Iowa Medicaid Pharmaceutical and Therapeutics Committee
Minutes

Date: March 8, 2012

Chairperson: Charles Wadle, D.O.

Time: 9:30 a.m. to 12:08 p.m.

Location: Des Moines Botanical Center, Willow Room, Des Moines, Iowa

Committee Members Present: Charles Wadle, D.O.; Hayley L. Harvey, DDS, MS; Carole Frier, D.O.; Jolene Kelly, PA-C; Susan Purcell, R.Ph., CGP; and Jerry Jochims, M.D.

Iowa DHS Staff Present: Susan Parker, Pharm.D., Pharmacy Consultant

Iowa Medicaid Enterprise (IME) Staff Present: Tim Clifford, M.D.; Erin Halverson, R.Ph.; Megan Smith, Pharm.D.; and Melissa Biddle.

Chairperson Chuck Wadle called the meeting to order.

I. Chuck Wadle asked that each committee, DHS staff, and IME staff member introduce themselves to the public. The November 10, 2011 open session minutes were reviewed. Carole Frier made the motion to approve the minutes. Hayley Harvey seconded the motion. The motion passed with no objections.

II. PDL and Drug Rebate Issues (Dr. Clifford): Sovereign States Drug Consortium (SSDC) letters will go out to manufacturers in April, notifying them that the states will be meeting to go over bids in June. In the meantime, there will be a lot of work to do on the Preferred Drug List (PDL) regarding line extension drugs. As has been stated at previous meetings, the Healthcare Reform legislation passed in 2010 requires that medications deemed to be line extension drugs will require additional rebate to be returned to the federal government. To the extent that the definition of line extension was understood, the State began to redesign the PDL to avoid such drugs whenever possible. For example, it was clear that long-acting versions of pre-existing drugs were largely going to become line extension products. The issue for the states is that line extension drugs are at risk of losing much of their rebate, as most of that money would go back to the Federal government. This could easily make most of these drugs exorbitantly expensive to Medicaid programs. However, the rebate level of the new line extension drug has to be related to the rebate level of the original drug. Therefore, if the original drug doesn't have a large rebate, then the line extension drug won't have a large rebate either, so the State won't lose much money on that medication. On the contrary, if an old drug has accumulated a very large CMS rebate, then the new product will immediately inherit that large rebate, and all of the difference between this inherited larger rebate and the floor-level rebate that a new drug usually gets would all go to the Federal government. CMS has been very slow to clarify line extension rules, but they did release a draft interpretation in December. The FDA already has a chemical type designation table, and CMS believes this table's classification of drugs will work well in deciding whether a drug is line extension or not. With chemical types, the FDA decides

whether a product is the original product, a new form of an existing drug, or a combination product, et cetera. CMS thought that four of these classifications cross-walked well into what should be considered a line extension drug. Dr. Clifford believes that CMS will have a problem doing this. For example, the line extension law only applies to oral solid drugs. However, there are some new drugs out on the FDA website that are supposed to be considered line extension products, when the original drug was actually an injectable or an ointment. Thus, he thinks CMS is going to have to make some modifications. The other practical problem that CMS is going to have is that some of the original products have been around for quite some time. For example, Trilipix looks like a definite line extension to Tricor, but Tricor is probably also a line extension to another predecessor, Avadrug, and this line goes back certainly at least as far as a drug called Lipidil. So the problem with some of these drugs is that if you follow it back to find the original true parent drug, some of them go back to the beginning of medical rebate laws, or actually pre-date them. Thus some of these parent drugs may not even have any rebate history. Many of the conjugated estrogens go back to patents that the FDA has back in the 1940s, and the methylphenidate family goes back apparently to something that was released before Ritalin, as the FDA website says that Ritalin is a line extension drug. These issues will further delay CMS from moving ahead on a timely basis as it has done for the past 2 years. Even though it may not be known exactly what is going to be a line extension, or exactly what the original drug is going to be, to the extent that they and their corresponding negative financial consequence can be identified, they will be brought in front of the committee to see if PDL adjustments are warranted. CMS is currently accepting comments on their draft interpretation until early April, and it is expected it will take them many months to digest these comments. Once they see some of the issues, like the ones listed above, they'll have to do some research or find a better alternative or add-on to the FDA's chemical type designations, but eventually the bill will come due, and it will be retroactive to January of 2010. There are hundreds of line extension drugs right now, and many of them are surprising. Gleevec, for example, is line extension, for a different caplet or tablet version that came out before it and never really got out on the market. The next P&T Meeting in June will be heavily focused on line extension avoidance maneuvers.

III. PA Criteria/Pro-DUR Edits (Susan Parker): Informational Letter 1075 outlined changes to the PDL, new ProDUR quantity limits for Viibryd and Zavesca, and review of Federal Upper Limit (FUL) reimbursement. Informational Letter 1081 listed new prior authorization (PA) criteria for Nuedexta and Daliresp, along with changes to the criteria for the Anti-Acne Products-Topical and Topical Retinoids for Acne categories. Providers were also sent a notice regarding NCPDP D.0 implementation and NCPDP 5.1 termination, effective March 12, 2012. A letter to DHS from the DUR Commission dated December 8, 2011, recommended changes to the PA criteria for these categories: Anti-Acne Products–Topical, Topical Retinoids for Acne, Dextromethorphan and Quinidine (Nuedexta), and Roflumilast (Daliresp). A letter to DHS from the DUR Commission dated Febuary 2, 2012, recommended changes to the PA criteria for Bystolic and Viibryd, and it also suggested ProDUR edits for OTC pseudoephedrine, dextromethorphan/guaifenesin 10-100 mg syrup, sucralfate tablets, clobazam, and short-acting narcotics.

IV. Legislation: As has been mentioned at previous meetings, the department has been tasked with finding a replacement reimbursement methodology for Average Wholesale Price (AWP). The resulting AWP replacement report was provided to the legislature, and also posted to the website, in December. The legislature is currently looking at language in the appropriations bill

to switch to an average acquisition cost, and they're also reviewing the current dispensing fee. In coordination with that, the 200 pages of CMS regulations mentioned above covered a variety of topics in the outpatient pharmacy program, in addition to the rebate segment already discussed, such as reimbursement for pharmacy drugs. Previously, in the code of federal regulations, they defined Medicaid programs as reimbursing at an estimated acquisition cost, but they're now proposing to change the language to state an actual acquisition cost. Thus the recommendation provided to the legislature coincides with the new rules. They are also encouraging states to do cost of dispensing fee studies in order to pay the pharmacies more accordingly, and moving toward a more actual ingredient cost. Once the legislature finalizes the appropriations bill, a state plan amendment will be put in place to incorporate any changes in reimbursement as directed.

V. IME Updates: Goold Health Systems was awarded the Pharmacy Point-of-Sale contract, which should make for a seamless transition, but there will be a new MMIS vendor.

VI. The public speakers were:

SPEAKER	SUBJECT
Teresa Schulties from Pfizer	Xalkori

At 9:58, motion to go to closed session was made by Sue Purcell and seconded by Jolene Kelly. The motion passed with unanimous approval. Open session resumed at 11:14.

VII. Written Public Comment: Sue Purcell brought up one written public comment that had mentioned changes to reimbursement methodology for compounded medications. Susan Parker responded that in terms of compound billing there really haven't been any changes. Non-rebatable, non-drug products within a compound have not been reimbursable. CMS did recently clean up their rebatable file, and non-drug products that were previously listed as rebatable were removed from the pharmacy program coverage. However, Iowa Medicaid has closely monitored these non-drug products and have programmed them as non-covered, so Susan Parker does not think the State's covered products have changed. Sue Purcell persisted, saying that something had changed since January. She will send Erin Halverson and Susan Parker some examples. It was agreed that D.0 changes may be part of the problem.

VIII. PDL Discussion and Deliberation (Voting Block 1): All following recommendations were made to maximize cost savings to the program. It was recommended to make Actos 30mg, Actos 45mg, and Desogen preferred. Carafate Suspension and Ciloxan were recommended to become non-preferred and clonazepam odt to non-preferred with conditions. Hayley Harvey motioned to accept the above recommendations, and Sue Purcell seconded. The decision was unanimous.

IX. PDL Discussion and Deliberation (Voting Block 2): All following recommendations were made to maximize cost savings to the program. It was recommended to make DuoNeb, Medrol 4mg, and Nordette preferred. Hectoral 1mcg capsules and Oxandrin will be non-preferred. Carole Frier motioned to accept the above recommendations, and Jolene Kelly seconded. The decision was unanimous.

X. PDL Discussion and Deliberation (Voting Block 3): All following recommendations were made to maximize cost savings to the program. It was recommended to make PhosLo, pyroxidine 100mg/ml injection, and bupropion 75mg and 100mg tablets non-preferred. Simvastatin 80mg tablets will also be non-preferred as recommended by the DUR Commission; all existing users will be grandfathered. Wellbutrin 75mg and 100mg tablets will become preferred. Rilutek will be preferred with conditions in order to confirm diagnosis of use. Sue Purcell motioned to accept the above recommendations, and Jerry Jochims seconded. The decision was unanimous.

XI. Newly Released Drugs: All following recommendations were made to maximize cost savings to the program. Ferriprox, Firazyr, and Zirgan will all be non-preferred. Onfi will be non-preferred with conditions, and Caprelsa will be recommended. Xalkori will be non-recommended, and also referred to the DUR Commission for creation of prior authorization criteria. Sue Purcell motioned to accept all of these recommendations. Jolene Kelly seconded, and the vote was unanimously in favor.

XII. Newly Released Generic Drugs: All following recommendations were made to maximize cost savings to the program. The following will all be non-preferred: atorvastatin, atovaquone/proguanil, felbamate, gabapentin oral solution, imipenem/cilastatin, morphine sulfate er capsule, and olanzapine. Eprosartan, flucytosine, fondaparinux, and levetiracetam er will all be non-preferred with conditions. Fluocinolone oil and gablofen will both be preferred. Lamivudine will be non-recommended. Jerry Jochims motioned to accept the above recommendations. Hayley Harvey seconded the motion, and all members were in favor. However, atorvastatin and olanzapine will likely be discussed again at the June meeting.

XIII. New Dosage Forms and New Drug Names/Combinations: All following recommendations were made to maximize cost savings to the program. These drugs will all be non-preferred with conditions: Conzip ER Capsule, Sumavel DosePro, Duexis, and Juvisync. Sue Purcell motioned to accept these recommendations, and Hayley Harvey seconded. All members were in favor.

XIV. Review of Revised Documentation for New Drug Process: The Committee reviewed changes to the policy for new drug entities, specifically the exceptions to the non-preferred default policy. In the beginning, there was more allowance for a new chemical entity to be temporarily preferred on the PDL, prior to being reviewed by the P&T Committee. In the past, this caused issues with members starting on a new drug, and then having to switch after the Committee made that drug non-preferred. It was felt this written policy needed to be updated to reflect current business practices. This policy is always included in the posted Preferred Drug List on the www.iowamedicaidpdl.com website. No vote was needed.

XV. Line extension drugs and supplemental rebates: The current supplemental rebate contract does not address line extension issues. As the State has to be very specific about reasoning used to terminate a contract, this is a problem. The supplemental rebate agreement will need to be updated, as the State wants to be able to exit a contract if necessary, and also would like a clause added that would require the manufacturer to notify the state that they have a line extension drug under contract. In closed session, Dr. Clifford had mentioned that when a drug gets a new indication, it will then become a line extension drug. He readdressed this issue at this point, and reiterated that all rebates would be lost for that drug, no matter the indication for which it had been used, even if only 1% of overall usage was for this new indication. The State plans on

arguing with this rule, but unless it is repealed it could cause issues with existing contracts. Even if CMS offers a compromise allowing the indication to be verified through the prior authorization process, that drug would still be undesirable, as this process would overwhelm the current IME staff, and greatly inconvenience doctors and pharmacies as well. Contract language will be discussed at the SSDC Meeting in June, as it makes sense for all the states to take a joint approach to this. Operating the PDL to minimize losing money to the Federal government is probably going to be more important going forward than supplemental rebates just by themselves.

XVI. Managed care plans: Some states have managed care programs. Managed care plans can include a drug management program, and those drugs have been eligible for rebates since the 2010 health care reform. However, managed care plans are not privy to drug pricing, and usually make generics preferred immediately upon their release, which can be counter-productive to cost savings. Additionally, the managed care plans don't get a share of the generated rebates. In the future, the states will have to figure out how to operate the most cost effective drug benefit that makes a managed care plan, the state, and the Federal government equal partners. Any state thinking about going into managed care has to be more careful with set-up and structure. Several of the SSDC states have managed care programs for part of their populations, so this will also be discussed at the pool meeting in June.

XVII. Specialty drugs: This will be a topic of discussion at the annual meeting. Pricing is increasing for specialty drugs, and generic utilization elsewhere will not be enough to offset costs in these categories. In the future, a more sophisticated approach will be needed, including more specialists being consulted, in order to attempt to keep costs down while maintaining a high standard of care for these niche drugs. In general, the average brand prescription price is rising faster than the rate of inflation.

A motion was made by Carole Frier to adjourn the meeting. Sue Purcell seconded the motion. All in attendance approved. The meeting adjourned at 12:08 p.m. The next scheduled meeting will be June 14, 2012.