ✓ Ron Diamond asked how you balance risks and benefits and questioned whether we want Strattera as first line when it doesn't work as well and is expensive. Harold Harsch responded by saying that given the national diversion problem why not.
- ✓ Molly Cisco indicates that she is concerned about the number of prescriptions for these medications written by non-psychiatrists. Mike Witkovsky states that the data indicates that 1/3 of the prescriptions are written by psychiatrists. Molly Cisco responds that given that data she would want to encourage something non-addicting.
- ✓ Shel Gross questioned whether extended release is less divertible and if someone is started on Ritalin if there is a discussion later to switch to Strattera. Mike Witkovsky responds that classic dosing is to start with immediate release so you can establish effects then move to the long-acting forms if necessary. If there are risks, then alternatives may be discussed. Clarence Chou responded that there is an art to figuring out dosing which is done by trial and error.
- ✓ Barry Blackwell asked the percentage of children who don't respond or have side effects. Ron Diamond stated that switch studies show that switching leads to improvement which doesn't necessarily mean the drug is better. Barry Blackwell stated that the immediacy of effect is a double-edge sword which can lead to addiction.

Lyrica: Jim Vavra reviewed that Lyrica is currently off PDL but was requested to be reviewed after six months. The staff recommendations are to keep it off PDL. The PA committee voted to put it on the PDL. Susanne Seeger stated that Lyrica has many side effects such as weight gain and excessive sedation. She had up to five patients started on it and only one still on it. She stated that they are still gaining experience on how to dose. She indicated that there are other alternatives for pain. Mike Mergener stated that currently there are no mental health indications for Lyrica. The indications are for epilepsy and pain. He

stated that use for generalized anxiety is being investigated. Ted Collins stated that all insurance companies require PA for Lyrica. He added that it is easier to titrate the dose. Mike Mergener stated that increasing dose has no clinical advantage. There was a question as to why the PA committee voted to add it to the PDL. Jim Vavra responded that the testimony was positive for Lyrica. Harold Harsch stated that the studies for generalized anxiety disorder were positive and it will likely be approved. Mike Mergener agreed that it would likely get approval for generalized anxiety disorder and fibromyalgia. Ted Collins added that there is no FDA approval for the new indications yet.

Review of Cost and Utilization

Michael Mergener reviewed Medicaid and BaderCare Fee-for-Service and SeniorCare cost and utilization data for Antidepressants – SSRIs and Stimulants from January 1, 2006 through June 30, 2006. He also reviewed SeniorCare and Medicaid Claim utilization for Cymbalta and Lyrica. Cost data does not include the proprietary rebate information. It was noted that sertraline is highly used but very expensive. There was a request to have the information broken down by age groups. There was also a request to look back over time to look at trends. It was noted that grandfathering slows changes in market share. Many people on Medicaid became dually eligible for Medicare Part D in January which led to a 60% loss of recipients in Medicaid. People were also switched to managed care. Shel Gross asked if anyone looked at why people are requesting PA. The response was that it is difficult to get a clear picture due to grandfathering.

Other Issues:

Dianne Greenley stated that she understands that a consumer representative had resigned from the PA Committee and she wants to make sure that the seat is filled with another mental health consumer. Nominations for the seat can be sent to Jim Vavra.

Next Steps

The Medicaid Pharmacy PA Advisory Committee will meet in February 2007. Secretary Nelson proposed that the Mental Health Drug Advisors meet prior to that date to discuss the issues identified at today's meeting. A January meeting was recommended to allow time to gather data on HMOs, drug utilization, hospitalization trends, service utilization, performance reviews, and what occurs with the transfer from inpatient to outpatient services. The group requested advance notice for schedule planning.