Minutes
April 26, 2004
Drug Utilization Review (DUR) Board

Members Present: Brendan Joyce, Mary Koeneke, Norm Byers, Bob Treitline, Al Samuelson, Mark Biel, Leann Ness, John Savageau, Gary Betting, Pat Churchill, Cheryl Huber

Members absent: Greg Pfister, Kamille Sherman, John Windsor

The meeting opened at 1:05 PM in the Pioneer Room.

Norman Byers chaired the meeting. Paperwork was completed before the meeting. Norman Byers asked the board to review the meeting minutes from the previous two DUR Board meetings. Bob Treitline moved to accept the minutes as written. Al Samuelson seconded the motion. There was no discussion. Norman Byers asked for a voice vote and the motion passed with no audible dissenters.

Norman Byers asked for a budget update. Brendan Joyce gave the budget update. Rebate collections are in the low part of the cyclical nature during the past two months, but in the aggregate, the Department of Human Services, Pharmacy Services budget is nearly at what was appropriated. He mentioned that this is not due to prior authorization as nothing had been prior authorized at the time of the budget review. Any savings was most likely from the educational aspect and increased awareness of the pending prior authorization process thanks to the Department, the Medical Association, and the Pharmacy Associations efforts at education.

Norman Byers asked for an update on the prior authorization of PPIs and anti-histamines. Brendan Joyce stated that the roll-out will be completed this week and prior authorization will commence on both classes. Mary Koenecke asked for clarification of the grandfathering clause. Brendan Joyce stated that the Department of Human Services attorney-general / legal department staff's conducted a review of the issue. The research of legislative history determined that the grandfathering clause was defined during legislative committee discussion to mean that prior authorization is not required unless the prescription was **written** after the effective date for the prior authorization of that medication

Norman Byers asked the board to address a requested review of the language on the anti-histamine prior authorization form ("Use of leukotriene modifiers and inhaled nasal steroids will be closely monitored to determine if action should be taken on this class in the future."). Brendan Joyce stated that a pharmaceutical company requested the review and suggested a change of language. The original language was also suggested by a pharmaceutical company and they were contacted for their opinion of the proposed new language. In their opinion, the new language would possibly result in an increased use of certain medications for allergic rhinitis and did not see the need for a change. Mary Koenecke stated that the reason GlaxoSmithKline proposed the change is that it was their opinion (and hers) that the statement on the form reflects policy and those medications must be reviewed in order to have a policy on those medications. Mary Koenecke stated that she felt that there should be no statement on

the PA form regarding the intranasal steroids and leukotriene modifiers, but GSK offered the new language as a compromise to address concerns that there could be increased utilization of those products. Norman Byers and Brendan Joyce stated that they did not see an issue with the current language and that it was not policy. Also, to change the form before it is even used was not necessary. There was no motion to change the language. Mary Koenecke stated that she wanted to go on record that, in her opinion, the Board was overstepping its statutory authority.

Norman Byers asked for an update on the administrative rules. Brendan Joyce called on Melissa Hauer with the Department of Human Services legal department to give the update. She stated that the rules are final and will be going to the Adminstrative Rules Committee in July.

To complete the old business, Norman Byers asked for discussion regarding the motion made at the last meeting to prior authorize dispense as written (DAW) prescriptions. David Peske with the North Dakota Medical Association (NDMA) informed the DUR Board members that the NDMA Council had met the previous week and taken a position opposing the implementation of the prior authorization for DAW prescriptions. The council felt that this could be better addressed through targeted prescriber education. Also, the council was interested in more data such as the percentage of prescriptions and associated dollars of savings that could be expected with this prior authorization procedure. Brendan Joyce responded that DAW scripts accounted for one-percent of the total prescription volume. Brendan Joyce reiterated to the DUR Board that the decisions made by the board should not be based on cost, but on clinical measures.

Terry J. Flynn with Pfizer commented to the DUR Board next. He stated that with the low percentage of DAW prescriptions, the physicians must be using it judiciously and there should be no need to prior authorize DAW prescriptions. Brendan Joyce responded that this is a false assumption because first, the one percent is not evenly distributed throughout the prescribers in the state, and second, because there are many times that have been documented with the Department of Human Services and the Pharmacy Providers where the DAW was not used judiciously. One example involved patients being discharged from a hospital where they were on a generic medication, and then the primary care physician immediately switched the patient back to brand. Another example involved a single physician in the state prescribing DAW for certain narcotic products. In both of these examples, the physicians were contacted in a variety of methods (phone, mail, direct) and they refused to change to the generics. Brendan Joyce also stated that the Department of Human Services can try to educate, but without an enforcement component (prior authorization), we are powerless and can be vulnerable to abuse in these situations with no recourse. Also, a good prior authorization program serves as a very effective educational tool.

Sheree Spear with the North Dakota Mental Health Association asked three questions of the board. First, she asked if the Department of Human Services had met with the medical directors of the Human Service Centers since they are high prescribers of DAW medications for Medicaid. Brendan Joyce responded by explaining that any communication has been brief and informal since the Department cannot control the actions of these independent clinics.

The Department treats the physicians at the Human Service Centers the same as all other physicians providing services to Medicaid. The second question asked if a person had to try and fail on a generic to get authorization for a DAW prescription. Brendan Joyce explained that they would only have to try and fail a generic if a generic existed for that product. If there were no generic, there would be no valid DAW, so there would be no need to try a generic. The third question asked about the savings – was it pre- or post-rebate savings. Brendan Joyce responded by stating that he wants the DUR Board to focus on the clinical aspects and to not focus on the financial, but the $70 per prescription savings is based on pre-rebate dollars.

John Savageau expressed a concern that pharmacies should not switch generic manufacturers and asked if we could mandate that pharmacies only carry one generic of a product. Brendan Joyce responded by saying that we could not mandate this, but this could be a target of education.

Leann Ness stated that she didn't see much utilization of DAW in her practice. She did have a concern about the different generics that are on the market for narrow therapeutic index and she stated that she tries to keep her patients on the same manufacturer's product from fill to fill.

Al Samuelson and Cheryl Huber both stated that much of the use of DAW does come from the psychiatry fields of medications and they felt that physician targeted education for outliers should be tried. Brendan Joyce gave a brief overview of the programs in place for prescriber education (Retrospective Drug Use Review in place since 1996, Comprehensive Neuroscience program in place for psychiatric medications) and he mentioned that since this education is already in place and there are still problems with appropriate use of DAW, the next level of education (prior authorization) is needed.

Mark Biel stated that in his practice he has seen multiple issues with inappropriate use of DAW and felt that there was a need for prior authorization.

Norman Byers asked if there was any more discussion, and hearing none, he called for a vote. John Savageau interrupted the vote by stating that he had a concern with certain stabilized patients being affected by this prior authorization. Brendan Joyce stated that the DUR Board, by law, is an advisory body, which means that the Department of Human Services does not have to do what is recommended. Brendan Joyce stated that with this specific issue (DAW prior authorization), the Department of Human Services would not implement a broad prior authorization for all products at one time. The Department of Human Services would continue to work with prescribers, advocacy groups, and associations to determine the best possible implementation of the program to ensure success of the program.

Norman Byers asked for a vote again on the existing motion. It passed by a vote of 6 to 2 with Cheryl Huber and Al Samuelson opposing.

Norman Byers proceeded to the new business section of the agenda and called for comments regarding Paxil CR. Tom Feldstein presented clinical information regarding Paxil CR. After

discussion by the board and questioning of Tom Feldstein by the board, there was no motion to take any action on Paxil CR.

Norman Byers asked for comments regarding Wellbutrin XL. Tom Feldstein presented clinical information on the medication. Brendan Joyce asked Tom Feldstein why the market share of bupropion had shifted so significantly to the XL formulation when their own studies and market research showed that the shift shouldn't be so dramatic; it appeared that people were being switched over to the XL formulation whether or not they had problems with the previous formulations. Tom Feldstein was not sure why the switch was already so dramatic (as he is not in the sales and marketing division), but he did say that GlaxoSmithKline (GSK) would likely be happy from a sales and marketing standpoint to see that switch rate. He also stated that GSK, as a company, does not encourage physicians to switch patients from any medication who are clinically stabile, doing well, with no tolerability issues. He explained that there may be situations in which the patient asks the physician to switch. John Savageau asked why there were no studies to show differences in efficacy between the XL and the SR formulations. Tom Feldstein stated that those studies haven't been done because the product was approved due to bioavailability equivalence, not efficacy. John Savageau expressed a concern that given the Department of Human Services' financial situation, it is tough to justify paying more (in the aggregate) for a product when it hasn't been proven to be more effective. Cheryl Huber stated that compliance with once-a-day therapy would of course be better than the twice daily therapy.

John Savageau stated that since Wellbutrin XL has not been proved more effective and there are no efficacy studies between the XL and SR formulation, ND Medicaid should require failure of the SR formulation before approving payment for the XL formulation. Brendan Joyce asked if that was a motion. John Savageau moved that Wellbutrin XL be prior authorized with failure of the generic SR formulation as the criteria for approval. Mark Biel seconded the motion. Per policy, this motion was tabled until the next meeting.

Norman Byers asked for discussion on Lexapro. Tom Erickson presented clinical information on Lexapro. John Savageau pointed out that at 8 weeks, the trials show no difference in efficacy between the two products. There was no motion to take any action on Lexapro.

Norman Byers asked for discussion on Ditropan XL. Todd Johnson, a nursing home consultant pharmacist, presented information regarding the efficacy of Ditropan XL and Detrol LA for the patients he sees in the nursing homes. John Savageau stated that he didn't think the board should take any action on Detrol LA. Brendan Joyce stated that after review of the consistent numbers of people on Ditropan XL and the effect of the quantity limits on Ditropan XL, he recommended against taking any action on Ditropan XL. Nancy Spilde, an incontinence clinic nurse, presented information to the board that substantiated John Savageau and Brendan Joyce's comments. There was no motion made to take any action on Ditropan XL. There was subsequently no motion made for any action on Detrol LA.

Norman Byers asked for information on Ambien. Brendan Joyce stated that there is a different formulation of Ambien that will be brought to the market in the future (shortly before the patent on Ambien expires) and this type of product development is very common

and it is the Department of Human Services' desire to prepare for this pro-actively rather than respond after the fact when marketing has caused increased spending. The issue was tabled for the following meeting.

Norman Byers asked for information regarding the Health Information Design (HID) retrospective DUR criteria. Brendan Joyce explained that federal law requires the DUR Board to review and approve the process and concept of the vendor's retrospective DUR program. Handouts were provided to the Board with examples of a patient profile, a physician letter, a physician response form, and the types of interactions flagged by the HID system. John Savageau moved to accept the criteria and process that HID uses. Bob Treitline seconded the motion. Norman Byers asked for a voice vote and it passed with no audible votes against.

The next meeting was scheduled for June 21st.

Norman Byers asked for any additional comments, and Representative William Devlin (R-District 23) came forward to comment. He wanted to reply to issues discussed early in the meeting. Representative Devlin gave a brief history of prior authorization legislation and how it was defeated unanimously in the 2001 session and in his opinion would have failed again the 2003 session if there were not certain assurances with the grandfathering and the dispense as written issues. He stated he was the prime sponsor of the legislation that formed the DUR Board as it is structured today. He stated that his fear was that the staff with the Department of Human Services would interfere with the patient – physician relationship even though they do not see the patient. He stated that his fears are evidently realized. He stated that as chair of the rules committee, he was certain that the rules would not be approved as written and he was sure that the rules committee would agree with him. He stated his concern that it was not his intent that the DUR Board is an advisory board only. He questioned the purpose of the board even continuing to meet if the Department of Human Services did not need to abide by the board's recommendations. He suggested that the board adjourn until after the next legislative session and he would assure that this would be fixed in the next legislative session; the board would not be an advisory board, they would exist with ultimate authority over the Department of Human Services to determine how the prior authorization program is run.

Norman Byers adjourned the meeting at 3:30 pm.