STATE OF COLORADO

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Bill Owens
Governor

Stephen C. Tool
Executive Director

December 7, 2005

The Honorable Betty Boyd, Chairman
House Health and Human Services Committee
200 E. Colfax Avenue, Room 271
Denver, CO 80203

Dear Representative Boyd:

Enclosed please find a legislative report to the House Health and Human Services Committee, the Senate Health and Human Services Committee and the Joint Budget Committee on Health Care Policy and Financing's Pharmacy Utilization Plan FY 05-06.

C.R.S. § 26-4-408 (2005) requires the Department to provide the Pharmacy Utilization Plan.

The Pharmacy Utilization Plan FY05-06 describes the drug utilization mechanisms implemented by the Department and the estimated savings generated by those mechanisms.

Questions regarding the Pharmacy Utilization Plan FY 05-06 can be addressed to Cathy Traugott, Pharmacy Unit Supervisor, at Catherine.Traugott@state.co.us or to Christopher Underwood, Director, Rates and Analysis Division at Chris.Underwood@state.co.us.

Sincerely,

Stephen C. Tool
Executive Director

SCT:ct

Enclosure(s)

Cc: Representative Jerry Frangas, Vice-Chairman, House Health and Human Services Committee
Representative Bill Berens House Health and Human Services Committee
Representative Lauri Clapp, House Health and Human Services Committee
Representative Mark Cloer, House Health and Human Services Committee
Representative Gwyn Green, House Health and Human Services Committee
Representative Kevin Lundberg, House Health and Human Services Committee
Representative Anne McGihon House Health and Human Services Committee
Representative Jim Riesberg, House Health and Human Services Committee
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COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

REPORT TO THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE, THE SENATE HEALTH AND HUMAN SERVICES COMMITTEE AND THE JOINT BUDGET COMMITTEE

ON

PHARMACY UTILIZATION PLAN FY 05-06

DECEMBER 1, 2005

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INTRODUCTION

The Pharmacy Utilization Plan FY 05-06 is required by C.R.S. § 26-4-408(3)(b) (2005) as stated below.

> (b) The state department shall report to the health, environment, welfare, and institutions committees for the house of representatives and the senate and the joint budget committee no later than December 1, 2003, and each December 1 thereafter, on plan utilization mechanisms that have been implemented or that will be implemented by the state department, the time frames for implementation, the expected savings associated with each utilization mechanism, and any other information deemed appropriate by the health, environment, welfare, and institutions committees or the joint budget committee.

The Department of Health Care Policy and Financing (the Department) has continued to pursue reduction in pharmaceutical expenditure as outlined in SB 03-294 and SB 03-011 using the Pharmacy Utilization Plan. The Department has implemented several utilization mechanisms to control costs while allowing access to medications for clients who need them. Such mechanisms include limits and prior authorizations on certain drugs. The Department is also considering other utilization mechanisms to determine if they would result in any reduction in expenditure. The Drug Utilization Review (DUR) Board established by the Department continues to review drug utilization issues and make recommendations to the Department to optimize appropriate prescription drug use. The DUR Board findings are used by the Department to review identified drugs and to achieve expenditure reduction in pharmaceuticals. The Department has also contracted with the Business Research Division of the Leeds School of Business at the University of Colorado to assist the Department with more in-depth analysis of various drug utilization issues. Finally, the Department will continue to monitor monthly drug expenditures and provider/client utilization patterns.

Throughout this report, the Department identifies the utilization mechanisms that have been implemented to generate a reduction in expenditures to a specific prescription drug class, rather than attempting to identify a savings to the overall Department's pharmaceutical budget. The amounts reported for a specific drug class do not capture the possible increase in another prescription drug, which may act as a substitute. As an example, the reduction in expenditure from the implementation of prior authorizations, may have caused clients to shift to a generic alternative drug as a substitute. The reported reduction in expenditure detailed in this report are not offset by the increase in expenditure for a potential generic substitute. The direct increase in the utilization for the generic substitutes, directly related to the implementation of prior authorizations, is not measurable.

PLAN UTILIZATION MECHANISMS PREVIOUSLY IMPLEMENTED

The following calculations contain both FY 04-05 and FY 05-06 measures of the reductions in expenditure for each of the Department's utilization control initiatives. As FY 05-06 is not yet

complete, the FY 05-06 figures below are forecasts. The FY 04-05 data below varies from last year's Pharmacy Utilization Plan (FY 04-05 Report) as the data is now complete and also because the calculations were refined and improved.

The Department believes that it is important to note that unmeasurable market factors may affect the reduction in expenditure realized by the implementation of these prior authorizations. This is particularly true for the prior authorizations that were implemented more than two years ago. For those calculations, the Department determined the decrease in utilization realized shortly after the prior authorizations were implemented and extrapolated forward to determine the reduction in expenditure.

Proton Pump Inhibitors and Oxycontin: Implemented January 3, 2003

In January 2003, the Department established prior authorizations for proton pump inhibitors (PPIs) and Oxycontin. PPIs are used to treat a variety of gastrointestinal conditions such as gastro-esophageal reflux disease (GERD), ulcers, and various hypersecretory conditions. The Department has revised the PPI prior authorization criteria several times since implementation of the prior authorization process based on new medical information about these drugs and new formulations and drugs becoming available.

Oxycontin is a pain medication that is indicated for twice daily dosing. The Department implemented prior authorization criteria that restricted use to twice daily dosing of any particular strength of Oxycontin. Generic equivalents of Oxycontin recently became available and Oxycontin is subject to the generic mandate (C.R.S. § 26-4-406 (2005)). Thus, the Department believes that it will achieve additional reduction in expenditure within this drug class through the use of the generic equivalent of Oxycontin.

Based on the implementation of the prior authorizations, the Department's FY 04-05 reduction in expenditure within this drug class is estimated at $176,260 on the PPIs and $712,640 on Oxycontin and the FY 05-06 estimated reduction is $194,460 on the PPIs and $195,740 on Oxycontin. As with all other prior authorizations, the MMIS/Fiscal Agent prior authorization costs are paid from the administrative cost appropriations and those costs are not included in any of these calculations.

PHASE I: Implemented December 15, 2003

Phase I limited the quantities of certain medications that could be obtained by a client in a 30-day period. Those medications included the following: certain sleeping agents (Ambien and Sonata), a short-term pain medication (Toradol), anti-migraine products (Amerge, Axert, Frova, Imitrex, Maxalt, Relpax, and Zomig) and anti-nausea products (Anzemet, Emend, Kytril and Zofran). The details of the limits are included in the Pharmacy Utilization Plan FY 03-04. Using the same reduction in expenditure methodology described for Oxycontin and the PPIs above and recognizing that there are the same limitations on the calculation of reduction in expenditure, the Department estimated that Phase I resulted in an estimated reduction in expenditure within these drug classes of $2,449,270 in FY 04-05 and an estimated reduction in expenditure of $2,401,640 in FY 05-06.

PHASE II: Implemented March 4, 2004

In Phase II, prior authorizations were implemented for certain atypical antipsychotics (Abilify, Risperdal and Zyprexa), Cox-2 inhibitors (Bextra, Celebrex and Vioxx) and fentanyl products (Actiq and Duragesic patches). The details of the prior authorization criteria initially developed for these drugs and subsequent changes through October 2004 are included in the Pharmacy Utilization Plan FY 04-05. Any changes since October 2004 are discussed below.

Atypical Antipsychotics

Abilify, Risperdal and Zyprexa were placed on prior authorization for more than once daily dosing. New formulations of these drugs have been added to the prior authorization list. This utilization control mechanism has remained quite effective and the reduction in expenditure noted below is larger than the previous estimate in the FY 04-05 Report.

FY 04-05 estimated reduction in expenditures within this drug class: $2,174,690
FY 05-06 estimated reduction in expenditures within this drug class: $1,964,460

Fentanyl

Fentanyl is a strong analgesic narcotic. Currently, fentanyl is available in the outpatient setting through a lozenge (marketed as Actiq) and through a patch (marketed as Duragesic). The reduction in expenditure for both products of drugs from utilization controls historically was offset by drug price increases. In addition, the number of utilizers of the Duragesic patch has continued to increase even with the implementation of the prior authorization. Thus, the reduction in expenditure from Actiq was negated by the increased utilization of the Duragesic patch. However, a generic version of the Duragesic patch has recently become available and the Department expects the reduction in expenditure within this drug class to increase.

FY 04-05 estimated reduction in expenditures within this drug class: $0
FY 05-06 estimated reduction in expenditures within this drug class: $46,350

Cox-2 Inhibitors

Cox-2 inhibitor non-steroidal anti-inflammatory drugs (NSAIDS) have similar efficacy to the conventional NSAIDS. The daily cost of Cox-2 inhibitors was 5-10 times the cost of the older NSAIDS at the time the prior authorization was implemented. Subsequent to implementation of the prior authorization on Cox-2 inhibitors, Vioxx was withdrawn from the market effective September 30, 2004 and Bextra was withdrawn from the market effective April 7, 2005. Thus, the only Cox-2 inhibitor that is still on the market is Celebrex and this drug is still on prior authorization. Based on this the reduction in expenditure within this drug class is not as significant as initially projected in the FY 04-05 Report.

FY 04-05 estimated reduction in expenditure within this drug class: $404,300
FY 05-06 estimated reduction in expenditure within this drug class: $266,510

PHASE III: Implemented April 13, 2005

During FY 04-05, the Department identified certain other drugs that were investigated for prior authorization to lower the expenditures on drugs. Those drugs were: leukotriene receptor antagonists (Accolate and Singulair), non-sedating antihistamines (Claritin (Rx), Clarinex, Allegra and Zyrtec), nasal steroids (Beconase, Flonase, Flunisolide, Nasacort, Nasarel, Nasonex and Rhinocort), injectable rheumatoid arthritis drugs (Enbrel, Humira and Kineret), several injectables that should be administered in the physician's office or inpatient settings (Erbitux, Herceptin, Aldurazyme, Amevive, Remicade and Xolair) and other drugs (Bactroban, Strattera, Raptiva and Regranex). These drugs were considered for prior authorization because of increased utilization and overutilization of these drugs, potential inappropriate use of these drugs, and/or avoidance of possible double billing to the Medicaid program. The Department asked for input on the potential prior authorization of these drugs from the Colorado Medical Society, the Denver Medical Society, the Department's DUR Board, and manufacturers of the drugs. In addition, the Department posted the possible prior authorization criteria so that anyone from the public could submit comments. The Department received a number of comments on the list of drugs and changed the list of drugs accordingly. Prior authorizations were implemented for the drugs listed below. The current prior authorization criteria are also listed.

Name	Drug Indication	Manufacturer
LEUKOTRIENE RECEPTOR ANTAGONISTS	**The prior authorization criteria will apply to clients who are 21 years old and older. Clients under 21 years of age will not need to obtain a prior authorization.** **A prior authorization will be granted if a client has failed on an inhaled steroid/nasal steroid OR the client is currently using an inhaled steroid/nasal steroid and the providers wants to add a leukotriene to the client's drug therapy OR the client was on a leukotriene as of March 1, 2005 and the client was stabilized on the medication.** In addition, the client must be diagnosed as follows:	
Accolate	Drug must be prescribed for the prophylaxis and chronic treatment of asthma.	Zeneca
Singulair	Drug must be prescribed for the prophylaxis and chronic treatment of asthma or for the relief of symptoms of seasonal allergic rhinitis.	Merck

FY 04-05 estimated reduction in expenditure within this drug class: $5,710
FY 05-06 estimated reduction in expenditure within this drug class: $27,390

Name	Drug Indication	Manufacturer
OTHER DRUGS		
Bactroban Cream and Nasal Ointment	**Bactroban Cream** (mupirocin calcium cream) - approved for the treatment of secondarily infected traumatic skin lesions (<10 cm in length or 100 cm^2 in total area) caused by Staphylococcus aureus (Staph aureus) or Streptococcus pyogenes (Strep pyogenes). **Bactroban Nasal Ointment** (mupirocin calcium) - approved for the eradication of nasal colonization with MSRA (methicillin-resistant Staphylococcus aureus) in adult patients and health care workers as part of a comprehensive infection control program to reduce the risk of infection among patients at high risk of MSRA infection during institutional outbreaks of infections with this pathogen. **Bactroban Ointment** (mupirocin ointment) - does not require a prior authorization.	**GlaxoSmithKline**

FY 04-05 estimated reduction in expenditure within this drug class: $6,642
FY 05-06 estimated reduction in expenditure within this drug class: $31,890

Other Prior Authorizations Implemented

The Department also established a prior authorization on a new pain medication, Palladone, on April 5, 2005. There was concern about misutilization of the drug and a prior authorization was established shortly after the drug became available on the market. However, the drug was pulled from the market pursuant to an order by the FDA on July 13, 2005 and thus there will be no reduction in expenditure within this drug class based on this prior authorization.

In addition, the Department recently put promethazine on prior authorization for clients under the age of two effective September 1, 2005. Promethazine is an older drug that is often used to stop vomiting. The prior authorization was established pursuant to a recent black box warning stating that promethazine may cause breathing to slow or stop, and may cause death in children. According to the warning, promethazine should not be given to babies or children who are younger than two years old. Although the prior authorization was established primarily for the protection of the clients, the Department will achieve some reduction in expenditure within this drug class from this prior authorization. In FY 04-05, there were approximately 107 Medicaid clients under the age of two who were prescribed promethazine. Assuming that the Department will not pay for promethazine for any clients under the age of two now that the prior authorization is in place, the Department estimates that it will save $15,588 in FY 05-06 from the implementation of this prior authorization.

PLAN UTILIZATION MECHANISMS TO BE IMPLEMENTED IN FY 05-06

The Department is continuing to monitor drug utilization and trends to determine if additional drugs should be placed on prior authorization. In addition, the Department will continue to update existing prior authorization criteria based on drug utilization and trends as well as new medical information.

The Department is also exploring other options to achieve additional reduction in expenditure. The Department released on Request for Information on May 26, 2005 asking for information on relevant mechanisms and programs available for pharmacy utilization control and the costs associated with those programs. The Department received three responses. Two of the responses discussed pharmacy benefit management services, a component of which is utilization control, and the other discussed program involving pharmacies that receive special drug pricing pursuant to Section 340B of the Public Health Services Act of 1992. None of the responses dealt directly with drug utilization mechanisms. The Department is still considering releasing a Request for Proposal on drug utilization programs. In connection with that process, the Department has reviewed several other programs that have been implemented by other states.

However, the Department does not believe that it is prudent to invest significant time into additional utilization mechanisms until the impact of the implementation of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) is known. Effective January 1, 2006, person eligible for both Medicare and Medicaid (dual eligible) will receive the vast majority of their drugs through the Medicare program. The Department will incur a relatively small cost to provide Medicare excluded drugs to these dual eligibles as a Medicaid benefit. Based on the numbers submitted to the legislature previously, the Department determined that in FY 04-05, 13.7% of the Medicaid population was comprised of dual eligibles. The drug expenditures for this population were $129,021,719 or 44.4% of the total drug expenditures in FY 04-05. Clearly, the expenditure amount and the utilization pattern of the pharmacy program will change significantly with the implementation of the MMA. The Department has determined that it should wait to make any substantial changes to its current drug utilization programs until the Department can determine the actual impact of the MMA.

OTHER ACTIVITIES

DUR Board Activities

In accordance with federal law, the DUR Board performs various drug utilization review functions including retrospective drug utilization review and education to providers. The DUR Board also reviews certain policies of the Department and provides recommendations with regard to those policies.

The DUR Board is currently comprised of the following members:

- David A. Downs, Jr., M.D,
- Lucy Williams Loomis, M.D., M.S.P.H.,

- James R. Kant, R.Ph.,
- Robert D. McCartney, M.D., F.A.C.P.,
- Mary Newell, R.Ph.,
- Candace A. Rieth, Pharm. D.,
- Terrie A. Sajbel, Pharm. D.,
- Edra B. Weiss, M.D., F.A.A.P., and
- Timothy James Hartman, Pharm.D., BCPS, C.D.E. (pharmaceutical representative).

Cathy Traugott R.Ph., J.D. attends as the Department's representative but does not hold a voting position on the Board. Health Information Designs, Inc. (HID), the Department's contractor, provides assistance with the DUR Board. A HID representative attends the DUR Board meetings.

As described in more detail in the FY 04-05 Report, the Board meets on a quarterly basis and holds special meetings when deemed necessary. During FY 04-05, the Board considered a number of issues including the review of Phase III drugs and prior authorization criteria; review of PPI criteria; removal of prescription Vitamin D drugs from prior authorization; adding promethazine, Palladone and Trizivir to the prior authorization criteria; consideration of additional warnings of the use of atypical antipsychotics; and review of the retrospective drug utilization review criteria that is used to create client profiles and identify any potential misutilization issues (discussed below). The Department has considered all of the recommendations of the DUR Board and in many cases, has implemented the recommendations.

As also described in more detail in the FY 04-05 Report, the Board and HID review client drug profiles to determine if there are any utilization issues that need to be addressed. Educational letters are sent to providers regarding any prescribing practices that could be deemed inappropriate. The goal of the program is to inform providers of potential drug utilization problems and change prescribing habits toward better utilization protocols. In FY 04-05, the Board and HID reviewed duplicative use of selective serotonin reuptake inhibitors, therapeutic duplication of antiulcer medications, inappropriate use of stimulants in pediatric patients and general overutilization of stimulants, inappropriate therapy in elderly patients, overutilization of narcotics and skeletal muscle relaxants, therapeutic duplication of sedative/hypnotic agents, inappropriate use of promethazine in pediatric patients, and use of atypical antipsychotics in elderly patients who were not diagnosed with schizophrenia or bipolar disorder.

HID provides a quarterly and biennial report of its activities and the activities of the DUR Board. The most recent biennial report was for the first six months of FY 04-05. During that time, HID and the DUR Board looked at inappropriate therapy for the elderly, duplicative anti-ulcer therapy and overutilization of a variety of drugs including antidepressants, sleep agents and anti-anxiety agents. There were 1,248 clients identified with potential drug therapy issues. Letters were sent to physicians in 544 of those cases. The categories of drug therapy problems and percentage of cases in each category identified were as follows: 2% drug-disease interactions, 38% drug-drug conflict, 29% overutilization, 2% underutilization and 31% clinical appropriateness. There were 299 physicians who responded to the letters (a response rate of 55%). There were a variety of responses from the physicians, including modification or discontinuance of therapy, several who scheduled appointments to discuss the issue with the clients and several who tried to modify

therapy but the symptoms recurred. HID determined that the changes to appropriate therapy resulted in a reduction in expenditure of $105,479 to the Department during that time. They also estimated that the Department's return on investment was $15 for every dollar spent on the contract with HID, although the primary goal of the DUR program is provider education and appropriate drug therapy.

Utilization Research by the Business Research Division, Leeds School of Business at the University of Colorado

On April 1, 2005, the Department began working with the Business Research Division of the Leeds School of Business at the University of Colorado (BRD). The BRD performs a variety of research and analytical projects as directed by the Department to facilitate retrospective review of and reporting on the appropriateness of prescription drug use, provider prescribing habits, and the potential fiscal impact of drug utilization issues such as drug-drug interactions, drug-disease interactions and therapeutic duplication. For example, the BRD is determining how many hospital visits could be avoided if patients remained on their antipsychotic medications. In addition, the BRD is researching utilization control programs in other states to determine if any could be implemented in Colorado. Depending on the results of the projects, such information could be used to change current policies or develop new policies to achieve greater reduction in pharmaceutical expenditure.

Market Changes

Despite the utilization mechanisms that have been and will be implemented by the Department, as in past years, there are a number of market changes that are causing an increase in the pharmacy budget. Drug costs are constantly rising as new drugs often are very expensive and drug manufacturers are also increasing drug prices of older drugs. Further, the implementation of the MMA may lead to increases in the number of dual eligibles as low-income Medicare beneficiaries learn that they may qualify for Medicaid and therefore apply for Medicaid benefits. The federal government has estimated that this increase may be as large as one million people nationwide.

CONCLUSION

The Department has implemented a number of drug utilization mechanisms to control costs and throughout this report, the Department identifies the utilization mechanisms that have been implemented to generate a reduction in expenditures to a specific prescription drug class, rather than attempting to identify a savings to the overall Department's pharmaceutical budget. Some mechanisms to control costs involve certain restrictions on drugs while others involve obtaining utilization reports and information from contractors which can be used to determine other mechanisms to achieve reduction in expenditures. A summary of the estimated reduction in expenditures by drug class realized from these mechanisms is listed below.

FY 04-05 estimated reduction in expenditure by drug utilization mechanism:

PPIs $176,260
Oxycontin $712,640
Phase I.....$2,449,270
Phase II.....$2,578,990
Phase III $12,350
DUR Contract (annualized) $210,960

FY 05-06 estimated reduction in expenditure by drug utilization mechanism:

PPIs $194,460
Oxycontin.....$195,740
Phase I.....$2,401,640
Phase II.....$2,277,320
Phase III $59,270
Promethazine.....$15,590