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DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

MEDICAID PRESCRIPTION DRUGS



MAY 2015

PERFORMANCE AUDIT

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DIANNE E. RAY, CPA
STATE AUDITOR

May 14, 2015

Members of the Legislative Audit Committee:

This report contains the results of the performance audit of the Department of Health Care Policy and Financing's administration of Medicaid outpatient prescription drugs. 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. The report presents our findings, conclusions, and recommendations, and the responses of the Department.

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CONTENTS

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UNION AND CONSTITUTION
NIL SINE NUMINE
1876

REPORT HIGHLIGHTS

MEDICAID PRESCRIPTION DRUGS PERFORMANCE AUDIT, MAY 2015

DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

CONCERN

We found that the Department of Health Care Policy and Financing (Department) should improve its oversight, internal controls, and information systems related to the outpatient prescription drugs provided to Medicaid recipients to ensure the State only pays for allowable and covered prescription drug benefits, and identifies and prevents fraud, waste, and abuse related to recipients' prescription drug use and providers' prescribing activities.

KEY FACTS AND FINDINGS

- We estimated that the new method for paying for Medicaid recipients' outpatient prescription drugs, which the Department implemented in February 2013, has created an average savings of $14 per recipient receiving a prescription, or about $5.7 million annually.
- Between February 2012 and January 2014, the Department violated state regulations when it paid over $1.1 million for 5,154 Medicaid prescription drug claims that did not have approval to be dispensed. These payments are questioned costs.
- The Department has not ensured that Medicaid recipients utilize controlled substances appropriately, or addressed recipients' overutilization of prescription drugs. We identified 17 recipients who greatly exceeded the overutilization criteria in state regulations; each of these recipients received over 40 opioid prescriptions from more than 12 providers in 12 months. The Department did not restrict these recipients' benefits or access to prescription drugs through Medicaid.
- The Department paid $67,200 for 2,053 prescriptions that had been prescribed by providers who were excluded or terminated from serving Medicaid recipients, which violated federal and state regulations. These payments are unallowable costs.
- The Department does not regularly monitor providers who are a high risk for overprescribing to Medicaid recipients. We identified 492 Medicaid providers whose prescribing patterns for controlled substances indicated potential fraud, waste, or abuse.

BACKGROUND

- Medicaid is a federal-state program that provides health care coverage and services to eligible low-income individuals and families with children.
- All states' Medicaid programs cover the cost of outpatient prescription drugs for recipients.
- During Fiscal Year 2014, Colorado's Medicaid program provided about 5.5 million outpatient prescriptions for 498,507 recipients at a total cost of $453.2 million.
- In Fiscal Year 2014, about 85 percent of prescription drugs dispensed to Colorado Medicaid recipients were generic drugs.
- During Fiscal Years 2010 through 2014, the number of prescriptions covered by Colorado Medicaid increased 66 percent and average prescription costs increased 37 percent.

KEY RECOMMENDATIONS

The Department of Health Care Policy and Financing should:

- Strengthen internal controls and its pharmacy benefits management system to enforce proper authorization and payments for Medicaid prescription drug claims.
- Implement effective processes and controls over prescription drugs to address drug overutilization in Medicaid and help ensure over utilizing recipients use prescription drugs appropriately.
- Strengthen internal controls, information systems, and monitoring to detect and prevent health care provider fraud, abuse, and misuse related to prescription drugs in the Medicaid program.

The Department partially agreed with these recommendations.

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RECOMMENDATION LOCATOR

AGENCY ADDRESSED: DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

REC. NO.	PAGE NO.	RECOMMENDATION SUMMARY	AGENCY'S RESPONSE	IMPLEMENTATION DATE
1	33	Strengthen controls to enforce proper authorizations and payments for prescription drug claims by (A) keeping the pharmacy benefits management system updated; (B) eliminating the ability for pharmacies to override emergency fill authorizations and routinely monitoring emergency fills; (C) implementing routine, risk-based reviews to identify and address prescription drug claims that do not have prior authorizations; and (D) reviewing the 5,154 prescription drug claims that the audit identified, which violated state regulations, and recovering the questioned costs, as appropriate.	A AGREE B AGREE C AGREE D PARTIALLY AGREE	A NOVEMBER 2016 B NOVEMBER 2016 C NOVEMBER 2016 D DECEMBER 2015

AGENCY ADDRESSED: DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

REC. NO.	PAGE NO.	RECOMMENDATION SUMMARY	AGENCY'S RESPONSE	IMPLEMENTATION DATE
2	50	Implement effective processes to ensure the appropriate utilization of prescription drugs and address overutilization by (A) implementing special restrictions on prescription drugs that recipients receive through Medicaid when they meet established overutilization criteria, and (B) analyzing the claims paid for the 17 recipients identified by the audit who appeared to over utilize prescription drugs through Medicaid, notifying the recipients' prescribers of potential overutilization, and referring the recipients to the Department's Drug Utilization Review Program and to law enforcement, as appropriate.	A AGREE B PARTIALLY AGREE	A NOVEMBER 2016 B OCTOBER 2015
3	64	Strengthen controls to detect and prevent health care provider fraud, abuse, and misuse related to prescription drugs by (A) automatically denying claims originating from excluded and terminated providers; (B) periodically reviewing prescription drug claims to identify those originating from excluded and terminated providers, recovering payments for the claims as appropriate, and recovering payments for the unallowable claims identified by the audit; and (C) implementing routine processes to identify high risk prescribers using comprehensive criteria, periodically reviewing these prescribers' prescription drug claims, and referring them to the State's Medicaid Fraud and Control Unit, as appropriate.	A AGREE B AGREE C PARTIALLY AGREE	A NOVEMBER 2016 B NOVEMBER 2016 C OCTOBER 2015
4	74	Implement internal controls and oversight of its fiscal agent to ensure compliance with federal regulations to bill for and collect interest from manufacturers that are past due in paying prescription drug rebates, collect the unpaid interest identified by the audit, refund the federal portion of the interest to the federal government, and ensure the fiscal agent correctly billed for interest from April 2014 to April 2015.	AGREE	NOVEMBER 2016

CHAPTER 1

OVERVIEW OF MEDICAID PRESCRIPTION DRUG COVERAGE

Medicaid is a federal-state program that provides health care coverage and services to eligible low-income individuals and families with children (42 CFR, pt. 430.0). Medicaid is administered at the federal level by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) under Title XIX of the Federal Social Security Act, and at the state level by the Colorado Department of Health Care Policy and Financing (Department) under Section 25.5-4-104(1), C.R.S. Recipients may choose to receive health care services from any institution, agency, or health professional that has a contract with the Department to serve Medicaid recipients.

Federal regulations (42 CFR, pt. 440) require state Medicaid programs to provide all recipients certain basic services, including but not limited to inpatient and outpatient hospitalization, physician and rural health clinic services, and nursing facility services for recipients ages 21 and older. The Federal Social Security Act also gives states flexibility to provide recipients optional services that qualify states for federal matching payments. One optional service offered by all states is coverage of outpatient prescription drugs, which are prescriptions provided to Medicaid recipients outside of a hospital setting.

Under federal regulations, states have some discretion in the level of prescription drug coverage they provide Medicaid recipients, but states only receive federal matching funds to help cover a recipient's prescription if the Food and Drug Administration (FDA) has approved the drug and one of the following conditions is met:

- The drug manufacturer has an agreement with the U.S. Department of Health and Human Services to rebate Medicaid for a portion of the drug cost.
- The state determines that the drug is essential to recipients' health.
- The state has approved the recipient's physician to prescribe the drug through a prior authorization process [42 USC 1396r-8(a)].

OUTPATIENT PRESCRIPTION DRUGS

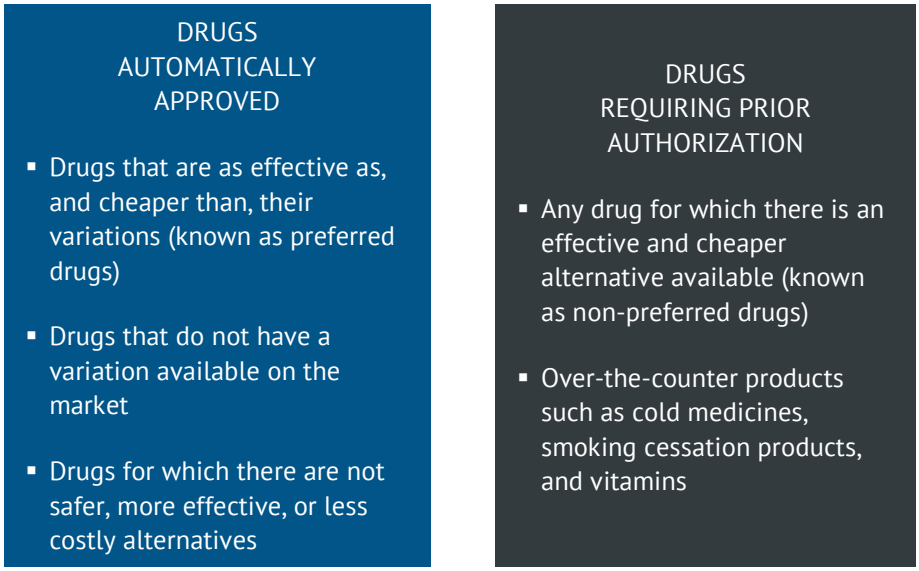
During Fiscal Year 2014, Colorado's Medicaid program covered about 5.5 million outpatient drug prescriptions for 498,507 recipients. Colorado's Medicaid program covers the costs of most brand name and generic prescription drugs for recipient outpatient treatment. Brand name drugs are unique, patent-protected products that are usually only available from a single manufacturer. Generic drugs have the same active ingredients as their brand name counterparts and are generally considered by the FDA to be equivalent in dose, strength, route of administration, safety, and intended use. Generic drugs are not protected by patents and are produced and sold by many different manufacturers.

The Department reviews drugs for safety, effectiveness, clinical outcomes, and cost effectiveness to the State to determine which drugs Medicaid will cover and which drugs it will not, and to set limits on the drugs that can be dispensed. In order for a recipient's prescription to be approved for payment by Medicaid, the prescription must first meet basic dosage and quantity limits established by the Department for safety and be safe for the recipient based on his or her age (e.g., generally recipients must be under age 65 to receive skeletal muscle relaxant drugs). Covered prescriptions that meet the safety limits are automatically approved by Medicaid to be dispensed to recipients. Medicaid restricts coverage of certain drugs that are less safe, less effective, or cost more than comparable drugs, and requires pharmacies to obtain prior authorization before dispensing them. For example, coverage for many brand name drugs is restricted with prior authorization because they often cost more than their generic counterparts. The Department also restricts Medicaid coverage of over-the-counter products to reduce costs, and federal regulations require recipients to get prescriptions for over-the-counter products in order for them to be covered by Medicaid [42 CFR 1396r-8(k)(4)].

Exhibit 1.1 outlines the types of outpatient prescription drugs that Colorado's Medicaid program covers and the types of drugs that it restricts.

EXHIBIT 1.1

STATE MEDICAID COVERAGE OF PRESCRIPTION DRUGS



SOURCE: Office of the State Auditor's summary of state regulations (Section 8.800.4 10 CCR 2505-10).

Colorado's Medicaid program does not cover the costs of drugs used for weight gain or loss, fertility treatment, or cosmetic purposes, such as hair growth treatment; or personal care items, such as deodorant and mouthwash (10 C.C.R. 2505-10 8.800.4).

MEDICAID PRESCRIPTION DRUG REIMBURSEMENT RATES

Colorado's Medicaid program covers the costs of outpatient prescription drugs for recipients on a fee-for-service basis, meaning that retail pharmacies are paid for each prescription that they fill for a recipient. The pharmacy that fills a prescription for a Medicaid recipient submits a prescription drug claim to the Department for payment. States determine the reimbursement rate for each prescription drug claim and CMS approves each state's rate setting methodology [42 CFR 430.10].

Colorado's Medicaid program pays pharmacies for prescriptions dispensed to recipients as described in the following section.

PAYMENTS BASED ON THE AVERAGE DRUG COSTS. The Department pays pharmacies for each prescription drug claim based on the average amount retail pharmacies in Colorado pay to purchase the drug from the wholesaler. The Department contracts with a health consulting company, Mercer, to determine pharmacies' costs to purchase prescription drugs in order to set the monthly rates that Medicaid will reimburse pharmacies for drug claims.

Each month, Mercer surveys Colorado pharmacies on their costs to purchase prescription drugs, reviews pharmacies' invoices for drug purchases, and uses the information to calculate pharmacy reimbursement rates for the upcoming month. According to the Department, Mercer does not use a pharmacy's purchase price to calculate the reimbursement rate for a drug if the pharmacy's price is significantly higher or lower than other pharmacies' prices, to ensure that average prices are not skewed by extremely high or low prices.

PAYMENTS FOR DISPENSING FEES. The Department pays each pharmacy a dispensing fee for each Medicaid prescription drug claim to cover the pharmacy's administrative costs for filling the prescription. The fees range from $9.31 per claim to $14.14 per claim based on the pharmacy's annual volume of prescriptions filled and whether the pharmacy is rural (without another pharmacy within 20 miles). Rural pharmacies receive a higher fee than other pharmacies, as shown in Exhibit 1.2.

EXHIBIT 1.2

STATE MEDICAID DISPENSING FEE TIERS
FEBRUARY 2013 THROUGH APRIL 2015

ANNUAL PRESCRIPTION VOLUME REQUIREMENTS	DISPENSING FEE PER CLAIM
Rural pharmacy (no volume requirement)	$14.14
1 to 59,999 Prescriptions	$13.40
60,000 to 89,999 Prescriptions	$11.49
90,000 to 109,999 Prescriptions	$10.25
110,000+ Prescriptions	$9.31

SOURCE: Office of the State Auditor's analysis of Department of Health Care Policy and Financing information.

FUNDING FOR PRESCRIPTION DRUGS

Federal regulations require that Medicaid be the payer of last resort and that all third party payments, such as from private insurance and individual co-payment, offset the costs of recipients' prescriptions that are billed to Medicaid [42 USC 1396(a)(25)]. State regulations (Sections 8.754.1.E and 8.754.5 10 CCR 2505-10) require Colorado Medicaid recipients to pay the pharmacy a $1 co-pay for each generic drug and a $3 co-pay for each brand name drug covered by Medicaid except for recipients under age 19, pregnant, or receiving the drug in emergency treatment, such as during emergency surgery, or in a long term care facility. The pharmacy is required to reduce the amount it bills the Department for claims by all third party payments, including the co-pay amount.

The following sources fund prescription drug claims paid through Colorado's Medicaid program:

- **DRUG MANUFACTURER REBATES.** To help reduce the cost of Medicaid prescription drug programs, federal regulations [42 USC 1396r-8(a)(1] require drug manufacturers to pay rebates in order for their drugs to be covered under Medicaid. Minimum rebate

amounts are set by CMS, vary by drug, and range from about 13 to 23 percent of the drug price. The majority of these federally mandated rebates are split between the state and federal governments. For the period of our review, February 2012 through January 2014, the state and federal governments each received 50 percent of most rebates; the 50/50 split continued until October 2014, when they were changed to the state typically receiving 49 percent of the rebates and CMS receiving 51 percent. For a small number of drugs, CMS receives the entire rebate amount. Some drug manufacturers also negotiate additional supplemental rebates with individual states [42 USC 1396r-8(a)(1)]. The states and federal government each receive one-half of the supplemental rebates. Since 2008, the Department has had supplemental rebate agreements with some drug manufacturers.

- **FEDERAL REIMBURSEMENTS.** For the period of our review, February 2012 through January 2014, the Medicaid federal matching rate for Colorado was 50 percent, meaning that the State was reimbursed 50 cents for each $1 that it spent on Medicaid outpatient prescription drugs. This federal matching rate continued until October 2014, when it was changed to 51 percent.

- **STATE GENERAL FUND.** The General Fund provides funding for the Medicaid outpatient prescription drug costs that remain after recipient co-pays, manufacturer rebates, and federal reimbursements.

Exhibit 1.3 shows the total number of Medicaid outpatient prescription drug claims and expenditures in Colorado for Fiscal Years 2010 through 2014.

EXHIBIT 1.3

MEDICAID OUTPATIENT PRESCRIPTION DRUGS CLAIMS AND EXPENDITURES (IN MILLIONS) FISCAL YEARS 2010 THROUGH 2014

	2010	2011	2012	2013	2014
NUMBER OF PAID PRESCRIPTION CLAIMS	3.3	3.8	4	4.3	5.5
EXPENDITURES BY FUNDING SOURCE					
DRUG MANUFACTURER REBATES [1]	$88.7	$115.9	$149.8	$179	$195.3
FEDERAL REIMBURSEMENTS AFTER REBATES [2]	$60.8	$66.3	$76.9	$68.6	$156.1
STATE GENERAL FUND AFTER REBATES [2]	$50.2	$73	$92	$86.6	$101.8
TOTAL EXPENDITURES	$199.7	$255.2	$318.7	$334.2	$453.2

SOURCE: Office of the State Auditor's analysis of data from the Colorado Financial Reporting System (COFRS).

[1] Drug manufacturer rebates represent the total rebates, including supplemental rebates, which manufacturers paid for Medicaid prescription drugs dispensed in Colorado.

[2] The federal reimbursements and State General Fund amounts are net of rebates because the federal government allowed Colorado to keep all rebates that drug manufacturers paid in these years.

PRESCRIPTION DRUG INFORMATION SYSTEMS

Pharmacies submit Medicaid prescription drug claims to the Department electronically through the pharmacy's point of sale system that processes and tracks prescription sales. The Department currently contracts with Xerox State Healthcare LLC (Xerox) as its fiscal agent to process prescription drug claims; in Fall 2015, Hewlett Packard will become the Department's new fiscal agent. The following systems process prescription drug claims:

- **MEDICAID MANAGEMENT INFORMATION SYSTEM (MMIS).** MMIS is Colorado's Medicaid claims processing and information retrieval system used for all Medicaid claims and services. The Department has contracted with Hewlett Packard to develop and implement a replacement to MMIS in Fall 2016.

- **PRESCRIPTION DRUG CARD SYSTEM (PDCS).** PDCS is a pharmacy benefits management system created and managed by Xerox that interfaces with MMIS to process prescription drug claims, approvals, and denials. According to the Department, when a pharmacy submits a prescription drug claim through PDCS, the system automatically approves or denies the claim for reimbursement based on recipient eligibility information in MMIS and approval criteria programmed in PDCS. PDCS submits approved claims to MMIS for payment and MMIS records the transaction in the State's accounting system. PDCS also tracks approved and denied prescription drug claims, and information on Medicaid recipients, pharmacies, and covered drugs. The contract for managing PDCS is with Xerox but, in April 2015, the Department selected a new system manager, Magellan Medicaid Administration, which will replace the system in Fall 2016.

- **DRUG REBATE ANALYSIS AND MANAGEMENT SYSTEM.** Xerox uses its Drug Rebate Analysis and Management System (DRAMS) to generate and track the rebate invoices that it sends to drug manufacturers to request rebates. DRAMS generates quarterly rebate invoices based on paid prescription drug claims, the federal rebate amounts set by CMS, and rebate amounts stated in the State's supplemental rebate agreements with drug manufacturers. The Department has contracted with Magellan Medicaid Administration to develop and implement a replacement to DRAMS in Fall 2016.

AUDIT PURPOSE, SCOPE, AND METHODOLOGY

We conducted this performance audit pursuant to Section 2-3-103, C.R.S., which authorizes the State Auditor to conduct audits of all departments, institutions, and agencies of the state government. The audit was conducted in response to a legislative request. The purpose of the audit was to assess whether the Department has sufficient mechanisms to control Medicaid prescription drug costs and ensure the State only pays for Medicaid-covered drugs. Audit work was

performed from June 2014 through May 2015. We appreciate the cooperation and assistance provided by the management and staff of the Department of Health Care Policy and Financing during this audit.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The key objectives of the audit were to:

- Assess how effective Colorado's Medicaid program is in obtaining the most cost effective outpatient prescription drugs. This included evaluating requirements for the use of generic drugs and the use of drug rebates to identify any opportunities for further cost savings. This objective also included reviewing the Department's monitoring of providers' prescribing patterns and recipients' drug use to help detect and prevent fraud, waste, and abuse in the Medicaid program.

- Evaluate the Department's controls for ensuring payments for prescription drug claims are accurate and only for covered benefits.

This audit also reviewed the Department's compliance with the SMART Government Act in relation to the Medicaid program's coverage of outpatient prescription drugs. This audit did not review the eligibility of Medicaid recipients or any prescription drug benefits provided through Colorado's Medicaid Managed Care Program.

To accomplish the audit objectives, we performed the following audit work:

- Reviewed applicable federal and state laws and regulations and CMS guidance on Medicaid prescription drugs, as well as Department written policies, Medicaid Provider Billing Manuals, and lists of the prescription drugs covered and restricted by

Colorado's Medicaid program between February 2012 and January 2014.

- Reviewed the Department's contract with Xerox and interviewed Department and Xerox staff to understand procedures and system functionality for approving and paying prescription drug claims, and collecting manufacturer drug rebates.
- Analyzed electronic data for about 8.8 million prescription drug claims paid between February 2012 and January 2014 to determine whether the payments were appropriate.
- Reviewed Department controls over prescriptions for controlled substances and the actions the Department takes to address drug overutilization of Medicaid recipients.
- Reviewed other states' and federal practices for monitoring drug utilization and implementing drug utilization controls.
- Reviewed Xerox's electronic data on all rebate invoices it sent to all 468 drug manufacturers in Fiscal Year 2014.

We relied on sampling techniques to support some of our audit work. Specifically, we selected a random sample of 80 of the 10,953 paid claims for 11 types of drugs that the Department does not allow to be dispensed as emergency fills to determine if they were emergency fills. We reviewed a sample of the 17 Medicaid recipients who appeared to over utilize prescription drugs to determine the Department's processes for addressing overutilization. Additionally, we selected a random sample of 200 providers who prescribed high amounts of controlled substances to Medicaid recipients and reviewed the providers' medical license information to determine if they had received any suspensions or revocations on their medical licenses.

We planned our audit work to assess the effectiveness of those internal controls that were significant to our audit objectives. Our conclusions on the effectiveness of those controls, as well as specific details about the audit work supporting our findings, conclusions, and recommendations, are described in CHAPTER 2 of this report.

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CHAPTER 2

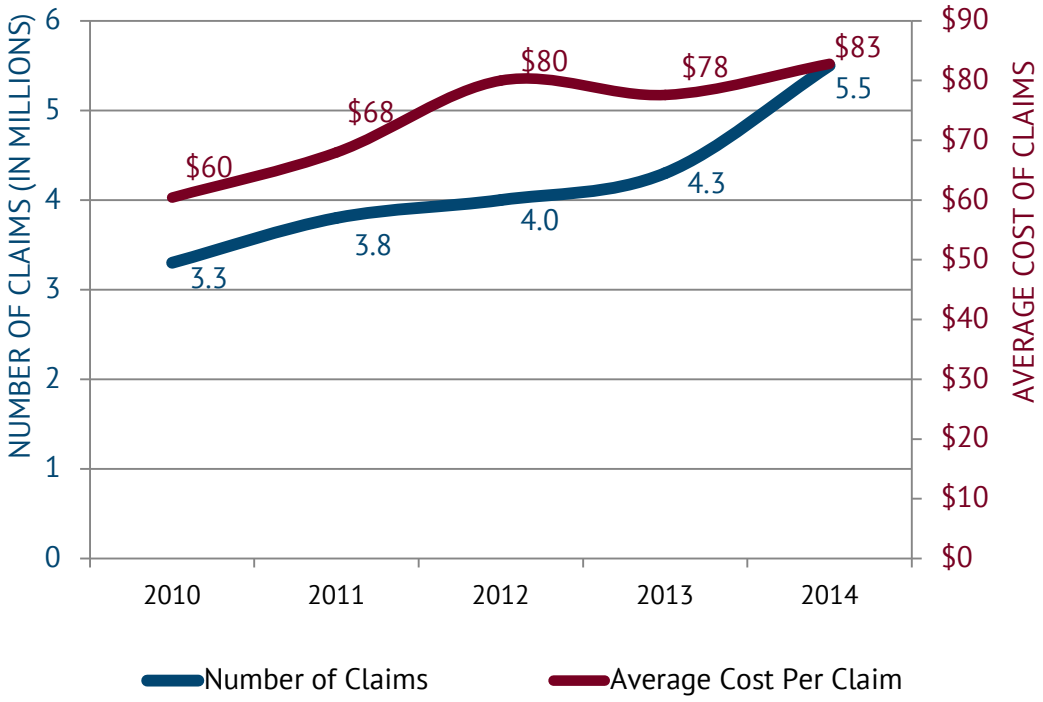
ADMINISTRATION AND CONTROLS OF PRESCRIPTION DRUGS

In Fiscal Year 2014, the cost of outpatient prescription drugs for Colorado's Medicaid recipients totaled over $453 million and represented 17 percent of all Medicaid spending for services provided on a fee-for-service basis. Medicaid spending for prescription drugs is driven by many factors, including the retail costs of the drugs, recipients' health conditions, the treatment recipients need, prescribing practices of health care providers, recipients' utilization of prescriptions, and Medicaid controls for approving and paying for prescriptions.

As shown in Exhibit 2.1, from Fiscal Year 2010 through Fiscal Year 2014 the number of prescription drug claims and associated costs to Colorado's Medicaid program increased. During this 5-year period, prescription drug claims increased by 66 percent while the average cost per claim increased by 37 percent.

EXHIBIT 2.1

TRENDS IN COLORADO'S MEDICAID PRESCRIPTION DRUG CLAIMS AND AVERAGE COSTS FISCAL YEARS 2010 THROUGH 2014



SOURCE: Office of the State Auditor's analysis of the Department of Health Care Policy and Financing's data on Medicaid outpatient prescription drug claims and costs.

To respond to increased demand and higher costs for prescription drugs in the Medicaid program, the Department of Health Care Policy and Financing (Department) has developed several processes to control the costs of recipients' prescriptions and create cost savings for the State, as described in the following section.

COST SAVING PROCESSES

During the audit, we identified a number of Department processes that help ensure Medicaid recipients obtain lower priced prescription drugs when they are available and safe for the recipient, and control the costs the State pays for prescription drugs, as described below.

DISPENSING OF GENERIC DRUGS IN PLACE OF BRAND NAME DRUGS. Statute [Section 25.5-5-501(1)(a), C.R.S.] requires pharmacies to dispense a generic, rather than a brand name, drug to a Medicaid recipient in most circumstances. According to the Department, brand name drugs often cost more than their generic counterparts because brand name drug manufacturers incur the costs of drug research and development and some manufacturers charge higher prices for brand drugs, and because generic manufacturers sometimes have competition with other manufacturers which helps lower generic drug prices.

According to data from the Department, 85 percent of the prescription drugs dispensed to Colorado's Medicaid recipients in Fiscal Year 2014 were generic drugs, which represented about one third of the State's total Medicaid prescription drug costs (about $135 million out of the total $453 million). Exhibit 2.2 shows the top 10 therapeutic classes of drugs that were dispensed to Colorado's Medicaid recipients and Medicaid's costs for these drugs between February 2013 and January 2014, the most current data available during the audit. We found that recipients received generic drugs for these common prescriptions about 90 percent of the time.

EXHIBIT 2.2

COLORADO MEDICAID MOST PRESCRIBED DRUGS BY THERAPEUTIC CLASS, AND GENERIC AND BRAND CLAIMS FEBRUARY 2013 THROUGH JANUARY 2014

	DRUG THERAPEUTIC CLASS [1]		NUMBER OF CLAIMS	PERCENT OF TOTAL CLAIMS	AVERAGE COST PER CLAIM [2]
1	OPIOID PAIN RELIEVERS	GENERIC	497,567	98%	$26
		BRAND	11,921	2%	$476
2	ANTICONVULSANTS	GENERIC	233,159	86%	$36
		BRAND	38,487	14%	$410
3	ANTI-DEPRESSANTS	GENERIC	173,874	99%	$13
		BRAND	936	1%	$249
4	ANTIBIOTICS	GENERIC	166,507	99%	$17
		BRAND	95	<1%	$196
5	BREATHING TREATMENT [3]	GENERIC	36,338	23%	$23
		BRAND	122,367	77%	$61
6	ANTI-INFLAMMATORYAGENTS	GENERIC	126,057	99%	$19
		BRAND	123	<1%	$319
7	ANTI-ANXIETY TREATMENT	GENERIC	125,065	99%	$13
		BRAND	73	<1%	$304
8	ANTIPSYCHOTICS	GENERIC	99,931	87%	$40
		BRAND	14,665	13%	$650
9	SKELETAL MUSCLE RELAXANTS	GENERIC	90,073	99%	$14
		BRAND	53	<1%	$833
10	THYROID HORMONES	GENERIC	72,840	90%	$13
		BRAND	8,402	10%	$31

SOURCE: Office of the State Auditor's analysis of the Department of Health Care Policy and Financing's claims data.

[1] Drug therapeutic class refers to the typical medical use for the drugs.

[2] Average cost per claim includes dispensing fees but does not include cost reductions from manufacturer rebates and federal funds.

[3] During the audit review period several brand name breathing treatments, such as inhalers, were preferred drugs, and therefore were dispensed more than their generic counterparts, because clinical reviews found the brand name treatments to be more effective, safer, or less costly.

Statute [Section 25.5-5-501(1)(a), C.R.S.] requires the State's Medicaid program to cover the cost of a brand name drug only if:

- THE BRAND NAME DRUG IS MORE AFFORDABLE FOR THE STATE. Although rare, drug manufacturers can agree to provide the State a supplemental rebate for a brand name drug, which makes the final cost of the drug less than the generic equivalent.

- THE DRUG DOES NOT HAVE A GENERIC EQUIVALENT. In September 2014, the National Conference of State Legislatures reported that approximately 48 percent of prescription drugs did not have a generic equivalent.

- THE RECIPIENT HAS A DIAGNOSIS OF HIV/AIDS, CANCER, A MENTAL HEALTH CONDITION, OR EPILEPSY. Statute does not require a generic drug to be substituted for a brand drug for recipients with one of these diagnoses because of the limited availability of effective generic treatments and the potentially severe adverse side effects that the available generic drugs can cause for people with these conditions.

- THE GENERIC DRUG CAUSES AN ADVERSE REACTION OR IS NOT AS EFFECTIVE. A physician may prescribe a brand name drug to a recipient if the generic drug causes adverse side effects, an allergic reaction, or is not as effective in treating the recipient as the brand name drug equivalent dosage.

PREFERRED DRUG LIST. The Department maintains a Preferred Drug List pursuant to the Governor's Executive Order D004-07, (Section 8.800.16.A.1, 10 CCR 2505-10). The Department encourages Medicaid providers to prescribe, and pharmacies to dispense, preferred drugs. Preferred drugs are those that the Department prefers to cover because its clinical reviews have found them to be safer, more effective, and/or less costly than similar drugs. The Department classifies some drugs as non-preferred if it has identified a preferred drug that treats the same condition and is safer, more effective, and/or less costly. Often non-preferred drugs are brand-name drugs for which there is a preferred generic equivalent. For example, as of January

2014, the Department classified the generic drug Amphetamine Salts as a preferred drug and classified its brand name equivalent, Adderall, as a non-preferred drug because the Colorado Medicaid program's reimbursement rate for Amphetamine Salts was $32.81 for a 30 tablet prescription dispensed to a recipient while the rate for Adderall was $134.82 for the same dosage.

Although the Department encourages the use of preferred drugs, sometimes Medicaid recipients need treatment with a non-preferred drug because the preferred drug does not fully address their medical needs or causes adverse side effects. Pharmacies must obtain prior authorization from the Medicaid program to dispense a non-preferred drug to a recipient.

RESTRICTIONS ON DRUG QUANTITY. According to federal regulations, "restricted drugs" are those that states place limitations on [42 CFR 1396r-8(d)(1)]. As of January 2013, the Department placed quantity limits on 28 drugs to control waste and billing errors by pharmacies and help prevent overprescribing by prescribers. For example, the Department limits the quantity covered of Copaxone, which treats multiple sclerosis, to one 30-syringe kit prescription to prevent pharmacies from inadvertently billing Medicaid for each syringe in the kit. The Department also places restrictions on some preferred drugs. For example, the preferred drug Focalin XR that treats Attention Deficit/Hyperactivity Disorder, is a brand-name drug that the Department restricts by limiting the quantity that a pharmacy can dispense to 40 mg per day based on FDA dosing recommendations.

NEW METHOD TO PAY PHARMACIES FOR PRESCRIPTION DRUGS. In February 2013, the Department implemented the method to pay pharmacies for Medicaid outpatient prescription drug claims and dispensing fees described in CHAPTER 1. One of the goals of the new method was to reduce Medicaid costs by ensuring that payments for prescription drugs reflect actual costs for pharmacies to obtain and dispense the drugs. When it developed the new payment method, the Department estimated that it would save the Medicaid program about $4 million a year.

We evaluated the new payment method and concluded that it appears cost effective both because the Colorado Medicaid program's average rate per prescription for common drugs is lower than national average pharmacy costs, and because the cost of prescriptions per Medicaid recipient under the new payment method is lower than under the old method. First, we found Colorado's reimbursement rates for the 10 most prescribed drugs dispensed to Medicaid recipients between December 2013 and September 2014, the most recent data available at the time of our review, were at or below the national average pharmacy costs for each drug. For example, in September 2014, the national average cost for a 60 mg capsule of Cymbalta (a drug treating depression, anxiety, and fibromyalgia) was $7.04, while Colorado's reimbursement rate for pharmacies was $2.38. Second, when we compared the Department's drug costs per Medicaid recipient for February 2012 through January 2013 when the prior payment method was in place, to the drug costs per Medicaid recipient using the new method, we estimated that the new method created an average savings of $14 per Medicaid recipient who received a prescription, or about $5.7 million annually, which is about 2 percent of annual Medicaid prescription drug costs.

Through our audit we identified opportunities for the State to realize some additional cost savings. Specifically, we found that the Department can improve its processes, internal controls, and information systems to ensure that the Medicaid program: (1) only pays claims for allowable and covered prescription drug benefits, (2) better identifies and prevents fraud, waste, and abuse related to recipients' drug use and providers' prescribing activities, and (3) collects the full rebates due from drug manufacturers. The remainder of CHAPTER 2 describes our findings and recommendations.

CONTROLS OVER PRESCRIPTION DRUGS AND DISPENSING

Federal regulations allow state Medicaid programs to place limits on certain types of drugs to control drug costs and discourage fraud, waste, or abuse [42 CFR 1396r-8(d)(6)]. According to the Department, all pharmacies need prior authorization from the Department's fiscal agent, Xerox State Healthcare LLC (Xerox), to be reimbursed for a restricted drug or non-preferred drug prescription that is dispensed to a Medicaid recipient.

The Department's current pharmacy benefits management system called the Prescription Drug Card System (PDCS), managed by Xerox, is programmed to approve pharmacy prescription drug claims for unrestricted and preferred drugs, and deny claims for restricted and non-preferred drugs that do not have prior authorizations. If a recipient needs a restricted or non-preferred drug immediately, before a prior authorization can be obtained, the pharmacy can contact the Xerox Helpdesk and request an emergency fill. If authorized by Xerox, the pharmacy can dispense an emergency fill of up to a temporary 72-hour supply of the drug until the prescriber verifies the recipient's medical need for the full prescription.

WHAT WAS THE PURPOSE OF THE AUDIT WORK AND WHAT WORK WAS PERFORMED?

The purpose of the audit work was to determine whether the Department enforces payment restrictions on restricted drugs, non-preferred drugs, and emergency prescription fills in the Medicaid program, and whether it paid prescription drug claims in line with

federal and state regulations from February 2012 through January 2014 (the review period).

We reviewed the Department's Medicaid claims data for non-preferred variations of six drug classes from the Department's highest cost and most used drug classes for claims paid during the review period. These non-preferred drug claims totaled 51,461 claims. The six drug classes were long acting opioids, Attention Deficit/Hyperactivity Disorder treatments, proton pump inhibitors, growth hormones, skeletal muscle relaxants, and multiple sclerosis treatments. We also reviewed Department data for the 21,032 claims for over-the-counter drug products and the 44,028 claims for the 28 drugs that the Department required to be prescribed in limited quantities that were paid during the review period. To review controls over emergency fills, we reviewed a sample of 80 out of the 10,953 paid claims for the 11 types of drugs that the Department does not allow to be dispensed as emergency fills to determine if any were emergency fills. Altogether, for this area of the audit we reviewed the Department's controls over 116,601 prescription drug claims.

We also reviewed applicable federal and state regulations, Department written policies, Medicaid Provider Billing Manuals, Preferred Drug Lists, and drug quantity limit lists in effect during the review period to understand the authoritative guidance on prescription drug coverage. We reviewed the Department's contract with Xerox and interviewed Department and Xerox staff to understand prior authorization procedures, claims review and payment processes, and PDCS functionality for enforcing prior authorizations, drug restrictions, and authorizations for emergency prescription fills.

HOW WERE THE RESULTS OF THE AUDIT WORK MEASURED?

Overall, we applied the following requirements when evaluating whether the Department paid for any prescription drug claims that require prior authorizations without such authorization having been given:

- **PRIOR AUTHORIZATIONS FOR RESTRICTED AND NON-PREFERRED DRUGS.** State regulations specify that restricted and non-preferred drugs require prior authorizations in order to be paid by the Department and that the recipient's prescriber or pharmacy should submit the prior authorization requests to Xerox (Sections 8.800.1 and 8.800.7.A, 10 CCR 2505-10). The Department's Medicaid Billing Manual states that Xerox may provide a prior authorization only if the recipient qualifies for a restricted or non-preferred drug and has a medical need for the drug.

- **RESTRICTIONS ON EMERGENCY PRESCRIPTION FILLS.** According to state regulations, a pharmacy can request approval for an emergency fill of a prescription, and upon receiving authorization, the pharmacy can dispense up to a 72-hour supply of the drug (Section 8.800.7.C, 10 CCR 2505-10). The Department only allows drugs considered vital to a recipient's health to be dispensed as emergency fills. During the period we reviewed, the Medicaid Billing Manual listed 11 drugs or drug types that were not allowed to be dispensed as emergency fills. Examples of drugs that were not eligible for emergency fills for the period we reviewed were Promethazine, which treats allergies, pain, nausea, vomiting, and motion sickness; smoking cessation products; Tramadol, which treats moderate to severe pain; and Vivitrol, which treats opioid or alcohol dependence.

Department staff stated that if a pharmacist submits a claim for a non-preferred, restricted, or emergency drug prescription to Medicaid without obtaining an authorization, PDCS should deny the claim and notify the pharmacy that it must request authorization, and should only pay claims for these prescriptions after authorization has been obtained.

WHAT PROBLEMS DID THE AUDIT WORK IDENTIFY?

Overall, the Department's process and controls to restrict prescription drugs and control costs work as intended. However, we found that the

Department paid $1,138,140 for 5,154 Medicaid claims for non-preferred, restricted, and emergency prescriptions without prior authorizations (about 4 percent of the 116,601 claims reviewed). We could not determine whether these payments were allowable based on Department documentation and data, and therefore the $1,138,140 are questioned costs. Specifically, we found:

- **PAID CLAIMS FOR RESTRICTED AND NON-PREFERRED DRUGS WITHOUT PRIOR AUTHORIZATIONS.** We identified 4,172 out of the 72,493 claims for non-preferred drugs and restricted over-the-counter drugs we reviewed (6 percent) that the Department had paid even though the pharmacies did not obtain prior authorizations or emergency authorizations to dispense the prescriptions. Exhibit 2.3 shows these 4,172 claims that totaled $892,780 in questioned costs between February 2012 and January 2014.

EXHIBIT 2.3

RESTRICTED AND NON-PREFERRED PRESCRIPTION DRUGS WITHOUT PRIOR OR EMERGENCY AUTHORIZATIONS FEBRUARY 2012 THROUGH JANUARY 2014

DRUG TYPE	NUMBER OF CLAIMS	TOTAL PAYMENTS FOR DRUGS [1]
Non-Preferred Attention Deficit/ Hyperactivity Disorder Drugs	1,180	$528,390
Non-Preferred Opioids	650	$250,380
Over-the-counter Prescriptions	2,337	$113,760
Emergency Fills	5	$250
TOTAL	4,172	$892,780

SOURCE: Office of the State Auditor's analysis of the Department of Health Care Policy and Financing's Medicaid claims data.

[1] The total payments do not include dispensing fees paid to pharmacies.

- **Paid claims for prescriptions exceeded quantity limits without prior authorizations.** We identified 982 out of the 44,028 claims for drugs with quantity limits (2 percent) that the Department had paid even though there were no prior authorizations for the recipients to receive quantities that exceeded the Department's limits. Exhibit 2.4 shows these 982 claims that totaled $245,360 in questioned costs between February 2012 and January 2014.

EXHIBIT 2.4

QUANTITY LIMITED DRUGS
WITHOUT PRIOR AUTHORIZATIONS
FEBRUARY 2012 THROUGH JANUARY 2014

DRUG TYPE	QUANTITY LIMIT	NUMBER OF CLAIMS EXCEEDING LIMIT	TOTAL PAYMENTS FOR DRUGS [1]
Skin Cream	12 packets per 28-day prescription	972	$242,830
Migraine Treatment	6 tablets per 30-day prescription	10	$2,530
TOTAL		982	$245,360

SOURCE: Office of the State Auditor's analysis of the Department of Health Care Policy and Financing's Medicaid claims data.

[1] The total payments do not include the dispensing fees paid to pharmacies.

According to Department management, the 5,154 prescriptions that did not receive authorizations and approvals may have been appropriate but management was unsure whether the questioned costs we identified were improper payments without further investigation.

In addition, during our claims review for emergency fill prescriptions, neither we nor the Department could determine whether claims the Department had paid for drugs that are ineligible for emergency fills had been dispensed as emergency fills without conducting a manual time intensive review of each of the 10,953 claims. The Department does not track emergency fills in PDCS in a manner that allows for efficient analysis of all emergency fills.

WHY DID THESE PROBLEMS OCCUR?

The problems we identified occurred because the Department's internal processes or system controls did not always work effectively to ensure compliance with requirements for prior authorizations, as described in the following section.

THE DEPARTMENT DOES NOT ALWAYS ENSURE PDCS HAS CURRENT INFORMATION ON PRESCRIPTIONS REQUIRING PRIOR AUTHORIZATIONS. The Department reported to us that the primary reason PDCS automatically approved the non-preferred and restricted drug claims we identified without prior authorizations is because PDCS had not been updated to reflect current information. Specifically:

- THE DEPARTMENT DOES NOT IDENTIFY ALL NEW DRUGS AND DRUG VARIATIONS. According to the Department, it does not have the resources to track all manufacturer releases of new drugs or changes to existing drugs (such as changes in drug strength), which occur on an ongoing basis, because the Department's process to review drugs and identify those that should be restricted or non-preferred in PDCS is a manual and labor-intensive process. The Department reported to us that it attempts to identify all new drugs and changes to existing drugs weekly, but sometimes overlooks drug changes. For example, during the period of our review a new strength of an existing non-preferred drug was released; the Department did not identify the change and therefore did not notify Xerox to program the change in PDCS.

- THE DEPARTMENT DOES NOT HAVE A PROCESS TO ENSURE PDCS IS ALWAYS UPDATED WITH NEW QUANTITY LIMITS. The Department did not notify Xerox of all PDCS system changes needed when the Department established new quantity limits for prescriptions.

- THE DEPARTMENT DOES NOT ENSURE PDCS IS UPDATED ON DRUGS DESIGNATED AS OVER-THE-COUNTER BY THE FDA. The Department obtains information on the FDA's designations of drugs as over-the-counter or prescription from First Data Bank, a vendor that collects and publishes drug information. The Department said that it obtains these data from the vendor because the FDA does not make the information available in a format that can be downloaded into an electronic system such as PDCS; the information is only published on a searchable website. However, the Department reported that First Data Bank's data are not always current and do not always reflect the accurate FDA designation of a drug. The Department does not have processes to

verify the accuracy of the data from First Data Bank, such as by conducting periodic spot checks comparing them with FDA data. In addition, for the period of our review, PDCS had not been updated to recognize the generic version of one over-the-counter brand name drug that we identified and deny claims for the brand name version of the drug.

THE DEPARTMENT LACKS ADEQUATE CONTROLS OVER EMERGENCY FILLS. We identified two areas where the Department's controls related to paying claims for emergency prescription fills were not working as intended. First, pharmacies have the ability to enter a certain code when submitting a claim that overrides the requirement to obtain an emergency authorization from Xerox. As a result, PDCS does not always control emergency fills through the authorization process, as required by state regulations. The Department was unaware that this override existed prior to our audit identifying the problem. After we reported the problem to the Department, it identified 11 pharmacies that have used the override on about 170 prescription drug claims since 2008. Second, the Department does not have a method to identify all emergency fills without reviewing each claim individually because the emergency fill information is only viewable by reviewing individual claim notes. Therefore, the Department cannot efficiently monitor the use of the emergency fills or identify whether drugs that are prohibited from being dispensed as emergency fills are dispensed as emergencies.

THE DEPARTMENT'S REVIEWS OF PRESCRIPTION DRUG CLAIMS COULD BE IMPROVED. The Department reported to us that Xerox currently performs partial claims reviews to test whether prior authorization policies have been programmed into PDCS and work effectively. However, these reviews are limited in scope and do not include complete data sets because the reviews are labor intensive and must be completed quickly. The Department also reported to us that it does not have a risk-based process in place to focus prior authorization claims reviews on drugs that have the greatest impact on Medicaid expenditures. The Department could implement a more risk-based approach by targeting its PDCS claims reviews on the highest use

and/or highest cost non-preferred and restricted drugs to help ensure these drugs are properly programmed in PDCS.

WHY DO THESE PROBLEMS MATTER?

INCREASED MEDICAID COSTS. When controls over non-preferred, restricted drugs, and emergency fills are not working as intended, it limits the Department's ability to control prescription drug costs. When the Department pays pharmacies for non-preferred and restricted drug prescriptions without authorizations and without verifying that Medicaid recipients have a medical need to receive the drugs, the Department may be overpaying for treatment and paying for unnecessary prescriptions. For example, for the 972 claims for skin cream exceeding Department quantity limits without prior authorizations and 18 claims for Adderall that did not have prior authorizations that we identified, we estimated that the Department spent over $244,600 in questioned costs between February 2012 and January 2014 that could potentially be cost savings had these claims been reviewed and denied through the prior authorization process.

Additionally, when pharmacies are reimbursed for prescription drug claims that exceed the Department's quantity limits without Department approval, the Department could be paying for drugs that were never dispensed. For example, if a pharmacy bills for the incorrect unit amount (i.e., billing for individual packets inside of a larger kit) the pharmacy would be reimbursed for more units of a drug than it actually dispensed. This increases the costs of the Medicaid program without providing any additional health care benefits to recipients.

UNMONITORED EMERGENCY PRESCRIPTIONS. Since the Department cannot efficiently review claims data to identify emergency fills, it has limited ability to identify pharmacies or recipients that may be using emergency fills to circumvent the authorization process, or identify pharmacies that dispense emergency supplies of drugs that are not eligible for emergency fills. When the Department does not monitor the use of emergency fills, there is a greater risk that recipients could repeatedly obtain drugs and providers could repeatedly dispense prescriptions that the Department may not otherwise authorize.

RECOMMENDATION 1

The Department of Health Care Policy and Financing should strengthen controls to enforce proper authorizations and payments for non-preferred, restricted, and emergency prescription drug claims in the Medicaid program by:

A Implementing processes to keep its pharmacy benefits management system updated with current information on all drugs that require prior authorizations.

B Implementing functionality in its pharmacy benefits management system to eliminate the ability for pharmacies to override emergency fill authorizations and to clearly identify each prescription that is an emergency fill. Once this system functionality is implemented, the Department should monitor aggregate data on a routine basis for proper use of emergency fills.

C Implementing a routine risk-based claims review process to identify and address improper prescription drug claims that do not have prior authorizations, and provide information to update the pharmacy benefits management system.

D Reviewing the 5,154 prescription drug claims identified by this audit, which did not comply with state regulations, and recovering the questioned costs, as appropriate, from the pharmacies that received the funds.

RESPONSE

DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

A AGREE. IMPLEMENTATION DATE: NOVEMBER 2016.

The audit found that the Department's current process and controls worked as intended for about 96% of the 116,601 claims reviewed. The new pharmacy benefits management system, scheduled to be operational in November 2016, will be able to track new prescription and over-the-counter drugs and make necessary system updates through a more comprehensive and automated process. In the interim, the Department has improved the current manual process in February 2015 for monitoring new drug additions and changes to the system. The pharmacy system's drug reference information is updated weekly by First Data Bank (FDB). The Department started receiving a weekly email update from FDB which maps out what was added to the pharmacy system. This provides the Department's pharmacists with another resource to help identify which system programs need to be reviewed and possibly updated. The Department's data analysts will also continue to run a weekly report for identifying new drugs. The Department will complete the necessary system updates by October 2015 for the small number of drugs identified by the audit which required prior authorization prior to payment.

B AGREE. IMPLEMENTATION DATE: NOVEMBER 2016.

The new pharmacy benefits management system, scheduled to be operational in November 2016, will not permit pharmacies to override the prior authorization requirement for emergency fills. The Department also anticipates that the new system will be able to better track which claims are emergency fills. To disable the override in the current system would require a significant system change; the Department is evaluating whether that could be completed before the new system is operational. Until the current system can be updated

and/or the new system is operational, the Department will perform periodic claims analysis to monitor utilization of the override and pursue recovery of paid funds and/or perform provider outreach as appropriate.

C AGREE. IMPLEMENTATION DATE: NOVEMBER 2016.

The new pharmacy benefits management system, scheduled to be operational in November 2016, will have more comprehensive and automated processes to ensure the system is operating consistent with the Department's prior authorization policies. The Department currently performs testing prior to implementation of system updates and will supplement that process with periodic post-payment claim reviews until the new system is operational. Since the post-payment claim reviews will be highly manual and time-intensive, the Department will use a risk-based approach in order to make the process manageable with existing resources.

D PARTIALLY AGREE. IMPLEMENTATION DATE: DECEMBER 2015.

The Department will review the five claims which paid due to improper use of an override for emergency fills. Based on the review findings, the Department will pursue a recovery of paid funds where appropriate and perform provider outreach. For the remaining claims, the Department believes the majority of the recipients would have received a prior authorization as 84-89% of all prior authorizations are approved. Therefore, it would not be cost effective to secure the additional resources needed to review that volume of claims. Such a review would require the Department to determine if a prior authorization request would have been approved if one had been submitted for each Medicaid member. The Department would need to locate the medical records for each member and then manually review the records in light of the prior authorization criteria for the applicable drug and date of service. The review would have to be performed by staff with specialized clinical training (e.g., pharmacists) and would take several months to complete given the volume of claims. The Department could not complete such a review with existing resources and, since the review would likely substantiate that

most of the claims paid appropriately, the Department does not believe it would be cost effective to hire temporary clinical staff to conduct the review.

AUDITOR'S ADDENDUM

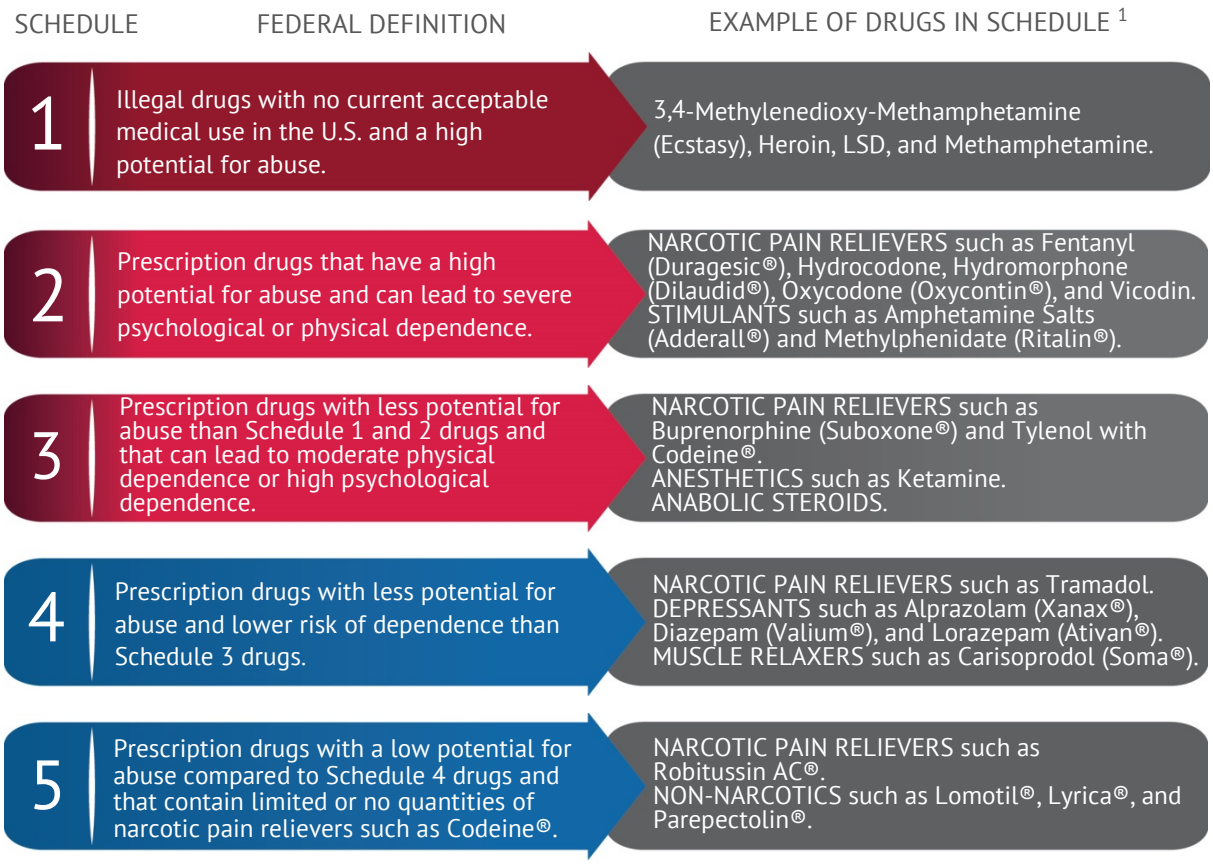
Because the Department was unable to provide evidence that the payments for any of the 5,154 claims were allowable uses of state and federal funds, we recommend the Department review them to identify and recover, as appropriate, any improper payments. The Department has only agreed to review five emergency fills totaling $250. This leaves 5,149 unauthorized and possibly unallowable claims totaling $1,138,140 that will not be reviewed. Without evidence to support that these payments are allowable under state and federal regulations, CMS could recover the federal portion of the questioned costs, which totals about $569,000; the State would be liable for these funds. Understanding the existence of resource constraints, it may be appropriate for the Department to review these unauthorized claims based on risk. For example, the Department could review: (a) the claims for the 650 opioid pain relievers, which, as discussed in the next section of the report, are at high risk of misuse; (b) the 1,180 Attention Deficit/Hyperactivity Disorder drug claims, which were the most costly unauthorized claims paid, at an average cost of almost $450 per claim; (c) the 982 drug claims that exceeded quantity limits to ensure pharmacies did not overbill Medicaid for drugs that were not dispensed; and/or (d) the claims for the recipients and pharmacies with the highest amounts of questioned costs. Alternatively, the Department could determine if the 5,149 claims are allowable by sending letters to the prescribers for these claims and checking whether the prescriptions were medically necessary and not fraudulent. Even if 84 to 89 percent of the $1,138,140 claims amounts that the Department does not agree to review were found to be appropriate, approximately $125,000 to $182,000 in payments would likely be found to be inappropriate and could be recovered based on the results of the review.

CONTROLS OVER DRUG UTILIZATION

Controlled substances are: (1) prescription and over the counter drugs that have a medical use but pose a danger of dependence and misuse for nonmedical purposes, and (2) non-prescription drugs that have no medical use and a high potential for abuse, such as heroin and methamphetamine. To help the federal and state governments monitor the manufacturing, distribution, and possession of controlled substances, the U.S. Drug Enforcement Administration (DEA) and the U.S. Code classifies them into one of five schedules, or categories, shown in Exhibit 2.5. The U.S. Code categorizes each drug based on whether the drug is commonly used for medical treatment, the potential for a person to abuse the drug, and the likelihood that the drug will cause dependence when abused [21 USC 812(b)1-5].

EXHIBIT 2.5

THE FIVE SCHEDULES OF CONTROLLED SUBSTANCES



SOURCE: U.S. Department of Justice Drug Enforcement Administration, Office of Diversion Control Controlled Substance Schedules [21 USC 812(b)1-5].

[1] The table shows examples of drugs in each schedule and not a comprehensive list of all controlled substances.

While Schedule 2 through 5 prescription drugs can have an important role in treating medical conditions, the use of these drugs for purposes other than prescribed, or without a prescription, has increasingly become a public health issue in Colorado. The U.S. Department of Health and Human Services sponsors the annual National Survey on Drug Use and Health that measures drug use nationally and by state. The 2013 National Survey on Drug Use and Health, the most recent survey available, ranked Colorado 12th among all states for prescription pain reliever misuse, and the University of Colorado Skaggs School of Pharmacy (Skaggs) found that more than 224,000

Coloradans misuse prescription pain relievers annually. Further, in a study released in October 2014, the Colorado Department of Public Health and Environment found that between 2000 and 2012, annual prescription drug overdoses more than doubled from 351 deaths to 807 deaths per year. According to the Centers for Disease Control, one common method of obtaining prescription drugs for non-medical purposes is through "doctor shopping" when individuals visit multiple prescribers and/or pharmacies to obtain prescriptions for a continuous supply of controlled substances for an addiction, recreational use, or resale.

To help control the types, quantities, and dosages of drugs that are dispensed to recipients through the Medicaid program, the Department has established global controls over all outpatient prescriptions. According to the Department, PDCS should deny prescription claims for several reasons established by the Department, including:

- Duplicate drug prescriptions
- A refill of the prescription before 85 percent of the supply has been used
- A prescription for a drug dosage or quantity that exceeds clinically determined safe levels of use or Department limits
- A prescription for a drug that is inappropriate based on the recipient's age

The Department's current fiscal agent, Xerox, programs the restrictions into PDCS to deny prescription drug claims that meet denial criteria.

Additionally, federal regulations require state Medicaid programs to conduct drug utilization reviews to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care [42 CFR 456.709]. The Department contracts with Skaggs to conduct these drug utilization reviews that examine Medicaid claims and recipients' medical information quarterly to identify problems such as

prescription drug abuse, "doctor shopping," and unsafe prescribing that may place recipients' health at risk. The Department and Skaggs determine the focus of each quarterly review. Reviews conducted in Calendar Year 2013 examined whether Medicaid recipients received inappropriate drugs based on their age, appeared to over utilize prescription drugs, received antipsychotic drugs for long periods, or received prescriptions above the FDA recommended doses. When Skaggs identifies a problem, the Department and Skaggs send the prescriber a letter explaining the problem and how the prescriber could address it, such as by reviewing the recipient's prescription history when determining his or her treatment in the future. In its 2013 reviews, Skaggs identified 142 recipients, each with a different prescriber, who appeared to over utilize prescription drugs for 2 weeks or more by using multiple opioids such as Morphine ER (extended release) and Oxycodone ER, which are prone to abuse. The Department and Skaggs sent letters to the 142 prescribers.

The Department also implemented a program called the Accountable Care Collaborative in 2011, which is optional for Medicaid recipients and offers them coordination of care. For recipients who participate in the program, the Accountable Care Collaborative provides most of their services through a single primary care provider, and additional services, such as referrals to substance abuse treatment or specialized mental health treatment, through a regional network of providers that coordinate with the primary care provider. According to the Department, when recipients participate in the Accountable Care Collaborative program, it can help identify and address their overuse of Medicaid benefits.

WHAT WAS THE PURPOSE OF THE AUDIT WORK AND WHAT WORK WAS PERFORMED?

The purpose of the audit work was to assess the effectiveness of the Department's controls over prescriptions for controlled substances and its monitoring of Medicaid recipients' prescription drug utilization.

We focused our review on the Department's controls over Schedule 2 and 3 prescription drugs because the DEA has identified them as having the highest potential for physical dependence and abuse. To evaluate the Department's monitoring and controls over recipients' Schedule 2 and 3 drug prescriptions, we assessed the actions that the Department took to address the drug overutilization of the 142 recipients that Skaggs identified in 2013. We also reviewed PDCS data on the 1,116,400 Medicaid claims for Schedule 2 and 3 prescriptions paid between February 2012 and January 2014, to: (1) identify the recipients who met the State's regulatory criteria for being over utilizers of prescription drugs, and (2) determine if the Department placed special restrictions on these recipients' ability to obtain prescription drugs through Medicaid.

We reviewed whether the Department complied with applicable federal and state requirements and assessed the Department's policies and procedures for identifying and controlling overutilization of prescription drugs by Medicaid recipients. We compared the Department's monitoring and utilization control practices to those in other states' Medicaid programs and in the federal Medicare Part D prescription drug program to identify practices that could be useful in Colorado. We also interviewed Department staff to understand how the Department monitors prescription drug use and controls drug utilization to prevent recipient fraud, waste, and abuse.

HOW WERE THE RESULTS OF THE AUDIT WORK MEASURED?

We used the following state statutes, federal regulations, and state regulations to evaluate the Department's controls over prescriptions for controlled substances and its monitoring of recipients' prescription drug utilization.

IDENTIFYING AND ADDRESSING OVERUTILIZATION OF PRESCRIPTION DRUGS. Statute requires the Department to implement prescription drug overutilization efforts within the Medicaid program. Specifically, Section 25.5-5-506(1), C.R.S., requires the Department to implement

a drug utilization review process to (1) "assure the appropriate utilization of drugs by [Medicaid] patients…" and (2) "address at a minimum…overutilization of…drugs." The statute further states that the General Assembly's intent is that the implementation of a drug utilization review process will produce savings within Medicaid [Section 25.5-5-506(2), C.R.S.].

Federal regulations [42 CFR 456.709(a)] require state Medicaid programs to have a drug utilization review program for covered outpatient drugs to ensure that drugs are appropriate, medically necessary, and not likely to result in adverse medical results. The drug utilization review program is required to include ongoing periodic review of claims data to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and Medicaid recipients, or with specific drugs or groups of drugs. Federal regulations further allow state Medicaid programs to use their drug utilization review programs to identify Medicaid recipients who may use prescription drugs at a frequency or amount that is not medically necessary and restrict such overuse [42 CFR 431.54(e)].

In addition, state regulations (Section 8.075.4, 10 CCR 2505-10) allow the Department to restrict the prescription drug benefits of a recipient whose utilization is without medical necessity and meets or exceeds any of the following:

- Use of three or more drugs in the same therapeutic category (e.g., Hydrocodone and Oxycodone are pain relievers in the same opioid category) in 3 months.
- Use of 16 or more prescriptions in 3 months.
- Use of prescriptions from three or more pharmacies in 3 months.

State regulations also allow the Department to use other analyses to determine a recipient's possible overutilization (Section 8.075.4, 10 CCR 2505-10). Department staff reported to us that they consider whether a recipient has obtained prescriptions from an excessive number of prescribers when determining whether a recipient may be

over utilizing drugs, but staff have not established a set number of providers that they consider excessive.

WHAT PROBLEM DID THE AUDIT WORK IDENTIFY?

The Department has not implemented effective processes that ensure Medicaid recipients utilize Schedule 2 and 3 drugs appropriately and that address and control recipients' overutilization of drugs. Although the Department has implemented a drug utilization review process as well as global controls to restrict the types, quantities, and doses of drugs that Medicaid covers, the Department does not have effective processes to control recipients' access to prescriptions when there is evidence that they overuse drugs.

Specifically, we found that for the period we reviewed, the Department did not restrict access to prescription drugs for any recipients identified as potential over users of Schedule 2 and 3 drugs. For example, the Department did not place special restrictions on access to drugs as allowed by federal regulations, or address overutilization as required by statute, for any of the 142 Medicaid recipients who appeared to be over utilizing opioids according to the 2013 Skaggs reviews. The Department reported to us that its only action related to these recipients was to send letters to each of the 142 recipients' prescribers to notify them of the potential overutilization. In the letters, the Department suggested that the prescribers consider prescribing drugs in different doses or strengths. The Department did not ask the prescribers whether the recipients had a medical need for the opioids they received or take any further action to address the overutilization of opioids.

In addition, the Department did not restrict access to drugs for any of the 17 recipients we identified who appeared to be extreme examples of potential over utilizers of prescription drugs based on our review of claims data. Overall, we found 14,310 recipients met at least one of the three overutilization criteria in state regulations (Section 8.075.4, 10 CCR 2505-10), but the 17 recipients each exceeded all three of the

overutilization criteria, and each exceeded at least one criterion by a significant margin. For example, one of the 17 recipients had 66 different prescriptions for 6 different types of opioids written by 41 prescribers and filled by 27 different pharmacies over a 12-month period. Details on these 17 recipients are shown in Exhibit 2.6 on page 47. According to the Department, during our review period, 10 of the 17 recipients were enrolled in the Accountable Care Collaborative; however, based on Department data, this program did not restrict the 10 recipients' access to prescription drugs or address their overutilization of drugs.

WHY DID THIS PROBLEM OCCUR?

Overall, the problem we identified occurred for the following reasons:

LOCK-IN PROCESS IS NOT IN PLACE. Although the Department initially reported that it had a Client Overutilization Program that locked-in a Medicaid recipient to one designated prescriber and pharmacy when the recipient appeared to over utilize prescriptions without medical need, the Department stopped the lock-in process in 2012.

The Department told us that the primary reason it does not lock-in recipients to a set number of prescribers or pharmacies is that the Department's Medicaid Management Information System (MMIS) does not have the functionality to effectively restrict a recipient to a single provider for a specified period by only paying claims to the single provider. In Fiscal Year 2012, the Department received a $222,900 appropriation of general funds and federal funds to implement changes in MMIS to restrict a recipient to a set number of providers so that it could fully implement the Client Overutilization Program. However, the Department reported to us that it did not implement the system changes to MMIS because other system changes were prioritized. According to the Department, when it implements a new MMIS system beginning in Fall 2016, the system should have the functionality to lock-in a recipient to a single provider, or up to 10 different types of providers, when there is evidence of drug overutilization. Nebraska has a five-tier system in which it restricts a recipient to a certain number of providers depending on the

egregiousness of the recipient's drug overutilization. The Department should consider this type of restriction on recipients' access to providers when implementing its new system.

The appropriation was also meant to create incentive payments for prescribers to agree to be the sole care provider for locked-in recipients because these individuals are often more difficult and time intensive to treat. The Department reported it has tried to recruit providers to participate in the Client Overutilization Program but that only 24 prescribers ever agreed to be sole providers for over utilizing recipients. The Department determined this was not enough to operate the lock-in program.

The Department reverted the 2012 state funding back to the General Fund and did not obtain the federal funds.

BESIDES ATTEMPTING THE LOCK-IN PROCESS, THE DEPARTMENT HAS NOT ESTABLISHED SPECIAL RESTRICTIONS ON OVER UTILIZERS' PRESCRIPTIONS. In August 2014, the Department implemented dosing limits for all Medicaid recipients that restrict an opioid prescription to a maximum of four tablets per day. However, the Department has not established mechanisms to restrict prescription drug benefits specifically for the recipients who have been identified as overusing or misusing prescriptions. Other states have various procedures to restrict overuse that the Department should consider implementing beyond a lock-in program. Indiana requires a prior authorization for all controlled substance prescriptions for recipients identified as overusing. Arkansas, California, Georgia, Florida, Pennsylvania, and Illinois restrict recipients' Medicaid coverage when they attempt to obtain multiple prescriptions for opioids in a month through Medicaid by automatically denying the claims or by capping the total number of days supplied of opioids that a recipient can receive per month across all of the recipient's opioid prescriptions. In addition, Arkansas denies claims for opioid prescriptions if the recipient is already taking a drug to treat opioid addiction.

Further, the Department has not defined what it considers an excessive use of prescribers. The Department should consider definitions

established by other states. For example, New Hampshire, North Carolina, and West Virginia define excessive use of prescribers as obtaining controlled substance prescriptions from three or more prescribers within 60 to 90 days.

WHY DOES THIS PROBLEM MATTER?

When the Department does not monitor and control overutilization effectively, the following results can occur:

RECIPIENTS CAN OVER UTILIZE DRUGS THROUGH MEDICAID. We requested that Department staff, including the staff pharmacist, perform a clinical review of the claims for the 17 recipients we identified as being potential over users of prescription drugs. The Department reported to us that these Medicaid recipients, shown in Exhibit 2.6, appeared to be over-utilizers of Schedule 2 or 3 drugs based on the recipients' claims and medical history, but could not confirm overutilization without further investigation. These recipients showed multiple indicators of over utilizing and greatly exceeded the criteria outlined in state regulations.

EXHIBIT 2.6

PRESCRIPTION CLAIMS HISTORY FOR MEDICAID RECIPIENTS WHO EXCEEDED OVER-UTILIZATION CRITERIA FOR ANY 3-MONTH PERIOD FEBRUARY 2012 THROUGH JANUARY 2014

RECIPIENT	NUMBER AND TYPES OF SCHEDULE 2 AND 3 DRUGS PRESCRIBED [1]	PRESCRIPTIONS IN 12 MONTHS	PRESCRIBERS IN 12 MONTHS	PHARMACIES IN 12 MONTHS	DAYS OF DRUG SUPPLIED IN 12 MONTHS	COST TO MEDICAID
1	5 Opioid Pain Relievers [2]	91	64	19	432	$ 1,270
2	5 Opioid Pain Relievers	80	21	14	586	$ 2,120
3	4 Opioid Pain Relievers	71	53	23	216	$ 790
4	6 Opioid Pain Relievers 3 Stimulants [3]	60 8	28	16	433 188	$ 1270
5	6 Opioid Pain Relievers	66	41	27	648	$ 4,530
6	6 Opioid Pain Relievers	65	17	14	966	$ 8,800
7	3 Opioid Pain Relievers	63	12	14	566	$ 2,170
8	5 Opioid Pain Relievers	61	32	24	576	$ 1,300
9	5 Opioid Pain Relievers	61	30	17	352	$ 4,440
10	4 Opioid Pain Relievers	60	32	29	491	$ 720
11	4 Opioid Pain Relievers 2 Stimulants	55 5	15	14	762 135	$ 1,710
12	3 Opioid Pain Relievers	60	21	13	475	$ 700
13	5 Opioid Pain Relievers	55	25	13	637	$ 1,570
14	5 Opioid Pain Relievers	54	36	13	183	$ 380
15	4 Opioid Pain Relievers	53	36	14	337	$ 510
16	5 Opioid Pain Relievers 2 Stimulants	40 12	14	20	847 355	$ 11,260
17	4 Opioid Pain Relievers 1 Stimulant	41 11	28	20	450 330	$ 1,610
					TOTAL COST	$ 45,150

SOURCE: Office of the State Auditor's analysis of the Department of Health Care Policy and Financing's data on paid fee-for-service outpatient prescription drug claims for Schedule 2 and 3 drugs.

[1] Types of drugs are counted as drugs that are not considered therapeutically equivalent. Multiple prescriptions at different strengths, and multiple brand and generic prescriptions of the same type, are counted as one drug type.

[2] Opioid pain relievers prescribed to these recipients were Acetaminophen-Codeine, Exalgo-ER (Hydromorphone), Fentanyl, Hydrocodone-Acetaminophen, Hydrocodone-Ibuprofen, Methadone, Morphine Sulfate-ER, Nucynta-ER, Oxycodone-Hydrochloride, OxyContin, and Roxicet/Endocet (Oxycodone-Acetaminophen).

[3] Stimulants prescribed to these recipients were Adderall-XR (Amphetamine Salts) and Methylphenidate-ER.

When the Department does not have processes to restrict prescription overuse by these types of recipients, it can negatively affect their health, increase Medicaid costs, and lead to illicit drug use, as described in the following section.

INEFFECTIVE AND UNSAFE DRUG USE. Inappropriate use of prescription drugs can cause the drugs to be both ineffective to treat a patient's condition and/or dangerous to a patient's health. For example, Department documentation showed that in 2013 and 2014 one Medicaid recipient had an opioid addiction and was receiving prescriptions for drugs used to treat the addiction from one prescriber while simultaneously receiving 49 prescriptions for opioid pain relievers from an additional 26 prescribers over a 7-month period. Opioid addiction treatment drugs and opioid pain relievers are contraindicated and effectively cancel out the intended use of the other drug, potentially causing the recipient to experience withdrawal.

In addition, when a recipient receives prescriptions from multiple prescribers, it may increase the risk of the recipient taking drugs that interact dangerously, overdosing, and experiencing long term health problems. According to an August 2012 study of two million individuals by the U.S. Centers for Disease Control, overutilization of opioids led to respiratory depression, brain damage, and coma, and these problems can cause increased costs for hospitalization and care. A drug utilization review released in Fiscal Year 2014 by Skaggs found that 197 Medicaid recipients had an opioid overdose between July 2012 and June 2013. The Skaggs review also found that the risk of overdose was 2 to 10 times higher for recipients receiving prescriptions lasting more than 100 days or getting prescriptions from more than two pharmacies.

ADDITIONAL HEALTH CARE COSTS. The State can incur costs for medically unnecessary drugs that are dispensed to recipients who over utilize prescription drugs. For the 17 Medicaid recipients we identified, the Department paid $45,150 for prescriptions for Schedule 2 and 3 drugs that, according to the Department, may not have been medically necessary. The Department stated in its Fiscal Year 2012 budget request that if the client overutilization program was not

implemented, the Department would continue to pay for avoidable expenses for recipients who over utilize services. The Department estimated that the implementation of a lock-in program for 200 recipients identified prior to Fiscal Year 2012 would have resulted in a reduction of $633,725 in General Fund expenditures for prescription drugs for Fiscal Years 2012 and 2013. The additional health risks cited above can also increase health care costs. For example, the August 2012 study by the U.S. Centers for Disease Control found that the total overall health care costs of opioid abusers were eight times that of non-abusers.

Diversion of drugs for illicit purposes. Prescription medications can be diverted for nonmedical use by recipients to sell on the street. Because Schedule 2 and 3 drugs are highly addictive and dangerous, it is important that individuals taking the prescriptions are under the care of a provider who can appropriately monitor usage. If recipients divert drugs, Department fraud and abuse services, state and federal law enforcement, and criminal prosecutors must use resources to detect, stop, and prosecute those involved in the sale of the drugs for nonmedical purposes.

RECOMMENDATION 2

The Department of Health Care Policy and Financing should implement effective processes to ensure the appropriate utilization of prescription drugs by recipients and address overutilization within the Medicaid program by:

A Implementing special restrictions over the prescription drugs that a recipient receives through Medicaid if he or she meets established overutilization criteria. The Department should consider implementing various types of restrictions, such as on the number of prescriptions, drug types, and/or drug combinations that the over utilizing recipient receives within a set time frame, and on the number of providers who can prescribe to the recipient through Medicaid.

B Analyzing the claims paid for the 17 recipients who appeared to over utilize prescription drugs through Medicaid, notifying the recipients' prescribers of potential overutilization, and based on the results of the analyses, referring the recipients to the Department's Drug Utilization Review Program and to law enforcement for investigation, as appropriate.

RESPONSE

DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

A AGREE. IMPLEMENTATION DATE: NOVEMBER 2016.

The Department agrees that some recipients identified by way of established overutilization criteria should be subject to some restrictions. The Department is currently addressing over utilization through the Accountable Care Collaborative (ACC), the utilization management vendor and other Department initiatives. The utilization management vendor provides a list of clients meeting overutilization criteria to the Department quarterly. The list is shared with the Regional Care Collaborative Organizations (RCCO) so they can outreach the clients to assess needs and provide follow-up resources; the RCCOs submit to the Department client specific information regarding activities and interventions.

Starting in May 2015, a letter will be sent to Medicaid recipients that includes a description of the overutilization, contact information for the Nurse Advise Line; and a request to contact their RCCO. In addition, the ACC is launching a telehealth model that uses video conferences to bring the chronic pain experts into primary care settings. This will help manage the care of Medicaid members with chronic pain. The new Medicaid Management Information System will permit additional provider types to serve as lock-in providers and allow for a client to have concurrent ACC and lock-in enrollment. In addition, the Department is in the process of procuring a new vendor for the Pharmacy Benefit Management System. This new system will limit recipients' utilization with respect to specific drug classes, number of prescriptions, and drug combinations. All of these system changes are scheduled to be operational in November 2016.

B PARTIALLY AGREE. IMPLEMENTATION DATE: OCTOBER 2015.

The Department currently serves 1.2 million Coloradoans and will process over 7 million prescription drug claims this fiscal year; the audit identified possible drug overutilization for 17 members which does not indicate ineffective processes. For state fiscal year 2013-14, the estimated cost savings based solely on the prior authorization policies implemented from the Drug Utilization Review (DUR) program exceeded $9 million. The DUR is an established and successful program. The utilization management vendor, in conjunction with the Department, analyzes claims data quarterly to identify all types of potential drug therapy problems. The retrospective analysis portion of the DUR program intervenes by providing notification to prescribers of the identified issues and is accompanied by prescriber education. The DUR program also develops clinical criteria which are used to develop utilization controls.

The Department and DUR program does agree to further review the drug utilization for the 17 recipients identified by the audit. If appropriate, the DUR program will send letters with our findings to the applicable prescribers. The letters will have to be drafted and then approved by the DUR Board at their quarterly meeting in August 2015. Since this review will be claim-based, it is important to note that it will be very difficult to determine with any certainty whether fraud has occurred. If the Department suspects potential member fraud, that information would be submitted to the applicable county. If possible provider fraud is identified through our processes, then that would be submitted to the Department's Program Integrity (PI) unit.

AUDITOR'S ADDENDUM

The audit identified 14,310 Medicaid recipients who met at least one of the overutilization criteria in state regulations, meaning all of these recipients may be over utilizing prescription drugs and may need restrictions on their use. This audit finding focused on the 17 recipients who greatly exceeded the criteria and were the

highest utilizers of Schedule 2 and 3 drugs in Colorado's Medicaid program to highlight the importance of having effective processes to curb prescription drug overutilization. However, the Department had not placed any special restrictions even on these 17 recipients who have indicators that they may be extreme over utilizers of prescription drugs. When the Department does not have processes to address drug overutilization for the highest risk recipients in Medicaid or ensure that the drugs these recipients receive are medically necessary and not likely to create adverse medical results, the Department is not meeting statutory and federal requirements.

CONTROLS OVER PROVIDERS

According to the Centers for Medicare and Medicaid Services (CMS), one of the most costly abuses related to prescription drugs in Medicaid is drug diversion, which is the prescribing or dispensing of prescription drugs for illicit purposes. Some fraudulent activities that CMS has identified in Medicaid include providers prescribing medications that are not medically necessary, providers prescribing medications for use by people other than the patient, pharmacies dispensing drugs or quantities of drugs that are different than prescribed, and pharmacies billing Medicaid for drugs that were never dispensed. According to the Centers for Disease Control and Prevention, the most commonly prescribed or dispensed drugs for illicit purposes are Schedule 2 and 3 drugs, such as opioid pain relievers. As described in Recommendation 2, Schedule 2 and 3 drugs have medical uses but are considered by the DEA as high risk drugs because they are likely to cause addiction and are often diverted for illicit non-medical purposes.

The Department and other states' Medicaid agencies help ensure quality of care for Medicaid recipients, control Medicaid costs, and prevent fraud, waste, and abuse such as drug diversion, by screening most health care providers who serve Medicaid recipients; however, currently recipients can go to a provider who has not been enrolled as a Medicaid provider by the Department. The providers of prescription drugs for Medicaid recipients include health care professionals who prescribe medications, such as general care physicians, specialists, dentists, and emergency departments, and pharmacies that dispense prescriptions. MMIS tracks Medicaid providers who actively serve recipients and interfaces with the PDCS pharmacy claims system to process payments to providers for their services.

According to the Department and federal regulations, the following two categories of providers are not eligible to provide services to Medicaid recipients:

- **EXCLUDED PROVIDERS** have been excluded from participating in Medicaid by the U.S. Department of Health and Human Services, Office of the Inspector General (OIG) because the providers have been convicted of fraud or criminal activity [42 U.S.C. 1320a-7]. The OIG tracks these providers on its List of Excluded Individuals and Entities, which is published monthly. There were 34 providers with addresses in Colorado on the OIG's December 2014 excluded list, the most recent list available during our audit.

- **TERMINATED PROVIDERS** have been terminated from participating in Medicaid by the Department. These include providers who have retired or are not in business, who do not possess a valid professional license, or who have been convicted of criminal activity, such as filing false Medicaid claims. The Department keeps a Terminated Provider List. There were 42 providers who had been terminated by the Department's Program Integrity Section as of July 2014, the most recent list available during our audit, and four of these providers were also on the OIG's excluded list because they had been convicted of fraud or criminal activity.

According to the Department, its staff perform monthly checks to monitor that Medicaid providers who actively serve recipients are not excluded or terminated from federal or state participation in the Medicaid program. In addition, the Department's Program Integrity Section reviews Medicaid prescription drug claims for inappropriate payments to providers active in the Medicaid program, recovers overpayments and inappropriate payments, and conducts preliminary investigations to determine whether there are credible allegations of fraud that should be referred to the Medicaid Fraud Control Unit at the State Attorney General's Office or other law enforcement [42 CFR 455.14 and 455.15]. The Program Integrity Section is also responsible for notifying the fiscal agent, currently Xerox, when a Medicaid provider has been terminated so that it can terminate the provider's status in MMIS.

WHAT WAS THE PURPOSE OF THE AUDIT WORK AND WHAT WORK WAS PERFORMED?

The purpose of the audit work was to assess the Department's controls to prevent paying Medicaid claims for prescriptions written by excluded and terminated providers, and the Department's processes for identifying and monitoring providers who prescribe Schedule 2 and 3 drugs to Medicaid recipients and who appear high risk for overprescribing or for committing fraud, waste, or abuse.

To determine whether the Department paid claims for excluded and terminated providers, we reviewed the Department's electronic data for the about 8.8 million prescription drug claims paid during the review period February 2012 through January 2014. To help us assess the Department's monitoring of providers who prescribe Schedule 2 and 3 drugs to recipients and who appear high risk for overprescribing or for fraud, waste, or abuse, we reviewed the Department's electronic data for the 1.1 million claims for Schedule 2 and 3 drugs paid during the review period. We also reviewed medical license information for a random sample of 200 providers that met one or more of the OIG's high risk criteria (described in the next section) to determine whether the providers had any disciplinary action by the State Medical Board for inappropriate prescribing practices.

As part of our audit work, we reviewed federal regulations and state statutes related to provider eligibility for serving Medicaid recipients, CMS guidance to states on monitoring providers' prescribing activities, and health care industry best practices for monitoring providers' prescribing patterns. We also interviewed Department staff and reviewed Department policies and procedures to understand how the Department terminates providers from the Medicaid program, enforces provider terminations and exclusions, prevents and detects drug diversion or unsafe prescribing patterns, and monitors providers for fraud, waste, and abuse.

HOW WERE THE RESULTS OF THE AUDIT WORK MEASURED?

We used the following federal regulations, federal guidance, and state statutes to evaluate the Department's controls and monitoring of providers.

EXCLUDED AND TERMINATED PROVIDERS. Federal regulations [42 CFR 1001.1901(b)(1) and (c)(4)] prohibit federal health care programs, including Medicaid, from paying for services furnished by an OIG excluded provider, or at the medical direction of or on the prescription of an OIG excluded provider. According to these regulations, prescriptions written or dispensed by providers who are excluded from Medicaid are invalid and not eligible for Medicaid reimbursement. Additionally, services rendered by terminated providers should not be covered by Medicaid. State regulations specify that Medicaid reimbursement for prescription drugs is allowable when the prescriber is licensed and the prescription order is valid [Section 8.800.12, 10 CCR 2505-10]. The U.S. Office of Management and Budget (OMB) Circular on allowable costs [OMB Circular A-87(C)(1)(c)] states that, for a cost to be allowable under a federal program, it must be authorized or not prohibited under State law or regulations.

DRUG UTILIZATION REVIEW PROGRAM. According to federal regulations [42 CFR 456.709(a)], the Department must have a program to review claims data at least quarterly to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among providers, pharmacists, and Medicaid recipients. Regulations require the program to educate providers on optimal prescribing practices, follow up with providers who have been targeted for intervention, and intensify monitoring of selected providers [42 CFR 456.711].

IDENTIFYING HIGH RISK PROVIDERS. In January 2012, CMS issued guidance to states for reducing prescription drug diversion and advised states to identify and screen high risk providers to prevent prescription drug fraud, waste, or abuse. However, neither CMS nor any other

federal agency has issued specific criteria that states should use for identifying Medicaid providers who may be overprescribing Schedule 2 and 3 drugs, which CMS has found are commonly involved in drug diversion, or identifying providers who may be high risk for possible fraud, waste, and abuse. In addition, the Department has not developed standard criteria to identify Medicaid providers who may be overprescribing Schedule 2 and 3 drugs or at high risk for fraud, waste, and abuse related to these prescriptions. The Department reported that Skaggs develops unique criteria for each of its drug utilization reviews to identify possible over utilizing recipients, but the Department does not have standard criteria to identify high risk providers. In the absence of any criteria developed by the Department, we used criteria developed by the OIG for reviewing Medicare Part D prescribing practices to evaluate Colorado Medicaid providers for possible over-prescribing. We used the following OIG Medicare Part D measures to identify providers in Colorado's Medicaid program who may be high risk for overprescribing, fraud, waste, or abuse:

- Those who write 400 or more prescriptions for Schedule 2 and 3 drugs for recipients in a year.
- Those who prescribe Schedule 2 and 3 drugs to 200 or more recipients in a year.
- Those who write 12 or more Schedule 2 and 3 drug prescriptions per recipient in a year.
- For providers with 40 or more claims, those with 75 percent or more of their total claims being for Schedule 2 and 3 drugs.

WHAT PROBLEMS DID THE AUDIT WORK IDENTIFY?

Overall, we found that the Department paid some Medicaid claims for prescription drugs prescribed by excluded and terminated providers, in violation of federal and state regulations, and the Department had not identified or monitored providers who are at an increased risk of over-

prescribing drugs to Medicaid recipients. The problems we identified are described in the following sections.

CLAIMS PAID FOR PRESCRIPTIONS WRITTEN BY EXCLUDED AND TERMINATED PROVIDERS. Between February 2012 and January 2014, the Department paid pharmacies for 2,053 claims for prescriptions that had been written by excluded and/or terminated providers. Specifically, the Department paid 1,011 prescription drug claims totaling $46,840 for six Colorado providers who were on the OIG's excluded list, and 1,042 prescription drug claims totaling $20,360 for three providers who were on the Department's terminated provider list. These 2,053 claims totaling $67,200 are unallowable costs.

LACK OF IDENTIFICATION AND MONITORING OF PROVIDERS WHO APPEARED HIGH RISK FOR OVERPRESCRIBING TO MEDICAID RECIPIENTS. We identified 492 providers whose prescriptions of Schedule 2 and 3 drugs for Medicaid recipients met at least one of the high risk criterion used by OIG for Medicare monitoring, as shown in Exhibit 2.7. During the period reviewed, just over 18,000 providers in Colorado prescribed Schedule 2 and 3 drugs for Medicaid recipients. The 492 prescribers appeared high risk for overprescribing, indicating potential fraud, waste, or abuse. The Department reported to us that it does not regularly review prescribing patterns of Medicaid providers to assure they prescribe Schedule 2 and 3 drugs to Medicaid recipients in a manner that promotes appropriate drug use.

EXHIBIT 2.7

MEDICAID PROVIDERS WHO MET RISK CRITERIA WHEN PRESCRIBING SCHEDULE 2 AND 3 DRUGS BETWEEN FEBRUARY 2012 AND JANUARY 2014

Providers who prescribed 400 or more Schedule 2 and 3 prescriptions to Medicaid recipients annually	207
Providers who prescribed Schedule 2 and 3 drugs to 200 or more recipients annually	113
Providers who prescribed 12 or more Schedule 2 and 3 drugs per recipient annually	163
Providers with 75 percent or more of total Medicaid prescriptions for Schedule 2 and 3 drugs annually [1]	98
TOTAL UNDUPLICATED PROVIDERS [2]	492

SOURCE: Office of the State Auditor's analysis of the Department of Health Care Policy and Financing's data on paid Medicaid claims.

[1] Includes only providers with more than 40 claims for Schedule 2 and 3 drugs in 12 months.

[2] This figure represents the total number of unduplicated providers who met at least one of the OIG risk criteria for overprescribing within 12 months during the review period. Seventy-seven of the 492 providers met more than one of the risk criteria, and 203 met the risk criteria in both years we reviewed.

To further evaluate the risk that these providers may be overprescribing or engaging in fraud, waste, or abuse, we reviewed the State Medical Board licensing history for a sample of 200 of the 492 providers to determine whether any of the sampled providers had been disciplined for inappropriate prescribing practices, including whether any had suspended or revoked licenses. We identified 12 of the 200 sampled providers (6 percent) who had disciplinary actions from the Medical Board for inappropriate prescribing practices; 7 of the 12 had their medical licenses restricted or suspended by the Board between February 2012 and January 2014, the period we reviewed. Specifically, there were three providers with controlled substance prescribing restrictions, two who were required to undergo additional monitoring, one who had a medical license suspended in mid-2013,

and one who had a voluntarily-surrendered medical license in 2014 after a Board investigation.

Department staff stated that in March 2013, they completed a review of providers for inappropriate prescribing practices related to opioids and had identified one of these 12 providers. The Department reported that it sent a letter to the provider regarding the overprescribing pattern but did not take any further action to determine whether the provider was overprescribing or ensure that the provider's Medicaid recipients were appropriately utilizing drugs.

WHY DID THESE PROBLEMS OCCUR?

Overall, the problems we identified occurred because the Department does not have internal controls to prevent paying claims for prescriptions written by excluded and terminated providers, and it does not have a process to regularly identify or monitor high risk prescribers. Specifically:

MMIS AND PDCS LACK FUNCTIONALITY TO PREVENT PAYMENT FOR PRESCRIPTIONS FROM EXCLUDED AND TERMINATED PROVIDERS. Department staff reported to us that prescriptions originating from excluded or terminated prescribers are not denied because MMIS pays pharmacy claims based on the eligibility of the pharmacy (i.e., the provider receiving the payment for the claim), and is not able to check the eligibility of the prescriber for prescription drug claims. According to the Department, some providers who prescribe to Medicaid recipients are not enrolled in the Medicaid program but MMIS does not have the functionality to deny a claim for a prescription originating from these providers. In addition, PDCS does not have information on provider eligibility to deny a claim before it is dispensed by the pharmacy. The Department reported to us that it plans to require all providers to be enrolled in the Medicaid program in order to serve Medicaid recipients, and it plans to add functionality to MMIS and PDCS to deny claims originating from excluded and terminated providers when the new systems are implemented in Fall 2016.

THE DEPARTMENT DOES NOT REVIEW PHARMACY CLAIMS TO IDENTIFY PRESCRIPTIONS ORIGINATING FROM EXCLUDED AND TERMINATED PROVIDERS. The Department does not review prescription drug claims to ensure that excluded and terminated prescribers are not issuing prescriptions to Medicaid recipients and the State is not paying for prescriptions issued by these prescribers.

THE DEPARTMENT LACKS ROUTINE PROCESSES AND CRITERIA TO IDENTIFY AND ADDRESS PROVIDERS WHO ARE HIGH RISK FOR OVERPRESCRIBING. The Department does not routinely review prescription claims data to identify and assess the prescribing patterns of providers who prescribe high quantities of controlled substances such as Schedule 2 and 3 drugs. The Department also has not developed standard criteria to routinely identify prescribers who may be overprescribing. In 2013, when Skaggs reviewed the opioid prescriptions that recipients received, the Department notified the recipients' providers of the possible drug overuse. Skaggs and the Department did not review to identify high risk prescribers or review for factors that indicate overprescribing, such as the factors that the OIG considers, including prescribing that exceeds average patterns, or prescription of high amounts of Schedule 2 or 3 drugs by providers who do not typically prescribe these drugs based on their practice type (e.g., general practice, non-surgical dentistry, or podiatry). According to the Department, it does not have a routine process or standard criteria or take steps to ensure prescribers are not overprescribing beyond notifying them of their prescribing patterns, because it can be difficult to determine the level of prescribing by providers that indicates inappropriate practices with certainty.

Further, the Department reported that it cannot efficiently monitor a provider's prescription history. During our review period, MMIS required all prescription drug claims to include the provider ID of the prescriber, but did not require a standard ID. As a result, pharmacies had the ability to record a prescriber's Medicaid ID number, DEA number, or National Provider ID on a claim. Some prescribers have numerous claims in MMIS under three different IDs making it difficult

for the Department to easily identify all prescriptions written by a provider and determine whether he or she might be overprescribing.

WHY DO THESE PROBLEMS MATTER?

When the Department pays Medicaid claims for prescription drugs prescribed by excluded and terminated providers, and does not monitor providers who are an increased risk of over-prescribing to Medicaid recipients, the following results can occur:

INCREASED STATE COSTS. We identified $67,200 in pharmacy reimbursements originating from prescriptions written by excluded and terminated providers. These claims are unallowable costs and CMS could recover the federal portion of these costs which we estimate was $33,600.

INCREASED PUBLIC COSTS AND RISKS OF DRUG MISUSE. While some of the prescribing of Schedule 2 and 3 drugs in high volumes, dosages, or to a large number of recipients that we identified may be legitimate, there is a risk that some of the prescriptions were not medically necessary. For example, if a prescribed drug was not for medical purposes, the Department could have paid for prescriptions that were re-sold by recipients on the street. Provider "pill mills" drive up public health and safety costs and require more resources to combat the illegal distribution and possession of controlled substances. A 2014 CMS briefing on health care fraud and program integrity reported that dollars spent on fraudulent and unnecessary care diverts funds away from legitimate health care services, increases the costs of Medicaid, and does not add value by treating medical conditions.

Further, when the Department does not identify and monitor providers who greatly exceed average prescribing patterns for intervention, there is a risk that recipients could be overprescribed medication which can be harmful by exposing them to unnecessary medications or dosages.

RECOMMENDATION 3

The Department of Health Care Policy and Financing should strengthen controls to detect and prevent health care provider fraud, abuse, and misuse related to prescription drugs in the Medicaid program by:

A Implementing system controls, such as in the Medicaid Management Information System (MMIS) and pharmacy benefits management system, to automatically deny claims originating from excluded providers and terminated providers. This should include updating both MMIS and the pharmacy benefits management system to include National Provider ID's for all Medicaid providers and requiring pharmacies to enter these IDs for all claims.

B Implementing a periodic review of prescription drug claims data to identify those originating from excluded and terminated providers, and recovering payments for the claims, as appropriate. This should include recovering payments for those unallowable claims identified by the audit, as appropriate.

C Implementing routine processes to identify high risk prescribers using comprehensive risk criteria, periodically reviewing these prescribers' prescription drug claims, and referring them to the State's Medicaid Fraud and Control Unit for investigation, as appropriate, when their prescribing practices appear fraudulent.

RESPONSE

DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

A AGREE. IMPLEMENTATION DATE: NOVEMBER 2016.

The Department is scheduled to implement a new MMIS and PDCS in November 2016 which will allow the Department to increase its current internal controls.

All existing providers will begin a revalidation process by resubmitting a provider application, undergoing a state-defined screening process, and paying an application fee, as appropriate for the provider type, and is approved by the Department to continue participating in the Medicaid program, beginning September 2015. This process will include ordering, referring, and prescribing providers as required by the Affordable Care Act (ACA) provider screening rule.

After the initial enrollment process, National Provider Identifiers (NPIs) will be verified monthly according to ACA provider screening rules, beginning in November 2016. The Department is designing and implementing all aspects of the Medicaid claims adjudication process in the new MMIS and PDCS, which includes additional NPI editing. All pharmacies will be required to enter NPIs for all claims. The new MMIS will edit all NPI fields to comply with federal and state regulations.

B AGREE. IMPLEMENTATION DATE: NOVEMBER 2016.

The Department agrees to strengthen controls to prevent and detect provider fraud, abuse, and misuse related to prescription drugs in the Medicaid program. On a monthly basis, the Department monitors that active Medicaid providers are not excluded or terminated from federal or state participation in

the Medicaid Program by checking the Managed File Transfer (MFT), OIG List of Excluded Individuals/Entities (LEIE), System for Award Management (SAM) and Cumulative Revocation Report (MIG file). If a match is found, the Department confirms that the match is correct and if appropriate, terminates the provider from the Medicaid program. Not all of the prescribing providers are enrolled in the Medicaid program.

The Department is scheduled to implement a new MMIS and PDCS in November 2016 which will allow the Department to increase its current internal controls and will be able to check the eligibility of the prescriber. To implement the requirements under the ACA Provider Screening Rule that providers submit an NPI and that the Department edit claims against NPI for billing, referring, rendering, and ordering providers, the Department has submitted a State Plan Amendment (SPA) to the Center for Medicare and Medicaid Services (CMS). That SPA has been submitted, but has not been approved by CMS and the requirements to fully implement these federal regulations are still under development and being negotiated with CMS. The pharmacies who received payment were not excluded or terminated. The Department will review the claims identified in this audit and recover as appropriate.

C PARTIALLY AGREE. IMPLEMENTATION DATE: OCTOBER 2015.

The Department disagrees with the underlying premise of this recommendation because there are currently established processes to identify outlier prescribers. The Department does agree to have the DUR program continue to review and revise selection criteria for identifying outlier prescribers. The audit used selection criteria developed by the OIG staff which differed from criteria used by the DUR program; therefore, it is was not unexpected that the audit identified different prescribers than the DUR program. The Department will consider incorporating the OIG's criteria in future DUR

projects. Prescribers identified by the DUR program may be targeted for educational outreach and/or referred to the appropriate licensing board. If possible provider fraud is identified through our processes, which would be submitted to the Department's Program Integrity (PI) Section. If a credible allegation of fraud is established by the PI Section, the Department will refer the case to the Medicaid Fraud Control Unit in the Attorney General's Office.

AUDITOR'S ADDENDUM

During the audit, the Department reported that it did not have specific criteria to identify high risk prescribers and could not provide any such criteria. In the absence of any criteria established by the Department, the OSA used OIG measures to identify the 492 high risk prescribers. The Department also reported that the Skaggs reviews identified high risk recipients who may over utilize prescription drugs, but the Department and Skaggs did not conduct reviews to identify or monitor high risk prescribers of Schedule 2 and 3 drugs, which are vulnerable to fraud, waste, and abuse. In addition, the audit found that, after identifying potential over utilizing recipients, the Department did not take steps to identify possible provider fraud so that further action could be taken.

PRESCRIPTION DRUG REBATES

For each prescription drug that Medicaid covers for a recipient, CMS requires the drug manufacturer to pay Medicaid a rebate. The rebates are meant to decrease Medicaid's costs for prescription drugs [42 USC 1396r-8, 2012]. CMS uses federal statutory formulas to set minimum rebate amounts that manufacturers pay for each Medicaid prescription drug claim based on the drug's purpose and whether it is a brand-name or generic. The minimum federal rebate amounts per prescription are 23.1 percent for most brand name drugs, 13 percent for most generic drugs, and 17.1 percent for drugs used exclusively for blood clotting or pediatrics [42 USC 1396r-8(c)(1)(B) and (3)(B)]; however, there is no maximum rebate percentage.

During the period of our review, February 2012 through January 2014, Colorado typically received 50 percent of all federally-established rebates that drug manufacturers paid and the federal government received 50 percent; for a small number of drugs, the federal government receives the entire rebate amount that the manufacturer pays. For example, during the fourth quarter of Fiscal Year 2014, one manufacturer paid Colorado a rebate of $4.7368 per tablet of a drug used to treat depression, and 10,241 tablets were dispensed to Medicaid recipients. The total rebate that the manufacturer paid Colorado that quarter was $48,510, of which the State and federal government each received about $24,255. The 50/50 rebate split between the federal and state governments continued until October 2014, when the federal government changed the matching percentages with Colorado receiving 49 percent of federal manufacturer rebates and the federal government receiving 51 percent.

Exhibit 2.8 compares total Medicaid program expenditures for prescription drug claims to the rebates that Colorado received in Fiscal Years 2010 through 2014.

EXHIBIT 2.8

EXPENDITURES FOR PRESCRIPTION DRUGS COMPARED TO DRUG MANUFACTURER REBATES RECEIVED (IN MILLIONS) FISCAL YEARS 2010 THROUGH 2014

FISCAL YEAR	EXPENDITURES	REBATES RECEIVED [1]	PERCENTAGE OF EXPENDITURES REBATED
2010	$199.7	$(88.7)	44%
2011	255.2	(115.9)	45%
2012	318.7	(149.8)	47%
2013	334.2	(179.0)	54%
2014	453.2	(195.3)	43%
TOTAL	$1,561.0	$(728.7)	47%

SOURCE: Office of the State Auditor's analysis of expenditure and rebate data reported by the Department of Health Care Policy and Financing.

[1] Rebates received represent the total rebates that drug manufacturers paid for Medicaid outpatient prescription drugs dispensed in Colorado.

CMS also requires manufacturers to pay interest quarterly when they do not pay rebates in a timely manner. During Fiscal Year 2013, the State collected $4,464 in interest.

The Department collects rebates through Xerox which calculates the rebates that drug manufacturers owe and bills manufacturers quarterly on behalf of the State. Xerox calculates each rebate by multiplying the drug rebate amount set by CMS by the number of paid Medicaid drug units dispensed for the drug during the quarter. Xerox uses its Drug Rebate Analysis and Management System (DRAMS) to prepare rebate invoices and distribute them to manufacturers. Manufacturers send rebate payments to the Department, which maintains a database tracking each invoice and the payments received. The Department pays CMS the federal portion of rebates quarterly by deducting the federal share of the rebate and any collected interest from the amount of federal funds that the Department requests from CMS for the Medicaid program.

WHAT WAS THE PURPOSE OF THE AUDIT WORK AND WHAT WORK WAS PERFORMED?

The purpose of the audit work in this area was to determine whether the Department collected prescription drug rebates and interest from manufacturers as required by federal statute (42 USC 1396r-8, 2012). We assessed the accuracy of Xerox's rebate calculations and invoicing by reviewing Xerox's electronic data on all rebate invoices that it sent to the entire population of 468 manufacturers during Fiscal Year 2014. We reviewed whether Xerox billed manufacturers for applicable interest during the first three quarters of Fiscal Year 2014. We also reviewed whether Xerox's processes complied with its contract with the Department.

Additionally, we reviewed the Department's controls and systems for collecting drug rebates and interest, and interviewed Department and Xerox staff to understand the rebate billing and collection process.

HOW WERE THE RESULTS OF THE AUDIT WORK MEASURED?

We evaluated the Department's controls for collecting drug manufacturer rebates and interest based on the following criteria:

BILLING AND COLLECTION OF REBATES AND INTEREST FROM DRUG MANUFACTURERS. Federal statute (42 USC 1396r-8, 2012) requires state Medicaid programs to bill manufacturers for rebates quarterly, and collect interest from manufacturers who do not make timely rebate payments. CMS written guidance states that drug manufacturers have 38 days from the invoice date to pay the rebates due, after which manufacturers are required to pay interest. According to federal regulations, the interest rate is the prevailing interest rate of 13-week U.S. Treasury bills. Federal statute (42 USC 1396r-8, 2012) also requires the state to reduce the amount of federal reimbursement for prescription drugs it requests from CMS by the federal share of the

invoiced rebate and the interest due regardless of whether the state collects the rebate and interest.

The statement of work in the Department's contract with Xerox, which is effective from 2006 through the end of 2015, requires Xerox to calculate and invoice manufacturers for rebates and interest on late rebate payments. The contract also requires Xerox to maintain an automated system that tracks the interest each manufacturer owes.

WHAT PROBLEM DID THE AUDIT WORK IDENTIFY?

Overall, while we did not identify problems with rebate calculations or collections, we found that many manufacturers were late in paying rebates and the State's Medicaid program did not bill for or collect interest on any late payments during the period we reviewed, as required by federal regulations. As shown in Exhibit 2.9, during the first three quarters of Fiscal Year 2014, a total of 267 drug manufacturers were late in paying rebates to the State, and none of these manufacturers were billed for interest. These manufacturers owe the State $3,062 in interest on late rebate payments for these three quarters.

EXHIBIT 2.9

UNBILLED INTEREST BY QUARTER
FISCAL YEAR 2014

QUARTER	NUMBER OF MANUFACTURERS NOT BILLED INTEREST	UNBILLED INTEREST MANUFACTURERS OWE
1st Quarter 2014 (July to September 2013)	120	$2,257
2nd Quarter 2014 (October to December 2013)	100	$340
3rd Quarter 2014 (January to March 2014)	144	$465
TOTAL	267[1]	$3,062

SOURCE: Office of the State Auditor's Office analysis of DRAMS data provided by the Department of Health Care Policy and Financing.

[1] This is the total number of unduplicated drug manufacturers that were not billed for interest during the three quarters. Some manufacturers had unbilled interest in multiple quarters.

WHY DID THE PROBLEM OCCUR?

These rebate interest billing and collection problems occurred for the following reasons:

XEROX DID NOT BILL DRUG MANUFACTURERS FOR INTEREST ON LATE PAYMENTS. Drug manufacturers did not pay the State for interest owed on late rebates because Xerox did not consistently invoice manufacturers for the interest. According to Xerox staff, in July 2013, DRAMS experienced technical difficulties calculating and tracking the interest manufacturers owed, and sporadically calculated interest on late rebate payments inaccurately. Xerox reported to us that it stopped calculating and billing interest for all manufacturers until it could repair its system. In November 2014, Xerox reported to us that it would begin manually calculating and invoicing the interest that manufacturers owed until it corrected the system problem, but as of April 2015, Xerox had not yet repaired DRAMS.

THE DEPARTMENT DID NOT ENSURE THAT XEROX BILLED DRUG MANUFACTURERS FOR INTEREST. The Department reported to us that it was unaware that Xerox was not billing for and collecting interest on rebates until notified by the audit team. Xerox did not communicate to the Department its system problems or its decision to cease invoicing manufacturers for interest. The Department's contract monitoring and reconciliations of invoices to the payments received did not identify that Xerox had not billed manufacturers for interest and that the State had not received interest payments for most of Fiscal Year 2014.

WHY DO THESE PROBLEMS MATTER?

When the State's Medicaid program does not bill for or collect interest on late drug manufacturer rebates, the following results occur:

INCREASED STATE COSTS FOR MEDICAID. When the Department does not comply with federal regulations by collecting interest for late rebates from drug manufacturers, the cost to the State of administering Medicaid is increased. This is because the State is

responsible for providing the federal government its share of the rebate interest that manufacturers owe regardless of whether the State collects the interest from manufacturers.

INACCURATE REPORTS TO CMS. The Department reports the rebate interest that manufacturers owe to CMS quarterly based on the interest Xerox bills the manufacturers. When manufacturers are not billed for the rebate interest that they owe, the Department does not accurately report rebate interest to CMS. We estimate that the State underreported and owes CMS $1,531, or 50 percent of the $3,062, in unbilled and uncollected rebate interest for the period we reviewed.

RECOMMENDATION 4

The Department of Health Care Policy and Financing should implement internal controls and oversight of its fiscal agent to ensure it complies with federal regulations to bill for and collect interest when manufacturers are past due in paying prescription drug rebates. The Department should collect unpaid interest from the drug manufacturers identified in the audit, refund the federal portion of the interest to the federal government, as appropriate, and ensure its fiscal agent billed manufacturers for interest correctly between April 2014 and April 2015.

RESPONSE

DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

AGREE. IMPLEMENTATION DATE: NOVEMBER 2016.

The current Department contractor, Xerox, is manually calculating drug rebate interest until the drug rebate system can be updated. The unpaid interest of $3,062 identified by the audit was included on the third quarter 2014 invoices sent to drug manufacturers. The Department will be implementing a new rebate system, scheduled to be operational in November 2016, which will allow the Department to monitor rebate interest amounts and interest collection through automated reports. To ensure that Xerox continues to calculate rebate interest until the new system is operational, the Department will manually review the total reported interest for each quarter to ensure that amount is greater than zero; the Department started this process in April 2015. In addition, the Department will manually review a sample of manufacturer invoices on a periodic basis to confirm that the applicable rebate interest is included.

APPENDIX A

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OFFICE OF THE STATE AUDITOR
SUMMARY OF FINDINGS RELATED TO THE
SMART GOVERNMENT ACT
MEDICAID PRESCRIPTION DRUGS PERFORMANCE AUDIT
DEPARTMENT OF HEALTH CARE POLICY AND FINANCING
MAY 2015

The SMART Government Act [Section 2-7-204(5), C.R.S.] requires the State Auditor to annually conduct performance audits of one or more specific programs or services in at least two departments. These audits may include, but are not limited to, the review of:

- The integrity of the department's performance measures audited.
- The accuracy and validity of the department's reported results.
- The overall cost and effectiveness of the audited programs or services in achieving legislative intent and the department's goals.

We selected the Medicaid Prescription Drugs performance audit for focused audit work related to the SMART Government Act. The Department's Fiscal Year 2015 SMART Government Act performance plan does not include performance measures or goals specifically related to outpatient prescription drugs because this service is not a major function of the Department, and therefore is not required to have performance measures under the SMART Government Act. However, in 2013 the Department established a goal to reduce Medicaid costs by ensuring that payments for prescription drugs reflect actual costs for pharmacies to obtain and dispense the drugs. This goal fits within the Department's broader performance plan strategy to ensure sound stewardship of Medicaid funds and financial resources through cost containment. The focus of our SMART Government Act review on this audit related to this goal.

OVERVIEW

During Fiscal Year 2014, the Medicaid program covered about 5.5 million outpatient prescriptions for 498,507 Medicaid recipients in Colorado. The total cost of these prescriptions was $453.2 million, of which Colorado paid $101.8 million and the federal government and drug manufacturer rebates covered the rest. According to federal regulations, a state receives federal funds to help cover prescriptions if the state either determines that the drug should be available to all Medicaid recipients for their health or

has given prior authorization for the drug to be dispensed to a recipient [42 USC 1396r-8(a)]. Federal regulations (42 CFR 456.709) and state statute (Section 25.5-5-506, C.R.S.) require the Department to monitor prescription drug claims and information and assure the appropriate utilization of drugs by Medicaid recipients, and federal regulations require the Department to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care [42 CFR 456.709].

GOALS AND PERFORMANCE MEASURES

One of the primary steps the Department took to accomplish its goal of reducing Medicaid expenditures by containing prescription drug costs was to implement a new method to pay pharmacies for outpatient prescription drug claims, beginning in February 2013. When it developed the new method, the Department estimated that it would save the Medicaid program about $4 million a year. Based on our audit work, we concluded that the new payment method has helped the Department achieve its goal both because Colorado's average rate per Medicaid prescription is lower than national average pharmacy costs, and because the cost of prescriptions per Medicaid recipient is lower under the new payment method than under the old method. As discussed in CHAPTER 2, we estimated that the new method created an average savings of $14 per Medicaid recipient receiving a prescription, or about $5.7 million annually. Another cost containment strategy that the Department implemented was to require pharmacies to dispense a generic drug, rather than a brand name drug, to Medicaid recipients in most circumstances. According to Department data, 85 percent of the prescription drugs dispensed to Colorado's Medicaid recipients in Fiscal Year 2014 were generic drugs. Other cost containment processes established by the Department are discussed in CHAPTER 2.

We also found that the Department has established internal processes to monitor Medicaid recipients' use of prescription drugs and the costs of drug claims, and annually reports this information to CMS. The Department also annually reports its pharmacy utilization plan to the House Health and Environment Committee and the Senate Health and Human Services Committee of the Colorado General Assembly. The Department's pharmacy utilization plan includes information on the Department's processes and controls to contain prescription drug costs. We reviewed the validity, reliability, and completeness of the data that the Department maintains and uses to monitor and report on Medicaid prescription drug claims and draw down federal funds to help pay for the claims. We found these data are reliable for reporting general information on Medicaid prescription drug utilization and costs.

IMPROVEMENTS COULD HELP THE DEPARTMENT BETTER ACHIEVE LEGISLATIVE INTENT AND DEPARTMENT GOALS

Although the Department has implemented processes that helped achieve cost containment of Medicaid outpatient prescription drugs, we found the Department could do more to contain costs, as well as improve the efficiency and effectiveness of its administration of prescription drug coverage and its compliance with federal and state requirements. As discussed in this report, we found that the Department could better control Medicaid prescription drug costs by: (1) strengthening controls to enforce prior authorizations for non-preferred, restricted, and emergency prescriptions and recover questioned costs; (2) addressing recipients' overuse of prescription drugs by restricting their access to drugs through Medicaid when they meet established overutilization criteria; (3) improving oversight of prescribers at high risk of overprescribing to prevent and detect provider fraud and abuse, and automatically denying claims originating from excluded or terminated providers; and (4) collecting interest when manufacturers are past due in paying Colorado prescription drug rebates.

In addition, our audit found that the data in the pharmacy benefits management system are not entirely accurate with respect to Medicaid prescription drug claims, and improving the data could help the Department monitor claims and contain costs. As we discuss in Recommendation No. 1, the Department should ensure the system is kept updated and develop a method to track and efficiently report on pharmacies' use of emergency prescription fills. As we discuss in Recommendation No. 3, the Department should begin accurately tracking all Medicaid providers and their prescribing practices using a consistent provider ID.

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GLOSSARY

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KEY TERMS

Brand Name Drugs

Unique, patent-protected drugs that are usually only available from a single manufacturer.

Controlled Substances

Prescription and over-the-counter drugs that have a medical use but pose a danger of dependence and misuse for non-medical purposes, and non-prescription drugs such as heroin and methamphetamine, that have no medical use and a high potential for abuse.

Department

Department of Health Care Policy and Financing.

Dispensing Fee

A fee that Colorado's Medicaid program pays to pharmacies to compensate them for their time and costs of filling and dispensing a prescription to a Medicaid recipient.

Drug Manufacturer Rebates

Federal regulations require drug manufacturers to pay states and the federal government rebates for their drugs to be covered under Medicaid.

Generic Drugs

Drugs that have the same active ingredients as their brand name counterparts and are generally considered by the Federal Drug Administration to be equivalent in dose, strength, route of administration, safety, and intended use; but are not protected by patents and are typically produced and sold by many different manufacturers.

Medicaid

A federal-state program that provides health care coverage and services to eligible low-income individuals and families with children.

Non-Preferred Drugs

Drugs that have a safer, more effective, or less costly alternative and require a prior authorization to be covered by Medicaid.

Opioids

Any synthetic-like narcotic that has opium-like effects, but does not contain opium.

Outpatient Prescription Drugs

Prescription drugs that Medicaid recipients receive outside of a hospital setting and that are covered by Medicaid.

Preferred Drugs

Drugs that the Department prefers Medicaid to cover because the Department's clinical reviews have found the drugs to be safer, more effective, and/or less costly than other similar drugs.

Prior Authorization

A cost containment measure that ensures that Medicaid only pays for certain prescription drugs if the Department has pre-approved the pharmacy to dispense the drug to the recipient.

Restricted Drugs

Prescription drugs that the Department limits, such as by limiting the quantity of the drug allowed to be dispensed or the age of the recipient who may receive the drug.

ABBREVIATIONS

CFR

Code of Federal Regulations

CMS

U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services

DEA

U.S. Drug Enforcement Administration

DRAMS
: Drug Rebate Analysis and Management System

FDA
: Federal Drug Administration

MMIS
: Colorado Medicaid Management Information System

OIG
: U.S. Department of Health and Human Services, Office of the Inspector General

PDCS
: Prescription Drug Card System

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