TESTIMONY BEFORE THE HUMAN SERVICES COMMITTEE

Excerpts from the Drug Utilization Review Board Meetings

Representative Jeff Delzer, Chairman

July 1, 2008

Chairman Delzer, members of the committee, I am Brendan Joyce, Program Administrator of Pharmacy Services in the Medical Services Division for the Department of Human Services. I appear before you to provide testimony on status of the findings and recommendations of the Drug Utilization Review Board regarding 2007 House Bill No. 1422.

March 12, 2007

Legislative Update
Currently, there is legislation in place that restricts placing the following classes of medications on Prior Authorization. These include AIDS, Cancer, Anti-psychotics, Anti-depressants, ADHD and Mood-Stabilizers. Over the next two years, the DUR Board will be responsible for reviewing these classes and making recommendations to the department regarding the plan of action the Board would take, if any. The DUR Board recommendations will be reported, periodically, to the Legislative Council.

June 4, 2007

Legislative Update
House Bill 1422 restricts placing the following classes of medications on Prior Authorization. These include AIDS, Cancer, Anti-psychotics, Anti-depressants, ADHD and Mood-Stabilizers. Over the next two years, the DUR Board will be responsible for reviewing these classes and making recommendations to the Department regarding the plan of action the Board would take, if any. The DUR Board recommendations will be reported, periodically, to the Legislative Council.

HIV/AIDS Review
The HIV/AIDS Review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. The Legislative Council gave a deadline of October, 2008 for these reviews to be completed. A periodic report will also be sent to the Council as each class is reviewed. T. Twogood suggested getting a consult from one of the Infectious Disease doctors that are currently prescribing to North Dakota Medicaid patients. C. Huber and B. Joyce will contact these physicians for guidance regarding this class of medications.

Oral Antineoplastic Review
B. Joyce reviewed utilization data of the antineoplastic medications. The Department suggests a registration process for the antineoplastic class of medications. Having a registration would allow physicians to include study information the patients are enrolled in as well as peer reviewed

literature endorsing utilization of specific products. Most private insurance companies require a prior authorization process with this class of medications. A. Samuelson suggested getting a consult from one of the Oncology physicians currently prescribing to North Dakota Medicaid patients. B. Joyce will contact these physicians for guidance regarding this class of medications.

August 20, 2007

Legislative Update
House Bill 1422 restricts placing the following classes of medications on Prior Authorization. These include AIDS, Cancer, Anti-psychotics, Anti-depressants, ADHD and Mood-Stabilizers. Over the next two years, the DUR Board will be responsible for reviewing these classes and making recommendations to the Department regarding the plan of action the Board would take, if any. The DUR Board recommendations will be reported, periodically, to the Legislative Council.

Oral Antineoplastic Review
At the June meeting, A. Samuelson suggested getting a consult from one of the Oncology physicians currently prescribing to North Dakota Medicaid patients. B. Joyce will contact these physicians for guidance regarding this class of medications. At this time, there is no new information to review and B. Joyce informed the Board members that this topic would be presented at a future meeting.

HIV/AIDS Review
At the June meeting, T. Twogood suggested getting a consult from one of the Infectious Disease doctors currently prescribing to North Dakota Medicaid patients. B. Joyce met with Dr. Martin, an Infectious Disease doctor in Bismarck. He works with the ND Department of Health and the Ryan White program (a federally funded program that provides HIV/AIDS medications to patients not on Medicaid). He sits on the Ryan White P&T Committee with other North Dakota Infectious Disease physicians and they have a formulary for the Ryan White program. Dr. Martin reviewed the ND Medicaid utilization data and stated that all utilization appears to follow the Ryan White formulary.

B. Joyce asked Dr. Martin if the law restricting prior authorizations on antiretrovirals was necessary, and Dr. Martin said that no law was needed if the Board had no intention of placing these medications on prior authorization. He also said such a law could keep immediate action from happening if a physician started moving away from the Ryan White formulary or practice standards. B. Joyce confirmed with Dr. Martin that the Ryan White P&T Committee would be willing to exert peer pressure on anyone prescribing in an outlier fashion (if that ever happens). A motion was made by B. Treitline and seconded by N. Byers that the Board take the view of Dr. Martin. This would mean that the restrictions would be allowed to sunset as related to antiretrovirals and no further action would be taken by the DUR Board as the Board has no intent to prior authorize any of the medications in this class. C. Huber called for a voice vote and the motion passed with no audible dissent.

ADHD Review
The ADHD review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. B. Joyce reviewed utilization data of the ADHD meds. Based on post-rebate information, Adderall XR is the most cost effective choice between Adderall XR and Vyvanse; given that Vyvanse is simply a less abusable follow-on product to Adderall XR as Adderall XR approaches its patent expiration. B. Joyce relayed information regarding the prior authorization of Sed/Hypnotics. The Board chose to leave Ambien as preferred to maintain market share in anticipation of the generic becoming

available and to keep market share from shifting to the follow-on product Ambien CR and other competitors. Due to the proactive nature of this decision, the Department is saving approximately 30,000 dollars a month with generic Ambien. B. Joyce stated the logic for the suggested prior authorization of Vyvanse is the same as used for Ambien.

B. Joyce asked the Board what their overall desired actions are for ADHD medications. T. Twogood stated that there is really nothing that would predict one ADHD medication would work better than another; therefore trying the most cost effective agent first would be a very valid approach. The Board stated that they would like to broaden the prior authorization stipulations and include step therapy and asked B. Joyce to bring such an approach back to the next meeting. B. Treitline made a motion and N. Byers seconded that the Board should recommend prior authorizing Vyvanse as presented in the packet (therefore requesting that the law should be allowed to sunset in relation to ADHD medications). C. Huber called for a voice vote and the motion passed with no audible dissent.

October 1, 2007

Legislative Update
House Bill 1422 restricts placing the following classes of medications on Prior Authorization. These include AIDS, Cancer, Anti-psychotics, Anti-depressants, ADHD and Mood-Stabilizers. Over the next year, the DUR Board will be responsible for reviewing these classes and making recommendations to the Department regarding the plan of action the Board would take, if any. The DUR Board recommendations will be reported, periodically, to the Legislative Council.

Oral Antineoplastic Review
At the June meeting, A. Samuelson suggested getting a consult from one of the Oncology physicians currently prescribing to North Dakota Medicaid patients. B. Joyce had no luck asking for guidance regarding this class of medications. At this time, there is no new information to review and B. Joyce asked Board members for suggestions of oncologists that would be willing to help the Board in this capacity. K. Krohn suggested an oncologist in Minot and she will ask for his guidance.

ADHD Review
At the August meeting, the DUR Board suggested a prior authorization on Vyvanse and also suggested broadening prior authorization guidelines for other agents in this class by incorporating step therapy. There was public comment by Rose Mullen, representing Eli Lilly. She reviewed Strattera related prescribing information with the Board. There was public comment by Susan Helgeland, representing Mental Health America of North Dakota. She spoke against restricting ADHD medications for ND Medicaid recipients. B. Joyce stated that post-rebate, Strattera and Daytrana are much more expensive than the other agents in this class. The Department suggests a prior authorization on Daytrana and Strattera. J. Hostetter asked for specific information regarding rebates. B. Joyce stated that he was unable to reveal that information. J. Hostetter said that it is very hard to give an opinion if not all of the information is presented. S. Setzepfandt was asked to explain to the Board the process involved with sharing rebate information. S. Setzepfandt said that it would be very difficult to reveal this information without legal involvement and closed door sessions. G. Pfister made a motion to modify the current proposed form, ADHD PA Form, to read ADHD Stimulant PA form and to remove Strattera. T. Twogood seconded the motion. Regarding the legislative review process for exempted classes, A. Samuelson made a motion to allow the DUR Board to manage and review ADHD. N. Byers seconded the motion. Chair, C. Huber, called for a voice vote. Individual votes were counted with 1 opposed, 2 abstaining and 9 yes votes. Motion passed.

Antidepressant Review
The Antidepressant review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. B. Joyce reviewed utilization data of the Antidepressant meds including a market share report. Based on post-rebate information, Cymbalta, Effexor XR, Lexapro, Paxil CR and Prozac weekly are the most costly medications in this class. There was public comment by Rose Mullen, representing Eli Lilly. She reviewed Cymbalta prescribing information with the Board. B. Joyce asked the Board if they would like the ability to review and manage antidepressants. B. Joyce stated that the Board could authorize a lifetime PA for these medications and review previous history to look for failure of other medications in the class, making the prior authorization process simpler for providers. C. Huber suggested that the form be reworked and called an SSRI PA form. B. Joyce said that he would have the form reworked and this information would be brought to the next DUR meeting.

December 3, 2007

Oral Antineoplastic Review
At the October meeting, A. Samuelson suggested getting a consult from one of the Oncology physicians currently prescribing to North Dakota Medicaid patients. B. Joyce met with an oncologist in Minot. The physician stated that no law was needed to prevent antineoplastics from being placed on prior authorization as long as the recommendations for PA come from the DUR Board and that the turnaround time for PA's also remained the same (over 98% reviewed in less than 8 hours and 100% in 24 hours). If the law was allowed to sunset on antineoplastic agents, a grandfather policy could apply that would allow patients currently receiving antineoplastics to keep receiving them without asking for a PA. There was no public comment. B. Treitline made a motion to recommend to the legislative council that antineoplastics no longer be exempt from prior authorization and that the DUR Board would be involved in the PA of certain agents using private insurance as a guideline. G. Pfister seconded. Chair, C. Huber called for a voice vote and the motion passed with no audible dissent.

Antidepressant Review
The Antidepressant review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. There was no public comment. C. Huber suggested at the October meeting that the antidepressant form be reworked and called an SSRI PA form. B. Joyce asked the members to review the reworked form. C. Huber asked why fluvoxamine was not included on the SSRI form. B. Joyce said that he did not include fluvoxamine because he did not want fluvoxamine used first line. G. Pfister also made the point that fluvoxamine is not approved for depression. B. Joyce said that fluvoxamine could be added to the form if the Board agrees that it needs to be. J. Hostetter made a motion to report to the legislators that SSRIs be allowed prior authorization status with the modification of the form to include fluvoxamine. C. Sorenson seconded. Chair, C. Huber called for a voice vote and the motion passed with one audible dissent. Motion passed.

Legislative Update
House Bill 1422 restricts placing the following classes of medications on Prior Authorization. These include AIDS, Cancer, Anti-psychotics, Anti-depressants, ADHD and Mood-Stabilizers. The DUR Board is in the process of reviewing these classes and making recommendations to the Department regarding the plan of action the Board would take, if any. The DUR Board recommendations will be reported, quarterly, to the Legislative Council. C. Huber asked that the Board receive a copy of the report that the Department presents to the legislature.

ADHD Review
At the October meeting, the DUR Board suggested limiting the ADHD review to a stimulant review. The Board suggested that Daytrana be prior authorized because of the side effect profile, the cost, and the lack of studies that show Daytrana to be more effective compared to the other

agents in the stimulant class. There was no public comment. B. Treitline made a motion to recommend to the legislature that stimulants be allowed prior authorization status. G. Pfister seconded the motion. Chair, C. Huber called for a voice vote and the motion passed with one audible dissent. B. Joyce asked the Board for advice on dosing of Concerta CD, Focalin XR and Metadate CD at 8am and noon. The general consensus of the Board is that this dosing pattern should only be approved by a rare exception.

Antipsychotic Review
B. Joyce reviewed low dose (sub-therapeutic) antipsychotic information with the Board. B. Joyce would like to monitor new starts on these agents to verify appropriateness. The Board suggested a survey to determine the use of low dose antipsychotics. Along with the low dose problem, the Department would like the Board to review alternative dosage forms of the antipsychotics such as zydis, soltabs, follow along products and injectables with large price differences. There was no public comment. For the next meeting, information will be provided on major issues surrounding the antipsychotics such as age, low dosages and special formulations.

February 4, 2008

Legislative Update
B. Joyce provided the Board a copy of his testimony to the Human Services Legislative Committee.

Antipsychotic Review
B. Joyce reviewed antipsychotic information with the Board. Along with the low dose issue, the Department would like the Board to review alternative dosage forms of the antipsychotics such as zydis, soltabs, follow along products and injectables with large price differences. There was no public comment. For the next meeting, information will be provided on major issues surrounding the antipsychotics such as poly-pharmacy, low dosages and special formulations.

April 7, 2008

Antipsychotic Review
B. Joyce reviewed antipsychotic information with the Board. Along with the low dose issue, the Department would like the Board to review alternative dosage forms of the antipsychotics such as zydis, soltabs, follow along products and injectables with large price differences. At the last board meeting, Dr. Samuelson asked that the Department bring information to the board regarding poly-pharmacy. Brendan reviewed the Comprehensive Neuroscience report with the board. This report showed board members the number of patients on multiple CNS medications, including antipsychotics. Also included in the pack was a draft letter to providers regarding the low dose antipsychotic issue. A motion was made by J. Hostetter to place alternate dosage forms of the antipsychotic medications on prior authorization. J. Savageau seconded the motion. Chair C. Huber called for a voice vote and the motion passed with one audible dissent. Larry Martinez, representing Ortho McNeil Jansen, spoke against prior authorization of Risperdal Consta. R. Treitline made a motion to prior authorize Invega. P. Churchill seconded the motion. Larry Martinez, representing Ortho McNeil Jansen, spoke against prior authorization of Invega. After much discussion, P. Churchill called for a vote. Motion passed with two audible dissents. A recommendation will be made to the legislative council that the DUR Board would prior authorize alternate dosage forms and Invega if given the opportunity to prior authorize the antipsychotic class of medications.

Anticonvulsant Review

The anticonvulsant review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. B. Joyce reviewed utilization data of the Anticonvulsant meds including a market share report. Jerry Clewell, representing Abbott, spoke against prior authorization of the anticonvulsants and suggested that the Board review the American Academy of Neurology position statement as well as the NICE guidelines. B. Joyce asked the Board if they would like the ability to review and manage anticonvulsants. Board members suggested bringing more information to the June meeting regarding this topic. Information requested includes a list of which products are going generic in the near future, which providers are prescribing this class of medications, parameters of treatment for anticonvulsants versus mood-stabilizers, and examples of changes that have been made to this class in other states. B. Joyce said that he would gather this information and bring it to the June DUR Board meeting.

June 2, 2008

Anticonvulsant Review
The board requested additional information at the April meeting regarding anticonvulsants. This information included which agents are going generic in the future, providers prescribing this class of medications, and examples of changes that have been made in other states. B. Joyce reviewed this information with the Board. There was no public comment. B. Joyce explained to the Board that if no recommendation is made regarding anticonvulsants, the Department will recommend to the legislature that the law does not need to exist. C. Huber spoke on behalf of the Board by stating that the Board has no recommendation at this time, related to the class of anticonvulsants.

Summary of Board Recommendations to Legislative Counsel
Previous board recommendations on HIV/AIDS, Oncology, ADHD, Antidepressants, and Antipsychotics were reviewed. G. Pfister asked for clarification of the wording on the Antidepressant recommendation. The correct wording will be: Antidepressants-DUR Board recommended placing **certain** SSRI medications on prior authorization and therefore removing the exemption for the antidepressant class of medications.

This concludes my testimony. I would be happy to answer any questions that you may have.