MENTAL HEALTH DRUG ADVISORY GROUP
Meeting Summary
February 23, 2006

Opening Remarks/Introductions

The Mental Health Drug Advisory Group met on February 23, 2006, to review and respond to the Prior Authorization Committee's recommendations from February 8, 2006, meeting regarding Anticonvulsants, Sedative Hypnotics, and Anti-depressants-Other. This group also discussed the upcoming consideration of Atypical Anti-psychotics.

Sinikka Santala, Administrator of the Division of Disability and Elder Services (DDES), opened the meeting by discussing the efforts of DDES and the Division of Health Care Financing (DHCF) to work together to provide recommendations to Helene Nelson, Secretary of the Department of Health and Family Services (DHFS), regarding mental health drugs and their inclusion on the Medicaid preferred drug list (PDL). Helene Nelson reviewed the importance of having a good balance between people getting the medicines they need and the state paying reasonable costs for those medications.

Group members introduced themselves. The following members were present: Barry Blackwell, Virginia Bryan, Clarence Chou, Molly Cisco, Ted Collins, Kay Cram, Ron Diamond, Robert Driscoll, John Easterday, Dianne Greenley, Shel Gross, Harold Harsch, Cathy Kunze, Jenny Lowenberg, Mark Moody, Linda Oakley, Pam Pauloski, Ken Robbins, Molli Rolli, Sinikka Santala, Michelle Thoma, and Michael Witkovsky.

Ms. Santala reviewed the agenda.

Secretary Helene Nelson's Charge to the Group

Secretary Nelson reviewed her charge to the Mental Health Drug Advisors Group. She reports that state statute requires the secretary to appoint a Wisconsin Medicaid Prior Authorization Advisory Committee to make recommendations related to a PDL. She has an advisory group to assist in making decisions. She reports that there was not a PDL until the last few years.

Secretary Nelson states that advocates and others have suggested a two-step process. She is looking for advice and comments from the Mental Health Drug Advisors Group regarding the PA Committee's recommendations. The PA committee will meet prior to the Mental Health Drug Advisors Group. Secretary Nelson announced that she will suspend her decisions until she hears from the Mental Health Drug Advisors Group also. She indicates that there was an informal committee prior to this group being established. In addition to providing advice regarding mental health drugs and their inclusion in the PDL, this group will provide comments on grandfathering, step therapy, drug utilization,

and PDL implementation strategies. The purpose of this meeting is to review Anticonvulsants, Sedative Hypnotics, and Anti-Depressants-Other.

Future agendas may focus on other issues or smaller work groups may be established. The frequency of meetings for the Mental Health Drug Advisory Group will depend on the subjects needing to be addressed.

Discussion and Comments from Group Members on Secretary's Charge to Group

Shel Gross identified two scenarios, one would be if this group agreed with the PA committee's recommendations and the other would be if the group disagreed. He questioned whether the Secretary would communicate her decisions and the rationale for them to the group. Secretary Nelson stated that she doesn't think there is a conflict because this is not a voting group but rather an opportunity for her to hear more voices. The Secretary also indicated her decisions would be shared with the group.

Overview of Prior Authorization Committee's Recommendations from February 8, 2006 Meeting

Mark Moody, Administrator of DHCF, announced that twenty-nine classes of drugs were considered by the PA Committee on February 8, 2006. Of those classes, Anticonvulsants, Sedative Hypnotics, and Anti-Depressants-Other will be discussed by the Mental Health Drug Advisors Group. Mr. Moody explained the handouts and handed out corrected Cost and Utilization information for Medicaid and SeniorCare. Dianne Greenley requested that future handouts include both the generic and brand names for drugs.

Overview of Prior Authorization Committee's Recommendations from February 8, 2006, Meeting Regarding: Anticonvulsants

The PA committee recommended that all the drugs be on the preferred list except Phenytek, Tegretol XR, and Lyrica. The reasons these were not included is because Phenytek and Tegretol both have generics available and Lyrica is not just indicated for seizure disorders, but also for diabetic neuropathy. If a drug is non-preferred, it may be covered if a Prior Authorization (PA) is submitted.

Discussion and Comments from Group Members on Prior Authorization Committee's Recommendations

Ken Robbins asked for clarification on the Cost and Utilization sheets, questioning whether it lists cost despite type of usage. It was clarified that cost is based on all usage.

Ron Diamond noted that Tegretol has a significant amount of brand name usage despite having a generic available.

Clarence Chou questioned whether there was any way to break down who is prescribing the drugs by provider type. Mike Mergener explained that it could be done to an extent based on provider number but it would depend on how the providers identified themselves. Dr. Chou requested that that be part of the utilization data. Helene Nelson clarified that utilization could be part of another discussion.

Overview of Prior Authorization Committee's Recommendations from February 8, 2006, Meeting Regarding: Sedative Hypnotics

The PA committee recommended that all the generics and Ambien be preferred drugs on the PDL and Restoril, Doral, Lunesta, Ambien CR, Sonata, and Rozerem be non-preferred. The rationale for excluding Restoril is because it is available as generic temazepam in other doses. The initial recommendation was to include Lunesta but there was concern of switching from Lunesta to Ambien and back to Lunesta. The estimated savings would be $112,000 per quarter from rebates. Most of the drug prices are similar.

Discussion and Comments from Group Members on Prior Authorization Committee's Recommendations

Clarence Chou asked how long the recommendations are good for. Mike Mergener answered that the drugs are typically reviewed yearly but they can be reviewed sooner if a clinical issue makes it necessary.

Helene Nelson indicated that this is an area where she is looking for feedback because the PA Committee's vote was so close.

Harold Harsch stated that he wanted to make a case for Rozerem to be included especially considering the safety advantages for elderly patients.

Ronald Diamond questioned what the PA Committee members reasons were for having different recommendations. Mike Mergener answered that Rozerem is new on the market and has a different mechanism of action; it has advantages but others thought more clinical experience was necessary. The Lunesta decision is an effort to preserve market share when Ambien goes generic.

Ken Robbins stated that it is difficult to pick off the drugs one by one and questioned whether an overall cost savings was the goal. Helene Nelson responded that the group is not operating with a fiscal target. Mark Moody added that they are not trying to base decisions on a fiscal target but that decisions should be based on clinical merits. Dr. Robbins stated that it is complicated but he would make an argument for Lunesta to be included. Mr. Moody reported that Lunesta offers a rebate.

Shel Gross questioned whether generics are automatically on the PDL and whether the PA committee was assuming that Ambien will be included when the generic becomes available. Mike Mergener answered that it is the general policy of the state that when a drug becomes available as a generic and everything else is equal, it will be included.

Mark Moody clarified that the original decision was not either Ambien or Lunesta, but Ambien and Lunesta. The concern was that Lunesta's market share would build and when Ambien became available as a generic, it would be difficult to switch patients from Lunesta to generic Ambien,

Ron Diamond commented that it is important to focus on what we would want to start with. He states that there are very few of these drugs that wouldn't be first choice. He questions whether there is a convincing reason that there are a large number who would need to start on Lunesta

Cathy Kunze stated that looking at the cost charts for Sedative Hypnotics it seems like a small amount of money and she questions if there is a percentage of a cost trying to be shaved off. Mark Moody responded that fifty-five classes are being reviewed and this class is in the top fifty-five. The PA Committee is looking at classes with significant expenditures and looking for places to save money.

Molly Cisco referenced the Provider Synergies monograph, which contained the indications and noted that Lunesta and Ambien CR are the only drugs indicated for treatment of insomnia. She questions whether one of these should be on the PDL. Ron Diamond responded that the indications were more of a marketing strategy and that any of the drugs in this class could be used for this indication. Molli Rolli responded that she doesn't think Ambien CR has an advantage and that there is no difference for long-term treatment. She didn't know the advantages of Lunesta. Harold Harsch responded that the advantages of Lunesta are that it works for some people when Ambien doesn't.

Clarence Chou commented that the group seems to be forming a matrix – what works clinically, where is the state getting the most for its money, and how the classes compete. He asked to get a more clear direction from the state. Helene Nelson responded that the classes stand independently of each other and that there is a trade off between clinical efficacy and cost savings. She states that it is necessary to try and make sure there are options. If the drugs are the same then pull back from the higher costing alternative. She reported that DHFS contracted with a PDL consultant to begin this process. She states that sometimes the consultant's and committee's recommendations differ.

Shel Gross questioned the risks of switching drugs within this class. He used anti-depressants as an example of where making the right choice regarding the first line drug makes a difference. The response was that the response to medications in this class is quick with low risk of switching.

Dianne Greenley asked whether the group was talking about grandfathering. Mark Moody responded that there is not grandfathering in this class because there is no change from current status. He states that if Lunesta was added there wouldn't be switching.

Pam Pauloski asked why Rozerem is in this class if it is not a sedative. Harold Harsch responded that it promotes sleep in a different way.

Linda Oakley stated that the conversation has helped figure out the purpose. She stated that if there is no current cost advantage, Lunesta should be included as preferred. Mark Moody explained that if Lunesta is on the PDL there would be a market shift with more Lunesta being prescribed. Then those people would be on Lunesta and when Ambien goes generic there might be a temptation to take Lunesta off PDL.

Harold Harsch suggested that if the goal is to simplify then suggested taking off temazepam because there is no advantage. Secretary Nelson responded that drugs are not being removed unless there is something bad about them or they are costly.

Molli Rolli questioned the PA procedure and whether it is uniform across classes and what rationale physicians need to provide for a drug not on the PDL. Mike Mergener responded that for the most part they try to keep it consistent but occasionally additional questions need to be asked. Primarily physicians need to answer two questions – has the patient tried and failed a preferred drug or does the patient have a condition which precludes use of a preferred drug. Ron Diamond stated that the PA process for brand name clozapine is more complicated on purpose.

Molly Cisco questioned why Michael Witkovsky voted Nay. Dr. Witkovsky responded that he was interested in having Rozerem available especially because of its benefits for pediatrics.

Barry Blackwell stated that the manufacturers of Ambien are trying to extend their patent while Lunesta is studying the long-term effects of use. He questions why the company doing the wrong thing should be rewarded while the one doing the right thing is being punished. Michael Witkovsky stated the clinical efficacy of the drugs are similar while the costs are dramatically different. Mark Moody clarified that after rebates the costs are similar. Jenny Lowenberg stated that the group is here to do what is best for consumers. Ron Diamond stated that there are long-term studies of Ambien CR and clarified that information is not purely scientific because it is contaminated by drug company representatives.

Ken Robbins stated there are merits for Lunesta especially in the elderly. He reports that Ambien has more memory problems and Lunesta is safer for dementia.

Shel Gross stated that people are staying on drugs a long time and the committee should look at appropriateness of care of individuals. Clarence Chou questioned shifts. Ted Collins stated that continued use was examined with 51% of people getting at least 365 doses in one year and prescribed almost universally in a thirty day supply.

Molly Cisco questioned whether there are addictive qualities to these drugs. Barry Blackwell responded that you have to distinguish between addiction and dependence.

<u>Overview of Prior Authorization Committee's Recommendations from February 8, 2006, Meeting Regarding: Anti-Depressants-Other</u>

Mike Mergener reported that the PA committee recommended all the drugs in this class be preferred except nefazodone, Wellbutrin XL, and Cymbalta. The committee recommended removing the PA requirement on Wellbutrin XL for all recipients 18 and younger because of the once daily dosing. There is an estimated cost savings of $290,000 per quarter from new patients starting off on lower cost drugs.

Discussion and Comments from Group Members on Prior Authorization Committee's Recommendations

Cathy Kunze stated that the exception for Wellbutrin XL is great for kids but also applicable for adults. She states that some adults don't always remember to take their medications due to disorganization. She states she always remembers her AM dose, but if people don't get their PM doses they don't have enough drug in their system and don't see the therapeutic response. Ron Diamond responded that it is nice to have a once per day dose but suggested that there be a public discussion of whether it is worth the cost. Ted Collins responded that Wellbutrin XL is twice as expensive and the rebates are not big enough to offset the cost.

Shel Gross questioned whether a doctor could get PA without failure of a preferred drug. Mike Mergener responded that they could stating the patient had a condition preventing the use of the preferred agent.

Shel Gross questioned whether nefazodone was recommended on the PDL. Mike Mergener responded that it was not because it has a black box warning.

Harold Harsch stated that the once daily dosing is better, but the cost issue has to be considered.

Barry Blackwell stated that he did research on compliance and found no difference between once daily dosing versus three times per day. He states that people are able to remember due to meal times but compliance decreases with more than three times per day dosing.

Ken Robbins stated that Wellbutrin XL has a cross-over advantage for ADHD and suggested that there be a comparison of costs to stimulants.

Clarence Chou stated that this may be a comparison of apples to oranges and questioned what cost is being prevented. He brought up the costs of smoking as an example and the saving of something that improves compliance.

Molly Cisco suggested for those people who need medication monitoring there may be an increase in services provided with not having the once daily dosing option. She also questioned the cost of time away from work for someone who has to take medications at different times. Dianne Greenley questioned whether that would be considered a condition for PA. She furthered questioned whether that has been communicated to providers. James Vavra responded that the questions on the PA depend on the class. Ms.

Greenley requested that there be more clarification on conditions. Mike Mergener stated that information gets back to providers. Mark Moody stated that there needs to be a balance between special questioning and consistency regarding PA forms. Secretary Nelson stated that she appreciates the comments and variation on themes. Ron Diamond suggested that he and others write an article regarding the PA process.

Linda Oakley suggested staying with the big picture: taking pills is always complicated and that conditions in behavioral health have to be considered.

Cathy Kunze stated that as a person suffering from depression, the quality of her life has improved because of timely treatment that is superior to old forms. This has increased the number of days of work and her ability to contribute. She states that this is much more valuable than what can be saved by not including the drugs.

Jenny Lowenberg stated that she had been under the impression from the state that the PA process is easy but her impression from providers is it is not. Barry Blackwell stated that part of the problem is that the state doesn't require managed care to follow the same PDL.

Molly Cisco questioned whether the rebate is lost if it is not put on PDL. Secretary Nelson responded that it could be costly if a lot of PA's are granted.

Molli Rolli questioned why the list does not include tricyclics and MAO-Is. Mike Mergener responded that there are no restrictions on those drugs. Dr. Rolli stated that Cymbalta is highly utilized first line by pain physicians. Dr. Mergener responded that they would need to complete a PA and stated that there are a number of other drugs for neuropathic pain. Dr. Rolli suggested that doctors working with neuropathic pain be included in the group.

Dianne Greenley suggested that the managed care PDL vs. state PDL be put in the parking lot issues.

Pam Pauloski asked if there is a limit to the number of PAs and how that is decided. Mark Moody responded that there is no specific limit and each prescription is based on its merit. He added that they rely on the physician's judgment. He states that the problems occur when someone shows up at a pharmacy with a prescription but no PA. Helene Nelson responded that PA is within the scope of the committee but not on today's agenda.

Barry Blackwell stated that tricyclics work for pain and suggested that Cymbalta does not work any better. Cathy Kunze responded that Cymbalta did work for her personally. She states that for people with disabilities, pain syndrome is common and it might be nice for people to have Cymbalta as a first choice. Harold Harsch responded that Lilly did do studies to show the benefits of Cymbalta and noted the risks of trycyclics. He states that he would like Cymbalta included. He stated that in addition people respond differently to anti-depressants. Mark Moody responded that the issue is not whether they are available

but whether it is first line treatment. Dr. Harsch responded that it is not people with simple depression by the time physicians are treating patients with this coverage. He added that for people over sixty-five is another benefit of Cymbalta. Molli Rolli stated that this may not be the drug you start with for depression in general but it would be for some one with neuropathic pain.

Jenny Lowenberg questioned if the cost sheet shows what purpose the medication is being prescribed for. Mark Moody responded that there may be a way to figure it out but it is difficult from claims data. Clarence Chou stated that he has ideas about the cost data that he would like to discuss in more detail after the meeting.

Ken Robbins stated that not only are pain physicians using Cymbalta but also physicians working with the elderly. He states that there is data for Cymbalta for pain and depression. Jenny Lowenberg questioned whether that would be a condition allowing PA. She suggested that there be caveats for each class rather than so many PAs needed.

Clarence Chou questioned whether there is any data on multiple medications from different classes. Mike Mergener talked about the Behavioral Pharmacy Project, which gives feedback to doctors regarding unusual prescribing practices. Shel Gross requested that that information become shared with the group. Cathy Kunze questioned where it is housed. John Easterday responded DHFS. Ron Diamond volunteered to discuss the project in other forums.

Molly Cisco stated that she thinks it is really important to have a once daily dose option.

Discussion: Upcoming consideration of Atypical Anti-psychotic drugs

Mark Moody explained TOP$, the The Optimal PDL $olution, a multi-state purchasing consortium. He discussed the Provider Synergy states comparisons. He reports that 18% of spending is on the Atypicals. Mr. Moody added that the state could save $1million per quarter with a reasonable PDL. The PA Committee will discuss Atypical Anti-psychotics on 3/29/06. This group will discuss on 4/12/06. The materials have been included in the packets sent for this meeting. Today's discussion is to preview.

Dianne Greenley asked whether the old Antipsychotic medications or just the Atypical Antipsychotics were being reviewed. Mike Mergener responded that the Atypicals will be reviewed.

Molly Cisco asked why some states have not reviewed. Mark Moody responded that some states have legislative exemption. Ms. Cisco suggested that they all be preferred.

Barry Blackwell asked if all the states are using the same data. Mark Moody responded that they are. Dr. Blackwell commented that not all the states have come to the same conclusion. He questioned which states saved the most money and whether it is correlated to what they left off. Mr. Moody responded that he will try to get that data to the group. He indicates that the TOP$ states are Maryland, West Virginia, Wisconsin,

Louisiana and Delaware. Secretary Nelson states that Wisconsin will make its own decision. Ron Diamond asked if the rebate is already negotiated. Mr. Moody responded it is not reflected in the current costs. Dr. Diamond questioned whether this group had access to that information. Mr. Moody indicated that they would, but they would have to figure out a way to do it within confidentiality guides.

Shel Gross asked if it is on the table to delay the decision. He suggested that a delay would be beneficial in order to consider CATIE study results. He also talked about not wanting to overload case managers as they are already overloaded due to Medicare Part D issues. Ron Diamond responded that he can't imagine that the CATIE Study, given its design, could be useful enough to delay discussion. Harold Harsch stated that the cognitive findings may be useful.

Molli Rolli noted that seven of eight states left Wellbutrin XL on the PDL. The response was that this is a function of how other states price generics.

Ron Diamond asked when rebates are negotiated that if they were declined can the company come back with another offer. Mark Moody responded that it is a one time shot. Helene Nelson responded that they could come back with another offer when it is re-reviewed.

Shel Gross questioned whether it is a conflict of interest for pharmacists on the PA committee to recommend adding Atypical Antipsychotics to the PDL. Mark Moody responded that there are three pharmacists, one is a faculty member, one is a benefits consultant, and one is a retail pharmacist working for Aurora. Secretary Nelson responded that she wants to hear all voices and she takes comments based on their merit. Her goal is that people get the medicines they need and the state can afford to purchase them. She states that the PA committee is not controlling the decision. She adds that they are good people with a mix of backgrounds who were appointed with thoughtfulness. The process is one of integrity going piece by piece.

Virginia Bryan asked if there is testimony at the PA committee. Mark Moody responded that there is.

Jenny Lowenberg stated that mopping up Part D is all of our responsibility. She adds that physicians will take the path of least resistance which will put some clients in difficult situations. She states that the process of providing testimony has limitations for consumers. Helene Nelson states that it is important to have a design process where affected people speak out.

<u>Next Steps</u>

Sinikka Santala announced that the next meeting is scheduled for April 12, 2006, with three to four hours to discuss Atypical Anti-psychotics. Ms. Santala reviewed the parking lot issues identified for future meetings included utilization of drugs, prescribing practices, streamlining PA, data collection, testimony process, and HMO formularies. Secretary Nelson clarified that the group does not want to overload the next meeting with

these issues. The group agreed. Secretary Nelson suggested that at the end of the next meeting the group decide how to proceed.

John Easterday offered to talk about the CATIE study with anyone who is interested. Helene Nelson suggested that the entire group have the information.

Secretary Nelson stated that she appreciates the quality of people who have agreed to serve on this group.