MENTAL HEALTH DRUG ADVISORY GROUP
Meeting Summary
February 21, 2007

Opening Remarks/Introductions

The following members were present: Joyce Allen, Virginia Bryan, Clarence Chou, Molly Cisco, Ted Collins, Kay Cram, Hugh Davis, Ron Diamond, John Easterday, Shel Gross, Harold Harsch, Kevin Hayden, Richard Kilmer, Catherine Kunze, Jenny Lowenberg, Michael Mergener, Mary Neubauer, Molli Rolli, Sinikka Santala, Susanne Seeger, James Vavra, and Michael Witkovsky.

Sinikka Santala, Administrator of the Division of Disability and Elder Services, introduced two new members: Ken Casimir and Mary Neubauer and announced a third new member: DeeAnne Pederson, who was not present at the meeting. Ms. Santala reviewed today's agenda.

Multi-year Policy Plan for Electronic Health

Secretary Kevin Hayden introduced the topic of electronic health records and the speaker, Kathy Farnsworth. Ms. Farnsworth gave an overview of Wisconsin's eHealth Initiative (see attached PowerPoint presentation). She indicates that they are at the beginning stages of the planning. She reports that there are four different eHealth models with two models having more patient involvement. Ms. Farnsworth indicates that she will get the names of the models and the website to the group. Eight models will likely be funded. It is unclear at this point if the eight will include the four current models. Dr. Chou questioned if any of the models worked well for large numbers of people. Ms. Farnsworth indicated that she would get back to the group with the numbers of patients in each of the model groups.

Dr. Diamond raised a concern about how small mental health and substance abuse clinics would be affected. He noted that small rural providers don't have the resources that the large hospitals do. Joyce Allen reported that there are approximately 800 Outpatient Mental Health Clinics and many are not attached to a 51 board, Wisconsin's County Based Service System. Wisconsin's plan is for all providers to participate in the eHealth initiatives. The State will assist smaller providers so they are able to participate. She reports that there is currently a survey going on with providers. There will be a public summit on March 15 where there will be an update on the survey. Ms. Farnsworth indicates that she will get back to the group on how the smaller clinics are being affected.

Ms. Farnsworth indicated that the Mental Health and Substance Abuse information that is included in the databases varies by State depending on State law. Patients may be able to decide which information is made available in the electronic exchange and what information is not made available. The information in the record is separate from the information in the electronic exchange.

Secretary Hayden responded to the concerns regarding the security of the electronic record. He noted that there are unfortunately already gaps in the security of paper records. He assured the group that they would be going slowly with the process and money would not be spent foolishly. Patient safety is enhanced with the electronic record. He stated that sixty percent of medical doctors are in large groups and reports that there is a lot of work to be done in order to bring it across the state. Secretary Hayden indicated that he will be inviting Kathy Farnsworth back to speak to the group on a regular basis. The ability to expand and modernize the program will be useful. Secretary Hayden indicates that the Federal government is requiring vendors to conform to a standard of inter-operability.

Dr. Harsch questioned whether a person would want their dermatologist reading the records from the marriage counselor. Ms. Farnsworth responded that there are data sets which determine what information is designated to be exchanged with which group of providers. It is designed around particular uses decided by the local medical community. Demographics, pharmacy, labs, and parts of the medical history will likely be included. There is a lot of room for stakeholder input.

There was a question on whether there was a report on the Security Privacy Project. A workgroup has been established and grant funding is available through activities of the chart on slide 8 which reports back to the board. The summary will say how far they got on the grant to the Security Privacy Group. Content of the reports will lay out the implementation plan. It was noted that the implementation plan on slide 18 does not reflect suggestions to make changes to HIPAA regarding Mental Health and Substance Abuse. Ms. Farnsworth indicated that she will share the draft implementation report that includes the HIPAA recommendations.

There was a question about what occurs with the electronic transfer when a consumer moves to another state. Ms. Farnsworth reports that that is an issue yet to be worked out. She indicates that the federal government has to look at similarities and differences between eHealth initiatives across the states.

There was some discussion regarding a consumer interest and advisory group. Ms. Farnsworth indicates that they have not finalized the composition of the advisory group for the next stage. There may be a work group with multiple subgroups. The number of members has not been determined. She notes that they are looking at breadth of stakeholders to represent people across various groups. She indicates that the workgroup will consist of providers and users of services across specialties. She reports that the meetings are always open meetings and if there are people not on the workgroup who have input they can contact her or a group representative.

Secretary Hayden reported that the pace is deliberately slow so that partners are able to reach a consensus. The proposal will be more likely to be endorsed if the workgroup has reached a consensus. Ms Farnsworth noted that the eHealth Care Quality and Patient Safety Board Advisory Groups will remain the same but workgroups may change.

Secretary Hayden indicated that he will be inviting Kathy Farnsworth back to speak to the group on a regular basis.

Prior Authorization Committee's Recommendations from February 7, 2007 Meeting

Anticonvulsants:

Jim Vavra indicated that generic lamotrigine is more expensive than the brand name Lamictal. It is anticipated that when more manufacturers start making it, then the price may decrease. The grandfathering for this class will continue.

Anti-Depressants-Other:

Mr. Vavra noted that nefazodone was recommended as non-preferred due to safety issues. Emsam was recommended as non-preferred by staff and Provider Synergies, but the committee recommended it as preferred. Mike Mergener explained that Emsam is a MAOI patch. There are some safety issues due to two of the three strengths having dietary restrictions like other MAOIs. Other drugs are also contraindicated and have to be discontinued for a period of time prior to the use of Emsam. Selegiline is available in other forms. Mike Witkovsky noted that this drug has an important niche due to the flexibility of choice at the point of prescribing.

Molli Rolli indicated that she was confused why the PDL is now being used for safety. She states that it seems like a different goal than what was used in the past. She has an issue with considering safety because there are a lot of other medications on the PDL that are dangerous such as clozapine. She states that prescribing safety is another mission. Mr. Vavra responded that the administrative rule includes safety as a basis for PA. Susanne Seeger questioned who makes the PA decisions. Staff responded that STAT PA is an electronic PA system where a decision can be made immediately based on input the pharmacist enters. Dr. Seeger agreed that there are other medications that are on the PDL that are not safe.

Shel Gross questioned whether the system monitors drug-drug interaction. Mike Mergener responded that is does but that the electronic system depends on how quickly the information regarding the drug-drug interaction is entered into the system.

Clarence Chou noted that Accutane was a good example for considering safety because the government clamped down after all the warnings. He indicates that this is an issue which needs further discussion.

Mike Witkovsky indicated that Emsam is a new product and questioned whether it is worth the cost. He indicates that safety, whether it does what is says it does, and ease of prescribing are all pieces to consider.

Ted Collins noted that the first Prior Authorization included drugs where there was abuse potential.

Molly Cisco reported that when she was first on the Medicaid Prior Authorization Committee consumers wanted safety to be considered and the committee decided that it wouldn't be. They decided that PDL would only be based on efficacy and cost. She indicated that the rules are being changed half way through. A Preferred Drug List, which is based on efficacy, safety, clinical benefits, and cost, is what Medicaid uses in place of a formulary. Evidenced based medicine is applied to the process as much as possible.

Dr. Mergener indicates that Emsam seems to be a niche drug and states that maybe medical PA should be considered. Harold Harsch and Molli Rolli both stated that this is not a first line drug. Molly Cisco questioned whether it is easier for consumers and Dr. Rolli responded that it may be for someone who has a feeding tube. Dr. Witkovsky responded that there is some advantage to a patch. Clarence Chou asked if there was a cost issue. Mike Mergener responded that Emsam is very expensive, about $360 per script. There will still be grandfathering in this class.

<u>Sedative Hypnotics:</u>

Richard Albertoni presented the committee's recommendations. Molly Cisco stated that originally the Medicaid PA committee recommended Lunesta as a non-preferred drug and this group overturned that decision. She questioned whether it is less addicting. Mike Mergener responded that the newer agents are less addicting but there are not many differences among the class with the exception of Rozerem.

Molli Rolli objected to no grandfathering in this class. She questioned why this class is being treated differently. She indicated that for people who are really ill it could be a huge issue. Mike Witkovsky reported that although he didn't vote the same way the majority of the committee members voted, he indicates that they felt that insomnia shouldn't be a chronic problem and sedative hypnotics tend to be prescribed by primary care physicians. He stated that they felt it was assigned as a behavioral health class when in practice it is not and they were concerned about long-term use.

Molli Rolli stated that Lunesta has the best data for long-term use and it is not being included. Ken Casimir agreed with this point.

Molly Cisco indicated that she was worried about the grandfathering issue. She feels it is a slippery slope and is concerned about what will be next. She indicates that they were originally told that there would only be PDL for Antidepressants and they didn't have to worry about Antipsychotics. Now the whole process has changed. Mike Mergener responded that for the most part mental health drugs are the only ones that have grandfathering.

Clarence Chou stated that data is important. He indicates that if there are changes we should make changes on a timely basis.

Shel Gross stated that if long-term use is the concern, then a requirement for PA should be in place for the entire class. He indicates that we shouldn't just target Lunesta when that is the drug which has had testing done. He questions what the populations are. Molly Cisco recommends looking at long-term use. Mike Mergener responded that they ran everyone who ever got a prescription of a sedative hypnotic and the average person filled a month's supply each month for six months. It is being used as a lifetime drug by people. He indicates that the studies show that people fall asleep twelve minutes faster with the medications than with placebo and sleep eighteen minutes longer.

Ted Collins stated that he is opposed to Ambien CR being on the PDL. Ambien will go generic April 21. If Medicaid grandfathers, Ambien CR will always be a preferred agent. If Medicaid does not grandfather and patients remain on Ambien CR, the switch to generic Ambien will be challenging. Mike Mergener indicated that the discussion at the MA PA meeting included comments that if Ambien is added, those taking Ambien have no reason to switch to CR.

Antiparkinson's Agents – Zelapar and Azilect:

Rich Albertoni presented the committee's recommendations. Dr. Mergener stated that Azilect has no psychiatric application and when used in high doses in mice, tumors may occur. It is a new MAO-B inhibitor, similar to selegiline. There are some safety concerns and it is usually added as an adjunct therapy. Some PA Committee members thought it would postpone the use of carbidopa/levodopa. The entire class will be reviewed in August.

Stimulants and Related Agents – Daytrana:

Rich Albertoni presented the committee's recommendations. Mike Witkovsky indicated that the concern was cost relative to other options. The patch may be important for some. The time of onset is ninety to one hundred and twenty minutes after application and the effect remains for a period after removal.

Mental Health Drug Advisors Final Comments

- Harold Harsch – Disappointed that Strattera is not a preferred agent.
- Ted Collins – Doesn't think Ambien CR should be preferred.
- Cathy Kunze – Thinks this is a great process. Had concerns regarding consumers not being informed when there is a change to generic.
- Shel Gross – Stated that safety issues did arise when Atypicals were reviewed.
- Richard Kilmer – Stated that when drugs become available generically, there is no sense to how the drug manufacturer's price the product.
- Jenny Lowenberg – Questioned if there is a consistent way for pharmacists to explain from the State's perspective when a product switches to generic. Staff responded that there is a policy available for pharmacists.
- Molly Cisco – Disagrees with the grandfathering issue for Sedative Hypnotics and feels it is a slippery slope. Feels it is wonderful that Strattera is available for

adults. Thinks that the educational piece was great with Antipsychotics and wants it to continue on a regular basis.

- Virginia Bryan – Thinks the slippery slope of grandfathering is a concern.
- Ken Casimir – Thinks that Wellbutrin XL is a wonderful product and very valuable.
- Clarence Chou – Thinks the breakdown of who is prescribing should be recurring to determine if this process is changing prescribing patterns. Concerned that psychotropics are being prescribed by non-mental health providers.
- Joanne Berman – Likes the addition of data. Thinks that the CNS committee came up with good ideas and hopes it continues with DUR. She would like the opportunity to make recommendations to DUR.
- Susanne Seeger –Not opposed to reviewing safety issues. Thinks that it seems that for some medications safety is blown out of proportion due to cost whereas with cheaper drugs the safety is downplayed. Is concerned where the Antiparkinson's are discussed. If there is not a neurologist as a member of the PA Committee, she feels that they should be invited when classes that impact neurologists are reviewed. She feels this class should either be included as a mental health drug or there should be an advisory committee of neurologists.
- Mary Neubauer – Is concerned regarding the slippery slope of the grandfathering process and thinks that not grandfathering Sedative Hypnotics will feed into it.

Next Steps

Sinikka Santala announced that the next meeting is scheduled for August 29, 2007.