Office of Missouri State Auditor

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Department of Social Services
Prescription Drug Oversight

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CITIZENS SUMMARY

Findings in the Audit of the Department of Social Services Prescription Drug Oversight

Prescription Drug Cost Trends

The Missouri's Medical Assistance Program (Medicaid), Children's Health Insurance Program (CHIP), and the Missouri Rx (MORx) program processed approximately 33.2 million prescription drug claims totaling $959 million during calendar year 2016. Missouri's Medicaid and CHIP programs cover the costs of outpatient prescription drugs for participants on a fee-for-service basis. In calendar year 2016, the cost of outpatient prescription drugs for Missouri's Medicaid and CHIP participants totaled over $953 million and represented 14 percent of all Medicaid and CHIP spending. To respond to increased demand and higher costs for prescription drugs, the Department of Social Services (DSS) has developed several processes to control the costs of drug prescriptions including, but not limited to, providing incentives to pharmacies who dispense generic drugs instead of brand name drugs, implementing processing edits in the claims processing system to require the usage of lower cost drugs before higher cost drugs, and actively seeking supplemental rebate opportunities. After peaking in 2015, prescription drug payments decreased in calendar year 2016 and decreased further in 2017.

Prescription Drug Monitoring Programs

Missouri does not have a comprehensive statewide prescription drug monitoring program (PDMP) to help the Department of Social Services identify Medicaid and CHIP prescription drug fraud and abuse. Prior to July 2017, Missouri was the only state in the nation that did not have a statewide PDMP. St. Louis County, through the County Department of Public Health, established a PDMP in March 2016 due to a lack of a statewide PDMP.

Physician-Administered Drugs

The DSS did not implement system controls to require collection of national drug codes for all physician-administered drug claims, which limits the ability of the DSS to bill the prescription drug manufacturers for rebates for those drug claims.

Excluded Drug Claims

The DSS controls are not sufficient to deny all drug claims for drugs excluded from the Medicaid program.

In the areas audited, the overall performance of this entity was **Good**.*

*****The rating(s) cover only audited areas and do not reflect an opinion on the overall operation of the entity. Within that context, the rating scale indicates the following:

Excellent: The audit results indicate this entity is very well managed. The report contains no findings. In addition, if applicable, prior recommendations have been implemented.

Good: The audit results indicate this entity is well managed. The report contains few findings, and the entity has indicated most or all recommendations have already been, or will be, implemented. In addition, if applicable, many of the prior recommendations have been implemented.

Fair: The audit results indicate this entity needs to improve operations in several areas. The report contains several findings, or one or more findings that require management's immediate attention, and/or the entity has indicated several recommendations will not be implemented. In addition, if applicable, several prior recommendations have not been implemented.

Poor: The audit results indicate this entity needs to significantly improve operations. The report contains numerous findings that require management's immediate attention, and/or the entity has indicated most recommendations will not be implemented. In addition, if applicable, most prior recommendations have not been implemented.

Department of Social Services
Prescription Drug Oversight
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Honorable Michael L. Parson, Governor
and
Steve Corsi, Psy. D., Director
Department of Social Services
Jefferson City, Missouri

We have audited certain operations of the Department of Social Services, MO HealthNet Division related to prescription drug oversight in fulfilment of our duties under Chapter 29, RSMo. This audit was conducted to evaluate the effectiveness of internal controls over prescription drug payments administered in the Medicaid Assistance Program, Children's Health Insurance Program, and Missouri Rx Plan. The scope of our audit included, but was not necessarily limited to, the year ended December 31, 2016. The objectives of our audit were to:

1. Evaluate internal controls over significant management and financial functions as they relate to oversight of prescription drugs.

2. Evaluate compliance with certain legal provisions as they relate to oversight of prescription drugs.

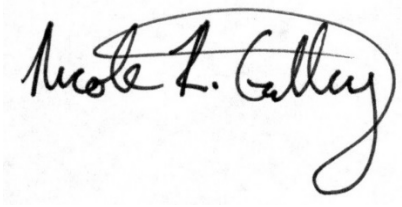
3. Evaluate the economy and efficiency of certain management practices and information system control activities as they relate of oversight of prescription drugs.

4. Analyze prescription drug cost trends and evaluate the effectiveness of cost containment procedures.

Except as discussed in the following paragraph, we conducted our audit in accordance with the standards applicable to performance audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform our 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 such a basis.

Government Auditing Standards require us to obtain and report the views of responsible officials of the audited entity concerning the findings, conclusions, and recommendations included in the audit report. Since the Department of Socials Services does not have the authority to change state laws, we could not obtain views of responsible officials for part of the finding, conclusion and recommendation outlined in finding 2 of the Management Advisory Report. The views of the department were obtained and included where appropriate.

For the areas audited, we (1) identified deficiencies in internal controls, (2) identified non-compliance with legal provisions, (3) identified no significant deficiencies in management practices and operations, and (4) determined costs have declined in recent years and found cost containment procedures to be generally effective. The accompanying Management Advisory Report presents our findings arising from our audit of prescription drug oversight.



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Department of Social Services
Prescription Drug Oversight
Introduction

Background

The Missouri Department of Social Services (DSS) MO HealthNet Division provides medical services to eligible participants within defined programs, including the Medical Assistance Program (Medicaid), Children's Health Insurance Program (CHIP), and the Missouri Rx (MORx) program. Within the MO HealthNet Division, the pharmacy program oversees outpatient prescription drug payments. Prescription drug expenditures for these 3 programs totaled approximately $959 million in the year ended December 31, 2016. Prescription drugs were available to more than 1 million Medicaid, CHIP, and MORx participants as of December 31, 2016.

Missouri's Medicaid program covers the costs of most brand name and generic prescription drugs for participant 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.

Medicaid program and CHIP

Missouri provides medical services to low income and vulnerable citizens through the federal Medicaid program and CHIP. Medicaid and CHIP are administered at the federal level by the U.S. Department of Health and Human Services (DHHS), Center for Medicare and Medicaid Services (CMS) under Title XIX of the federal Social Security Act, and at the state level by the DSS.

According to federal regulation 42 CFR Section 440 subpart A, state Medicaid programs provide participants certain basic services, including but not limited to inpatient hospital services, outpatient hospital services, rural health clinic services, and nursing facility services for participants ages 21 and older. The Federal Social Security Act also gives states flexibility to provide participants 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 participants outside of a hospital setting. Federal regulation 42 CFR Section 457 subpart D, state CHIP program provide participants certain basic services, including but not limited to inpatient hospital services, outpatient hospital services, physician services, surgical services, clinic services, prescription drugs, and over-the-counter medications.

State Medicaid and CHIP programs allow the state the discretion to determine which prescription drugs are preferred over other drugs for each functional therapeutic class the state would like prescribers to use. The state has a preferred drug listing which is reviewed by two advisory groups, the Drug Prior Authorization Committee and Drug Use Review Board. These groups meet on a quarterly basis to help advise which drugs should be on the list. If

a prescriber would like to use a different prescription than what is on the preferred drug list, prior authorization is required.

Missouri Rx plan

The DSS administers MORx, a state-funded program, to provide prescription drug assistance to Missourians in need by coordinating benefits with the Medicare Part D Prescription Drug Program. The MORx program pays 50 percent of the participant's out-of-pocket costs on medications covered by the participant's Medicare Part D plan.

Individuals receiving Medicare and Medicaid benefits are eligible for MORx coverage and are automatically enrolled in the program. Prior to August 2017, individuals with Medicare only were eligible for MORx coverage; however, under Section 208.790, RSMo, effective August 28, 2017, eligibility rules changed to cover only individuals who meet both Medicare and Medicaid eligibility guidelines.

Drug rebates

According to federal regulation 42 USC 1396r-8 (a), the federal matching funds are only available to help cover a participant's prescription if the prescription drug meets one of the following conditions: the drug manufacturer participates in the drug rebate program with the U.S. DHHS; the state determines that the drug is essential to the participant's health; the Food and Drug Administration has given the drug a rating of 1-A; or the prior authorization process applies to the prescribing and dispensing of the drug.

The Deficit Reduction Act of 2005 amended section 1927 of the Social Security Act to address rebates for physician-administered drugs, which are medications administered by a physician in an outpatient hospital setting. Effective January 2008, the Social Security Act, 42 U.S.C. Section 1396r-8(a)(7) requires states to capture drug utilization data using National Drug Codes (NDCs), for single-source and top-20 multiple-source drugs from the provider when the claim is submitted to the state. As required by 42 U.S.C. Section 1396r-8, NDCs are used to identify and bill the drug manufactures for rebates for applicable drug purchases. Federal regulation 42 CFR Section 447.520 prohibits federal reimbursement for physician-administered drugs for which the state has not required the submission of claims using NDCs to identify the drugs. Based on data from manufacturers, the CMS calculates a per-unit rebate amount states can bill for each drug administered. The states are to report the applicable drug utilization information by NDC to the manufacturers and bill the manufacturers quarterly for the drug rebate amounts. States are required by 42 U.S.C. Section 1396r-8 to offset the Medicaid and CHIP prescription drug claims by the rebate amounts.

Scope and Methodology

The scope of audit included, but was not necessarily limited to, the year ended December 31, 2016.

We obtained an understanding of internal controls that are significant within the context of the audit objectives and assessed whether such controls have been properly designed and placed in operation. We also obtained an understanding of legal provisions that are significant within the context of the audit objectives, and we assessed the risk that illegal acts, including fraud, and violations of applicable contract, grant agreement, or other legal provisions could occur. Based on that risk assessment, we designed and performed procedures to provide reasonable assurance of detecting instances of noncompliance significant to those provisions.

We analyzed outpatient drug payments using the DSS's provided outpatient drug claims paid during the quarter ended December 31, 2016. Our review period was limited to a quarter at the request of the department in an effort to reduce the volume of data being transmitted. Due to the recurring nature of prescription drug data, we determined this information was sufficient to achieve our audit objectives. Outpatient drug claims require NDCs when providers submit drug claims through the Medicaid Management Information System (MMIS) and are run through all the edits within the system. We reviewed and evaluated the DSS's procedures for approving and processing outpatient drug claims, procedures for collecting drug utilization and billing for drug rebates, procedures for addition and exclusion of preferred drug list and clinical edits, and procedures for monitoring of opioid drug claims.

We obtained a listing of deaths recorded in the state for the period 2010 to 2016 from the Missouri Department of Health and Senior Services (DHSS). We matched these records to Medicaid, CHIP and MORx participant drug claims to determine if any deceased participant continued to receive program benefits after the participant's death.[1] In addition, we matched these records to the prescribers of the Medicaid, CHIP and MORx drug claims to determine if any claims were prescribed by deceased prescribers. Although we used computer-processed data from the DHSS for our audit work, we did not rely on the results of any processes performed by the DHSS system in arriving at our conclusions. Our conclusions were based on our review of the issues specific to the audit objective. We determined the deceased participants and providers were appropriately removed from eligibility.

We analyzed all drug claims paid in the quarter ended December 31, 2016, for those participants who had been locked in to designated provider(s). We ensured the edits within the MMIS only allowed drug claims to be paid if the locked in provider(s) had prescribed or fulfilled the prescriptions or if there was a referral form. If the edits did not stop an inappropriate payment, we

[1] Acknowledgement: The data used in this document/presentation was acquired from the Missouri DHSS. The contents of this document including data analysis, interpretation or conclusions are solely the responsibility of the authors and do not represent the official views of DHSS.

ensured the established procedures identified and corrected the error. We determined the lock-in edit was working or DSS identified and corrected the errors.

Erectile dysfunction (ED) drugs are on the list of excluded drugs unless used to treat a condition other than sexual or erectile dysfunctions. We queried the Medicaid, CHIP, and MORx participant drug claims to obtain a listing of all ED drug claims paid. We then obtained a listing of registered sex offenders from the Missouri State Highway Patrol and compared it to the listing of ED drug claims. We determined 2 registered sex offenders obtained ED drugs. The claims included documentation the drugs were for medical conditions other than sexual or erectile dysfunctions.

We reviewed the geographical data of the prescriber compared to the participants to determine if there was a pattern of a prescriber prescribing an abnormal amount of opioids. In addition, during this review we looked for doctors or pharmacies that pull participants from a wide geographical area, which may indicate abuse. We did not identify any prescribers or pharmacies with prescribing or dispensing patterns indicating abuse.

We obtained a listing of the excluded and non-preferred drugs from the DSS. We matched these records to Medicaid, CHIP, and MORx participant drug claims to determine if the system-required prior authorizations restricting these drugs were working.

We reviewed physician-administered drug claims billed with procedural codes for the year ended December 31, 2016. Physician-administered drug claims do not require the NDCs when providers submit the drug claims through MMIS and are instead billed using a procedural code. The drugs paid for these claims are not eligible for the drug rebate program. Drug claims billed with procedural codes include, but are not limited to, outpatient drug claims in the 340B Drug Pricing program, prescription drug claims in the Gateway to Better Health Medicaid waiver program, and claims for which Medicare part B is the primary payer (also known as Professional Crossover claims).

Department of Social Services
Prescription Drug Oversight
Management Advisory Report - State Auditor's Findings

1. Prescription Drug Cost Trends

The Missouri's Medical Assistance Program (Medicaid), Children's Health Insurance Program (CHIP), and the Missouri Rx (MORx) program processed approximately 33.2 million prescription drug claims totaling $959 million during calendar year 2016. Table 1 shows the total Medicaid and CHIP prescription drug payments for the year ended December 31, 2016:

Table 1: Medicaid, CHIP, and MORx prescription drug payments for the year ended December 31, 2016

	Medicaid	CHIP	MORx
Prescribed drugs	$ 933,328,381	19,863,729	5,810,701
Drug rebates - federal	(417,939,354)	(5,639,269)	0
Drug rebates - state	(29,938,147)	0	0
Cost after drug rebate	485,450,880	14,224,460	5,810,701
Federal financial participation[1]	(307,122,244)	(13,838,528)	0
State financial participation	$ 178,328,636	385,932	5,810,701

[1] Federal financial participation is the portion of the claim reimbursed by the federal government.

Source: Prepared by the SAO using federal reports provided by DSS and SAM II data compiled by SAO.

Prescription drug payment rate

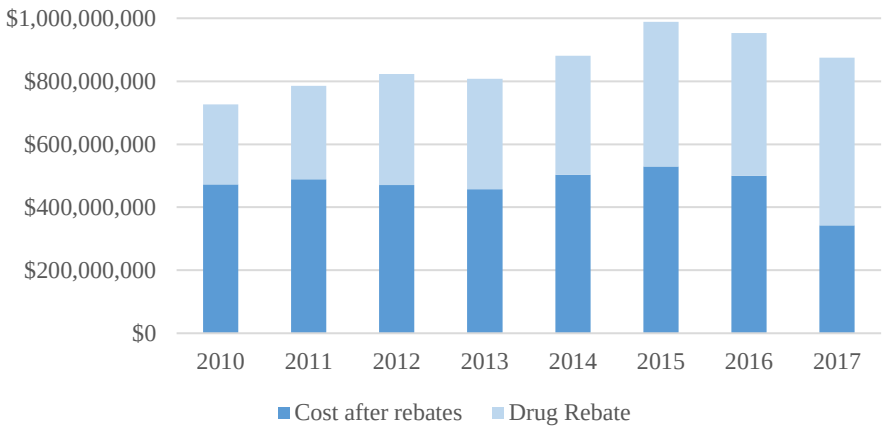
Missouri's Medicaid and CHIP programs cover the costs of outpatient prescription drugs for participants on a fee-for-service basis. The pharmacy filling a prescription for a participant submits a prescription drug claim to the Department of Social Services (DSS) for payment. DSS determines the payment rate for each prescription drug claim and U.S. Department of Health and Human Services, Center for Medicare and Medicaid Services (CMS) approves each state's rate setting methodology. Missouri's rate setting methodology is set forth in 13 CSR 70-20.070.

Prescription drug payment trend

In calendar year 2016, the cost of outpatient prescription drugs for Missouri's Medicaid and CHIP participants totaled over $953 million and represented 14 percent of all Medicaid and CHIP spending. Spending for prescription drugs is driven by many factors, including the costs of the drug, number of participants, participant's health conditions, the treatment participants need, prescribing practices of health care providers, utilization of prescriptions, and controls for approval and payment.

Total annual Medicaid and CHIP prescription drug spending increased by an average of 6.5 percent per year from calendar year 2010 to 2015, but decreased by 4 percent in 2016, and decreased an additional 8 percent in 2017. Figure 1 shows total prescription drug payments, from calendar year 2010 to 2017, broken down by drug rebate collected and cost after rebate.

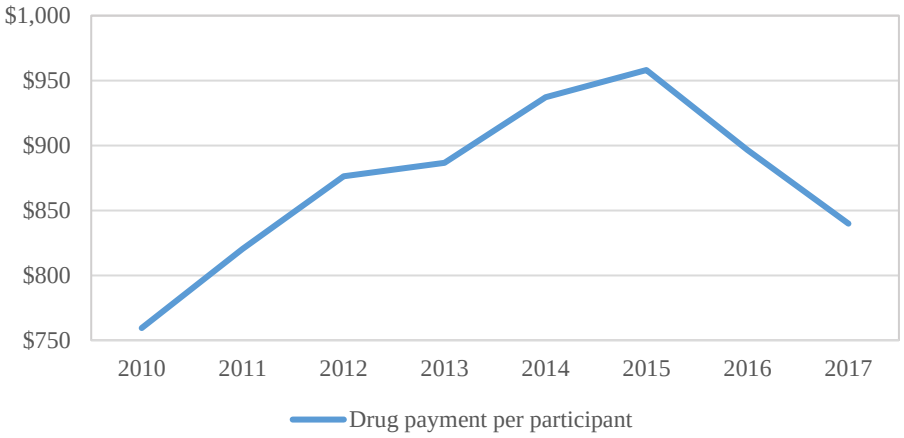
Figure 1: Prescription drug payments, calendar year 2010 to 2017



Source: Prepared by the SAO using federal reports provided by DSS

The number of Medicaid and CHIP participants has fluctuated in recent years; however, the prescription drug payment per participant follows a similar trend to the fluctuation of total prescription drug payments. Payments per participant have decreased by more than $100 (12 percent) from 2015 to 2017. Figure 2 depicts the trend of the prescription drug payments per participant.

Figure 2: Prescription drug payments per participant, calendar year 2010 to 2017

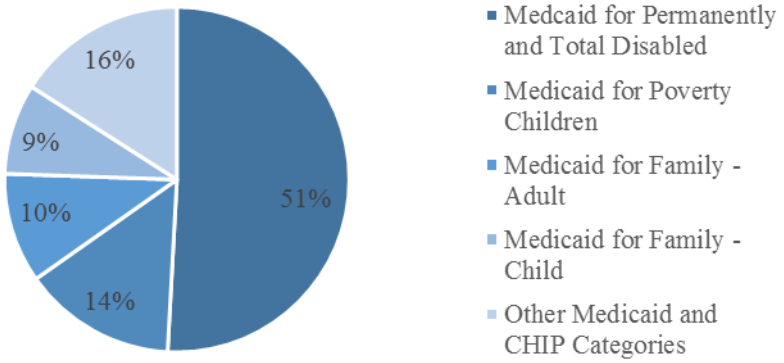


Source: Prepared by the SAO using federal reports provided by DSS and data published on the DSS website[2]

DSS determines the Medicaid and CHIP eligibility for each participant in order to provide approriate services. Figure 3 shows the prescription drug payments in the quarter ended December 31, 2016, by the Medicaid and CHIP eligibility categories.

[2] dss.mo.gov/mis/clcounter/history.htm

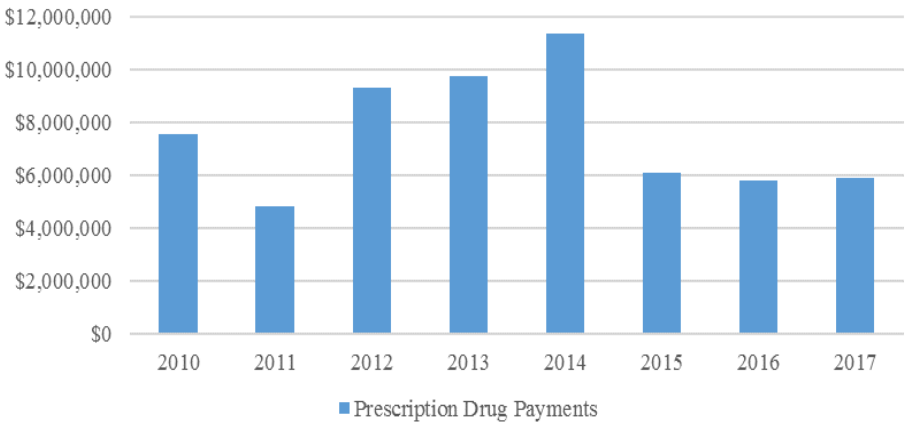
Figure 3: Prescription drug payment by Medicaid and CHIP eligibility category



Source: Prepared by the SAO using drug claim data provided by DSS

Total annual MORx plan prescription drug spending has decreased in the most recent years. Per Section 208.788, RSMo, the MORx plan benefits are limited to monies appropriated by the legislature and signed by the governor. Figure 4 shows total prescription drug payments, from calendar year 2010 to 2017 for MORx.

Figure 4: MORx Prescription drug payments, calendar year 2010 to 2017



Source: Prepared by the SAO using state expenditure data for the MORx Fund

A major factor driving the cost of prescription drugs is the drugs being dispensed. Using quarterly data, we estimated in Appendix A the annual amount paid for the 10 prescription drugs making up the largest dollar amount in prescription drug spending for the quarter ended December 31, 2016. The top ten drugs from quarter ended December 31, 2016, accounted for approximately 18 percent of total prescription drug payments in the quarter. Table 2 lists the estimated annualized amount paid and the cost per participant for these 10 prescription drugs.

Table 2: Top ten drugs by amount paid

Drug Name	Common Treatment	Annualized Amount Paid	Participants	Cost Per Participant
Lurasidone HCL	Mental disorder	$ 34,448,156	37,162	$ 927
Paliperidone Palmitate	Mental disorder	28,196,848	7,639	3,691
Albuterol Sulfate	Lung disease	27,096,120	208,310	130
Insulin Glargine	Diabetes	26,026,544	40,097	649
Methylphenidate HCL	Attention deficit hyperactivity disorder	25,980,684	52,918	491
Adalimumab	Various, including rheumatoid arthritis	23,600,140	3,267	7,224
Somatropin	Growth failure	22,573,540	5,053	4,467
Aripiprazole	Mental disorder	21,314,712	74,582	286
Lisdexamfetamine Dimesylate	Attention deficit hyperactivity disorder	20,934,876	26,631	786
Fluticasone - Salmeterol	Asthma	19,703,848	32,294	575
Total		$ 249,875,474		

Source: Prepared by the SAO using drug claim data provided by DSS

Cost control measures

To respond to increased demand and higher costs for prescription drugs, the DSS has developed several processes to control the costs of drug prescriptions including, but not limited to, providing incentives to pharmacies who dispense generic drugs instead of brand name drugs, implementing processing edits in the claims processing system to require the usage of lower cost drugs before higher cost drugs, and actively seeking supplemental rebate opportunities.

To reduce misuse of opioid drugs, the DSS implemented the Opioid Pharmacy Intervention (OPI) Program in 2010. The program's goals are to target and reduce opioid misuse, reduce adverse effects on participants, and identify prevention opportunities. Prescribers of opioids in Missouri receive packets of educational information identifying patients who are at potential risk for abuse, dependence, or adverse side-effects. The information highlights prescribing practices that are potentially at odds with the program's goals. If a malpractice behavior is not corrected by a provider, DSS can escalate the case. If educational attempts are not successful and prescription malpractice is still taking place, DSS will make a referral to the Bureau of Narcotics and Dangerous Drugs and submit supporting documentation. In such cases, claims submitted by this provider may be denied until the case is resolved. DSS also monitors participants' drug claims to determine if opioid abuse may be occurring. If DSS personnel believe a participant is misusing opioids, they can limit when and where the participant can obtain such drugs.

Using quarterly data, we estimated in Appendix B the annual amount paid, and number of participants for the 10 prescription opioid drugs with the most expenditures for the quarter ended December 31, 2016. The top ten opioid drugs from the quarter ended December 31, 2016, accounted for approximately 2 percent of the total prescription drug payments. Table 3 lists the estimated annualized amount paid and the costs per participant for these 10 opioid drugs.

Table 3: Top ten opioid drugs by amount paid in quarter ended December 31, 2016

Drug Name	Annualized Amount Paid	Cost Per Participant
Oxycodone HCL	$ 15,997,492	$ 327
Hydrocodone/Acetaminophen	6,720,776	30
Oxycodone HCL/Acetaminophen	5,502,920	64
Morphine Sulfate	1,982,276	96
Buprenorphine	1,773,080	770
Tramadol HCL	1,663,504	18
Fentanyl	1,570,124	159
Hydrocodone Bitartrate	1,183,656	771
Morphine Sulfate/Naltrexone	637,676	1,056
Acetaminophen with Codeine	570,660	18
Total	$ 37,602,164	

Source: Prepared by the SAO using drug claim data provided by DSS

Conclusion

After peaking in 2015, prescription drug payments decreased in calendar year 2016 and decreased further in 2017. DSS has implemented multiple measures to reduce the cost of reimbursing prescription drugs. The department continues to innovate and identify cost-reducing solutions.

2. Prescription Drug Monitoring Programs

Missouri does not have a comprehensive statewide prescription drug monitoring program (PDMP) to help the DSS identify Medicaid and CHIP prescription drug fraud and abuse. While the state has recently begun to implement a PDMP, the system does not capture all activity necessary to be of use to the DSS. In addition, St. Louis County has implemented a regional PDMP that can provide some benefit to the DSS, however, the St. Louis County PDMP is not statewide and the department has not utilized the data available.

PDMPs typically collect data from pharmacies on dispensed prescriptions for controlled substances, including information on the prescriber, patient and pharmacy, and make the data available to authorized users through an electronically-accessible database. This data allows prescribers and pharmacies access to patient history in the PDMP database prior to prescribing and dispensing controlled substances. In addition, DSS could access the patient history in the PDMP to ensure participants in the Medicaid

and CHIP programs are not prescribed controlled substances outside of the program.

CMS issued an informational bulletin on January 28, 2016, highlighting best practices for addressing prescription opioid overdoses, misuse and addiction. The bulletin suggested Medicaid agencies use PDMPs as they have been shown to be effective in addressing these concerns. CMS bulletins suggest Medicaid agencies require prescribers and pharmacies access patient history in the PDMP database prior to prescribing and dispensing controlled substances, thereby enhancing the drug utilization review program oversight activities.

State PDMP is not useful for detection of fraud and abuse

Prior to July 2017, Missouri was the only state in the nation that did not have a statewide PDMP. Executive order 17-18 required the Department of Health and Senior Services to create and oversee a PDMP. The DHSS program is a voluntary program where dispensers of controlled substances, pharmacy benefit management organizations, and other health care entities can provide data about the prescriber, pharmacy and drug prescribed. However, the dispenser must remove individual patients' information before sending the data. Without information on specific patients, this program is of limited use to the DSS for the purposes of detecting prescription drug fraud and abuse. Without the individual patient information, the DSS cannot determine if a participant was prescribed controlled substances outside of the program and doctors and pharmacies cannot use the data effectively. Additionally, since the program is voluntary, the data is likely not complete. Complete PDMP data could assist DSS to enhance their drug utilization review program oversight activities.

St. Louis County PDMP contains necessary information, but does not contain statewide data

St. Louis County, through the County Department of Public Health, established a PDMP in March 2016 due to the lack of a statewide PDMP. As of August 2018, 10 cities and 48 of the 114 (42 percent) counties in Missouri, participate in the St. Louis County PDMP database. The St. Louis County PDMP requires dispensers within the participating jurisdictions to report all controlled substances dispensed, regardless of patient location. Dispensers not located within one of the participating jurisdictions are under no obligation or requirement to submit information to the PDMP.

The data collected by the St. Louis County PDMP includes information about the prescriber, the pharmacy, the patient, and the drug prescribed. The information is consistent with what is recommended by CMS bulletins for use in detecting prescription drug fraud and abuse in the Medicaid program. The St. Louis County PDMP requires prescribers and pharmacies access a patient's history in the PDMP database prior to prescribing and dispensing controlled substances.

According to DSS officials, the agency has not tried to obtain access to data for either of these monitoring programs. Although it does not contain statewide data, the St. Louis County PDMP can help the state program better identify potential inappropriate prescribing and use of controlled prescription drugs. Requiring prescribers and pharmacies to access a patient's history in the St. Louis County PDMP database prior to prescribing and dispensing controlled substances would enhance the drug utilization review program oversight activities. Agency officials provided no reasoning for not utilizing the St. Louis County PDMP data, but stated they could use it to make inquiries on participants that the DSS Missouri Medicaid Audit and Compliance Lock-In Unit is reviewing to determine if participants are filling prescriptions outside of the Medicaid or CHIP benefit and/or are using multiple pharmacies.

Recommendation

The General Assembly take action to improve the state's PDMP and create a comprehensive PDMP that meets the needs of the Medicaid and CHIP programs.

The DSS create procedures to utilize the St. Louis County PDMP until a more comprehensive statewide system becomes available to enhance the state's program oversight.

Auditee's Response

The department's written response is included at Appendix C.

3. Physician-Administered Drugs

The DSS did not implement system controls to require collection of NDCs for all physician-administered drug claims, which limits the ability of the DSS to bill the prescription drug manufacturers for rebates for those drug claims. As a result, approximately $170,000 was paid for drug claims for which no manufacturer rebates could be collected. By not collecting NDCs on these claims the DSS did not comply with federal requirements related to drug rebates, and the drug claims for which rebates were not billed are not allowable for federal reimbursement. A similar finding was noted in a prior audit report.[3]

The DSS has controls in the claims processing system to deny claims that lack the NDC. However, our testing found the DSS allowed payment for physician-administered drug claims totaling $170,343 incorrectly submitted as procedural claims (which do not include NDCs) from April through October 2016. Because these claims lacked the required NDCs, the DSS could not bill the prescription drug manufacturers for rebates as required by federal regulations. The DSS identified the erroneous claims and modified the claims processing system to prevent the submission of physician-administered drug claims as procedural claims, thereby ensuring NDCs are

[3] SAO, *State of Missouri Single Audit*, report number 2018-016, finding number 2017-015.

submitted as required in the future. However, the DSS did not recoup these identified improper payments from the providers or reimburse the DHHS for the unallowable costs.

Federal regulation 2 CFR Section 200.303 requires the non-federal entity to "[e]stablish and maintain effective internal control over the Federal award that provides reasonable assurance that the non-Federal entity is managing the Federal award in compliance with Federal statutes, regulations, and the terms and conditions of the Federal award." Such controls should ensure NDCs are collected for all physician-administered drug claims, prescription drug manufacturers are billed for rebates, and only allowable costs are claimed for federal reimbursement. In addition, controls should be established to recoup and reimburse the DHHS for claims identified as noncompliant.

Recommendation

The DSS continue to establish controls to ensure the required drug utilization data is obtained for all physician-administered drug claims and claim only allowable costs for federal reimbursement. These controls should include procedures to recoup and reimburse the DHHS for claims identified as non-compliant.

Auditee's Response

The department's written response is included at Appendix C.

4. Excluded Drug Claims

The DSS controls are not sufficient to deny all drug claims for drugs excluded from the Medicaid program. As a result, 56 drug claims totaling $5,170 for excluded drugs were paid in error during the 4th quarter of 2016.

Federal regulation 42 USC 1396r-8 (d) (2) provides a list of drugs that may be excluded from coverage of Medicaid programs. DSS established the following drugs to be excluded from the Medicaid program:

- Drugs used to promoted fertility
- Drugs used to treat sexual dysfunction
- Drugs used to promoted weight loss
- Drugs used to promote hair growth
- Drugs used for cosmetic purposes
- Quazepam commonly used to treat insomnia symptoms
- Drugs without a prescription

DSS utilizes the Medicaid Management Information System (MMIS) to process all Medicaid claims, including outpatient prescription drug claims. Excluded drugs can be allowable if the physician prescribes the drugs for a purpose different from excluded treatment, and the drug must be approved by prior authorization, according to DSS personnel. DSS established various edits on MMIS to identify and deny drug claims for drugs excluded from coverage. In addition, DSS has a manual process to turn off the National Drug Code (NDC) associated with the excluded drugs. However, this process failed

for 13 drugs. The DSS paid 56 drug claims totaling $5,170 from October through December 2016 for drugs excluded from the Medicaid program. The prescription drugs associated with the 56 drug claims were for the treatment of sexual dysfunction or fertility, promoting weight loss, or promoting hair growth. DSS has a manual process in place to update the MMIS to exclude drugs for payment and DSS personnel stated they might have missed these drugs. The questioned claims were not prior authorized for a different purpose. Since these drugs were not allowable expenditures of the Medicaid program, the federal program should not be charged for payments made and the state should reimburse the DHHS for claims identified as noncompliant.

Recommendation

The DSS evaluate existing procedures to ensure the claim processing system identifies and prevents payments for unallowable claims. These controls should include procedures to recoup and reimburse the DHHS for claims identified as non-compliant.

Auditee's Response

The department's written response is included at Appendix C.

Appendix A
Department of Social Services - Prescription Drug Oversight
Top 10 Most Costly Prescription Drugs, by Amount Paid
Year Ended December 31, 2016

Drug Name	Amount Paid Per Quarter Ended 12/31/16	Annualized Amount Paid*	Participants	Amount per Participant	Units Dispensed	Amount per Unit	Units per Participant
Lurasidone HCL	$ 8,612,039	$ 34,448,156	37,162	$ 927	291,872	$ 30	8
Paliperidone Palmitate	7,049,212	28,196,848	7,639	3,691	7,203	979	1
Albuterol Sulfate	6,774,030	27,096,120	208,310	130	7,013,947	1	34
Insulin Glargine	6,506,636	26,026,544	40,097	649	415,084	16	10
Methylphenidate HCL	6,495,171	25,980,684	52,918	491	1,928,732	3	36
Adalimumab	5,900,035	23,600,140	3,267	7,224	3,444	1,713	1
Somatropin	5,643,385	22,573,540	5,053	4,467	10,266	550	2
Aripiprazole	5,328,678	21,314,712	74,582	286	862,277	6	12
Lisdexamfetamine Dimesylate	5,233,719	20,934,876	26,631	786	595,754	9	22
Fluticasone - Salmeterol	4,925,962	19,703,848	34,294	575	1,219,323	4	36
Total	$ 62,468,867	$ 249,875,468					

* Using the quarterly data provided, we estimated the annual amount paid for these 10 drugs. We made the assumption that the number of participants would not fluctuate over the year, because these drugs are maintenance drugs and it is likely a participant would remain on the drug for the entire year.

Appendix B
Department of Social Services - Prescription Drug Oversight
Top 10 Most Costly Opioid Drugs, by Amount Paid
Year Ended December 31, 2016

Drug Name	Amount Paid Quarter Ended 12/31/16	Annualized Amount Paid*	Participants Quarter Ended 12/31/16	Annualized Participants*	Amount per Participant	Quarterly Units Dispensed	Cost per Unit	Units per Participant
Oxycodone HCL	$ 3,999,373	$ 15,997,492	12,221	48,884	$ 327	2,917,457	$ 1.37	239
Hydrocodone/Acetaminophen	1,680,194	6,720,776	55,223	220,892	30	8,241,286	0.20	149
Oxycodone HCL/Acetaminophen	1,375,730	5,502,920	21,562	86,248	64	3,754,819	0.37	174
Morphine Sulfate	495,569	1,982,276	5,145	20,580	96	729,367	0.68	142
Buprenorphine	443,270	1,773,080	576	2,304	770	5,157	85.96	9
Tramadol HCL	415,876	1,663,504	23,316	93,264	18	3,868,551	0.11	166
Fentanyl	392,531	1,570,124	2,466	9,864	159	67,253	5.84	27
Hydrocodone Bitartrate	295,914	1,183,656	384	1,536	771	25,007	11.83	65
Morphine Sulfate/Naltrexone	159,419	637,676	151	604	1,056	16,165	9.86	107
Acetaminophen with Codeine	142,665	570,660	7,880	31,520	18	535,860	0.27	68
Total	$ 9,400,541	$ 37,602,164						

* Using quarterly data, we estimated the annual amount paid for these 10 drugs. We made the assumption that the participants would not remain on the drug for the entire year, because these drugs are regulated and intended for short durations.

Missouri Department of
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November 30, 2018

Honorable Nicole R. Galloway, CPA
Missouri State Auditor
P.O. Box 869
Jefferson City, MO 65102

Dear State Auditor Galloway:

Please find below the Department of Social Services' (DSS) responses to the recommendations from the audit of DSS prescription drug oversight.

2. Prescription Drug Monitoring Programs Audit Recommendation:

The General Assembly takes action to improve the state PDMP and create a comprehensive PDMP that meets the needs of the Medicaid program.

The DSS create procedures to utilize the St. Louis County PDMP until such time a statewide system becomes available to enhance the state's program oversight.

DSS Response:

Missouri Medicaid Audit and Compliance (MMAC) initiated steps to gain access to the St. Louis County PDMP data. As of September 22, 2018, MO HealthNet and MMAC are authorized users of the St. Louis County PDMP.

3. Physician-Administered Drugs Audit Recommendation:

The DSS continue to establish controls to ensure the required drug utilization data is obtained for all physician-administered drug claims and claim only allowable costs for federal reimbursement. These controls should include procedures to recoup and reimburse the DHHS for claims identified as noncompliant.

DSS Response:

MO HealthNet identified claims in September 2016 (JIRA ticket was created on September 30, 2016 with the "fix" put into production November 30, 2016 by WIPRO) and the modification was completed in February 2017 in the Medicaid Management Information System (MMIS) to prevent submission of physician-administered drug claims as procedural claims, thereby ensuring NDCs are submitted when required. Going forward, MO HealthNet has made the necessary system changes to ensure accuracy.

4. Excluded Drug Claims Audit Recommendation:

The DSS evaluate existing procedures to ensure the claim processing system identifies and prevents payments for unallowable claims. These controls should include procedures to recoup and reimburse the DHHS for claims identified as non-compliant.

DSS Response:

DSS has a system in place to prevent overpayments of excluded drug claims. The MO HealthNet Division (MHD) self-identified a number of claims in late calendar year 2016 that constituted excluded drug claims. Once identified, MHD initiated recoupments of those claims to ensure reimbursement to DHHS for the FFP for those excluded claims. At the start of calendar year 2017, MHD started a new process to review and update the system twice monthly with new NDC's so that the system identifies and prevents payments of unallowable claims. DSS is committed to the continual improvement of claims processing regarding payment for excluded drugs.

Thank you for allowing the Department of Social Services the opportunity to prepare and submit this response.

Sincerely,

/s/

Steve Corsi, Psy. D
Director