Legislative Services Agency

MINUTES

Medicaid Program Drug Product Selection Study Committee

November 19, 2008

MEMBERS PRESENT:

Senator Becky Schmitz, Co-chairperson
Senator Keith A. Kreiman
Representative Andrew Wenthe, Co-chairperson
Representative Lisa K. Heddens
Representative Linda L. Upmeyer

MEETING IN BRIEF

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I. Procedural Business

Call to Order and Adjournment. The meeting of the Medicaid Drug Product Selection Study Committee was called to order by temporary Co-chairperson Andrew Wenthe at 10:05 a.m., Wednesday, November 19, 2008, in Room 116 of the State Capitol in Des Moines. The meeting adjourned at 4:00 p.m.

Roll Call and Introductions. Roll call was taken and Senator James A. Seymour was excused. Members of the Committee, staff, and observers introduced themselves.

Election of Permanent Co-chairpersons. Members of the Committee unanimously elected temporary Co-chairpersons Senator Becky Schmitz and Representative Andrew Wenthe as permanent Co-chairpersons.

Adoption of Rules. Members of the Committee adopted procedural rules which are available from the Legislative Services Agency.

II. Background

The Legislative Council established the Medicaid Program Drug Product Selection Study Committee to convene public and private stakeholders to review current law for drug product selection under the Medicaid program. The Committee is comprised of three senators and three representatives. The Committee was allotted one meeting day.

III. Department of Human Services (DHS)

Medicaid Program Overview — Pharmacy Benefit. Ms. Eileen Creager, Bureau Chief, Long Term Care, DHS, introduced Dr. Timothy Clifford, M.D., Medical Director of Goold Health Systems and Iowa Medicaid Enterprise Pharmacy Medical Director. Dr. Clifford presented a quick overview of the Medicaid program which was established by Title XIX of the Social Security Act in 1965 and is jointly funded by the federal government and the states. The program covers a wide range of medically necessary services. Prescribed drugs are an "optional service" but if a state provides this service, all United States Food and Drug Administration (FDA)-approved prescription drugs for which a rebate agreement has been signed must be covered. However, a state may subject any covered outpatient drug to a prior authorization requirement. Due to several factors including the federal Deficit Reduction Act of 2005, the Iowa Preferred Drug List (PDL) design, and supplemental rebates, Iowa now recoups over 40 percent of every dollar spent on drugs in the Medicaid program. The cost per Medicaid recipient for drugs has remained flat due to the Deficit Reduction Act and the PDL.

Cost Factors. Dr. Clifford discussed the cost drivers and cost controllers of pharmacy benefits. Copays are used in the private sector to control costs but are not much of a factor in Medicaid due to the nominal copayment amounts required. Iowa has utilized prior authorization requirements since 1992 to assure that a drug prescribed is the most economical and appropriate drug therapy and is used only as long as it is medically necessary. Since 1987 the federal government has assigned an upper limit price for certain generic drugs and requires states to implement these

rates. Additionally, with regard to generic drugs, Iowa implemented the State Maximum Allowable Cost (SMAC) program in 2003 to publish lists of selected generic drugs along with the maximum price at which Medicaid will reimburse them to allow greater flexibility in setting drug prices and reacting to marketplace changes.

Preferred Drug List. Iowa implemented the PDL in 2005 to identify drugs which are good first choices for most people and to select the most economical drugs identified for inclusion on the PDL. Nonpreferred drugs require authorization prior to dispensing. Iowa is in a bargaining pool called the Sovereign States Drug Consortium, to negotiate directly with drug manufacturers for supplemental rebates over and above the federally required rebates. Rebate negotiations are confidential by federal law and by contract. The PDL constantly changes with the availability of new drugs and generic drugs but must contain costs. Many "new" drugs are closely related to the original drugs so need to be assessed as to whether they provide superior outcomes and are significantly different enough to be included on the PDL. The PDL is matched with a strong prior authorization program that is responsive to member and provider needs. Tools used to facilitate changes in the PDL include "grandfathering" in existing users of a drug that is now unlisted, providing personal letters to prescribers regarding members impacted by the change, and providing extended timeframes for transition to a different drug.

In 2003, the Medical Assistance Pharmaceutical and Therapeutics Committee (P&T Committee) was established within DHS for the purpose of developing and providing ongoing review of the PDL. Reevaluation of mental health drugs on the PDL is a priority for this year, specifically antidepressants, antipsychotics, and stimulants, concentrating on drugs that are derived from a preexisting parent drug. The P&T Committee is legislatively directed to consider whether or not there is a significant variation in therapeutic or side effect profiles within affected therapeutic drug classes for mental illness. There is one psychiatrist on the P&T Committee who consults with other psychiatrists in the state and then makes recommendations for inclusion or removal of mental health drugs on the PDL.

Dr. Clifford stated that for certain drug categories, arguments are made that generics are not as effective as brand name drugs. He stated that the safety of generic drugs is the domain of the FDA and cautioned that the state should not become involved in this determination. He stated that the FDA has been clear that generics are no better or worse than brand name drugs.

Dr. Clifford stated that in Iowa, the turnaround time for prior authorization of a nonpreferred drug is about one hour and to his knowledge is the best of any state. He stated that if a patient is prescribed a nonpreferred drug and the pharmacy is unable to obtain the required prior authorization, the system allows a one-time override of the prior authorization requirement so that the prescription can be filled once.

Drug Program Administration. Dr. Clifford explained that Medicaid has two contracts related to administration of the Medicaid drug program, one involving claims processing and the other for medical services such as prior authorization and the PDL. Dr. Clifford said that the PDL results in various savings, calculated before administrative costs are deducted, resulting from supplemental rebates, federal rebates, and prior authorization requirements. Ms. Jennifer Vermeer, Director, Iowa Medicaid Enterprise (IME), explained how savings from the PDL are reflected in DHS

appropriations and offered to provide the Committee with a summary of how pharmacy functions of IME are funded.

Representative Upmeyer distributed copies of a journal article entitled "Use of Atypical Antipsychotic Drugs For Schizophrenia In Maine Medicaid Following A Policy Change" which considered the effects of disallowing use of certain drugs in a Medicaid program. Dr. Clifford opined that the study was flawed in several respects and that existing users of a drug should be grandfathered in if the medication is removed from a PDL. Copies of the final agenda and attachments of the Iowa Medicaid P&T Committee meeting held on November 13, 2008, were also distributed to the Study Committee.

IV. Iowa Psychiatric Society

Dr. Kevin Took, child and adolescent psychiatrist at Blank Children's Hospital in Des Moines, discussed the need for practicing psychiatrists who serve Medicaid recipients to have input into the development of the PDL and in drug utilization review for mental health drugs. Dr. Took stated that on November 13, 2008, the P&T Committee decided to include mental health drugs on the PDL without consulting the mental health work group of the Drug Utilization Review (DUR) Committee. He stated that due to the uniqueness of psychiatric patients related to disease management and treatment compliance, the Society urges that legislation be adopted giving the psychiatric community a statutory right to provide input into the PDL process as to mental health drugs.

Ms. Vermeer stated that while she would like to see a mechanism for feedback from the DUR and the P&T Committee regarding the PDL, it is DHS that makes the final decision about what drugs are included on the PDL. She invited Dr. Took to communicate his concerns directly to her in the future.

V. National Alliance for the Mentally Ill — Iowa

Margaret Stout, Executive Director, National Alliance for the Mentally Ill in Iowa, stated that the Alliance is a consumer advocate group. She stated that the Iowa mental health system is already in a funding and access crisis. Ms. Stout expressed concern about who will monitor the PDL to ensure that it is based on more than just cost considerations. The Medicaid appeal process concerning the PDL should be simple and understandable. Ms. Stout urged delaying recommendations limiting access to psychiatric medications since many current medications will go off patent in the near future.

VI. Iowa Pharmacy Association

Mr. Thomas Temple, Executive Vice President and CEO, Iowa Pharmacy Association, explained that the Association represents more than 2,200 pharmacists and nearly 900 pharmacies in Iowa. He discussed the background of Iowa's drug product selection law which permits a pharmacist to use judgment in dispensing a generic drug, unless the prescriber or the consumer asks for a brand name drug. Among the Association's concerns with the PDL are including brand name drugs on the PDL when there is a generically equivalent product which is less expensive in the marketplace, the lack of transparency in negotiations of and information about pricing discounts offered for

pharmaceuticals, and consolidation of responsibilities for the PDL process and the DUR process with one vendor, Goold Health Systems.

Mr. Temple urged the legislature to direct IME to reestablish the DUR peer review process within organized pharmacy and medicine in the state to ensure that there is a checks and balances system within the Medicaid pharmacy program and to reconnect provider physicians and pharmacists with their colleagues. Mr. Temple also encouraged the Medicaid program to expand the Medication Therapy Management Program. Mr. Temple stated that he would provide written recommendations for changes to the Study Committee.

VII. Iowa Medical Society

Ms. Karla Fultz McHenry, Vice President Public Policy and Advocacy, Iowa Medical Society, discussed the Society's concern with the PDL since its implementation in 2005, and current issues including two-hour wait times for prior authorizations and placement of mental health drugs on the PDL. She recommended that the PDL be based on scientific and economic considerations that achieve appropriate, safe, and cost-effective drug therapy, without using cost containment as the driving factor. The Iowa Medical Society recommends changes that direct DHS to provide greater transparency in the process used to determine the clinical effectiveness of drugs placed on the PDL, provide information to appropriate stakeholder groups if there are issues concerning a class of drugs, and encourage better communication between DHS and stakeholders regarding the PDL including inappropriate prescribing patterns. Ms. McHenry also encouraged DHS to provide the public with more opportunities to review clinical information, studies, and recommendations being made about the PDL before decisions are made. Ms. Vermeer responded that DHS would make such information available sooner in the process and would provide educational information regarding proper prescribing patterns.

VIII. Diabetes Drug Discussion

Mr. Russ Sobotta, R.Ph and Senior Manager for State Government Affairs, Sanofi-Aventis, discussed the impact on individuals with diabetes of restricting the choice of insulin under the Medicaid program. He noted that on November 13, 2008, the P&T Committee lifted restrictions in the PDL on the long-acting insulin Lantus. Mr. Sobotta observed that prior to this action only three states, including Iowa, restricted the use of Lantus in their state Medicaid programs. Mr. Sobotta said that while his organization did not have any specific recommendations for the Study Committee, the structure of the Medicaid pharmacy program should encourage quality of care with regard for each patient's condition, total treatment costs, and overall cost impact to the state and to the patient, and not just focus on the control of costs by evaluating drug costs alone.

IX. Pharmaceutical Research and Manufacturers of America (PhRMA)

Mr. Khalil Nuri, Director State Policy, PhRMA, proposed several recommendations to consider relative to Iowa's Medicaid Drug Program**,** and suggested that the state undertake a study and report on how the PDL has been working since its implementation and how to maintain the program focus on patient health and appropriate access to medications. Mr. Nuri opined that

transparency in the process is important as well as having experts involved in decision making. Mr. Nuri told the Committee that he would provide a written list of the recommendations he discussed.

X. Iowa Nurses Association

Ms. Linda Goeldner, Executive Director, Iowa Nurses Association, spoke on behalf of psychiatric nurses and advanced nurse practitioners regarding the issue of limiting the number of drug options for Medicaid patients, particularly patients who are new to the Medicaid system and have been successfully using a medication whose use is restricted by the Medicaid program. Ms. Goeldner said that changing a patient's medication to save money can have the unintended and costly consequence of destabilizing the patient or requiring a hospital stay. She stated that at present the only way that patients on a restricted medication are grandfathered into the Medicaid system is through the prior authorization process. On behalf of long-term care nurses, Ms. Goeldner expressed concern about the six-week waiting period for changing medications.

XI. Iowa Retail Federation

Mr. Jim Henter, President, Iowa Retail Federation, introduced Ms. Nicole Valentine, Regional Director, State Government Affairs, National Association of Chain Drug Stores (NACDS), to discuss the drug product selection process from the perspective of chain drug stores that are members of the NACDS in Iowa, including Dahl's, Hy-Vee, Target, Wal-Mart, and Walgreens. Ms. Valentine provided issue briefs arguing against proposed legislation in some states that would create obstacles to the existing generic substitution practices of pharmacists for immunosuppressant and epilepsy drugs by requiring prior consents from the prescriber and patient for such substitutions. Ms. Valentine expressed concern about the methodology of drug rebates for the Medicaid program which results in an artificial price for some brand name drugs making them cheaper than generics so that the brand name drug is put on the PDL instead of the generic. She said that this causes a hardship for pharmacies that must stock the brand name drug only for the Medicaid population when there is no private market for that drug. Ms. Susan Parker, PharmD, Pharmacy Consultant, Bureau of Long Term Care, DHS, noted that a policy exists to deplete such stock when there are changes to the PDL.

XII. Discussion and Final Report

The Study Committee discussed the prior authorization process, and use of first failure drug requirements where the required drugs are known to have a high failure rate. DHS was encouraged to offer incentives to the Sovereign States Drug Consortium to consider the total costs of utilizing a PDL and to be more transparent about drug rebate negotiation and decision making by the P&T Committee.

The Study Committee directed that information and recommendations provided during the meeting as well as responses to data requests by DHS and others be compiled in a final report to be presented to the Standing Committees on Human Resources of the Senate and House of Representatives and to the Joint Appropriations Subcommittee on Health and Human Services.

XIII. Materials Filed With the Legislative Services Agency

The materials listed were distributed at or in connection with the meeting and are filed with the Legislative Services Agency. The materials may be accessed from the <Additional Information> link on the Committee's Internet page:

http://www.legis.state.ia.us/aspx/Committees/Committee.aspx?id=242

1. "Iowa Medicaid Pharmacy Program" — Dr. Clifford, M.D., IME Pharmacy.
2. Iowa Psychiatric Society: "Mental Health Medications on the Preferred Drug List".
3. NAMI Iowa — Iowa's Voice on Mental Illness dated November 19, 2008.
4. Iowa Pharmacy Association presentation.
5. "Best Practices for a Sound PDL", by Ms. McHenry, Iowa Medical Society, November 13, 2008.
6. "Competing Policies: Economic Impact of Diabetes on Iowa and Iowa Medicaid Activities" — from Mr. Sobotta, Senior Manager for State Government Affairs, Sanofi-Aventis.
7. "Protecting Medicaid Patient Access to Prescription Drugs," Mr. Khalil Nuri, PhRMA, submitted November 25, 2008.
8. Statement to the Medicaid Program Drug Product Selection Study Committee dated November 19, 2008 — Iowa Nurses Association.
9. National Association of Chain Drug Stores (NACDS) handout — from Ms. Valentine, Regional Director, State Government Affairs, NACDS.
10. "Use of Atypical Antipsychotic Drugs For Schizophrenia In Maine Medicaid Following A Policy Change" — Mr. Stephen Soumerai, et al., Health Affairs, April 1, 2008.
11. Iowa Medicaid Pharmaceutical and Therapeutics (P&T) Committee Meeting, November 13, 2008, Final Agenda.
12. Iowa Pharmacy Association Recommendations submitted November 20, 2008.
13. DHS Response to Iowa Pharmacy Association Recommendations submitted December 15, 2008.
14. DHS Response to inquiries submitted December 19, 2008.

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