Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: September 1, 2005

Chair: Michael A. Flaum, M.D.

Time: 9:30 a.m. to 2:00 p.m.

Location: Iowa State Capitol, Room 116, Des Moines, Iowa

Committee Members Present: Bruce Alexander, R.Ph., Pharm. D., BCPP; Bradley J. Archer, M.D.; Michael A. Flaum, M.D.; Carole A. Frier, D.O.; Hayley L. Harvey, DDS, MS; Matthew Osterhaus, R.Ph.; Susan Purcell, R.Ph, CGP; Priscilla Ruhe, M.D.; and Mary Winegardner, PA-C, MPAS

Iowa DHS Staff Present: Eileen Creager, Bureau Chief; Susan Parker, Pharm. D., Pharmacy Consultant; and Brad Horn, Attorney General's Office

IME Staff Present: Thomas Kline, D.O., Iowa Medicaid Medical Director; Tim Clifford, M.D.; John Grotton, R.Ph.; Sandy Pranger, R.Ph.; and Julie Bueno, R.Ph.

Dr. Flaum called the meeting to order.

I. Dr. Flaum welcomed two new P&T committee members, Bruce Alexander and Matthew Osterhaus.

II. Dr. Flaum asked that each committee member, DHS, and IME staff introduce themselves to the public.

III. The minutes from the June 2nd open session were reviewed. Mary Winegardner noted that her name needed to be added to the list of committee members present. Susan Purcell made the motion to approve the minutes with the change as noted. Dr. Ruhe seconded the motion. All Committee members approved with none opposing or abstaining.

IV. Dr. Frier nominated Susan Purcell for the vice-chair position. Mary Winegardner seconded the motion. All Committee members approved with none opposing or abstaining. Dr. Frier nominated Dr. Flaum for the chair position. Dr. Archer seconded the motion. All Committee members approved with none opposing or abstaining.

V. Susan Parker reviewed the 2005 legislation by first reading House File 825, 81st GA, § 9 (Iowa 2005):

> "The medical assistance pharmaceutical and therapeutics committee established pursuant to section 249A.20A shall develop options for increasing the savings relative to psychotropic drugs, while maintaining patient care quality. This subsection shall not be construed to amend, modify, or repeal the exception provided pursuant to section 249A.20A relating to drugs prescribed for mental illness. The committee shall submit a report of any options the committee recommends to the general assembly by January 1, 2006. Any options developed or recommended shall not be implemented without an affirmative action enacted by the general assembly."

Susan Parker went on to review House File 825, 81st GA, § 29 (Iowa 2005) regarding reimbursement to pharmacy dispensing fees and House File 841, 81st GA, § 42 (Iowa 2005) regarding co-payments for prescription drugs under the Medical Assistance Program. The Committee held a discussion. Dr. Flaum recapped that the legislation was asking this committee to review this.

VI. The Committee held a discussion on the formation of a sub-committee to draft a report on alternative cost-saving mental health drugs. It was noted that there would be no funding for the sub-committee and these meetings would not have to be open session. It was predicted that the sub-committee would meet perhaps three to four times via teleconferences over the next few months. Sandy Pranger gave the names of two volunteers: Dr. Mark Purtle, a Des Moines internist, and Sherry Baze, a nurse practitioner from Children's Hospital Physicians in Des Moines. Susan Purcell, Matthew Osterhaus, Bruce Alexander, and Dr. Flaum indicated interest in participating as sub-committee members. Dr. Flaum made a motion to approve all six, and any others that may be added later to the sub-committee. Dr. Ruhe seconded the motion. All Committee members were in favor with none opposing or abstaining.

VII. The Committee filled out Conflict of Interest Disclosure forms. Brad Horn reminded the Committee that these forms would be public information.

VIII. Dr. Clifford gave an update on the prior authorization statistics and savings over the past quarter (Report 2). Dr. Clifford reviewed the chart on prior authorization volume by month. Overall, denials have been constant and with the increase in prior authorizations in the past couple of months there has been high percentage of approval. Dr. Clifford then reviewed the prior authorization count, average determination time, and approval rate charts. Dr. Clifford reviewed the chart reflecting average times for the prior authorization steps. Dr. Flaum questioned the approval rates. Dr. Clifford explained that the approval rate is approvals plus denials. Matthew Osterhaus asked for clarification on the determination time of six hours in January. Dr. Clifford explained that a vast majority was being turn over very quickly so that the individual claims that were taking longer were diluted by many of them being done quickly.

IX. Dr. Clifford reviewed the top ten PDL categories (Report 3). Dr. Flaum questioned why it wouldn't be expected that the approval rates would change because of the educational level of the process at this point. Dr. Clifford explained that the only new issue would be the choice of drug and that there also would not be much difference due to reasons such as new members and doctors entering into Medicaid, but he does expect a higher approval rate.

X. Dr. Clifford reviewed pre-rebate claims with prescription fill dates for Quarter 4 of 2004 and Quarter 2 of 2005 (Report 4). The pre-rebate savings is at $3.5 million. Dr. Flaum asked if the Committee could have this kind of report for the Recommended Drug List. Dr. Clifford said that this will sent directly to the Committee members within the next couple of days.

XI. Dr. Clifford reviewed the claims numbers and dollar value, actual versus projected regression model, and predicted values based on the regression model (Report 1). Although not quite finished, the supplemental rebates for Quarter 2 of 2005 will come in at $4 million. The total savings for pre-rebates and the supplementals will total over $7.5 million. This is better than first predicted, and better than last quarter but not 100% effective for the entire quarter. Results should be similar in the next two quarters. A discussion was held on the possibility of prior authorization denial messaging that would direct the provider to go to a preferred product so that no prior authorization is needed. Currently the system will only allow 42 characters. Sandy Pranger said this will be looked into. Dr. Flaum made a note to bring this up at the next meeting.

XII. The DUR Prior Authorization Recommendations to the Department of Human Services was reviewed (Attachment 3 on the agenda). Susan Parker explained that these were initial recommendations during PDL development, made by Dr. Clifford to refer to the DUR Commission for prior authorization criteria development. Shown on Attachment 3 are some of the categories that have come back from the DUR Commission to DHS on specific categories for specific drugs. These categories already have preferred or non-preferred drugs but there may be additional criteria now. Susan Purcell asked what the plan was to notify pharmacists and physicians of new changes. Susan Parker said that the Department of Human Services sends out informational letters to everyone thirty days in advance before the change would be effective and that notification would also be posted on the website of www.iowamedicaidpdl.com.

XIII. There were three public comment speakers. The first speaker was Susan Barlow, a registered dietitian and certified diabetes educator in the Medical Affairs Department at Amylin Pharmaceuticals in San Diego, California, who spoke about the drugs Byetta and Symlin. The second speaker was Steven Woods, Pharm. D., medical scientist liaison in the Global Medical Affairs Department at Shire Pharmaceuticals, who spoke on the bipolar drug Equetro. The third speaker was Scott Setzepfandt, R.Ph., with Roche and Senior Regional Manager at the

State Government Affairs, who spoke on the subject of prior authorization requests and denials plus the volume of prescriptions of products within a therapeutic class not being made public record so that it is hard for drug representatives to report to their companies on drug demands, and that the P&T Committee members affiliated with Iowa Pharmaceutical Association, research institution, or group that does research must disclose these affiliations to avoid conflicts of interest.

XIV. The Committee discussed disclosures and sharing information among the committee members. The Committee will review disclosures at the December meeting. Eileen Creager will compile this information. Documents from the P&T meeting binders will also be posted on the website unless there is financial information from manufacturers.

XV. Dr. Flaum made a motion to go to closed session. Dr. Ruhe seconded the motion. A role call vote was taken and all were in favor.

Open session reconvened at 12:40 p.m. Susan Purcell acted as chair since Dr. Flaum had a previous commitment for a short period of time. A quorum was present.

XVI. The Committee members signed a Confidentiality Agreement and Conflict of Interest forms. Regarding being involved in research with other company or organizations, Brad Horn recommended that if a Committee member thinks there may be a conflict of interest, it should be brought to the attention of the other Committee members.

XVII. The Committee members completed their expense reports.

XVIII. Public comment letters were reviewed. Dr. Frier asked for a status update on Topamax. Dr. Clifford said that Topamax is still non-preferred and requires authorization. Dr. Archer asked if all the denied prior authorization requests were from neurologists. Sandy Pranger said the majority of denials for Topamax were for the diagnosis of migraines and the neurologists wanted to use Topamax as first line treatment. Dr. Clifford added that a lot of the denied prior authorization requests were for off-label uses as well.

XIX. Susan Parker defined the terms preferred and non-preferred and how they relate to non-preferred drugs on the preferred drug list requiring a prior authorization. Recommended and non-recommended are drugs exempt from the Preferred Drug List that pertain to HIV/AIDS, cancer, and transplant, as well as drugs prescribed for mental illness, with the exception of drugs that do not have a significant variation in therapeutic or side effect profile within a therapeutic class. The P&T Committee has decided this will only apply to drugs prescribed for mental illness that have a generic equivalent. Susan Parker read excerpts from the legislation.

XX. Dr. Kline commented on the legislation that Susan Parker had reviewed earlier in the morning open session regarding the smoking cessation and weight reduction. Iowa Medicaid Enterprise Medical Services and Pharmacy Services are working with DUR to finalize a comprehensive program. Once finalized, it will be brought back to the P&T Committee for further discussion.

XXI. Dr. Kline reviewed the new drugs Alphanate, Alphanine SD, and Aptivus. Dr. Frier made a motion to approve these drugs as recommended drugs. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining.

XXII. Dr. Kline reviewed the new drug Asmanex Twisthaler. Matthew Osterhaus asked if there were any other steroid inhalants with once a day dosing that are on the preferred drug list. Dr. Clifford responded no, but there is a good history of dealing with this manufacturer with positive negotiations. Dr. Ruhe made a motion to approve Asmanex as a non-preferred drug. Mary Winegardner seconded the motion. All were in favor with none opposing or abstaining.

XXIII. Dr. Kline reviewed the new drug Baraclude. Dr. Harvey motioned to approve Baraclude as a preferred drug. Dr. Frier seconded the motion. All were in favor with none opposing or abstaining.

XXIV. Dr. Kline reviewed the new drug Byetta. The Committee held a discussion. Susan Purcell made a motion to approve Byetta as a preferred drug with conditions. Dr. Ruhe seconded the motion. All were in favor with none opposing or abstaining.

XXV. Dr. Kline reviewed the new drugs Equetro, Flebogamma, Fosamax Plus D, and Herceptin. Dr. Clifford commented that Equetro really belongs in the PDL anticonvulsant class as a non-preferred drug. The Committee held a discussion regarding Equetro. Susan Purcell made a motion to change the PDL category of Equetro to anticonvulsant. Dr. Frier seconded the motion. All were in favor with none opposing or abstaining. Dr. Frier made a motion to change Equetro to a non-preferred drug. Mary Winegardner seconded the motion. All were in favor with none opposing or abstaining. Susan Purcell made a motion to approve Flebogamma, Fosamax Plus D, and Herceptin. Matthew Osterhaus seconded the motion. All were in favor with none opposing or abstaining.

XXVI. Dr. Kline reviewed the new drugs Minirin, Niravam, and Prialt. Mary Winegardner made a motion to approve these drugs. Dr. Frier seconded the motion. All were in favor with none opposing or abstaining.

XXVII. Dr. Kline reviewed the new drugs Profilnine SD, Revatio, and Symlin. Dr. Clifford talked more on Symlin. John Grotton clarified that Symlin will remain on the PDL until DUR makes a recommendation. Dr. Ruhe made a motion to approve these drugs. Susan Purcell seconded the motion. All were in favor with none opposing or abstaining.

XXVIII. Dr. Kline reviewed the new drugs Taxol, Triglide, and Ventavis. Dr. Clifford talked more on Ventavis and said that DUR is looking at subsets on drugs and to refer back to Revatio. (Dr. Flaum rejoined the meeting at this point.) Susan Purcell made a motion to approve Taxol and Triglide as reviewed and to approve Ventavis as a preferred drug with conditions. Dr. Frier seconded the motion. All were in favor with none opposing. Dr. Flaum abstained.

XXIX. Dr. Clifford reviewed the new generic drugs: Anagrelide HCL as a preferred drug, Estradiol/Norgestimate as a non-preferred drug, Fexofenadine HCL & Pseudoephedrine ER as a non-preferred drug, Momatesone Furoate Lotion as a non-preferred drug, Niacin ER as a non-preferred drug, and Octreotide Acetate as a non-preferred drug. Dr. Flaum made a motion to approve these drugs as reviewed. Susan Purcell seconded the motion. All were in favor with none opposing or abstaining.

XXX. Dr. Clifford gave an update on annual reviews. There is a firm commitment from Maine, Utah, and Iowa to go together. Dr. Clifford will know more in about a week. The Iowa contract will have to be re-negotiated in October. Dr. Clifford will have all the information at the December meeting. Dr. Flaum asked if the three states will need to have identical preferred drug lists. Dr. Clifford responded that each state can customize their preferred drug list and that this P&T committee work will not change.

XXXI. Dr. Clifford gave an update on Medicare Part D. Currently there are about 50,000 duals. Susan Parker explained that the State will covered Medicare Part D excluded medications for duals to the extent they cover the excluded drugs for the regular Medicaid population. The Iowa region has 17 formularies for Medicare Part D. October 27 through November 11 is the enrollment time for this program. A member can change enrollment after November 15.

XXXII. Susan Purcell made a motion for the meeting to be adjourned and Matthew Osterhaus seconded it. All were in favor with none opposing or abstaining.

The meeting adjourned at 2 p.m. The next scheduled meeting will be December 8 and 9, 2005, in Room 116 of the State Capitol Building.