STATE OF COLORADO

DEPARTMENT OF HEALTH CARE POLICY & FINANCING

1570 Grant Street
Denver, Colorado 80203-1818
(303) 866-2993
(303) 866-4411 FAX
(303) 866-3883 TTY

Bill Owens
Governor

Karen Reinertson
Executive Director

March 1, 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 04-05.

C.R.S. § 26-4-408 (2004) requires the Department provide the Pharmacy Utilization Plan.

The Pharmacy Utilization Plan FY 04-05 is the plan set for pharmaceuticals changes by the Department for FY 04-05. Phase III will allow certain pharmaceuticals to be obtained with a Prior Authorization when criteria is met. This phase is scheduled for implementation February 15, 2005.

Questions regarding the Pharmacy Utilization Plan FY 04-05 can be addressed to Martha Warner, Pharmacy Unit Supervisor, at Martha.Warner@state.co.us. Her telephone number is 303-866-3176.

Sincerely,

Karen Reinertson
Executive Director

KR:mw

Enclosure(s)

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

PHARMACY UTILIZATION PLAN FY 04-05

As of DECEMBER 1, 2004

Pharmacy Utilization Plan
FY 04-05

INTRODUCTION

The Pharmacy Utilization Plan FY 04-05 is required by Section 26-4-408(3)(b), C.R.S. (2003) 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 and will continue to achieve the savings outlined in SB03-294 and SB03-011 using the Pharmacy Utilization Plan. To this end, the Department has implemented and continues to implement several utilization mechanisms to control costs while allowing access to these medications for clients who need them. Such mechanisms include limits and prior authorizations (PAs) on certain drugs. In addition, the Drug Utilization Review (DUR) Board established by the Department reviews drug utilization issues and makes recommendations to the Department to optimize drug use. The DUR Board findings are used by the Department to review such drugs and to achieve pharmaceutical savings. Finally, the Department will continue to monitor monthly drug expenditures and provider/client utilization patterns.

PLAN UTILIZATION MECHANISMS PREVIOUSLY IMPLEMENTED

Proton Pump Inhibitors and Oxycontin: Implemented January 3, 2003

In January 2003, the Department established PAs 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. Due to overutilization of these medications, the Department created PA criteria to restrict use to indications approved by the Food and Drug Administration (FDA) and in certain instances, required use of H2 blockers (older products used to treat ulcers and other gastrointestinal conditions) before long-term use of the PPIs would be granted. Oxycontin is a pain medication that is indicated for twice daily dosing. The Department determined that Oxycontin was often prescribed more often, which is outside of the FDA-

approved indication. The Department implemented PA criteria that restricted use to twice daily dosing of any particular strength of Oxycontin.

On October 7, 2004, the Department lifted the PA requirement for PPIs for clients under the age of two. In addition, the Department is currently revising the PA criteria based on new medical information about these drugs.

Through the PA process, the Department's FY 04-05 estimated savings are $969,032.79 on PPIs and $147,339.99 on Oxycontin.

The savings for PPIs is somewhat affected by the shortage of Prilosec OTC (over the counter), which has been in short supply since June 2004. Use of Prilosec OTC instead of prescription PPIs saves the Department money because Prilosec OTC costs the Department $0.67 per pill and prescription PPIs range from $3.58 to $5.73 per pill. The manufacturer of Prilosec OTC is hopeful that the product will be available again in full supply by December 2004.

PHASE I: Implemented December 15, 2003

As described in the Pharmacy Utilization Plan FY 03-04 (03-04 Report), that fiscal year's plan was divided into two phases. Phase I limited the quantities of certain medications that could be obtained by a client in a 30-day period. Those medications include 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 03-04 Report. As predicted in the 03-04 Report, Phase I was implemented on December 15, 2003. Phase I resulted in a savings of $ 1,093,253.21 in FY 03-04 and is estimated to result in a savings of $1,831,959.10 in FY 04-05.

PHASE II: Implemented March 4, 2004

In Phase II, PAs were implemented for certain atypical antipsychotics (Abilify, Risperdal and Zyprexa), Cox-2 inhibitors (Bextra, Celebrex and Vioxx) and fentanyl products (Actiq and Duragesic patches). Originally scheduled for implementation in January of 2004, Phase II was actually implemented on March 4, 2004. The delay was due to problems with the system changes and a delay in receiving approval from the Centers for Medicare & Medicaid Services.

A few changes were made to criteria that were described in the 03-04 Report. The criteria that were actually implemented are as follows:

Atypical Antipsychotics:

These agents are FDA approved for once daily dosing. The half-life ranges from 20-70 hours with a mean of 30 hours. Once daily dosing has been shown to be safe and

effective when compared to multiple-daily dosing. Also, once daily dosing significantly reduces cost by using the highest tablet strength rather than multiple low-dose tablets. Before the implementation of Phase II, these atypical antipsychotics were often dosed at more than once a day. The PA criteria are:

Zyprexa	Restricted to once daily dosing for all strengths of Zyprexa, except for the 20 mg tablet.
Risperdal	Restricted to once-daily dosing for all strengths of Risperdal, except twice-daily dosing may be approved for clients who are 65 years old or older, long-term care patients, client with renal or hepatic impairment, or for clients with concern for orthostatic hypotension or syncope. In addition, there is no restriction on the 3 mg and 4 mg tablets, the 2mg M-Tab, 1mg/ml solution and all strengths of Risperdal Consta.
Abilify	Restriction to once daily dosing for all strengths of Abilify, except the 30mg tablet.

Savings in FY 03-04: $702,575.23
Estimated savings in FY 04-05 $(1,247,365.39)

Fentanyl:

Fentanyl is a strong analgesic narcotic. Actiq delivers fentanyl through a lozenge. Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. The drug is contraindicated in the management of acute or postoperative pain. It is also contraindicated in use in opioid non-tolerant patients. The maximum dose is 4 units per day.

Duragesic administers fentanyl through a patch. Most patients are maintained adequately with the patch when it is applied at 72-hour intervals, however, some patients may require application of the patch at 48-hour intervals to maintain adequate analgesia. The PA criteria are:

Fentanyl:	
Actiq	4 units per day and for use in cancer clients only who have already received and are tolerant to opioid drugs for the cancer pain.
Duragesic patches	Every 48 hour intervals (or every 2 days) for one fentanyl patch use

For both products, if a client is a hospice patient, there is no restriction on the number of Actiq (for cancer diagnosis) or Duragesic patches the client may receive. The savings for both drugs from utilization controls are offset by drug price increases. Over the time

period of this analysis, drug prices for both fentanyl products have increased between 12%-18%.

Savings in FY 03-04: $(70,025.88)
Estimated savings in FY 04-05 $260,500.37

Cox-2 Inhibitors:

Cox-2 inhibitor non-steroidal anti-inflammatory drugs (NSAIDS) have similar efficacy to the conventional NSAIDS. Studies report a lower incidence of bleeding; however, the clinical significance of this difference in patients without a coexisting risk factor for gastrointestinal bleed is questionable. The daily cost of Cox-2 inhibitors is 5-10 times the cost of the older NSAIDS. These agents have been growing in expenditures since they were introduced to the market. This class of drugs requires a prior authorization for clients between the age of 18 and 65. When implemented, clients under the age of 18 could not receive a prior authorization. Use of the Cox-2 inhibitors is limited to FDA-approved indications and dosing guidelines. The PA criteria were:

Drug	**Approved Indications**	**Dose**
Vioxx	Osteoarthritis	12.5-25 mg daily
	Rheumatoid Arthritis	25mg daily
	Acute pain and Dysmenorrhea	50mg daily for 5 days
	Migraine	25-50mg daily for 5 days/month
Celebrex	Osteoarthritis	200mg daily; 100mg twice a day
	Rheumatoid Arthritis	100-200mg twice a day
	Familial Adenamatous Polyposis	400mg twice a day for 6 months
	Acute pain and Dysmenorrhea	Up to 600mg day 1; 200mg twice a day for no more than 30 days
Bextra	Osteoarthritis	10mg daily
	Rheumatoid Arthritis	20mg daily
	Primary dysmenorrhea	20mg twice a day as needed

The savings for all three drugs from utilization controls are offset by drug price increases. Over the time period of this analysis, drug prices for these products have increased between 8%-9%. The analysis of FY 03-04 did not have the anticipated savings. However, FY04-05 is forecasted to generate savings for the Department.

Savings in FY 03-04: $(45,583.67)
Estimated savings in FY 04-05 $1,813,231.86

Subsequent to implementation, several changes have been made to the criteria. They are:

1. Based on information provided by health care providers and the recommendation of the DUR Board, the Department lifted the PA requirement on atypical antipsychotics for patients 18 years of age and younger effective July 21, 2004. There was general concern that pediatric and adolescent clients are different from adult clients and often metabolize the drugs much more quickly than adults. Thus, the once daily dosing will not always work for these clients. System changes to lift this requirement were implemented October 7, 2004. Between July 21 and October 7, a PA was still required in order to fill the prescription but the PAs were automatically granted. Thus, the savings that the Department originally forecasted for these drugs for FY 04-05 will not be met.

2. Effective September 30, 2004, Vioxx was withdrawn from the market. Vioxx had more FDA-approved indications than Celebrex or Bextra. Thus, it is not clear what change in the estimated savings this withdrawal will have.

3. Effective October 7, 2004, the use of Cox-2 inhibitors is no longer restricted to clients who are 18 years or older.

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: Gail Bosch, R.Ph., CGP, David A. Downs, Jr., M.D, Lucy Williams Loomis, M.D., M.S.P.H., 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 D. Hynek, R.Ph. (pharmaceutical representative). Cathy Traugott R.Ph., J.D. attends as the state representative and does not hold a voting position on the Board. The Department contracts with Health Information Designs, Inc. (HID) to provide assistance with the DUR Board and a HID representative attends the DUR Board meetings.

The Board has regularly scheduled meetings on a quarterly basis and holds special meetings when deemed necessary. An introductory meeting for the current Board members was held on March 16, 2004. Subsequent regular and special meetings were held on April 20, 2004, May 24, 2004 (special meeting), July 20, 2004 and October 19, 2004. The next meeting is scheduled for January 25, 2005. A number of topics have been discussed at those meetings, including the use of atypical antipsychotics in the pediatric and adolescent community, review of Phase III drugs and PA criteria, review of

PPI criteria 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.

On the nights of the regularly scheduled meetings, the Board also meets in executive session to discuss client profiles. Because this discussion includes protected health information (as defined by the Health Insurance Portability and Accountability Act of 1996 and the corresponding regulations), the Board meets in executive session pursuant to provision of the Colorado Open Meetings Act. (C.R.S. § 24-6-402(3)(a)(III).) During the executive session, the Board members review the client profiles and determine if there are any utilization issues that need to be addressed. If so, a letter identifying those issues is sent to the client's physician. The letter explains the potential drug therapy problem and asks the physician to respond regarding the accuracy of the determination and any changes that were made to the client's therapy. During the months in which the DUR Board does not meet, HID runs client profiles and performs the same function. For each run, a particular potential drug therapy problem for a drug or class of drugs is chosen and the clients that may have that drug therapy problem are identified. Such drug therapy problems include drug-disease interactions, drug-drug conflicts, overutilization and underutilization. The system also identifies any other potential drug therapy problems for those clients. If those issues are identified as warranting intervention, letters are sent regarding those potential drug therapy issues as well. In FY 04-05, the Board and HID have reviewed duplicative use of selective serotonin reuptake inhibitors, therapeutic duplication of antiulcer medications and inappropriate use in pediatrics and general overutilization of stimulants.

HID provides a quarterly report of its activities and the activities of the DUR Board. The most recent report is for the last fiscal quarter of FY 03-04. In that quarter, HID and the DUR Board looked at therapeutic duplication of atypical antipsychotics and 232 clients were identified. Letters were sent to physicians in 223 of those cases. The categories of drug therapy problems and percentage of cases in each category identified were as follows: 2% drug-disease interactions, 14% drug-drug conflict, 69% overutilization and 15% clinical appropriateness. There were 114 physicians who responded to the letters (a response rate of 51%). 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. Changes to appropriate therapy result in savings to the State. HID will provide the Department with a report regarding such savings later this year.

OTHER ITEMS OF NOTE

Market Changes:

Despite the utilization mechanisms that have been and will be implemented by the Department, there are a number of market changes that are causing an increase in the pharmacy budget. Drug costs are constantly rising. New drugs often are very expensive and drug manufacturers are also increasing drug prices of older drugs. In addition, utilization of the fee-for-service pharmacy program is increasing. Many clients who were in Medicaid HMOs have transitioned to the fee-for-service arena. In addition, the Medicaid population has increased in recent years.

Staffing of the Pharmacy Unit:

The Pharmacy Unit was fully staffed from January 1, 2004 until October 1, 2004. The Pharmacy Unit is currently staffed with Cathy Traugott, Pharmacist/Attorney; Marguerite Richardson, Pharmacy Relations; and Martha Warner, Pharmacy Supervisor. Ann Duenas was the Pharmacy Analyst but recently left for another state agency. The Department is currently in the hiring process for the position.

CONCLUSION

The savings from the Department's Pharmacy Utilization Plan FY 04-05 will total $6,380,884.48.

Phase II FY 04-05 Atypicals $(1,247,365.39), Fentanyl $260,500.37 Cox2 $1,813,231.86
Phase I FY04-05 $1,831,959.10
Oxycontin FY 04-05 $147,339.99
PPI FY 04-05 $969,032.79
Total estimated savings for FY 04-05 $ 3,774,698.73