

# **Office of the Colorado State Auditor**

## **Medicaid Prescription Drug Program**

**Performance Audit  
September 2004**



**The Caley Gordon Group**

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September 29, 2004

Members of the Legislative Audit Committee:

This report includes the results of our performance audit of the Medicaid Prescription Drug Program, which The Caley Gordon Group conducted on behalf of the Office of the State Auditor. The audit was conducted pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of state government. This report presents our findings, conclusions, and recommendations, and the responses of the Department of Health Care Policy and Financing.

Sincerely,

Kim Gordon  
President

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**Report Summary**

**Medicaid Prescription Drug Program**  
**Performance Audit**  
**September 2004**

**Authority, Purpose, and Scope**

This report presents the results of our performance audit of the Medicaid prescription drug program. The audit reviewed prescription drug claims to ensure the State is paying these claims appropriately and applying effective mechanisms for controlling prescription drug costs. The audit was conducted on behalf of the Office of the State Auditor under the authority of Section 2-3-102, C.R.S. and in accordance with generally accepted government auditing standards. We gathered information from Medicaid program policies, procedures, and prior authorization criteria. We analyzed claims data and prior authorization records and interviewed Department personnel and personnel from other states and the federal government. Audit work was performed between March 2004 and July 2004.

We acknowledge the cooperation of Department management and staff in providing information and data for our review. Additionally, we acknowledge the participation of staff from the Medicaid fiscal agent, Affiliated Computer Services.

**Overview**

Medicaid (Title XIX of the Federal Social Security Act) is a federal-state program that provides health care coverage to low income individuals and families. To receive federal funding under Title XIX, states must provide Medicaid benefits to certain categories of persons and must provide certain medical services to all Medicaid recipients. Federal law gives states flexibility to determine whether to include other types of medical care in their Medicaid State Plans, thus qualifying them for federal matching payments. One optional area of coverage is outpatient prescription drugs. All states, including Colorado, cover outpatient prescription drugs for their Medicaid eligible populations and Medicaid is currently the largest public payer of outpatient prescription drugs in the nation.

Colorado's Medicaid Program covers outpatient prescription drugs and some over-the-counter medicines when prescribed by a physician or by another licensed health care professional for health maintenance or for the cure, mitigation, or prevention of disease. The Program also covers drugs provided to individuals in hospitals, doctor's offices, and other institutional settings; however, drugs provided in these settings are not covered under Medicaid's outpatient prescription drug program but through different Medicaid service categories.

The Colorado Department of Health Care Policy and Financing is the single state agency responsible for the administration of Medicaid programs, including prescription drugs. In Colorado, Medicaid fee-for-service (FFS) prescription drug expenditures have grown by 78 percent during the past 5 years, from slightly less than \$98 million in Fiscal Year 1999 to more than \$174 million in Fiscal Year 2003. During this same time period, prescription drug expenditures increased an average of about 16 percent annually, compared with a 9 percent average annual growth for total Medicaid expenditures in the State.

## **Summary of Audit Comments**

### **Prescription Drug Payments**

Our audit reviewed Department efforts to control the price of prescription drugs and to ensure the accuracy of payments. We identified problems in the following areas:

- **Non-covered drugs.** We identified an estimated \$500,000 in questionable payments for non-covered drugs (drugs that are restricted by federal or state mandates) during Fiscal Year 2003. The Department could potentially lose \$242,000 in federal matching funds for payments made for drugs that appear to be ineligible for federal matching payments.
- **Fiscal agent pricing errors.** The Department's fiscal agent overpaid Medicaid pharmacy providers by more than \$1.4 million during Fiscal Year 2003 due to pricing errors. The Department needs to investigate and recover these overpayments from the fiscal agent.
- **Pricing limits.** The Department needs to apply common pricing limits used by other states to control the prices paid for prescription drugs. If Colorado implemented a State maximum allowable cost program (MAC), as other states have done, the Department could reduce Medicaid prescription drug program costs by an estimated \$12 million annually.
- **Drug rebates.** At the time of our audit, the Department had not recovered \$1.4 million in outstanding rebates from drug manufacturers. In addition, the Department did not know the amount of interest due the State on these outstanding rebate accounts.
- **Pharmacy records.** The Department should expand its oversight of pharmacy records to detect and deter fraudulent pharmacy billing practices. Department pharmacy audits should review hard copy prescription documentation and dispensing logs indicating that Medicaid recipients have, in fact, picked up their prescriptions.

### **Prescription Drug Utilization**

Our audit also reviewed Department efforts to control utilization of Medicaid prescription drugs. We found that the Department's utilization controls for one high cost drug saved the State approximately \$1.4 million during Fiscal Year 2003. Additionally, Department prescription limits on Oxycontin, a drug with a high street market value, reduced expenditures by about

\$550,000 during the first six months after implementation. However, we identified weaknesses in the Department's management of utilization controls in the following areas:

- **Prior authorization.** Our audit determined that, of a sample of 563 prior authorization records, 153 (or 27 percent), lacked information to support the authorization or were not approved in accordance with Medicaid prior authorization guidelines. We also found that the Department's prior authorization denial rate was 12.2 percent; significantly less than the rate among some other states, suggesting that Colorado's drug benefit program is less restrictive than it could be.
- **Pharmacy overrides.** Pharmacists may override prescription limits or prior authorization requirements in certain instances, such as emergencies. During Fiscal Year 2003, we identified almost \$1.25 million in questionable pharmacy overrides, including emergency and early refills. One home health provider alone submitted \$150,000 in emergency overrides to bypass the prior authorization approval process.
- **Preferred drug list.** A preferred drug list (PDL) is a list of drugs considered to be the most cost effective choice of drugs for treating particular conditions. Colorado is one of only six states that does not have either an operating preferred drug list or one that is pending. Other states have reported substantial savings from implementing preferred drug lists.
- **Prescription or dispensing limits.** States may control inappropriate drug utilization by imposing limits restricting the amount of certain drugs that Medicaid recipients may receive. We found that the State could realize savings if it adopted additional prescription and dispensing limits, as other states have done.
- **Fiscal agent oversight.** Our audit identified significant overpayments, improper payments, and questionable prior authorization approvals. All of these issues raise serious concerns about the Department's effectiveness in overseeing the fiscal agent and managing the Medicaid prescription drug program. Our findings could be addressed if the Department adequately monitored fiscal agent activities.

The Department of Health Care Policy and Financing agreed or partially agreed with 9 of the 10 recommendations in this report. The full texts of the Department's responses are contained in the body of the report.

## RECOMMENDATION LOCATOR

### All Recommendations addressed to the Department of Health Care Policy and Financing

Recommendation Number	Page Number	Recommendation Summary	Agency Addressed	Agency Response	Implementation Date
1	15	Improve oversight of payments for non covered and restricted, covered drugs to ensure payments are accurate and allowable.	Department of Health Care Policy and Financing	Partially Agree	July, 2005
2	18	Ensure accurate fiscal agent drug pricing and enforcing standard recovery procedures from the fiscal agent for payments made due to pricing errors.	Department of Health Care Policy and Financing	Agree	April, 2005
3	20	Evaluate and implement additional prescription drug pricing limits such as a comprehensive State Maximum Allowable Cost Program and the Department of Justice's Average Wholesale or Average Sales Price program.	Department of Health Care Policy and Financing	Agree	July, 2005
4	23	Maximize drug rebate collections by improving the drug rebate accounting system and tracking rebate amounts to establish benchmarks and monitor trends. Use the dispute resolution services of the Centers for Medicare and Medicaid Services, when appropriate.	Department of Health Care Policy and Financing	Agree	March, 2005
5	25	Improve oversight of pharmacy record keeping to ensure adequate controls for detecting and deterring fraudulent billing practices.	Department of Health Care Policy and Financing	Agree	December, 2004
6	31	Improve the effectiveness of the prior authorization program and ensure that Medicaid payments are appropriate for restricted, covered drugs.	Department of Health Care Policy and Financing	Agree	April, 2005
7	34	Strengthen controls over pharmacy overrides by conducting regular audits, expanding analytical review to detect patterns of misuse or abuse, conducting provider education and outreach, and establishing additional internal controls for drugs that are clinically inappropriate or subject to fraud and abuse.	Department of Health Care Policy and Financing	Agree	November, 2005

## RECOMMENDATION LOCATOR

### All Recommendations addressed to the Department of Health Care Policy and Financing

8	36	Implement a preferred drug list. Where appropriate, adopt best practices and partner with other states to reduce administrative burden. Produce fiscal impact analyses and share findings with the public.	Department of Health Care Policy and Financing	Disagree	
9	37	Assess, identify, and adopt other State Medicaid “best practices” for prescription drug coverage limits.	Department of Health Care Policy and Financing	Agree	July, 2005
10	40	Develop a strategic plan for overseeing fiscal agent activities that includes: conducting internal analytical reviews and audits, reviewing the adequacy of the fiscal agent's quality control processes and procedures, identifying and recovering incorrect or improper overpayments from the fiscal agent, and developing and disseminating useful reports.	Department of Health Care Policy and Financing	Agree	July, 2005

# Description and Overview of Medicaid's Prescription Drug Program

## Chapter 1

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### Medicaid Program

Medicaid (Title XIX of the Federal Social Security Act) is a federal-state program that provides health care coverage to low income individuals and families. Medicaid is an entitlement program. This means that any state participating in the program must serve all eligible and enrolled individuals. To receive federal funding under Title XIX, states must provide Medicaid benefits to the following categories of persons:

- Low-income families with children
- Recipients of Supplemental Security Income (SSI) for the Aged, Blind and Disabled (this includes disabled children)
- Individuals qualified for adoption assistance agreements or foster care maintenance payments under Title IV-E of the Social Security Act
- Qualified pregnant women
- Newborn children of Medicaid-eligible women
- Various categories of low-income children
- Some low-income Medicare beneficiaries.

Federal Law requires certain basic services be available to all Medicaid recipients. These federally-required services include:

- Inpatient and outpatient hospitalization
- Physician services
- Medical and surgical dental services
- Laboratory and radiology services
- Nursing facility services for persons age 21 and older
- Rural health clinic services.

Title XIX gives states flexibility in determining whether to include other types of medical care in their Medicaid State Plans, thus qualifying them for federal matching payments. One optional area of coverage is outpatient prescription drugs. Although the level of optional service coverage varies across state Medicaid programs, all states cover outpatient prescription drugs for their Medicaid eligible populations.

## **Medicaid Program Administration**

By statute, the Colorado Department of Health Care Policy and Financing (the Department or HCPF) is the single state agency responsible for the administration of medical assistance programs (Medicaid) in accordance with Title XIX of the federal Social Security Act. Individuals determined to be eligible for benefits under the Medicaid Program are free to choose a provider from any institution, agency, or health professional, who has agreed to serve Medicaid recipients and who has a contract with the Department. The Colorado Department of Human Services (DHS) determines an individual's eligibility for Medicaid through county departments of social services and certain non-county entities. The Department of Human Services also administers programs such as mental health and developmental disabilities that receive Medicaid funding.

The Department of Health Care Policy and Financing contracts with a fiscal agent—currently Affiliated Computer Services (ACS)—to process provider claims for services rendered under the rules and regulations defined by the Department. As part of its Medicaid plan, each state is required by federal regulations to have an automated claims processing and information retrieval system. In Colorado, ACS processes prior authorization requests (discussed in detail later in the report) and claims for Medicaid prescription drug benefits using the Medicaid Management Information System (MMIS) and the Prescription Drug Claim System (PDCS). The Department is responsible for overseeing all fiscal agent activities to ensure the fiscal agent makes provider payments in an accurate and timely manner.

The Department also delegates the management of the Medicaid drug information file used to price prescription drug claims to its fiscal agent. It is ACS's responsibility to manage Colorado's drug information file so Medicaid will only pay for covered drugs. The fiscal agent contracts with First Databank, a proprietary database vendor used by most states' Medicaid programs, to maintain coverage status, pricing information, and the status of federal rebate agreements. According to Department personnel, ACS has one staff who manages the drug information files for eight Medicaid programs. This individual screens and removes non covered drugs from the authorized payment lists, based on each state's specific criteria.

## **Medicaid Spending**

Funding for the Medicaid program is shared between the federal and state governments and is based on a state's per capita income. If a state's per capita income is equal to or greater than the national average, the federal share is 50 percent. If a state's per capita income is lower, the federal share increases up to a maximum of 76.6 percent. Colorado's federal share (or match) is typically 50 percent. However for a short period in Fiscal Year 2003 the federal share was 52.95 percent. Nationally, Medicaid spending grew at an average annual rate of 11.5 percent between 1992 and 2002, from \$119.5 billion to \$257.3 billion. In 2003 two categories of Medicaid recipients—people who are elderly (aged 65 and older) and people who are disabled—were responsible for a majority of the total national expenditures for Medicaid. These two groups of recipients accounted for almost 70 percent of expenditures but represented only about 25 percent of the total Medicaid population. By contrast, adults (under age 65) and children represented about 75 percent of enrollment but were responsible for less than one-third (about 31 percent) of total Medicaid spending.

Like other states, Colorado has experienced steady growth in both Medicaid spending and in the number of Medicaid recipients. From Fiscal Year 1999 through Fiscal Year 2003 Colorado's Medicaid expenditures increased by 44 percent from about \$1.8 billion to more than \$2.6 billion. Correspondingly, the number of recipients increased by 42 percent from 231,000 in 1999 to 329,000 in State Fiscal Year 2003.

According to Department of Health Care Policy and Financing personnel, a number of factors have contributed to the increases in Medicaid expenditures and recipients in Colorado. These factors include the economic downturn in recent years resulting in increased caseloads and cost shifting to fee-for service which resulted in fewer recipients being enrolled in managed care.

## **Prescription Drug Coverage**

Colorado's Medicaid Program covers outpatient prescription drugs and some over-the-counter medicines when prescribed by a physician or by another licensed health care professional for health maintenance or for the cure, mitigation, or prevention of disease. The Program also covers drugs provided to individuals in hospitals, doctor's offices, and other institutional settings. However, drugs provided in these settings are not covered under Medicaid's outpatient prescription drug program but through different Medicaid service categories. Prescription drugs must be dispensed by licensed authorized practitioners on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records. States opting to provide prescription drugs are required to cover all drugs approved by the Food and Drug Administration (FDA) that are made by manufacturers that have entered into a federal rebate agreement. In exchange, states receive rebates based on formulas established in federal law. Other than this requirement, states have significant flexibility over the design of their prescription drug benefits. For example, states can limit the number of doses, require generic equivalents for brand name drugs, or make coverage of all or some medications subject to prior authorization.

In general, Medicaid prescription drug coverage can be classified into one of four categories:

- Covered as a regular benefit with no restrictions or limitations (i.e. diabetes medication)
- Covered but with restrictions or limitations (i.e. smoking cessation products)
- Not covered because drugs are not eligible for federal matching funds (i.e. drugs with no federal rebate agreement); and
- Not covered because the state voluntarily chooses to exclude coverage (i.e. Colorado excludes over-the-counter cough & cold products for persons more than 21 years of age in some situations).

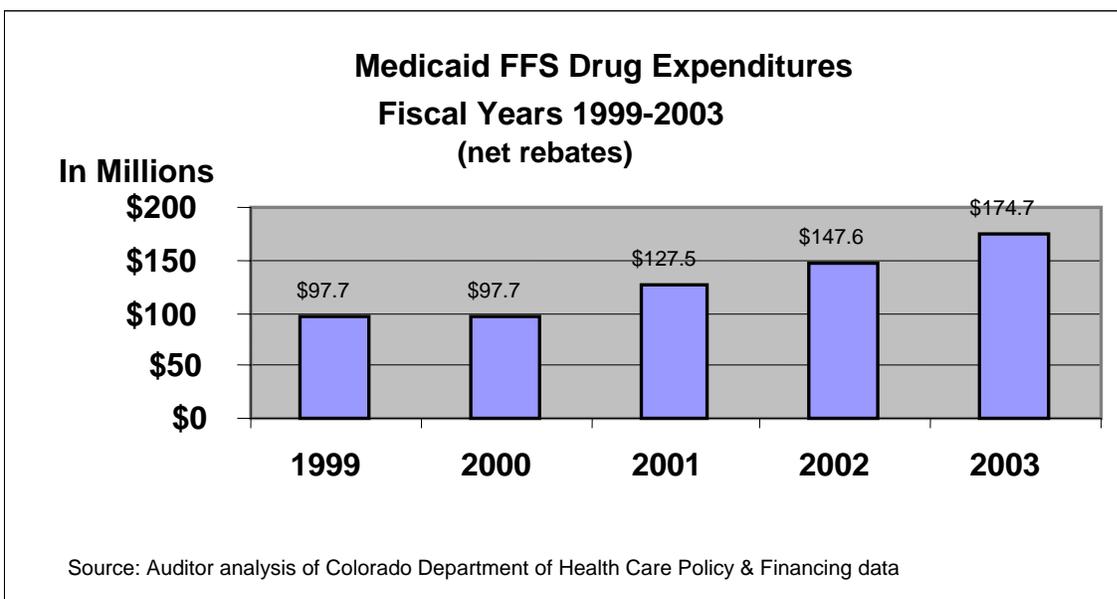
## **Medicaid Prescription Drug Spending**

Medicaid is currently the largest public payer of outpatient prescription drugs. According to one national study, in 2002, Medicaid programs and Medicaid managed care plans spent an estimated \$29.7 billion for prescribed drugs. In addition, prescription drugs are one of the fastest growing Medicaid expenses. Nationally, Medicaid expenditures for prescribed drugs doubled between 1998 and 2002 and quadrupled since 1992. In a June 2004 issue paper, the Kaiser Commission on Medicaid and the Uninsured reported:

The share of Medicaid spending attributable to prescribed drugs also grew in recent years. In 1998, less than 8 percent of Medicaid expenditures were for outpatient prescribed drugs; by 2002, this share climbed to over 11 percent. Between 2000 and 2002, expenditures for prescribed drugs (fee-for-service only) increased by an average of 18.8 percent per year, faster than any other major type of Medicaid-covered service.

In a 2001 national survey, Medicaid officials in 48 states identified pharmacy costs as one of the top two or three factors responsible for the overall rise in Medicaid costs. Thirty-six state officials cited pharmacy costs as the number one factor. It should be noted that the rapid growth of drug expenditures is not limited to Medicaid. The Federal Centers for Medicare and Medicaid Services (CMS) estimates that prescription drug spending by private insurers grew by an average of 17.4 percent per year between 1999 and 2002, comparable to the 18.0 percent growth in Medicaid.

As the following exhibit shows, Colorado's Medicaid fee-for-service (FFS) prescription drug expenditures have grown considerably (78 percent) during the past 5 years, from slightly less than \$98 million in Fiscal Year 1999 to more than \$174 million in Fiscal Year 2003.



*Note: Actual FFS drug expenditures are greater because these figures are net of drug rebates.*

Overall, during Fiscal Years 1999-2003, fee-for-service prescription drug expenditures increased about 16 percent per year compared with an average annual growth of 9 percent for total Medicaid expenditures in the State.

## **Audit Scope & Methodology**

This audit reviewed the Department of Health Care Policy and Financing's oversight of the Medicaid fee-for-service, outpatient prescription drug program. More specifically, the audit determined whether:

- Payments for prescription drug claims were made for covered benefits only and were priced accurately.
- Drug utilization controls such as prior authorization and other dispensing limits were appropriate, properly implemented, and effective in decreasing or lowering the rate of growth of prescription drug expenditures.
- The Department of Health Care Policy and Financing has adequately identified and implemented cost containment programs that either reduce or slow the rate of growth in prescription drug expenditures.
- The Department of Health Care Policy & Financing exercised adequate program management oversight and implemented sufficient controls to ensure compliance with all federal and state statutes, administrative rules, and policies and procedures.

We reviewed Medicaid program policies, procedures, and prior authorization criteria. We analyzed claims data and prior authorization records and interviewed Department personnel and personnel from other states and the federal government. We acknowledge the cooperation of Department management and staff in providing information necessary for our review.

# Prescription Drug Payments

## Chapter 2

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### Overview

As previously mentioned, Medicaid prescription drug coverage has contributed significantly to the steady increase in total Medicaid spending. Projections are that as the population ages and the use of higher cost drugs becomes more prevalent, spending will increase even more. Therefore, containing the cost for Medicaid prescription drug coverage has become an area of focus for most states' Medicaid agencies. In Colorado, as in other states, cost containment strategies generally take two forms:

- Strategies that reduce payments to pharmacies by reducing either or both the amount paid for the drug itself or the amount paid to the pharmacy for dispensing the drug.
- Strategies that reduce or limit utilization of drugs on the part of Medicaid recipients.

In this chapter, we discuss the first of these two strategies—reducing the amounts paid to pharmacies for prescription drugs. In addition, we evaluate whether the Department has implemented adequate methods to ensure the accuracy of Medicaid payments. The accuracy of Medicaid prescription drug payments is critical not only for budgetary purposes but also as a means of protecting against fraud and abuse by ensuring improper payments are not made for drugs not covered under Medicaid.

Overall, we found that although the Department has adopted measures to reduce prescription drug payments, it does not do enough to ensure these measures are enforced. Adequate controls do not exist to ensure against the payment of non covered or restricted drugs or to identify and recover improper payments, overpayments, or rebates due the State. As a result, we estimate that in Fiscal Year 2003 the Department made Medicaid payments totaling \$1.9 million for drugs that potentially were not eligible for federal matching funds, were restricted under Colorado's Medicaid drug benefit plan, or were overpaid due to pricing errors. We also found that if Colorado implemented a State maximum allowable cost program (SMAC), as other states have done, Medicaid prescription drug program costs could be reduced by an estimated \$12 million annually.

# Non Covered Drugs

Non covered drugs are those drugs for which Medicaid will not pay. Within the Colorado Medicaid Program there are two basic categories of non covered drugs. These are drugs restricted by federal mandates and drugs restricted by state mandates:

**Drugs restricted by federal mandates.** There are two types of federally-defined, non covered drugs:

- DESI Drugs - In 1962, the Federal Food, Drug and Cosmetic Act was amended to require that drugs sold in the United States be regulated more closely. Under the provisions of the 1962 amendments, all new drugs must be shown, by adequate studies, to be both safe and effective before they can be marketed. The Drug Efficacy Study Implementation (DESI) program was established within the Food and Drug Administration (FDA) to review the effectiveness of drugs. If a DESI review indicates a lack of substantial evidence of a drug's effectiveness for all of its labeled purposes, federal matching funds will not be available under Medicaid. An example of a DESI drug is Midrin, which is promoted for the treatment of migraine headaches. According to federal law, federal matching funds are not available for drugs with a DESI classification.
- Drugs with no signed rebate agreement - The Medicaid Drug Rebate Program created in 1990 by the Omnibus Budget Reconciliation Act (OBRA), requires a drug manufacturer to enter into a national rebate agreement with the Secretary of the Department of Health and Human Services (DHHS) if state Medicaid programs are to receive federal matching funds. The drug rebate program is administered by the federal Centers for Medicare and Medicaid Services (CMS). Drug manufacturers must sign agreements with DHHS and CMS to have their drugs covered by Medicaid. Approximately 550 pharmaceutical companies participate in this program. Forty-nine states, (Arizona is excluded,) and the District of Columbia cover drugs under the Medicaid Drug Rebate Program. The Colorado Department of Health Care Policy and Financing's Administrative Rules state that "only those drugs supplied by companies participating in the federally-approved Medicaid drug rebate program are regular drug benefits." Colorado's Medicaid program rules permit drugs not covered by rebate agreements to be covered, but, only if there is no equivalent substitute. In these instances, physicians must obtain advance approval from the Department for Medicaid to pay for a drug without a rebate agreement. If approved, Medicaid pays for these non covered drugs entirely with State funds. According to federal law, federal matching funds will only be available for covered, outpatient drugs when a drug manufacturer has an active rebate agreement with DHHS. CMS has the ability to disallow federal payments and can do so retroactively if it discovers states are covering drugs that don't have a drug rebate agreement with DHHS.

**Drugs restricted by state mandates.** The Omnibus Budget Reconciliation Act authorized state Medicaid agencies to exclude or restrict the drug benefit coverage of certain federally-defined drug categories. Colorado has excluded or set limits on several drug categories to reduce drug utilization and costs. The following table describes each category of drugs Colorado has chosen to exclude or limit:

<b>Colorado Medicaid OBRA 90 Exclusion Categories</b>		
<b>Category</b>	<b>Coverage</b>	<b>Criteria</b>
<b>Agents to treat anorexia or weight gain</b>	Not Covered	
<b>Agents to promote fertility</b>	Not Covered	
<b>Agents used for cosmetic or hair growth purposes</b>	Not Covered	
<b>DESI drugs</b>	Not Covered	
<b>Agents used for relief of cough and colds</b>	Limited	Covered for children under age 21; Limited Coverage for Adults over 21 years of age.
<b>Prescription vitamins and minerals (except prenatal vitamins and fluoride preparations)</b>	Limited	Multivitamins are not covered. Vitamins can be obtained when a specific vitamin deficiency exists.
<b>Non-prescription or Over-the-Counter Drugs</b>	Limited	Persons with End Stage Renal Disease needing vitamin supplements due to dialysis. Aspirin and insulin are covered
<b>Source:</b> Auditor analysis of Department of Health Care Policy and Financing data.		
<b>Note:</b> Limited coverage requires prior authorization approval		

## **Non Covered Drug Payments**

Despite the non covered status of certain drugs, we identified at least \$500,000 in questionable payments for these drugs during Fiscal Year 2003. Consequently, we estimate the Department also could potentially lose up to \$242,000 in federal matching funds because it made payments for these federally-defined, non covered drugs that appear to be ineligible for federal matching payments. Specifically, we found:

- **Payments for federally-defined, non covered drugs.** We compared Fiscal Year 2003 paid drug claims with April 2004 drug rebate and DESI drug data obtained from the Centers for Medicare and Medicaid Services' (CMS) web site. We identified \$44,000 in questionable payments for DESI drugs that did not appear to be eligible for Medicaid coverage. We also found that the Department paid for drugs that no longer had federal rebate agreements. That is, the national rebate agreements with the drugs' manufacturers had terminated. We estimate the potential amount of the Department's payment for these non covered drugs to be \$414,000.

We recognize the inherent limitations in comparing claims data from Fiscal Year 2003 with CMS rebate and DESI drug information from April 2004. Data on the status of rebate agreements and DESI drug designations are time sensitive—drugs are continuously added and deleted from these two data sources. Therefore, drugs that may have been covered in Fiscal Year 2003 may not have been covered in April 2004.

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However, these data were the most reliable available during our review. In addition, our comparison highlights discrepancies between the databases and, as described in greater detail later in this section, underscore the need for the Department to establish an ongoing reconciliation process with the CMS drug rebate product file and the DESI list to ensure that drugs found on the Medicaid drug file are eligible for federal matching funds. Department staff have told us that some of the incorrect payments we identified are explained by the differences in the dates of the data used in this analysis. We have provided the Department with all of the data related to the questionable payments so that staff can conduct a comprehensive evaluation or reconciliation.

- **Payments for state-restricted or non covered drugs.** We evaluated Fiscal Year 2003 Medicaid payments for 733 clients on 2,253 claims for the OBRA Exclusion categories outlined in the above table. We found improper payments totaling \$49,000 for agents used for cosmetic purposes, cough and cold products for persons over 21 years, multivitamins, and over-the-counter drugs or other restricted items that should have billed as supply items. We did not identify any improperly paid claims for drugs to treat anorexia, weight gain, or to promote fertility.

The Department also pays for some other restricted items, such as smoking cessation drugs that are not included in the OBRA exclusion categories. In reviewing four years of data, we found that the payment requirements for smoking cessation products were adhered to, and no recipient obtained more than a one-time, lifetime benefit. However, we did identify other improper payments. Specifically, we found \$34,000 of payments for non covered items (including an estimated \$2,000 in pharmacy dispensing fees) were for medical supplies and infant formula. These two items are covered by Medicaid but under different Medicaid program categories. Therefore, they should not have been paid for with Medicaid prescription drug funds.

## Controls Over Inaccurate Payments

As previously stated, the Department contracts with another entity to serve as its fiscal agent. Affiliated Computer Services (ACS) is responsible for processing claims submitted by providers in accordance with state Medicaid policy and contractual provisions. Claims processing is to occur in a timely and accurate manner. The fiscal agent's responsibility includes ensuring payments are not made for drugs that are disallowed either by federally-defined criteria or by Colorado's State Medicaid Plan. Although the Department, through its contractual agreement, has delegated responsibility for claims' payment to the fiscal agent, it retains ultimate statutory authority and responsibility for this function.

We identified several areas in which the Department needs to be more diligent and proactive in its oversight and management of this critical and costly aspect of the Medicaid prescription drug program. These areas are described below.

- **Adopt adequate procedures for verifying data accuracy.** The Department's fiscal agent does not use the most accurate and current information to determine whether prescription drug claims are eligible for payment. Because the eligibility for federal funds for certain drugs may change frequently (e.g. drugs are added and deleted from DESI and rebate lists,) timely updates are essential. Currently, ACS policies and

procedures do not require staff to verify the accuracy of their data on the covered/non covered status of prescription drugs (held at First Databank) with the Centers for Medicare and Medicaid Services' drug rebate product data file and the federal DESI list. As a result, discrepancies exist. When the First Databank data are incorrect, the state Medicaid program pays for non covered drugs AND loses the federal match. When the data from CMS are inaccurate, the state Medicaid program pays for the non covered drugs but retains the federal share. Because the fiscal agent does not compare the data contained within these two systems, the State can potentially lose 100 percent of its federal match when the fiscal agent makes a payment for a federally-defined non covered drug.

- **Implement monitoring and reporting mechanisms.** Currently the Department produces reports for payments of some restricted and non covered drugs. However, these utilization reports are of limited value. For example, the Department does not produce a report that monitors payments of DESI drugs. In fact, Department staff were unaware the fiscal agent had potentially paid claims for this non covered drug category. The Department should routinely produce and review reports that trend claims by drug, prescriber, recipient, or pharmacy. Reports of this nature would provide timely notice of inappropriate billing patterns and provide opportunities to develop procedures and provider education to eliminate inaccurate payments in the future.
- **Recover improper overpayments from the fiscal agent** - The State's contract with ACS states, "*the contractor shall be liable for the actual amount of all Contractor-caused overpayments, duplicate payments or payments that should have been denied....The contractor shall be liable for the actual amount of the Contractor-caused overpayments that are not recovered...*" Although the Department has the ability to invoke financial penalties and recover improper payments from the fiscal agent, Department staff told us this has occurred only one time. However, staff were unable to provide us with any details about this particular recovery. The Department should actively pursue recoveries from the fiscal intermediary as a remedy when payment policies and procedures are not followed.

## Recommendation No. 1:

The Department of Health Care Policy and Financing should improve its oversight of prescription claims' payments of non covered and restricted, covered drugs to ensure payments are accurate and allowable by:

- a) Requiring the fiscal agent to compare drug rebate product files and DESI drug lists from the Centers for Medicare and Medicaid Services with data from First Data Bank on at least a monthly basis to ensure the most accurate data are used to determine allowable payments.
- b) Developing and reviewing monthly claims paid reports to ensure the fiscal agent is not processing drug claims that are not eligible for Medicaid reimbursement.
- c) Identifying and recovering from the fiscal agent all monies incorrectly paid for drug claims for DESI drugs, drugs with no federal rebate agreement, and any other payments which are not allowed under federal or state Medicaid statutes, rules, or plans.

## **Department of Health Care Policy and Financing Response:**

- a) Partially Agree. Implementation Date: July 2005. Effective October 2004, the Department will compare the drug rebate product files and DESI drug lists from CMS at least monthly. The Department will review the scope of work in its contract with the Fiscal Agent to determine how to best shift this comparison from Department staff to the Fiscal Agent. If additional resources are necessary, resources will be requested.
- b) After comparison of the drug rebate files and DESI, whether by Department staff or the Fiscal Agent, the Department will review and report any outliers.
- c) The Department will follow the procedures set forth in the Fiscal Agent contract to recover any payments inappropriately paid or in violation of federal guidelines.

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## **Prescription Pricing**

Medicaid prescription drug payments have two components: the drug ingredient cost and the dispensing fee, which is intended to compensate pharmacies for the administrative costs of distributing the drugs. States attempt to control pharmacy reimbursements by adjusting the payment formula for the drug portion of the payment and/or by reducing the amount of the dispensing fees. Pricing for drug costs is based on either a percentage discount off of the Average Wholesale Price (AWP) or a percentage increase added to the direct price. The AWP is the average list price that a manufacturer suggests wholesalers charge pharmacies and is typically less than the retail price, which will include the pharmacy's own mark up. The AWP is referred to as the sticker price because it is not the actual price larger purchasers, such as Medicaid, typically pay.

The federal government uses two methods to limit the amounts it will match for specific drugs paid for by state Medicaid programs. The first method is the federal upper limit (FUL). The FUL is the maximum allowable price at which the federal government will reimburse for drugs with generic equivalents. The second method is referred to as "lower of pricing" because it reimburses the lower of: 1) the estimated acquisition cost of a drug plus a dispensing fee; **or** 2) the usual or customary charges to the public. To ensure continued receipt of full federal matching funds for prescription drugs, states must enforce these two limits.

We reviewed the Department's adherence to the federal and state pricing limits for Fiscal Year 2003 by comparing paid claims data with the pricing limits in effect during the period the claims were paid. We found the Department's fiscal agent did not consistently apply the correct price limits. Consequently, during Fiscal Year 2003, the State overpaid Medicaid pharmacy providers more than \$1.4 million as described below:

- **Federal upper limit.** We reviewed 100 percent of the claims paid for a sample of 96 different drugs with a federal maximum allowable limit (FUL). We determined the fiscal agent paid 33 percent of the claims incorrectly. Based on the findings from our sample review, we estimate that if the appropriate upper limit had been applied on all of the more than 511,300 claims for all of the 428 drugs for which there was an FUL, the State would have spent \$1.4 million less for prescription drugs during Fiscal Year 2003.
- **Lower of Pricing.** To evaluate the accuracy of the Department's lower of pricing formulas; we reviewed pricing information for a sample of 829 drugs representing more than 18,200 pharmacy claims in Fiscal Year 2003. We found that 550 claims were paid incorrectly resulting in almost \$4,300 in overpayments because the lower of pricing method was not followed. We also assessed whether price changes were implemented correctly during the audit period by calculating the amounts paid before and after the date of a price change. We did not identify any pricing errors among the 829 drugs we reviewed.
- **Dispensing fees.** Pharmacies participating in the Medicaid program may charge Medicaid a "reasonable" fee per prescription dispensed. Each state Medicaid program has the discretion, with approval from the federal Centers for Medicare and Medicaid Services, to determine what "reasonable" means for their state program. In Colorado, dispensing fees vary depending on whether the pharmacy is a retail, institutional, or government provider. Currently the fees are set at \$4 for retail pharmacies and \$1.89 for institutional providers. There is no dispensing fee applied when the prescription is filled by a government provider. We assessed whether dispensing fees were applied appropriately and found that one institutional provider was paid the retail dispensing fee of \$4.08 instead of \$1.89. This error represented an overpayment of \$124 for 59 claims.

## Pricing Audits

Overpayments due to pricing errors can be attributed to weaknesses in fiscal agent oversight. We identified weaknesses related to a lack of adequate mechanisms to monitor payment activities. Specifically, we found that the Department needs to strengthen its audits of the accuracy of prescription drug claims' pricing. This should include:

- **Conducting routine audits of claims pricing activities.** Currently the Department relies on the fiscal agent to self-monitor and self-report results of its price monitoring activities. In the past, the Department conducted monthly claims' pricing audits for all Medicaid claims, including prescription drugs. The Department stopped conducting these monthly internal audits in April 2003. According to staff, the Department had to redirect staffing resources to meet the implementation requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996.

In our May 2001 Performance Audit of the Medicaid Management Information System, we recommended that the Department conduct regular claims audits on at least a quarterly basis. The Department agreed with this recommendation and stated that reviews were being done. In our current audit, we have identified gaps in compliance with pricing limits resulting in significant Medicaid prescription drug overpayments. Consequently, we are reiterating our previous recommendation that the Department conduct regular audits for pricing accuracy.

In addition to the lack of routine internal audits, the Department does not have a regular timetable for periodic independent or external audits. The last external drug claim audit was conducted in Fiscal Year 2003 and the Department has no plans, at present, for future audits of this nature. Periodic external audits would supplement the schedule of regular internal audits and provide additional independent assurances about pricing accuracy.

- **Sample sizes are not sufficient to evaluate compliance.** The Department processes approximately 18 million Medicaid claims per year. According to Department staff more than 4 million of these are prescription drug claims. When the Department conducted its monthly audits of all Medicaid claims payments, staff reviews 45 claims, including 3 drug claims each month. We question whether this sample size is sufficiently large to demonstrate compliance or to identify problems such as those identified in our audit. According to Department staff, sample size was not risk-based or based on any other specific criteria. We believe the Department should evaluate the total number of claims, as has been done in this audit, and determine an appropriate sample size from which to audit prescription drug claims. The Department could make use of any one of a number of readily available software applications to assist in this process. Selecting an appropriate sample size and conducting regular audits and/or analytical reviews ensure adequate audit coverage and increase the likelihood that improper payments and practices would be identified and addressed.

The Department needs to intensify its monitoring activities to identify improper payments and to recover over payments from the fiscal agent due to drug claims' pricing errors. The Department should conduct independent audits and increase the frequency of analytical reviews. Audits should be detailed and encompass statistically valid samples of drug claims for each type of pricing limit including: federal upper limits, lower of pricing, and dispensing fees. Changes to post payment recovery procedures should be made, if appropriate, and the Department should take steps to recover overpayments due to pricing errors from the fiscal agent and pharmacy providers. Given the volume and frequency of drugs claims that are processed and paid, the Department should implement these improvements as soon as possible.

## **Recommendation No. 2:**

The Department of Health Care Policy and Financing should ensure the accuracy of fiscal agent drug pricing by strengthening its audits of the prescription drug program to include pricing components and larger sample sizes, increasing the frequency of analytic reviews, using cost-effective, available software applications, and establishing and enforcing standard recovery procedures from the fiscal agent for payments made due to pricing errors.

### **Department of Health Care Policy and Financing Response:**

Agree. Implementation Date: April 2005. The Fiscal Agent currently reviews pharmacy claims in their monthly claim review process in which they check for accuracy of adjudication. The Department will work with the Fiscal Agent to increase the number of pharmacy claims they review each month. The Department will develop a pricing review

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of pharmacy claims to assure that only appropriate drugs are paid. The Department is currently participating in the Payment Accuracy Measure (PAM), a study that includes pharmacy claims and features statistically valid sampling. The next iteration of the project, Payment Error Rate Measurement (PERM), will enter a pilot year from October 2004 through September 2005. In FY 05, the Department will conduct a Claims Accuracy Payment System review with an emphasis on pharmacy claims.

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## Other Pricing Limits

In addition to the federally-mandated pricing limits discussed in the previous section, there are other limits states may impose on the prices they pay for prescription drugs. As described below, two of the more common limits used in other states are State Maximum Allowable Costs (SMAC) and Department of Justice Average Wholesale Pricing (AWP) or Average Sales Pricing (ASP):

- **State Maximum Allowable Costs (SMAC).** According to the National Pharmaceutical Council, in 2002, thirty-six states imposed state-specific upper limits or maximum allowable costs. A list of these states can be found in Appendix A. State MAC programs are similar to the Federal Upper Limit (FUL) program. However, an important difference is that State MAC lists typically include more drugs and assign lower prices than the FUL list. State Medicaid Programs also have greater flexibility in selecting drugs eligible for their MAC lists and in establishing limits on drug prices. According to a recent national study, states with established MAC programs have reported annual pharmacy budget savings of up to 4 percent.

In contrast with other states, Colorado currently administers a very limited state MAC program. Colorado has a limit on only one drug, clozapine. To demonstrate the fiscal impact of implementing a SMAC, we calculated the savings from the Department's enforcement of a maximum allowable cost on clozapine (an anti-psychotic prescribed for people with schizophrenia)—in Fiscal Year 2003. As a result of the SMAC on Clozapine during that period, the Department's expenditures for the drug decreased by 17 percent, or \$430,620.

To further emphasize the impact and potential savings of a comprehensive State MAC program, we obtained the Medicaid SMAC lists from Washington and Arkansas. We applied the maximum allowable costs in these states to Colorado's Fiscal Year 2003 prescription drug claims. We found that if Colorado adopted both of these states' MAC lists, it has the potential to achieve more than \$12 million in savings annually. It should be noted that our savings estimate assumes that all of the drugs on the Washington and Arkansas MAC lists would be applied in Colorado. Colorado could choose not to include all of the drugs on one or both of these lists or add additional, different drugs. Any of these changes would affect the amount of the potential savings. It should also be noted that pharmacies might bear a financial loss or a reduction in profits if a state-imposed price control program were implemented. In addition, if the Department caps the reimbursement for drug ingredient costs for certain drugs, some pharmacy providers may opt to stop participating in the Medicaid program. Regardless, we believe the savings potential from an expanded MAC program merits serious consideration by the Department.

- **Department of Justice AWP or ASP Pricing.** In 2001 the United States Justice Department revealed that in the early 1990s, pharmaceutical manufacturers falsely inflated average wholesale prices for some injectable and inhalation drugs. State Medicaid programs relied on the false prices and costs reported by pharmaceutical companies in calculating their reimbursements to pharmacists and doctors. Consequently, states paid substantially more than the true and correct price for these drugs. In 2001 the Justice Department released a list of 479 drugs with inflated AWP and compiled more accurate, alternative average wholesale price data for these drugs. This information, the “certified AWP,” is available to State Medicaid programs through First Databank. Currently, HCPF does not enforce the Justice Department’s AWP prices for these 479 drugs because Department staff believed pharmaceutical industry lawsuits would block the implementation of these price limits shortly after introduction to states in 2001. However, since that time, some states have implemented the Department of Justice’s AWP prices and none have been sued by manufacturers. Like the SMAC program, the lack of price limits for high cost injectable or inhalation drugs is another example of a missed opportunity to establish new financial controls on the Medicaid drug program budget.

We believe the Department of Health Care Policy and Financing should evaluate, implement, and report on other cost-effective price limits for its prescription drug program such as a state maximum allowable cost program and the Justice Department’s average wholesale pricing. A review of the professional literature and other states’ Medicaid programs suggests that State MAC programs are cost effective. A recent study of five State MAC programs found that, although creating and administering MAC lists can be tedious and resource-intensive, focusing on more aggressive pricing of generic drugs with a Federal Upper Limit can minimize the additional resources needed to start and maintain a State specific upper limit program. If non-Federal Upper Limit drugs are added, States should focus on drugs with the highest volume. Also, the resources needed to implement and administer a MAC program are minimized when states collaborate on one or more elements of the MAC list operations.

### **Recommendation No. 3:**

The Department of Health Care Policy and Financing should evaluate and implement additional prescription drug pricing limits such as a comprehensive State Maximum Allowable Cost Program and the Department of Justice’s Average Wholesale or Average Sales Price program.

#### **Department of Health Care Policy and Financing Response:**

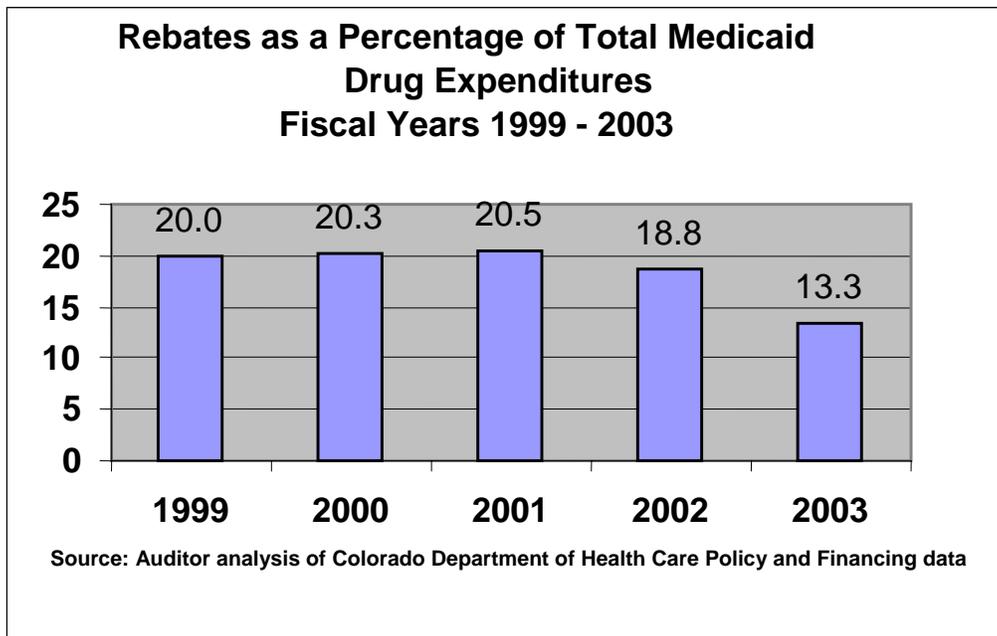
Agree. Implementation Date: July 2005. The Department agrees that it should evaluate and implement a State Maximum Allowable Cost program after complete review. This has been studied and implemented in several states and there have been significant savings. The Department further agrees that it should evaluate the Department of Justice’s Average Wholesale or Average Sales Price and determine whether implementation is beneficial and feasible in Colorado.

## Drug Rebates

Since 1991, state Medicaid programs have been able to recover a portion of their prescription drug payments by requesting rebates from drug manufacturers. State Medicaid programs reimburse pharmacies for dispensing prescription drugs to Medicaid recipients and recover a portion of these expenditures by submitting invoices to the drug manufacturers for rebates. Each state is responsible for developing an accounting system capable of properly recording and tracking rebate monies paid or owed and interest due on aged accounts. All prescription drugs are eligible for rebates except for drugs that:

- Are dispensed by certain entities that purchase drugs at deep discounts and pass on savings to Medicaid.
- Do not have a signed federal rebate agreement.
- Are paid for solely from state-funded general assistance or other federal drug rebate programs.

During the past five years, Colorado's Medicaid percentage of rebates collected, as compared with total prescription drug expenditures, has remained relatively stable with the exception of Fiscal Year 2003. The decline in FY 2003 occurred as a result of the Department's change to a cash accounting system. Therefore, only two quarters of drug rebate collections were accounted for in that year.



Overall, the Department's collection rates are similar to the collection rates of four other states (Missouri, Oklahoma, Tennessee, and Washington) contacted during our audit. However, because of the increasing Medicaid caseload and the importance of controlling Medicaid expenditures, we question whether HCPF is doing enough to expedite recovery of drug rebate

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revenues and increase the collection rate for drug rebates. At the time of our audit, the Department had not recovered \$1.4 million in outstanding rebates from manufacturers. In addition, the Department did not know the amount of interest due the state on these outstanding rebate accounts. We identified a number of areas upon which the Department has failed to place sufficient emphasis or has not focused its efforts on this well-established means of reducing Medicaid prescription drug costs. Examples include:

- **Lingering dispute resolution.** Manufacturers can and do dispute rebate amounts claimed by states. Disputes delay payment of the rebate until the issue is resolved. To facilitate dispute resolution, the federal Centers for Medicare and Medicaid Services has established an alternative dispute resolution program in which CMS staff provide state Medicaid programs and manufacturers mediation and program clarification. However, unlike many other states' Medicaid Programs, the Department has not taken full advantage of this service. Prompt resolution of disputes is critical because the longer the dispute remains outstanding, the more difficult it is to collect the rebate. We found the Department has some unresolved disputes or aged accounts for which it has not collected rebate revenue going back as far as 1995. The lack of prompt resolution is of particular concern at this time because new CMS guidelines, currently under review at the federal level, if approved, will place a three-year time limit on the collection of outstanding manufacturer rebates. Thus, if the Department does not resolve its outstanding disputed rebates in a more timely fashion, they will become uncollectible.
- **Reliance on drug manufacturers to calculate and remit interest on aged account receivables.** According to federal regulations, the total undisputed amount of an invoice is to be paid by the manufacturer within 38 days of receipt of the invoice. Interest starts accruing on day 39. We found that the Department does not know the amount of interest due on its aged rebate accounts. The Department has no automated or electronic method to assess or to calculate interest on disputed amounts. Consequently, all interest is calculated manually. This is problematic because interest rates change daily, necessitating timely updates to existing account information. Consequently, the Department relies on the drug manufacturers to calculate and remit interest. Further, the Department has no system for verifying the accuracy of the amounts paid by the manufacturers.
- **The need for a more effective drug rebate accounting system.** A manual database, separate from the Medicaid Management Information System (MMIS,) is used to account for and track rebates owed to Medicaid. The current system does apply both price and rebate unit changes retroactively for at least 12 quarters by creating prior period invoices. However, the Department acknowledges that the process of setting up receivables based on these invoices is not automated. This means every prior period adjustment must be recorded manually for each manufacturer with an account receivable. There is no system to verify the accuracy of the prior period adjustments recorded to the receivables, so the Department has no way of knowing whether manufacturers pay the correct amount on outstanding or disputed rebates. The Department needs to be able to apply retroactive price and unit changes automatically to account receivables to help reduce the number and amounts of disputes and increase the likelihood of timely rebate payments and collection.

Unlike many revenues which automatically flow to recipient entities, prescription drug rebates require action on the part of the Medicaid agency for payment to occur. We do not believe the Department is being sufficiently proactive and assigning a high priority to the collection of drug rebates. By not placing adequate emphasis on reducing disputed fund balances, increasing collection rates, and expediting recovery of rebate revenues, the Department is not taking advantage of an established mechanism for containing costs. We contacted four other state Medicaid programs in Missouri, Oklahoma, Tennessee, and Washington to identify best practices in drug rebate collection. We found that most states have reassigned or allocated additional staffing resources to resolve disputed rebates and/or to reduce backlogs. Colorado has one accountant assigned to record and track rebate monies paid or owed and to resolve outstanding disputed amounts. In addition, at least one state has established maximum and minimum billing thresholds to preempt disputes related to billing units. This automated, online system edit compares amounts billed by pharmacies to allowed amounts determined by the Medicaid drug pricing formulas. If the billed amounts are lower or higher than these thresholds, the drug claims are rejected as a billing unit error. At a time when Medicaid prescription drug expenditures and the Medicaid caseload is increasing, we believe it is incumbent upon the Department to use every viable method to curtail costs.

### **Recommendation No.4:**

The Department of Health Care Policy and Financing should maximize drug rebate collections through the Drug Rebate Program by:

- a) Improving the drug rebate accounting system to increase the collection rate and expedite recovery of rebate program revenue. The system should be automated and include, at a minimum, the ability to calculate rebate receivables, monitor outstanding rebates, calculate and collect interest owed on late payments, and automate rebate receivables adjustments due to retroactive price and rebate unit changes.
- b) Tracking rebate amounts invoiced, disputed, and collected to establish benchmarks and evaluate trends.
- c) Evaluating staffing/workload and assigning staff resources to compute interest on unpaid balances, properly track pricing and rebate per unit changes, research disputed rebates, and resolve all outstanding disputes with manufacturers in a timely manner.
- d) Investigating and implementing system edits which will prevent payment of claims that could lead to rebate disputes (i.e. billing units, billed amounts, etc.).
- e) Using the dispute resolution services of the Centers for Medicare and Medicaid Services, when appropriate.

### **Department of Health Care Policy and Financing Response:**

- a) Agree. Implementation Date: March 2005. The Department will evaluate staffing levels and examine system processes to determine the most cost-effective means to improve the drug rebate program. This cost/benefit examination will include an

- exploration of automated processes used in other states for interest calculation and the modification of receivables for retroactive unit rebate amount price changes.
- b) The Department has started work on calculating additional metrics to measure rebate amounts invoiced, disputed, and collected.
  - c) Please see response to a) above.
  - d) The Department will track disputes to determine patterns of problems that could be eliminated via a system edit to prevent claim payment and implement system edits where appropriate.
  - e) The Department will resolve disputes with manufacturers in the most cost effective way possible, including, where appropriate, the dispute resolution services of the Centers for Medicare and Medicaid Services.
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## **Pharmacy Record Keeping**

Pursuant to State Board of Pharmacy regulations and Medicaid rules, pharmacies must maintain prescription records as a condition of participating in Colorado's Medicaid program. The State Board of Pharmacy requires an exact duplicate of the original prescription be available in a reproducible format. Medicaid rules stipulate prescription orders must contain the date, name, strength, and quantity of each drug prescribed, and that records be stored for six years unless an additional retention period is required elsewhere in regulations or in the provider participation agreement. In addition, Colorado's Medicaid administrative rules require participating pharmacies to respond to audit requests for information including prescription records within 21 working days.

Maintaining proper prescription records is important because it supports patient safety and provides an official record of a patient encounter. In addition, documentation of prescription drug sales creates an audit trail thereby providing one control over fraudulent billing activities. According to a recent General Accounting Office (GAO) report, various schemes are used to defraud Medicare, Medicaid, and private insurers. At least one of these schemes—pill mills—is used to defraud Medicaid prescription drug programs. In a pill mill scheme, two or more parties, usually including a pharmacy, collude to generate a flood of fraudulent claims that Medicaid pays. According to the GAO, after a prescription is filled, the Medicaid recipient sells the medication to pill buyers on the street who then sell the drugs back to the pharmacy. Medicaid recipients participate in this scheme in exchange for cash, drugs, or other inducements. Strong oversight of pharmacy record keeping can help counter this and other fraudulent practices.

Currently the Department has provider participation agreements with more than 900 pharmacies to dispense prescription drugs to Medicaid recipients. We contacted 474 of these providers and requested a copy of one prescription order and a signature log or evidence of an electronic sale for one paid Medicaid prescription drug claim during Fiscal Year 2003. We sent written requests at least twice, and, in some cases, we made repeated telephone requests. There were 62

pharmacies (13 percent) that did not respond within the time frame required by the Medicaid program. We referred the names of the noncompliant pharmacies to the Department for possible further action.

Although 397 of the 412 pharmacies that responded to our request provided the required documentation, 9 pharmacies did not provide a copy of a prescription and 15 submitted the wrong date or no date for the signature log. Pharmacies are required to maintain a chronological log that contains the Medicaid recipient's signature or electronic evidence that a "sale" occurred. The purpose of this requirement is to ensure Medicaid does not pay for prescriptions that are not picked up and that are eventually returned to a pharmacy's inventory. Dates are important because if prescriptions are not picked up within 14 days, pharmacies are required to reverse the claims to refund the payments for the original prescriptions. The log maintenance requirement was added by the Department in response to recommendations made in a July 1999 Medicaid Fraud and Abuse Performance Audit by the Office of the Colorado State Auditor. At that time we estimated a potential loss in Medicaid prescription drug refunds of between \$3 and \$9 million over a six year period.

Although we did not find the lack of prescription records to be widespread or documentation of prescription drug sales to be inadequate among the pharmacies we reviewed, we believe the Department can improve its controls in this area by strengthening pharmacy program audits. Pharmacy audits are important for detecting and deterring fraud and abuse in the Medicaid Program. Currently, the Department's audits do not include reviews of hard copy prescriptions. The Department's Program Integrity Unit should request copies of prescriptions on file and review them during audits to verify the pharmacy provider has the authority to submit a claim for payment. Also, the Department should follow-up on pharmacies that fail to comply with audit requests by referring them for additional investigation or other appropriate action. Finally, the Department should continue to require and review electronic or hard copy evidence of sales and prescription pickup by recipients.

## **Recommendation No. 5:**

The Department of Health Care Policy and Financing should improve its oversight of pharmacy record keeping to ensure adequate controls for detecting and deterring fraudulent billing practices. Oversight activities should include, but not be limited to:

- a) Conducting periodic reviews to ensure pharmacies are maintaining proper documentation, including reviews of hard copy documentation.
- b) Conducting follow-up activities on pharmacies that fail to respond to audit requests, including the 62 pharmacies identified in our audit.
- c) Continuing to recover prescription refunds from pharmacies that cannot provide adequate documentation of prescriptions dispensed and picked up.

**Department of Health Care Policy and Financing Response:**

- a) Agree. Implementation Date: December 2004. The Department agrees to conduct periodic reviews to ensure pharmacies are maintaining proper documentation. Pharmacy audits will include a request for a copy of the prescription. The Department has a contract with an auditor that requires copies of the original prescription documentation for pharmacy audits.
- b) The Department will conduct follow-up activities on the 62 pharmacies identified in the audit, including recoveries where appropriate.
- c) The Department will continue its efforts in recovering for prescriptions from pharmacies that cannot provide adequate documentation.

# Prescription Drug Utilization

## Chapter 3

### Overview

In Chapter 2 we discussed our findings relative to controls aimed at reducing pharmacy payments. In this chapter we discuss controls to discourage or decrease prescription drug utilization and overutilization and, thereby, decrease costs. These drug utilization limits range from administrative restrictions to patient-level limits or disincentives. The following table summarizes the most common types of utilization controls used by Colorado and other states.

Utilization Control Strategies		
Category	Type	Description
Administrative	<ul style="list-style-type: none"> <li>• Drug Utilization Review</li> <li>• Exclude Certain Drugs</li> <li>• Generic Substitution</li> </ul>	Change prescribing behavior or prevent inappropriate prescribing and dispensing.
	<ul style="list-style-type: none"> <li>• Prior Authorization</li> <li>• Formularies or Preferred Drug Lists</li> </ul>	Require physician or pharmacist intervention creating administrative hurdles delaying or preventing access to drugs.
Patient Level	<ul style="list-style-type: none"> <li>• Prescription Limits</li> <li>• Cost Sharing</li> </ul>	Impose additional financial burden on recipients
<b>Source:</b> September 2002 Kaiser Commission Report on Medicaid and the Uninsured.		

Federal law gives states the authority to implement prior authorization requirements and impose other limitations on drug benefit coverage to discourage waste, address instances of fraud or abuse, and to secure cost savings. A Medicaid program may require prior approval before paying for a prescription or over-the-counter drug and may design and implement a formulary (i.e. preferred drug list). Drug formularies and prior authorization programs must meet specific requirements established by federal, and in some instances, state statutes. If a state chooses to restrict drug coverage, it must specify in its State Plan the coverage limits for each drug class or drug. Drugs excluded from a formulary can be available through prior authorization if the drug has a federal rebate agreement.

Overall, our audit found the Department of Health Care Policy and Financing has been successful in reducing or slowing the rate of growth of expenditures for several high cost drugs or for drugs with a potential for abuse. The Department has accomplished this by using both administrative and patient level utilization controls. We estimate the Department's controls over

utilization in these cases resulted in approximately \$1.4 million in savings in Fiscal Year 2003 for one drug category and slowed the rate of growth in expenditures for another category. In addition, as a result of new prescription limits for Oxycontin, a drug with a high street market value, the Department realized a 27 percent reduction in expenditures in the first six months post implementation. Despite these improvements, however, we found that weaknesses in management and oversight have diminished the effectiveness of the Department's utilization controls in reducing costs, and monitoring and controlling for error, fraud, and abuse. For example, we estimate that as much as \$1.25 million in pharmacy overrides for emergency fills, early refills, and drugs for pregnant women were either clinically inappropriate or violated the Department's policies.

## **Utilization Controls**

Throughout this report, we have discussed various caps, limits, or restrictions on Medicaid prescription drug spending and use. Although these controls are to be adhered to, there are exceptions. Exceptions are permitted so that Medicaid recipients are not denied access to needed, potentially life-saving, medicines. However, price and utilization restrictions can only be waived when specific actions are taken. In the following sections we discuss two of these actions—prior authorization and pharmacy overrides. We found that the Department needs to do more to ensure these controls function in the ways in which they were intended. That is, limits or restrictions on payments and utilization are lifted only in specified situations and only when prescribed rules are followed. Otherwise, controls over Medicaid prescription drug spending serve little purpose and the potential for fraud and abuse increases.

### **Prior Authorization**

Prior authorization programs are one of the most common strategies used by states to contain costs by limiting recipient access to medications. Forty-eight states, including Colorado, currently operate a drug prior authorization (PAR) program. Prior authorization programs require physicians to request permission for a Medicaid recipient to obtain certain restricted prescriptions or over-the-counter drugs before a pharmacy can dispense and receive payment. For example, physicians can request, on behalf of a Medicaid recipient, prior authorization approval for smoking cessation products or to override a federal upper limit or generic mandate if the physician can show evidence of a recipient's allergic or adverse drug reaction to support the need for a brand name product. Federal law requires state Medicaid prior authorization programs to be responsive. Therefore, a prior authorization program must respond to requests within 24 hours and must allow pharmacies to dispense a 72-hour emergency supply when prior authorization staff is unavailable.

Among other functions and responsibilities, the Department of Health Care Policy and Financing delegates the administration of the Medicaid drug prior authorization program to its fiscal agent, Affiliated Computer Services (ACS). To carry out this responsibility, ACS operates a Prior Authorization Call Center on behalf of Colorado Medicaid. Call Center staff process prior authorization and override requests Monday through Friday from 8 a.m. until 10 p.m. EST. The Prior Authorization Call Center representatives are pharmacy technicians supervised by a nurse and clinical pharmacist. When a prior authorization request has been approved, the restriction or

control is lifted and the claim is paid. When ACS denies a prior authorization request, the client may appeal to the Department. Department staff then reviews the case and may overturn the denial.

The following table shows some of the drugs for which prior authorization is required by Colorado Medicaid. The Department added prior authorization restrictions or a combination of prior authorization restrictions and prescription limits to these drugs in Fiscal Years 2003 and 2004:

<b>Prior Authorization Requirements Adopted in Fiscal Years 2003 and 2004</b>		
<b>Effective Date</b>	<b>Drug Category/Drug</b>	<b>Description</b>
January 2003	Oxycontin	More than 2 times per day dosing requires prior authorization
January 2003	Claritin (non sedating antihistamine now available over-the-counter)	Requires prior authorization
January 2003	Proton Pump Inhibitors (gastric acid secretion reducers)	Clinical criteria requires prior authorization for extended therapy
March 2004	Selected Atypical Anti Psychotics (i.e. Zyprexa, Risperdal, and Abilify)	More than once daily dosing requires prior authorization
March 2004	Fentanyl patch (narcotic analgesic)	More than 1 patch every 48 hours requires prior authorization
March 2004	COX II (non steroid anti-inflammatory drugs)	For persons younger than 65 years prior authorization is required
<b>Source:</b> Colorado Medicaid Provider Billing Manual		

As a result of the implementation of prior authorization requirements for these drugs, we found the Department realized \$1.4 million in savings for one drug class—gastric acid reducers—and slowed the rate of growth in expenditures for Oxycontin, a narcotic pain reliever, by about \$550,000 (27 percent) six months after it imposed the prior authorization restrictions.

## **Prior Authorization Program Weaknesses**

Despite the Department’s success in reducing costs and decreasing the use of some drugs as a result of prior authorization requirements, we found a number of problems with the prior authorization program that significantly undermines its effectiveness. In addition, we found that the Department has been slow to establish additional prior authorization limits. We assessed the Department’s oversight of the fiscal agent’s performance in managing the Medicaid prescription drug prior authorization program. We selected several performance measures commonly used in the private sector to determine whether the fiscal agent was in compliance with federal and state statutes and with HCPF policies and procedures. The performance measures included: prior authorization denial rate, retroactive authorization rate, disagreement rate with decisions made by fiscal agent staff, and compliance with the federal requirement for prior authorization decisions within 24 business hours.

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Following are our findings in these areas:

- **Accurate and Consistent Application of Prior Authorization Criteria.** We reviewed 563 prior authorization records and compared those records with Medicaid prior authorization guidelines to determine whether the fiscal agent made the appropriate decision based on the clinical information recorded to approve a prior authorization. Of the 563 records for restricted drugs we reviewed, we identified 153 (or 27 percent) prior authorization approvals that were questionable. We questioned these approvals because either the information used to support the decision was insufficient or the approval was inconsistent with Medicaid prior authorization guidelines. Our review was conducted by a licensed pharmacist and physician. As stated previously, fiscal agent staff who make the decisions to approve or deny prior authorizations are not physicians. Neither are the Department staff who conduct subsequent reviews of prior authorizations approved or denied by ACS. Similar prior authorization reviews conducted in the private sector typically identify about 10 percent of claims approved by the fiscal agents as being questionable. More importantly, these private sector reviews typically incorporate reviews by licensed physicians.

We believe the 27 percent rate is unacceptably high. We found many exceptions and inconsistencies in the application of the prior authorization criteria suggesting fiscal agent staff need regular, ongoing training. For example, we noted multivitamins were approved for the following reasons: hair loss, vegetarian client, osteoarthritis, and pneumonia. Likewise, an over-the-counter moisturizing cream was authorized for a client with dry skin. We were unable to estimate the amount of inappropriate payments associated with these prior authorizations because we could not establish a link between the prior authorizations and the paid claims.

- **Denial Rate.** The Department's prior authorization denial rate is 12.2 percent which is significantly less than the rate among other states that more actively manage their drug formularies. These states report denial rates as high as 30 percent. The actual 12.2 percent rate suggests Colorado's drug benefit program is less restrictive than other states.
- **Retroactive Authorization Rate.** Almost one-fourth (23.5 percent) of the authorizations we reviewed were approved retroactively. We could not identify the reasons for the retroactive approval to determine whether the fiscal agent and HCPF staff followed Medicaid guidelines. It is possible these authorizations were given inappropriately to pay a drug claim because a provider had failed to obtain approval before the drug was dispensed. It is also possible the authorization was appropriate as in the case of a Medicaid recipient's retroactive eligibility. Regardless, retroactive authorizations need to be monitored to ensure the Department enforces prior authorization program procedures.
- **Compliance with 24-hour processing.** Federal law requires a state Medicaid program to act on a prior authorization request within 24 hours or 1 business day of receipt. We determined the fiscal agent processed prior authorization requests within 1 business day 98.4 per cent of the time. Thus, the prior authorization program does not appear to create significant delays in obtaining drugs as long as Medicaid recipients meet HCPF's prior authorization criteria.

It should be noted that our analysis of prior authorizations was very difficult and labor-intensive. We had great difficulty establishing linkages between prior authorizations and drug claims where federal upper limit pricing applied. We found many cases of duplicate prior authorizations, no prior authorizations in the system for the paid claim date, truncated identification numbers, and identification numbers that had been converted to different sequences when stored in the Medicaid Management Information System (MMIS). The Department should be concerned about the credibility of data stored in the prior authorization system. The Department should also investigate the prior authorization system to determine if the current system and its interface with drug pricing formulas are creating pricing errors resulting in higher payment amounts.

We do not believe the Department is managing the prior authorization program effectively enough to ensure that payments are appropriate. Most significantly, the Department is not adequately overseeing the activities of its fiscal agent to provide the needed assurances regarding the accuracy and consistency of prior authorization decisions. We found weaknesses related to: the lack of performance standards and independent audits; inconsistent application of prior authorization guidelines; and no physician oversight. We reviewed the fiscal agent contract and found no performance standards for the drug prior authorization program. Furthermore, Department personnel were unfamiliar with some prior authorization requirements such as the federal 24-hour prior authorization processing time limit.

In addition, ACS staff report that they produce a monthly common error report for HCPF which outlines documentation errors and corrective actions. We believe this type of report would be one tool for the Department to use in monitoring the prior authorization actions of the fiscal agent. However, we found no evidence the Department uses this report. We also found that the Department does not conduct audits of ACS prior authorization decisions to verify that fiscal agent staff interpret the prior authorization guidelines in the manner the Department intended. Approximately 1,900 PARS are processed monthly by ACS. HCPF officials review less than 100 PARs per year.

The absence of a licensed physician to oversee the clinical management of the drug prior authorization program is another concern. This is especially troubling given the high rate of questionable prior authorization decisions we identified. A physician needs to be available to the Department, either on a full- or part-time contractual basis, to provide guidance in decision making when the fiscal agent receives questionable requests or exceptions. A physician Medical Director can also be instrumental in providing oversight and monitoring of the application of guidelines as well as in establishing and defending the Department's policies on drug program limits with the physician community. We contacted five other State Medicaid programs. All five contract with or employ a physician consultant to oversee their utilization control programs.

## **Recommendation No. 6:**

The Department of Health Care Policy & Financing should improve the effectiveness of the prior authorization program and ensure that Medicaid payments are appropriate for restricted, covered drugs. This should be accomplished by:

- a) Developing and enforcing fiscal agent contract performance standards for drug prior authorization program administration to minimize the risk of prior authorizing non covered drugs.
- b) Increasing the frequency of analytical review and conducting independent audits of the fiscal agent's accuracy and consistency in following prior authorization guidelines and procedures.
- c) Increasing oversight of fiscal agent training to ensure proper interpretation and implementation of federal and state statutes, policies, procedures, and clinical prior authorization criteria.
- d) Hiring or contracting with a licensed physician to oversee drug and other utilization control programs.

### **Department of Health Care Policy and Financing Response:**

- a) Agree. Implementation Date: April 2005. The Department is starting the procurement of the Fiscal Agent contract and will clearly identify the requirement and performance standards to minimize the risk of prior authorizing non-covered drugs in the pharmacy prior authorization program. Under the current contract, the Department will develop and enforce prior authorization performance standards.
- b) The Department will determine the types of analytical reviews necessary to monitor prior authorization guidelines and standards and ensure that the data needs are met.
- c) The Department will ensure that Departmental policy interpretations regarding regulations are communicated to Fiscal Agent staff through meetings and trainings.
- d) The Department currently has a physician on contract for approximately 8.5 hours per week. The Department will use the physician, as time constraints and other priorities permit, to oversee drug and other utilization control programs. The Department does not currently have the resources necessary to expand the physician contract or to hire a physician.

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## **Pharmacy Overrides**

Pharmacists have the ability to override prescription limits or the prior authorization process by submitting certain codes through the point of sale electronic claims processing system. Pharmacists are expected to use their professional judgment when submitting override codes. The Department allows four codes to override generic mandates or to override a federal maximum allowable cost control. The Department also allows three other codes to override prior authorization requirements for emergency refills, early refills, and prenatal vitamins for pregnant women.

We reviewed pharmacy overrides to determine whether pharmacists were submitting codes appropriately and whether the Department was maximizing opportunities to prevent inappropriate drug utilization by Medicaid recipients. We found numerous questionable overrides. In all, we found that in Fiscal Year 2003, as much as \$1.25 million in pharmacy overrides for emergency fills, early refills, and medications for pregnant women were either clinically inappropriate or in violation of the Department's policies. We also noted that one home health provider alone submitted \$150,000 in emergency overrides to bypass the prior authorization approval process. We provided the Department with the details concerning this particular provider's overrides so that further action could be taken, if needed.

Specific problems we identified with pharmacy overrides were in the following areas:

- **Emergency Fills.** For all drug claims in Fiscal Year 2003 we identified many drug classes that are not considered "emergency drugs" according to our licensed physician and pharmacist reviewers. However, we found when claims for these non emergency drugs were submitted for reimbursement, they were treated as emergency drugs and were often dispensed in quantities greater than a 72-hour supply. For example, we found emergency override claims for quantities greater than a 72-hour supply for Viagra, over-the-counter vitamins, and iron supplements. We estimate if HCPF established criteria and implemented controls to limit the supply and prevent payment of these non-emergency drugs, a savings of approximately \$250,000 could be achieved annually. We also noted that one pharmacy provider represented 60 percent or \$150,000 of non emergency claims billed as emergencies. From the volume of overrides generated by this one provider, it would appear that the purpose of using the emergency override was to bypass the prior authorization process.
- **Early Refills.** Early refills refer to prescription refills made prior to the time in which the previously filled prescription for that same drug would have been consumed, if taken according to the prescribed dosage requirements. Early refill overrides often occur for drugs with a high abuse potential. We identified drug classes that were not clinically appropriate for early refill or had the potential for abuse, but had been overridden after receiving approval from the Department's fiscal agent. In Fiscal Year 2003, four out of the top five drug classes for early refills in the Medicaid Program were: narcotics/analgesics, muscle relaxants, anti-anxiety drugs, and drugs for sleeping disorders. We estimate if HCPF established criteria and imposed stricter limits on these drug classes and other drug classes that are not clinically appropriate for an early refill, the State could realize savings of up to \$980,000 annually.
- **Pregnant Women.** In addition to overrides in this category for women who are pregnant, we noted a lack of controls to prevent the use of this override for non pregnant women. While both the Medicaid Provider Billing Manual and the Provider Bulletin specifically state this override code is to be used only for prenatal vitamin prescriptions for pregnant women, we found the code was used in dispensing prescriptions for the elderly. Approximately 25 percent of the claims overridden in this category were for Medicaid recipients residing in nursing homes. A savings of approximately \$20,000 annually would be possible, if HCPF implemented the proper controls to enforce this particular override policy.

- **Generic Mandate Pharmacy Override.** At the beginning of Fiscal Year 2004, the Medicaid program added a new override code which allows pharmacies to override a generic mandate if their cost for a brand name drug is cheaper than the generic product equivalent. The Department has yet to conduct any monitoring activities for this override to confirm that pharmacies are submitting the lowest amount. A review of other state best practices suggests abuse of this override does occur. One state (Massachusetts) recovered \$1 million in overpayments from a pharmacy provider because the provider used the override code while billing at a higher rate. Another state revised its pricing policy so claims would only pay a State Maximum Allowable Cost when this code was submitted. The Department needs to establish regular monitoring activities and internal controls to prevent overpayments for this override code.

The Department engages in limited monitoring activities for this potentially high risk area. Although the Department produces a monthly override report for early refill overrides, it does not monitor claims for emergency fill overrides to determine whether they are truly emergency requests. Reports for pregnant women overrides are conducted on an ad hoc basis. These reports are not trended by drugs, drug classes, recipients, providers, or prescribers to detect patterns of misuse or abuse. Finally, as stated above, HCPF has not yet conducted any monitoring activities for the generic override to confirm that pharmacies are submitting a lower billed amount.

## **Recommendation No. 7:**

The Department of Health Care Policy and Financing should strengthen its controls over pharmacy overrides by:

- a) Enforcing existing policies by conducting regular audits of prescription drug claim overrides.
- b) Expanding analytical review of paid prescription drug claims to include routine analysis and trending of pharmacy override codes to detect patterns of misuse or abuse.
- c) Conducting provider education and outreach to reinforce the Department's policies and procedures concerning overrides and other utilization controls.
- d) Establishing additional internal controls to limit quantities dispensed and developing clinical guidelines to prevent pharmacy overrides for drugs that are clinically inappropriate or subject to abuse.
- e) Establishing controls to prevent fraudulent billing practices for the "brand cheaper than generic" override and expanding post payment pharmacy audit criteria to include the identification of overpayments resulting from "brand cheaper than generic" overrides.

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## Department of Health Care Policy and Financing Response:

- a) Agree. Implementation Date: November 2005. The Department will develop reports of pharmacy claims that include pharmacy override usage and will expand its analytical review to include analysis of pharmacy override codes.
  - b) The Department currently does claims analysis to detect patterns of misuse and abuse. The Department will expand this function as resources permit.
  - c) Provider outreach materials will be given to Fiscal Agent provider enrollment staff to be included in trainings and for the call center in answering provider inquiries. Policy changes will be explained in timely provider bulletins.
  - d) The Department currently reviews, and will continue to review products that may need to be limited and/or prior authorized to stop abuse.
  - e) The Department has submitted a request for systems change to the Fiscal Agent in order to pay brand name drugs if they are less costly than generics. This item will be brought into development as soon as possible, with an estimated completion date of October 31, 2005.
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## Preferred Drug List

A preferred drug list (PDL) is a list of drugs that is considered the most cost effective choice of drugs for treating particular conditions. Typically, a state-appointed pharmacy and therapeutics committee recommends placing preferred drugs on the list based on sound medical evidence. State Medicaid programs then create the PDL. Preferred drug lists may cover all drug classes or be limited to selected classes of drugs. One distinction most preferred drug lists have over prior authorization programs is that, although prior authorization traditionally creates a negative list—drugs that require authorization to be prescribed; preferred drug lists generally create a positive list—drugs preferred by the state’s Medicaid program that do not require prior authorization. Other states’ PDLs have been successful in limiting both utilization and drug expenditures. Oregon officials noted a market shift of approximately 30 percent in favor of drugs on its preferred drug list. Likewise, two other states with preferred drug lists have reported savings—Florida (\$81 million in one year) and Michigan (\$850,000 per week).

Colorado is one of only six states that does not have either an operating preferred drug list or one that is pending. We believe the Department should develop and implement a “preferred drug list” using prior authorization controls. Colorado should also review best practices of other states to identify opportunities for partnerships which could reduce the administrative burden and justify the cost of managing an evidence-based preferred drug list. For example, thirteen state Medicaid programs recently contracted with the Oregon Health Sciences Center’s Drug Effectiveness Project to evaluate 25 Drug Classes to be added to their preferred drug lists. Colorado should investigate the cost/benefit of joining this partnership.

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## Recommendation No. 8:

The Department of Health Care Policy and Financing should implement a preferred drug list. Where appropriate, the Department should adopt the best practices of other states, partner with other states to reduce administrative burden, and produce fiscal impact analyses and share findings with the public.

### Department of Health Care Policy and Financing Response:

Disagree. The issue of a preferred drug list has been discussed several times in the General Assembly and has never met with approval. Additionally, the biggest issue facing all State Medicaid pharmacy programs at this time is the implementation of Medicare Part D. The Department has spoken with other states that currently have PDLs who are very concerned about their ability to continue utilizing their PDLs when the implementation of Medicare Part D will remove a large share of the utilization under state control.

#### *Auditor Addendum*

*As reported in the audit, Colorado is one of only a handful of states that has not adopted a preferred drug list. It is incumbent upon the Department to continue to pursue policies and practices with the potential for significant cost savings despite previous or potential setbacks. The implementation of Medicare Part D is a legitimate consideration in establishing a preferred drug list. However, flexibility exists in the design of preferred drug lists. There are ways in which the Department can address the issue of the Medicare Part D dually eligible segment of the Medicaid population and still implement a preferred drug list.*

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## Prescription or Dispensing Limits

To control inappropriate drug utilization, states may impose limits restricting the amount of certain drugs that Medicaid recipients may receive. Limits vary and can be applied to: all drugs in a therapeutic class, to minimum or maximum quantities per prescription, to minimum or maximum quantities of refills, or to parameters based on age or gender. Some limits operate independently and other limits work in concert with the prior approval process. Colorado currently imposes maximum monthly quantity limits on selected drugs and drug classes. Colorado has implemented additional limits on quantities for some drugs, but this occurred in Fiscal Year 2004. A list of these limits is available in Appendix B.

A review of other states' Medicaid programs suggests the Department has not been as aggressive as other states in managing costs using benefit limits. We found other states have adopted other cost-effective prescription limits which could be beneficial for Colorado. These limits include:

- Michigan's dose optimization program limits coverage based on the dosing of certain high cost medications (anti-cholesterol, antidepressant and anti inflammatory). For example, if an individual is currently prescribed a 50 mg. tablet to be administered twice daily but a 100 mg. dose of the same medication, to be taken once a day, is available, less expensive, and clinically appropriate, coverage of the 50 mg will be limited.
- Alabama recently implemented coverage to four brand-name prescriptions per recipient per month and expects to save the state \$7.3 million annually.

In addition, there are other limits that have been adopted by various states:

- Maximum quantities per month.
- Maximum number of prescriptions per month.
- Maximum number of brand name prescriptions per month.
- 15-day supply on the initial fill for chronic medications. This limit is intended to address the need to adjust prescriptions for long-term conditions within the first month. Rather than initially prescribing unlimited refills for medications that may have to be adjusted or changed due to patient intolerance or poor response within the first few weeks, this cost containment method limits the initial prescription to a 15-day supply.
- 14-day supply of antibiotic prescriptions, plus 1 refill. Some individuals take antibiotics for an indefinite period, even when there is no clinical need. This measure limits the supply of antibiotics to a period typically sufficient for the medication to have been effective against the infection for which it was originally prescribed.
- 30 day supply for narcotic analgesics (excluding Schedule II narcotics) plus 1 refill. Limits the supply of highly addictive narcotics with the potential for abuse and/or fraud.
- 30 day supply for sedative/hypnotics plus 1 refill. Limits the supply of highly addictive narcotics with the potential for abuse and/or fraud.

The Department should establish additional dispensing limits. These limits can be determined by assessing drug utilization reports that point to areas of patient safety, misuse, waste, or abuse. We recognize that administrative challenges are common during program start up. However, we believe that Colorado, like other states, can overcome administrative challenges and realize substantial savings.

## **Recommendation No. 9:**

The Department of Health Care Policy and Financing should assess, identify, and adopt other State Medicaid “best practices” for prescription drug coverage limits.

## **Department of Health Care Policy and Financing Response:**

Agree. Implementation Date: July 2005. The Department agrees to continue to assess, identify and adopt other “best practices” for prescription drug coverage limits. The Department has already limited a list of drugs and is currently looking at another extensive list of drugs to control. The Department is currently doing the research and gathering public comment on the list it is considering for controls.

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## **Fiscal Agent Oversight**

In Fiscal Year 2003 Colorado spent more than \$201 million for Medicaid outpatient prescription drugs. As we have stated throughout this report, these costs are expected to continue growing as the population ages, life expectancies increase, and greater numbers of more efficacious drugs are introduced into the marketplace. At the same time however, Colorado, like other states, is faced with difficult decisions in terms of providing increasingly costly services in a time of budget shortfalls. It is for this reason that the Department of Health Care Policy and Financing needs to ensure that it uses its limited financial resources only as intended and maximizes opportunities for greater efficiencies. Our audit estimated \$3.1 million in Medicaid prescription drug claims that were inappropriately or improperly paid during Fiscal Year 2003. We believe this estimate to be a conservative one.

Contractual agreements make clear the rules regarding prescription drug pricing, restrictions, and payments. In addition, the Department has the authority to recover losses resulting from payment errors. The fact that the Department is not taking necessary monitoring and enforcement actions to identify and recover misspent monies raises serious concerns about its effectiveness in managing this essential Medicaid benefit. A reiteration of some of our more significant findings supports this overall conclusion. Specifically, we found that the Department, through its fiscal agent, made the following improper or inaccurate payments or overpayments:

- More than \$450,000 for drugs that potentially were not eligible for federal matching payments because no rebate agreement was in effect or the drugs were not approved for Medicaid coverage by the Federal Drug Administration (DESI drugs).
- Almost \$50,000 for drugs that had state-imposed restrictions or were not eligible for Medicaid coverage under Colorado's State Medicaid Plan.
- More than \$1.4 million for drugs whose costs exceeded federal or state price limits.
- As much as \$1.25 million for pharmacy overrides that were clinically inappropriate or violated Department policies.
- An indeterminate amount for prior authorizations that were not accurately, consistently, or appropriately applied.

In addition to these overpayments, we identified several areas in which the Department could save considerably by being more diligent in collecting funds due the State (drug rebates and fiscal agent recoveries) or by being more aggressive in pursuing proven cost containment measures (i.e. preferred drug lists and dispensing and pricing limits). For all of these areas, the Department has at its disposal the services of its fiscal agent. However, the Department does not adequately monitor fiscal agent activities to ensure requirements are being adhered to. In other cases, the Department needs to work with the fiscal agent to develop the needed systems, programs, or edits to access potentially greater benefits for the Medicaid Program and its recipients.

Overall, we believe the existing situation to be unacceptable, particularly given the current environment of dwindling budgets, potential service cutbacks, and increasing Medicaid caseloads. Therefore, the Department needs to improve its oversight and administration of the fiscal agent's Medicaid Prescription Drug Program claims processing and payments activities as soon as possible. This is not the first time we have made recommendations to the Department in this area. In our May 2001 performance audit of the Medicaid Management Information System, we made several recommendations to the Department for improving the accuracy of Medicaid claims payments. Among them were recommendations for the Department to implement the following with regard to the fiscal agent: expanded quality assurance procedures; regular audits; staff training; performance measures; and corrective action plans. In our current audit, we find that these recommendations have not been fully implemented. Consequently, we are restating some of them in addition to making new ones specifically directed toward the prescription drug program. Specifically, we believe the Department of Health Care Policy and Financing needs to strengthen its oversight of fiscal agent activities to ensure the accuracy of prescription drug claims' payments and the efficiency and effectiveness of cost containment efforts by:

- Developing a strategic plan, including timetables, for implementing additional contract provisions, prescription drug program components, performance measures, and overpayment recovery plans.
- Conducting routine internal analytical reviews for claims' payment accuracy similar to the data matches and other reviews that were a part of our current audit.
- Reviewing and ensuring the adequacy of the fiscal agent's processes and procedures for quality control.
- Developing an internal audit plan and schedule for periodic audits of prescription drug claims and payments, including evaluating the effectiveness of various cost containment measures.
- Identifying and recovering from the fiscal agent incorrect or improper overpayments as outlined in the terms of the contract with the fiscal agent.
- Developing, utilizing, and disseminating useful reports.

## **Recommendation No. 10:**

The Department of Health Care Policy and Financing should improve its oversight and management of fiscal agent activities related to the Medicaid prescription drug program by implementing a strategic plan, including timelines for completion, for the following:

- a) Conducting internal analytical reviews and audits.
- b) Reviewing the adequacy of the fiscal agent's processes and procedures for quality control.
- c) Identifying and recovering from the fiscal agent incorrect or improper overpayments
- d) Developing and disseminating useful reports.

## **Department of Health Care Policy and Financing Response:**

- a) Agree. Implementation Date: July 2005. The Department will determine the types of analytical reviews necessary to monitor pharmacy claim processing and ensure that the data needs are met. See also Response to Recommendation 2.
- b) The Department will review all the Fiscal Agent processes related to pharmacy processing for pharmacy claims payment accuracy. An ongoing metric will be developed as part of quality control reporting.
- c) Any incorrect or improper overpayments will be collected.
- d) The Department will review and determine which of the current reports are useful, how any reports can be modified to be more useful, and what other reports are needed.

Maximum Allowable Cost (MAC) Programs			
State	Federal Upper Limits	State-Specific Upper Limits	MAC Override Provisions
Alabama	Yes	Yes	Dispense as written, brand medically necessary
Alaska	Yes	No	Brand medically necessary and reason for medical necessity
Arizona* - - -			
Arkansas	Yes	Yes	Brand medically necessary, prior authorization
California	Yes	Yes	Medically necessary and other products unavailable at MAC rate
Colorado**	Yes	Yes	Brand medically necessary
Connecticut	Yes	No	Brand medically necessary
Delaware	Yes	Yes	Brand medically necessary
District of Columbia	Yes	No	Brand medically necessary plus an explanation
Florida	Yes	Yes	If drug is on Florida Negative Formulary
Georgia	Yes	Yes	Prior authorization
Hawaii	Yes	No	Brand Medically necessary
Idaho	Yes	Yes	Prior authorization
Illinois	Yes	Yes	Prior authorization request by physician or pharmacist
Indiana	Yes	Yes	Brand medically necessary, prior authorization
Iowa	Yes	Yes	Brand medically necessary, Med Watch form and prior authorization
Kansas	Yes	Yes	N/A
Kentucky	Yes	No	Brand necessary, brand medically necessary, Prior Approval on some drugs
Louisiana	Yes	Yes	Brand necessary, brand medically necessary
Maine	Yes	Yes	Medically necessary, brand Medically necessary Prior Approval on some drugs
Maryland	Yes	Yes	Brand medically necessary and reason for medical necessity
Massachusetts	Yes	Yes	Dispense as written, brand medically necessary, prior authorization
Michigan	Yes	Yes	Dispense as written and prior authorization
Minnesota	Yes	Yes	Brand medically necessary or dispense as written. Brand medically necessary must be handwritten on the prescription by the prescriber, no pre-printed Dispense AsWritten allowed.
Mississippi	Yes	No	Prior authorization for brand multi-source
Missouri	Yes	Yes	Prior authorization
Montana	Yes	No	Brand necessary, prior authorization
Nebraska	Yes	Yes	Medically necessary
Nevada	No	No	Brand medically necessary
New Hampshire	Yes	Yes	Brand medically necessary, MedWatch form for Prior Approval
New Jersey	Yes	No	Brand medically necessary
New Mexico	Yes	Yes	Medically necessary, Brand necessary
New York	Yes	No	Dispense as written, brand necessary, or brand medically necessary
North Carolina	Yes	Yes	Brand medically necessary
North Dakota	Yes	Yes	Dispense as written
Ohio	Yes	Yes	Prior authorization
Oklahoma	Yes	Yes	Brand medically necessary
Oregon	Yes	No	Dispense as written, brand medically necessary
Pennsylvania	Yes	Yes	Brand necessary, brand medically necessary, or prior authorization
Rhode Island	Yes	No	Brand medically necessary with medical justification
South Carolina	Yes	Yes	Brand medically necessary with certification by prescriber and Prior Approval.
South Dakota	Yes	Yes	Brand medically necessary
Tennessee* - - -			
Texas	Yes	Yes	Brand necessary, brand medically necessary
Utah	Yes	Yes	Brand medically necessary plus prior approval

Maximum Allowable Cost (MAC) Programs			
Vermont	Yes	Yes	Dispense as written
Virginia	Yes	Yes	Brand necessary
Washington	No	Yes	Brand medically necessary
West Virginia	Yes	No	Brand medically necessary (hand written by prescriber)
Wisconsin	No	Yes	Brand medically necessary
Wyoming 14	Yes	Yes	Brand medically necessary
As reported by State drug program administrators in the 2002 National Pharmaceutical Council Survey.			
<b>Source:</b> Pharmaceutical Benefits 2002			

\*Within Federal and State guidelines, individual managed care and pharmacy benefit management organizations make formulary/drug decisions.

\*\* Colorado had one state MAC for one drug in effect at the time of this survey.

<b>Colorado Medicaid Prescription Drug Limits</b>	
<b>Effective December 15, 2003</b>	
<b>Drug</b>	<b>Limit</b>
<b>Sleeping Agents</b>	
Ambien 5mg & 10mg	14 tablets/30 days
Sonata 5mg & 10mg	14 tablets/30 days
<b>Ketorolac</b>	
Toradol (ketorolac)Tablets	Limit to 5 days of therapy every 30 days = 20 tablets per 30 days, and The prescription documents the patient received either IM or IV Ketorolac up to 24 hours immediately prior to receiving the oral tablet prescription.
<b>Anti-Migraine</b>	
Amerge 1mg and 2.5mg	9 tablets / 30 days
Axert 6.25mg and 12.5mg	6 tablets/ 30 days
Frova 2.5mg	9 tablets / 30 days
Imitrex 25mg, 50mg and 100mg	9 tablets / 30 days
Imitrex Nasal spray	6 inhalers / 30 days
Imitrex Injection	4 injections / 30 days
Maxalt 5mg & 10mg	9 tablets / 30 days
MLT 5mg & 10mg	
Relpax 20mg & 40mg	6 tablets / 30 days
Zomig 2.5mg & 5mg	9 tablets / 30 days
ZMT 2.5mg & ZMT 5mg	
Zomig Nasal Spray	6 inhalers/ 30 days
<b>Anti-emetics</b>	
Anzemet 50mg tablet	10 tablets/ 30day
100mg tablet:	5 tablets / 30 days
Emend 125mg	5 tablets/ 30 days
80mg	10 tablets/ 30 days
Tripak	3 packs / 30 days
Kytril 1mg	8 tablets / 30 days
oral suspension	40ml / 30 days
Zofran 4mg & 4mg ODT	48 tablets / 30 days
8mg & 8mg ODT	28 tablets / 30 days
24mg	8 tablets / 30 days
4mg/5ml oral solution	240ml / 30 days
<b>Source:</b> Colorado Department of Health Care Policy & Financing	

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