Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: June 8, 2006

Chair: Michael A. Flaum, M.D.

Time: 9:38 a.m. to 3:37 p.m.

Location: Grimes Building, 2nd Floor State Board Room, Des Moines, Iowa

Committee Members Present: Bruce Alexander, R.Ph., Pharm.D., BCPP; Michael A. Flaum, M.D.; Carole A. Frier, D.O.; Hayley L. Harvey, DDS, MS; Priscilla Ruhe, M.D.; and Matthew Osterhaus, R.Ph.

Committee Members Absent: Bradley J. Archer, M.D.; Mary Winegardner, PA-C, MPAS; Susan Purcell, R.Ph, CGP

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

Iowa Medicaid Enterprise (IME) Staff Present: Thomas Kline, D.O., Iowa Medicaid Medical Director; Tim Clifford, M.D.; John Grotton, R.Ph.; Sandy Pranger, R.Ph.; Chad Bissell, R.Ph., Pharm.D.

Chairperson Dr. Michael Flaum called the meeting to order.

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

II. The March 9th, 2006 open session minutes were reviewed. Dr. Ruhe made the motion to approve the minutes. Dr. Harvey seconded the motion. All committee members approved with none opposing or abstaining.

III. PDL list (Dr. Clifford): In August, letters will be sent out to manufacturers to seek supplemental rebate offers for 2007. Negotiations will occur in September, so there will be time to get things ready for the November meeting. Report 2 shows some of the changes happening with Medicare Part D taking effect on January 1st, 2006. The dual eligibles have gone over to the Medicare drug plans, except for the benzodiazepines, the barbiturates, and essentially the OTC drugs (cough and cold products, payable OTC drugs, prescription vitamin and minerals, and weight loss products) that are covered by the state. The report has been sorted by PDL category to represent the greatest percentage of the remaining drug classes for 2006. Not surprisingly, the atypical antipsychotics are 14.4% of the budget now. Percentage-wise, this has increased since the dual eligibles have left. The elderly population drives a lot of the Medicaid budget because of the medical drugs that they're taking, like multiple cardiac drugs and diabetes drugs. One of the consequences of that is that the average cost of a generic

drug so far has gone down in the remaining Medicaid population, and that's because the need for a lot of chronic maintenance-type generic drugs has disappeared with the elderly going. What has gotten disproportionately higher, on the generic side, is antibiotic prescriptions. The average cost of the brands has actually gone up a little bit, and that's because the elderly were on less expensive brands. Five of the top six categories are psych categories: atypical antipsychotics, anti-depressants, anti-convulsants, stimulants, and amphetamines. All of the psych categories together make up to about 41.5 % of the budget. By the end of the year it's likely going to be closer to 43 or 44%. Pretty close to 50% of the dollars went over to Medicare Part D. The only categories that remain unchanged are the benzodiazepines, the barbiturates, and the covered OTC dugs, because they still have access to those drugs. With Medicare Part D, all of the states are having problems to some degree, and probably all of the stores are having significant problems, as well. At some point, even if the state didn't think it was providing an emergency benefit to the Medicare Part D people, the fact is that they still are, whether they intended to be or not. The reason for that is people become retroactively eligible for Medicare Part D over the course of a year. That will be an ongoing process to deal with. There also seems to be a lot of arguments breaking out in long-term care facilities, whether something should be considered a Medicare Part D drug or Medicare Part B drug. The preferred drug plan needs to have some kind of tag to distinguish copay and to help with location code issues in nursing homes. For the next meeting, a post-rebate version of this will be provided to see how much it changes. At this point, the preferred drug list is becoming visibly mature. This next time, when drugs are reviewed, it will be found that there are going to be very few categories where there's going to be much of a discussion. There should be pretty good agreement as to the direction most of the categories are going in. However, there is going to be a lot more in-depth work in the problematic categories.

IV. PA statistics (Dr. Clifford): Report 1: As expected, with 50% of the dollars disappearing with Medicare Part D, the number of PA requests has gone down considerably. For the month of May 2006, there were just fewer than 4000 Prior Authorizations (PAs). The approval rate is really no different; still 67-70%. The PA team has always had a phenomenally good determination time, but with fewer PA requests, it has gotten even better. The average time there is 0.44 hours. The big PA categories are the same as before. When looking at the major changes occurring in the Preferred Drug List (PDL) over the course of this year, the big one initially in the first quarter was Nexium becoming one of the non-preferred PPIs. Then right now, in this May-June period, new starters on the albuterol CFC inhalers and Lantus insulin are starting to be blocked, as part of the process of switching over to Xopenex HFA and Levemir. That's a good part of what the PA unit is dealing with right now. On August 1st, all of the established users will need to be switched over. Over 800 scripts a week are going to have to be switched beginning in August. Already, about 600-650 a week has been converted, so the 40-45% mark has been reached. Giving the physicians a couple of months to go ahead to start to do this has had a good effect. It was definitely better to switch over the new users first, to get the physicians in the habit of writing them, before they had to switch over their established people. The Levemir and Lantus conversion has been a little bit more complicated. In Maine, GHS took a look at physicians that have a huge number of people on Lantus, and if a physician had more

than 30 members, they were given an additional 60 days to go ahead and complete the transfer over. That's something that should be considered here, too. It would be a good idea to identify just those selective large practices, and send them a notice to let them know they're going to have some additional time to go ahead to make the change over. Once that was done for the special community in Maine, they felt much more comfortable about the transition. If the committee wanted to go ahead and do this, in the next couple of days we would go ahead and run the analysis, identify how many remaining Lantus patients there are that need to be switched over, and then go ahead.

V. Prior Authorization Criteria: Susan Parker reviewed Attachment 1: Starting with the PEG, referencing the last meeting, there was concern regarding patients with the PEG, primarily the combination products. There was concern that if there was a need to have testing done, a PA would be required for that. That concern went back to the Drug Utilization Review (DUR) Commission at the May meeting, and they amended the language by making it only apply to the single-ingredient PEG product. The DUR commission amended their previous recommendation so that prior authorization is required for single-ingredient polyethylene glycol 3350 products only. This would only affect Miralax and its generic forms.

VI. Smoking Cessation (Dr. Tim Clifford): The second issue that went to the DUR Commission was to provide the Department with PA criteria for the smoking cessation products, and they decided that while the original criteria covered the OTC nicotine replacement patches, maybe there was a need to amend that to include other alternative forms for patients who had trouble with the patches. The DUR Commission would like the P & T Committee to review the costs and come up with an additional rapid releasing nicotine product. Bruce Alexander summarized what had taken place at the DUR Commission meeting the previous day, stating that there was a passionate discussion, emphasizing the behavioral factor. Bupropion is available, and will continue to be available. There was a data-driven decision to change the covered products. All products (NRT) have a similar efficiency rate. The DUR Commission felt as though the State should extend coverage to include a rapid release product, but it's not necessary to open the door to include all smoking cessation products. Dr. Flaum asked about pricing for these products, and Dr. Clifford said that he could give approximate prices. Nortriptyline costs less than 30 cents a day for the state Medicaid program. Bupropion is less than $2.50 a day. The nicotine patches are under $3.00 a patch per day. The gum is just under $3.30 a day. The lozenges would be just about $4.50 a day. Nasal spray would be in the $5.00-$5.50 per day range and an inhaler would be almost $8 per day. These daily prices were modeled after Maine's utilization. The other thing to understand about the Maine data is that the greatest utilization is with the preferred products, Nortriptyline, Bupropion, nicotine patch, and the gum. In Maine there is not much usage of the others because of the way it's structured on the PDL. If the PDL were to make all of these products available, probably 10% of the prescriptions would be for the lozenges, 5% would end up on the nasal spray, and right around 12-12.5% on the inhaler. Maine's structure does not distinguish between Nortriptyline and Bupropion, because they can not tell when somebody's using it for smoking cessation, or depression, or some other reason. So, they really only monitor the patches and the

gum. If usage of those two are limited, it's about 80% patches and 20% gum. In Maine, the smoking cessation products have been covered since 1998. Early on, they went primarily with the patches and the gum, because they wanted to control costs, and because there really hasn't been any data showing superiority of other products. They do allow people to use the patches and the gum concurrently. The only other thing that might be worth knowing is that the Maine Bureau of Health, which is independent from the Medicaid program, set up their own program directed at providing a Quitline, smoking cessation advice, and providing free products for smoking cessation. They went with nicotine patches, gum, and Bupropion. Those are their three covered products. GHS also processes their non-Medicaid tobacco program prescriptions, and they process about 900 prescriptions a month. The Maine Medicaid program, consisting of about 300,000 members, also does about 900 prescriptions a month. John Grotton stated that in Maine, the major cause for increased smoking cessation prescriptions was the increase in the cigarette tax, which made them about $5.00 per pack. Then they went from 400 to 900, actually peaking at 1200 prescriptions per month. Also, every January it goes through the roof again, because everyone makes resolutions to quit smoking. It will start to level off about this time of year (June) and start coming back down. Dr. Flaum asked about overall cost data based on program. Dr. Clifford says that the department requested a prediction on how much might be required, depending upon what the benefit was. The most accurate prediction Dr. Clifford could give the state was based on one that was already in place in Maine. They took a look at the smoking prevalence rate in Maine and compared it to what's published in Iowa (on the website), in order to do some kind of a crosswalk, since Iowa has about 30% more Medicaid people. Based on the differences in the smoking prevalence rate, then going ahead and assuming, at least to begin with, that the state is providing nicotine patches, the original cost assumption was right around $1.3 million in the first year. That is also assuming that the SSDC can arrange for a supplemental rebate deal with the manufacturer. When the next most cost-effective, shorter-acting product is added to the program, the gum, the state should stay within 5-10% percent of that. It's not going to be a substantial increase. An estimate was also done including the cost of adding the lozenges, the inhaler, and the spray. That would be somewhere on the order of several hundred thousand more dollars. In Maine, they have not been pressured to add any of those products to the PDL, because there's already a process to get access to them. This may be one of the differences between Maine and Iowa, but if someone fails on Bupropion, the patch, or the gum, and they still want to try to stop smoking, there is an exceptions process for them to be able to get access to some other product. Back when Maine first began covering the nicotine products, they had to do surveys, phone interviews, and mail surveys 9 months out, in order to deem whether it was effective. In the Medicaid population, at 9 months out, Maine had just under a 22% smoking abstention rate, which would be deemed a great success by many people in many diseases, but also maybe a disaster from someone else's point of view. However, Maine was happy with that, considering what was being prevented in the way of other medical illnesses, and in terms of the reduced visits. If good professional counseling, especially something like the Quitline is added into the picture, it's possible to see 27-28% abstention rates at 6-9 months out. But in the end, it comes back to the fact that the smoking cessation products are no different than any other PDL drug category from

the P & T Committee's point of view. There are many products that are comparable in efficacy. They have some substantial clinical differences. The fact is that most people can tolerate the more cost-effective products, and that most of the people that are going to respond are going to respond to the cost-effective products. So it seems to still make sense that the State would want to expose most of the people to the most cost-effective products, in order to conserve the drug budget, which is what has been done all along. There would be exceptions, of course. From a medical point of view, there are some people out there who just can not tolerate skin patches, and there are some people out there that just have uncomfortable side effects from using the gum. To put it in perspective, when looking at the quarterly report under smoking cessation products, out of roughly 2700 smoking cessation prescriptions, less than 50 would be for a lozenge, an inhaler, or a spray, where access is controlled through the exception process. Those prescriptions would have to meet the PA criteria requirements. Everything has to be done properly, through state law, and the state would have to specify what's covered. Matt Osterhaus pointed out that from a retail point of view, that patches and gum are the most commonly used. Susan Parker pointed out that the exceptions process previously discussed would not actually require Exceptions to Policy, but merely Prior Authorizations, and Dr. Clifford concurred.

VII. Weight Loss Products: The last thing on Attachment 1, Susan Parker brought attention to the weight loss agents,. They felt at this point in time, it would be best to defer any decision to add additional weight loss agents until there was more concrete information on what the actual program was going to be for the Department.

VIII. Policy for Review of Drug Status: Susan Parker read through Attachment 2. In the past, the Department came up with a formal policy for new drug review that was written out and documented so that everybody knew what the process was. A similar strategy for review of drug status was developed, most of which (A-F) have been ongoing in the committee process since implementation. Then Section G was added, which was requested by the Medicaid Director, Gene Gessow, to be part of the written policy. This will become part of the posting on the website. The purpose of this is to get more formalized documents, so that it will be accessible for people to understand. Dr. Ruhe moves that these policies for review of drug status on the PDL/RDL be accepted with the understanding under section G. the word manufacturers would be deleted and insert the members of the public, and Dr. Flaum seconds. This motion received unanimous approval with no abstentions

Open session recesses at 10:45, and reconvenes at 11:00.

IX. The public speakers were:

SPEAKER	SUBJECT
Kenneth S. Wayne, M.D. from Ottumwa Regional Health Center	Tiotropium
Karen Lasch, M.D. from Takeda Pharmaceuticals	Amitza
Kenneth E. Korber from CV Therapeutics, Inc.	Ranexa
Steven Berry, M.D. from Boehringer-Ingelheim/Pfizer/CIC	Spiriva HandiHaler

Scott Setzepfandt, R.Ph. from Roche Labs, Inc.	Boniva Injectable
Rick Larsen, M.D. from Forest Pharmaceuticals/St. Luke's	Campral
Julie Kenkel, Pharm.D. from Boehringer-Ingelheim	Spiriva & Atrovent
Lyndon Braun, Pharm.D. from Santarus	Zegerid
Cathy Callaway from IA Tobacco Prevention Alliance	Smoking Cessation
Aaron Swanson from IA Department of Public Health	Smoking Cessation
Kerry Finnegan from Central IA Tobacco Free Partnership	Smoking Cessation
Beth Ritter Ruback from Clean Air for Everyone	Smoking Cessation
Sandra Quilty from American Cancer Soc.& IA Tobacco Comm.	Smoking Cessation
Jennifer Harbism from IA Academy of Family Physicians	Smoking Cessation
Randall Yontz from American Heart Association	Smoking Cessation
Micki Sandquist from American Lung Association	Smoking Cessation
Threase Harms from CAFÉ Iowa	Smoking Cessation

Motion to recess at 12:37 and reconvene in closed session at 1:30 was made by Dr. Ruhe and seconded by Matt Osterhaus. The motion passed with unanimous approval.

Open session resumed by Dr. Flaum, with Dr. Ruhe seconding, at 2:20 pm.

X. PDL Reconsideration: Dr. Clifford reviewed the drugs recommended for status reconsideration on the PDL. Feiba VH was recommended to be listed as a non-recommended drug, due to its cost differential when compared to other recommended drugs within the same therapeutic category. Maxair Autohaler was recommended to switch back to preferred, due to a friendly relationship with the manufacturer of Xopenex HFA that allows Maxair to remain preferred. This business agreement was not known when the P & T Committee discussed this category in March. Mebendazole was recommended to change to preferred, because the brand product, Vermox, which was previously preferred, has disappeared from the market. Single ingredient PEG is recommended to change to non-preferred, per the DUR Commission's recommendation. Matt Osterhaus moved to accept the recommendations as presented. Dr. Ruhe seconded, followed by unanimous approval with no abstentions.

XI. Review of New Drugs: Dr. Kline reviewed the new drugs. Amitiza, Mimyx, NeoBenz Micro, and OptiNate were all recommended to be added as non-preferred, due to other more cost-effective options currently available on the PDL. Dr. Harvey moved to make Amitiza, Mimyx Cream, NeoBenz Micro, and OptiNate non-preferred, and Bruce Alexander seconds the motion. This motion was approved unanimously. Then the committee reviewed Ranexa, which was recommended to be added as non-preferred, because it's not intended to be used as first-line therapy. Sutent was recommended to be added to the Recommended Drug List as a recommended drug due to its cost efficacy, whereas Taclonex, U-Kera, Vivaglobin, and Vusion were all recommended to be added as a non-preferred due to other more cost-effective options currently available on the PDL. Then Dr. Ruhe moved to make Vivaglobin preferred, in conjunction with the DUR Commission's PA Criteria, and Matt Osterhaus seconds the motion and it was approved unanimously. Finally, Dr. Ruhe moved to make Ranexa, Taclonex, U-Kera,

and Vusion Ointment non-preferred and Sutent recommended, and Dr. Flaum seconds. This motion was also approved unanimously.

XII. Newly Released Generic Drugs and Dosage Forms: On the generics, the recommendation was to maintain the brands Cefzil and the Flonase Nasal Spray as preferred agents, and to make the generics non-preferred at this time due to the fact that the brand name products are more cost effective at this time . There are not any other forms of Atrovent HFA, so the recommendation would be to make it preferred. Due to the existing contacts and the end-year review coming up, the recommendation for Boniva Injection would be to make it non-preferred at this time. Climara Pro was recommended be added as non-preferred. Another form of Loestrin, with iron, should be added as non-preferred, since there are many preferred alternatives available. With RibaPak, the recommendation was to be added as non-preferred because of the current Rebetol deal. Finally, it was recommended to make the Zegerid capsules, non-preferred, with the understanding that this is an important drug to consider for the annual review. The PPI class is going to be one of the top five considerations in terms of what needs to be dealt with to control the drug budget next year. This drug may very well be an important player in a three drug PPI class for next year, but right now the current recommendation would be to add it as non-preferred. Bruce Alexander moves to accept the recommendations, and Matt Osterhaus seconds. The motion passed with unanimous approval.

X Spiriva (Dr. Clifford): Right now, what the State has in place are the clinical PA requirements and criteria that were recommended by the DUR Commission. However, the company is seeking more favorable placement for the drug. As discussed during the closed session, they have made a substantial offer, which would make the drug, from a financial point of view, very comparable to the Atrovent HFA. Then the question for the DUR would be whether there's still a strong clinical reason to redirect people away from one product that has very comparable cost, and that now has much more substantial data and studies out in support of it. The tide is gradually turning in favor of the drug. Unlike many other drugs, there hasn't been anything startlingly bad or upsetting about Spiriva, so the committee should be interested in adding this drug as preferred at some point in the near future. It would be valuable to the DUR Commission to know about the drug financially. This is a different situation than it was when it was first reviewed last year. The cost data for this drug class should be shared with the DUR Commission, so that they can take a look at the drug again and see if they have any new recommendations to make before the P & T Committee reconsiders the drug, either at the next session in early fall or at the annual review in November.

VIII. Nicotine: Matt Osterhaus would like to see the P & T Committee move forward, and he thinks that having options like gum, patches, and Bupropion makes sense. He also thinks that the other drugs should be covered, but only if need is demonstrated. However, Dr. Flaum is concerned about the political costs, and how it will affect the credibility of the P & T Committee and the legislature. Dr. Clifford thinks that he can give a little bit of perspective that may help. He narrowed down the discussion. Currently, the State covers Nortriptyline and Bupropion – that's not going to change. It

was recommended to not talk about drugs where the manufacturers haven't given the P & T Committee any clinical data or cost data; that leaves Nicotine. Dr. Clifford referenced earlier public comments from very passionate people talking about five different forms of Nicotine. In the past what has been done with multiple forms of drugs is that the most cost-effective products are determined to be preferred. Medicaid members still get the drug they need, and if they need access to the non-preferred drugs, they get a PA and get approved. The DUR Commission has taken a look at these five forms, and there really is not any strong clinical data to support one form over the other. The majority of people who will respond to a nicotine product will respond to the patch or the gum, if they are designated as preferred on the PDL. If the other products are covered, but non-preferred because they cost substantially more, then people will still have access to them if they need it. With open access, all we can go on is what we've seen before. In the first year, on the low end, it'll be $200,000, and at the high end it shouldn't be any higher than $300,000. Looking at it from the other perspective, if all five formulations were covered two years ago, and then PDL was put in place and had to look for savings in the category, we would non-prefer the inhalers, the nasal spray, and the lozenges. Dr. Ruhe cited the American Lung Association guidelines for treatment of nicotine dependency, and stated that her patients do not want nasal sprays, inhalers, or gum. She recommended lozenges to be included with the gum. Bruce Alexander says in addition to behavioral treatment, the patch is commonly needed and recommended to add on a rapid-acting product at the economic recommendation from the P & T Committee. Matt Osterhaus moves that Iowa Medicaid cover all five forms of nicotine replacement, and Dr. Ruhe seconds. The motion passes, with no oppositions. Dr. Ruhe would like to see the lozenges preferred. John Grotton says that more people in Maine like the gum than the lozenges. Most people use a combination of patches and gum, which would be allowed as a combination therapy. Dr. Clifford thinks that, for the sake of managing the budget, the Committee should go with the patches and the gum as preferred initially, expecting that will cost $1.3 to $1.5 million the first year. Preferred and Non-Preferred separations can be revisited over time, in terms of what's happening in the most recent studies and budget allocations, or if any new superior drug comes out in the future. Susan Parker explained how the PA process works, in association with Quitline. Dr. Flaum thinks the Committee needs to treat the nicotine replacement drugs as mental health drugs, keeping in mind the economic impact. Matt Osterhaus makes a motion to make patches, gum, and lozenges preferred, and Dr. Frier seconds. Bruce Alexander is against the motion, because he thinks the Committee should consider the economic impact of the preferred products. Dr. Flaum is also opposed, because he thinks all products should be preferred. Matt Osterhaus withdraws his motion, and Dr. Frier follows suit. Dr. Clifford reminded the P & T Committee that a motion initially preferring just the patches and the gum needs to be done with the understanding that the deal that's available is going to be the branded versions that are rebatable, and therefore coverable by Medicaid that the State can also get supplemental rebates on. There would be covered products in all five formulations, but in terms of what's preferred, there can only get the additional advantage of the supplemental rebate on the patches, the gum, and the lozenges. There would still be that cost difference between them, but there can be substantial supplemental rebates on the patches and the gum, and really what is being discussed is the Nicoderm products.

The SSDC will try to actively solicit some bids on those other formulations. There has not been success on the inhaler or the nasal spray before, but it will be tried again. On average, patients use 12 pieces of gum a day, so there would have to be some allowances for more than that. John Grotton asked if the DUR Commission would be determining the PA criteria. Dr. Flaum made a motion to make patches and gum preferred, and all other forms non-preferred, and Dr. Harvey seconded.

IX. Campral: Bruce Alexander asked about Campral. Dr. Flaum asked if it could put on the September agenda, and requested an updated literature review, and asked to see a review of the PAs submitted.

A motion was made by Dr. Flaum to adjourn the meeting. Bruce Alexander seconded the motion. All in attendance approved the motion. The meeting adjourned at 3:37 p.m. The next scheduled meeting will be September 14, 2006.