MENTAL HEALTH DRUG ADVISORY GROUP
Meeting Summary
August 29, 2007

Welcome / Introductions

Members Present: Joyce Allen, Virginia Bryan, Ken Casimir, Clarence Chou, Molly Cisco, Ted Collins, Ronald Diamond, John Easterday, Shel Gross, Harold Harsch, Richard Kilmer, Catherine Kunze, David Larson, Jenny Lowenberg, Michael Mergener, Mary Neubauer, Susanne Seeger, Michelle Thoma, Karen Timberlake, Jim Vavra, Michael Witkovsky.

John Easterday, Administrator of the Division of Mental Health and Substance Abuse Services, opened the meeting and reviewed the agenda. He asked the group for feedback on whether there should be a meeting in February due to no mental health medications being reviewed at that time. Ron Diamond suggested that the group meet to strategize about Risperdal becoming generic in 2008. Shel Gross recommended that the group discuss access to psychiatry services. The consensus of the group was to meet in February and determine through the course of this meeting what topics would be appropriate. John Easterday announced that Karen Timberlake, Deputy Secretary Department of Health and Family Services, would be joining the meeting. Members introduced themselves.

Prior Authorization Committee's Recommendations from August 15, 2007

Jim Vavra, Director of Bureau of Fee-For-Service Health Care Benefits (BHCB), led the overview of the PA Committee's Recommendations regarding the mental health classes reviewed at the August 15, 2007 meeting.

Shel Gross noted that there were only six MA PA Committee members present to vote at the August 15 meeting. He questioned how many members there are on the committee and who was not present. Jim Vavra responded that there are eleven members and identified those who were not present. Molly Cisco questioned whether Michael Witkovsky should still be on the committee since he is under contract with the DHFS. John Easterday responded that there have been other contracted persons on the committee and that there is not a conflict since he is not an employee.

Alzheimer's Agents:

Harold Harsch noted there is no clinical reason for Razadyne to be non-preferred other than financial reasons. Mike Mergener commented that Cognex has significant side effects. Harold Harsch agreed that there is no clinical reason to use Cognex first. Jim Vavra stated that grandfathering will continue in this class with no end date.

Antidepressants, SSRIs:

After reviewing the recommendations, Jim Vavra noted that grandfathering is still in place with no end date. Molly Cisco reports that she has heard from parents that Lexapro is effective. Michael Witkovsky responded that it has good clinical benefits but the cost issues are abominable.

Antiparkinson's Agents:

Harold Harsch noted that there were a couple of letters submitted from neurologists saying that Mirapex and Azilect should be on the PDL and he questions why staff is recommending that they be non-preferred. Jim Vavra responded that Azilect is new and costly. Patients taking Mirapex for Parkinson's Disease would be grandfathered. Molly Cisco asked which drugs in this class cause problems with gambling. Michael Mergener responded that both Mirapex and Requip have been associated with compulsive behavior. Susanne Seeger questioned whether there was a neurologist present on the MA PA Committee. Jim Vavra responded that there was not but that there was testimony from neurologists.

- Susanne Seeger recommended that a neurologist who can vote be on the committee. She also stated that a lot of physicians prescribe Mirapex. She indicated that she likes it and can't see why one would be on and the other not.
- Ron Diamond questioned whether one has a clinical advantage.
- Harold Harsch responded that he has patients on Mirapex but not Requip.
- Michael Mergener responded that there are no head to head studies comparing Requip to Mirapex. There are placebo controlled trials with the endpoints for the studies being different. He stated that there is no convincing data that one is better than the other.
- Jim Vavra indicated that cost is a factor.
- Michael Mergener indicated that he has looked at the data and it appears due to the dosing that 80% of the Requip and 76% of the Mirapex prescriptions were for Restless Leg Syndrome (RLS). Michael Witkovsky recommended looking at the data of how they are being used to figure out ways to affect that.
- Michelle Thoma questioned if there was discussion regarding the Neupro patch and asked whether it would be preferred. DHCF staff responded that any new product that comes up in a class is non-preferred until reviewed.
- Shel Gross noted that Mirapex is not a lot more expensive than Requip whereas Azilect is quite a bit more and suggested that since it has a clinical purpose it should be included as preferred.
- Michael Witkovsky stated that Azilect is long acting and has some utility.
- Jim Vavra responded that it is available by PA for niche uses.
- Catherine Kunze questioned how long it is taken for RLS and whether there is a tolerance. Ron Diamond responded that it is usually taken long-term. Michael Mergener responded that there is no reference to tolerance or dose creeping in the literature.

Antipsychotics, Atypical:

Jim Vavra indicated that there was not a lot of discussion at the MA PA committee meeting. He explained that staff had provided two cost sheets for this class, one with staff recommending Invega as non-preferred and one recommending Invega as preferred, however, the one recommending Invega as non-preferred was discussed at the meeting.

- Ron Diamond commented that Invega is a metabolite of risperdone and he sees no clinical advantage. He states that it should be discussed in light of Risperdal going generic in 2008.
- Ken Casimir stated that the jury is still out on Invega and he thought it could wait to see if it has clinical utility; however, he thinks Abilify should be preferred due to its unique properties and Zyprexa should be preferred due to agitated patients responding to it well. Ron Diamond indicated that the agitation would provide for an easy PA.
- Harold Harsch stated that Abilify and Zyprexa should be available as first line. Abilify is less sedating and therefore the first choice for many people. He gave an example of someone being discharged from an inpatient setting stabilized on Zyprexa and due to the barriers of getting the prescription filled did not continue on medications and needed to be re-hospitalized.
- Michael Witkovsky noted that pharmacists can fill a two week supply without PA. There was discussion about the barriers with this process. Jim Vavra responded that DHCF staff has made great efforts to inform pharmacists of the 14 day emergency period.
- Clarence Chou agreed that hospital discharges are a problem repeatedly regarding the PA process.
- Harold Harsch stated that it makes no sense to have Abilify and Zyprexa non-preferred.
- Catherine Kunze suggested that the group continue to look at the PA process to make sure it is going well. She stated that even when she is resourceful, the process can take two to three days when she has the energy to do it. She stated that the quality of life and other costs are crucial and this process can be cruel. She indicated that consumers sometimes have enough to deal with without these glitches.
- Clarence Chou requested to see a breakdown of who is writing scripts for this class. Michael Mergener responded that they have done this for antidepressants. He indicates that the majority of prescriptions are written by non-psychiatrists.
- Clarence Chou reports that a number of the patients he sees have been given prescriptions because they are sedating.
- Michael Witkovsky stated that he would hate to see the PA system dissolved due to pharmacy issues and thinks education is important. He also notes that there are huge costs for relapse.
- Shel Gross questioned why the staff is recommending Invega when the committee did not. Jim Vavra responded that it is based on cost. Michael Mergener responded that there was an effort to price this product to be neutral with the least expensive drugs and it gives prescribers another option when there is no cost deterrent.
- Ken Casimir responded that there may be a bit of an ethical dilemma if we are rewarding the pharmacy industry.
- John Easterday responded that with these decisions there is a balance between clinical efficacy and cost. Michael Mergener responded that the decision wouldn't be based just on price. He states that there is no evidence that Invega is less effective. He states that there are claims of even dosing and that there are some pharmacokinetics that make sense.
- Ken Casimir responded that the equation is complex and he would take a step back and ask whether the more expensive pill is a better answer.
- David Larson questioned whether Invega is genuinely a different drug. Michael Mergener responded that that is an ongoing question with quasi-new drugs coming out

just as a drug is about to come generic. He states that it is a metabolite of risperidone with stated benefits of less dosage creep, not being metabolized in the liver leading to less drug interactions and side effects and slod levels are more even with fewer peaks.

- David Larson responded that side effects are a big issue for Risperdal and if Invega is a cleaner product with the same efficacy that is critical.
- Joyce Allen noted that it appears as though there is less risk for glucose abnormalities and dyslipidemia and less weight gain for Invega according to the Provider Synergies materials. Michael Mergener indicated that Risperdal has relatively low weight gain also but agreed that this is a consideration. Ron Diamond responded that there are no head to head studies. He indicates that the complex meta-analyses show some advantages but feels it is unclear at this time.

Stimulants and Related Agents:

- Molly Cisco questioned the conditions for Strattera. Jim Vavra responded that there is no PA required for people over 18.
- Grandfathering will continue with no end date.
- Michael Witkovsky noted that Daytrana had some discussion. He states that it has little to offer as a first line agent which he indicates he had to convince other committee members of due to some of the testimony. He states that it may be a niche drug once some one is stabilized. He felt there are concerns with it that others minimized.
- Shel Gross questioned why Provigil is non-preferred. Michael Witkovsky responded that its benefit is highly selective and is reserved for situations where others fail. He indicates that it may have some utility for Attention Deficit Disorder and there are times it is clearly appropriate but is not first line. Jim Vavra added that there are cost factors.
- Harold Harsch stated that Strattera is the only non-divertible drug and should be first line. Ron Diamond responded that if there are reasons to be concerned about diversion than those can be used as reasons for PA.
- Michael Witkovsky responded that the medications can be given at school if there is a concern about parents diverting.
- Shel Gross questioned the information in the Provider Synergies materials about a black box for suicide with atomoxetine. Ken Casimir stated that there wouldn't be the same difficulties here as there is with antidepressants because you are not prescribing this to depressed patients.
- Michael Witkovsky noted that there are also liver warnings with atomoxetine.
- Susanne Seeger questioned whether Provigil is off for all conditions. Michael Mergener responded that the non-preferred status applies to the drug but the other conditions would be basis for PA approval.

Sedative Hypnotics:

Jim Vavra reported that following the February 7, 2007 meeting of the MA PA Committee and the February 21, 2007 Mental Health Drug Advisory Group meeting, Secretary Hayden directed staff to review Sedative Hypnotics after the release of generic Ambien, zolpidem. Based on Secretary Hayden's request, DHCF is recommending that zolpidem be preferred and Ambien CR and Lunesta be changed to non-preferred with no grandfathering. The MA PA committee voted at the August 15, 2007 meeting to accept the recommendation. Michael Mergener explained the

market share graph. He indicates that the slight dip for Ambien was when Lunesta was added to the PDL as a preferred agent and the big dip was when zolpidem became available.

- Molly Cisco questioned whether there has been discussion regarding dosing restrictions. Michael Mergener responded that they have been talking about cost saving initiatives and that issue has been included in discussions. He also notes that both Lunesta and Ambien CR have been doing studies for long-term use.
- Clarence Chou questioned why there is no grandfathering and states that he has seen benefits of long-term use. Michael Mergener responded that the change of price has been dramatic.
- Catherine Kunze questioned if there was a way to notify consumers prior to them going to the pharmacy to fill their prescription such as prescriber and patient receiving letters.
- Molly Cisco stated that no grandfathering is a slippery slope and a bad policy.
- Ron Diamond stated that for him he is willing to consider grandfathering in some areas and is very much non-supportive of it in other areas.

Comments from Group Members

Ron Diamond – Most of the problems people are having are with Part D. The MA program is pretty clean. More education may be needed regarding PA. As a prescriber he would like all drugs available; however, if that is done there would be no rebate and then the State will be paying full price for all drugs. He agrees to some restrictions if the system is easy.
Ted Collins – Principal concern is paliperidone. With Ambien the competition lowered the price and the potential is there for this to happen with risperidone. It doesn't make sense to put people on paliperidone.
Clarence Chou – It would be nice to have a tracking system finding out who is prescribing psychotropic drugs. It would be nice to know what isn't working and when other costs occur such as hospitalizations. We don't have a denominator including quality of life and side effects.
Shel Gross – Have been supportive in general of PA process; however, any process that creates problems that were described today is disturbing. Hasn't heard a lot about access problems until this meeting. With antipsychotics, differentiates between Zyprexa and Abilify. The side effect profile is much better for Abilify and hasn't heard Zyprexa is used a lot except in inpatient. In looking at the market share data, it is interesting that Abilify market share has increased despite being non-preferred. Only Abilify and Zyprexa are approved for maintenance of Bi-polar so at least one should have preferred status. Impressed with the side effect profile of Abilify which is important. We save a lot of money in atypical antipsychotics so we should shift that money to counties paying match for services.
Michelle Thoma – Overall, the recommendations will capture 80% of her patient population and the exceptions are covered. A couple concerns are things that weren't reviewed and the time that will elapse before they are reviewed such as Seroquel XR and the Neupro patch. Sees Invega as a wait and see product. Regarding the educational component, sees dual eligibles as the biggest problem.
Richard Kilmer – The big worry for pharmacists is not getting paid. Part D is a nightmare, the State is much easier. A lot of pharmacists don't know about the 14 day option. A lot don't want to deal with PA, paper claims frighten pharmacists because the chances of getting paid go way down. He estimates that 90% of pharmacists don't do it.

Mary Neubauer – The nightmare of Part D needs to be explored. Feels strongly that Abilify should be on due to having less metabolic issues.
Virginia Bryan – Has concerns about 14 day process and PA and what effect the tamper resistant pads will have on that.
Jenny Lowenberg – The position at NAMI is to have open access but she is also aware of financial constraints. PA is pretty porous and easy but if there are instances where it is being avoided that is a concern. Would like to see a push for colleagues to do the right thing. Concerns about the barriers with drugs being non-preferred.
Molly Cisco – The money saved from PDL should be used for community mental health services which are falling apart because there is not enough funding. Grandfathering is a policy issue and should be considered for all mental health drugs. Regarding Invega, we should take a do no harm stance and have it preferred if it has fewer side effects, less metabolic problems, and more stable dosing. Regarding Sedative Hypnotics there is a need to continue to watch usage and prescribing habits. Strattera should be preferred due to the non-diversion.
Susanne Seeger – There needs to be a neurologist on the MA PA committee who can vote. As someone who isn't a psychiatrist, it would be nice to not prescribe psychotropics but access to psychiatrists is limited.
Catherine Kunze – Abilify and Zyprexa should be easier for people to get. There should be a way to make it easier because hospitalization is not easy. Managed Care Organizations need to be held accountable at the minimum with access. This is even more critical as managed care is getting pushed throughout the state resulting in people going off fee for service.
David Larson – In regard to PA being needed at the time of hospital discharge there is a misnomer with the word prior. The drug is already being used and the person is stable. It makes no sense to have PA in this situation. The 14 day emergency supply process is not useful. It exposes people to the risk of relapse. One implication of PA is to use a different drug. Why would you do this when the drug has already been tested, utilized, and shown effective? The 14 day adds steps. The financial risk is relapse which will come out of other budgets. If you are talking about someone coming out of an inpatient stay, they are already at risk of instability. The importance of ease of prescribing post-hospitalization is critical. There is a problem with assessing new agents. It is not easily determined which needs are best or where they fit in relation to others. There is an argument for a fairly free array of choices especially for antipsychotics and secondly for antidepressants due to the difficulties of this population.
Ken Casimir – Would like to see more data regarding rebate offers. Abilify is getting a little more support due to side effects. Tolerability in the Catie trial shows olanzapine as the longest time of staying on the drug. The side effects taint our consideration of this.
Harold Harsch – The people who get hospitalized due to problems with medications are the people who are on antipsychotics and yet Abilify and Zyprexa are non-preferred. There are multiple examples given today of people who need to be re-hospitalized at high costs due to PA. This is not rare – Dr. Chou, Dr. Casimir, and I see it happening often so there are likely many places across the state where it is also happening. There may be a place for Invega even if it is a metabolite of risperidone. Desipramine is a metabolite of imipramine which is a highly different drug.
Michael Witkovsky – Create a group charged with the Quality Improvement of the Department's collaboration with pharmacies particularly around the general PA process; the 14 day emergency supply and authorization process; structures for dialogue between pharmacies of varying magnitude (single shop v. large international chain) and the State. The committee should be

mindful that HMOs/MCOs are as interested in evidence based practice as we are but are often held to formulary compositions negotiated by managers, not clinicians. These groups usually subcontract mental health care and behavioral medication management to other entities therefore co-ordination across systems is near impossible. The hospitals negotiate yet another tier of agreements with pharmaceutical companies with the apparent intent to provoke what happened in our discussion today – that we would begin to talk about dismantling the PA process to cover the industry created discontinuities in medication availability and in the process loose the $125 million dollars that the group advocated be shifted to other forms of mental health treatment. We should begin to track hospital days to measure the relationship between length of stay and medications used. Create a subgroup within the eHeath process to explore the possibility of creating a 'real time' data base that physicians, patients and pharmacists can use to: record prescriptions for which diagnoses and symptoms are recorded; follow the bills and claims paid to insert QI into the PA process as well as to monitor patient and physician behavior around prescribing; track monitoring of medications for harmful or lethal side-effects – cardiograms, serum blood levels, liver function or thyroid function studies; record all reported side-effects; measure duration of treatment at which doses; monitor 'dose creep', evaluate the prescribing, reactions to, outcomes and cost related benefits of all medications across prescriber specialty, practice domains, social groups of patients, diagnoses, targeted symptoms, and illuminate vividly any gaps in pharmacological treatment of psychiatric illnesses in the MA population in the State; measure discontinuation of treatment - intolerable side effects, non-compliance, formulary shifts, treatment goals met. Add Abilify to the PDL because it is safer than Invega and Zyprexa and it meets non-trivial niche populations needs - the very ill, children with epilepsy and traumatic brain injury, the elderly. Wait another 6 months to revisit the behavior of Invega in the 'real world' before adding to PDL.

Electronic Health Board Update

Alison Bergum gave an overview of the Wisconsin eHealth Initiative and Sensitive Information. (See handout.) Shel Gross and Michael Witkovsky are also on the 51.30 Workgroup for the Privacy Project of eHealth. They can be contacted regarding comments that Mental Health Drug Advisory Group members have. Michael Witkovsky's email is witkomt@dhfs.state.wi.us.

Discussion Regarding Tamper Resistant Paper for Medicaid Prescriptions

Jim Vavra gave an overview of the CMS Guidance and talked about what Wisconsin is doing. They have met with various organizations to discuss this. They have found that the paper does exist. They plan to either purchase the pads and make them available to prescribers or create a preferred vendor list and have them available at low cost to prescribers. They will be defining criteria of what is necessary. Pharmacy claim submission won't be modified. Compliance will be checked by post-payment audits. The education process is in the works and an update will go out quickly. They are working diligently to meet the deadline because it would be a big financial loss to the state if the deadline is not met. Jenny Lowenberg commented that this is another layer where screw ups can occur affecting consumers. Mary Neubauer questioned how consumer education would occur. Jim Vavra responded that they would be relying on pharmacists and physicians. Catherine Kunze suggested that information regarding the PA process be included with this education. Jim Vavra responded that if you have too many important things in one

letter there is a risk of something getting missed. Catherine identified the concern of a consumer having to return to the pharmacy multiple times because they would first have to return with a tamper resistant prescription and then they would have to return due to the PA and pharmacists not knowing about the 14 day thing. Jim Vavra suggested they include the stakeholder groups for the educational pieces. Molly Cisco recommended that this group ask John Easterday to talk to the governor about taking a stance on this issue.

Atypical Antipsychotic Intervention Final Report

Michael Mergener gave a brief overview of the atypical antipsychotic intervention that was done. Due to limited time, the group asked that this be discussed again at the February meeting.

Next Steps and Adjourn

The group has decided to meet in February to address some of the issues identified by the group. These include: Managed Care Organizations; PA process; prescribing practices of antipsychotics; atypical antipsychotics Intervention; other costs associated with medication use such as hospitalizations, quality of life, and the impact of side effects; strategies regarding one of the atypical antipsychotics becoming generic in 2008; access to psychiatry services; QI options regarding the Department's collaboration with pharmacies.

Summary Submitted by: Kay Cram