PERFORMANCE AUDIT

COST CONTAINMENT FOR STATE PRESCRIPTION DRUG EXPENDITURES

From The Office Of State Auditor
Claire McCaskill

Medicaid officials have been slow implementing new cost containment initiatives, updating current measures and recommending legislative or rule changes that are more favorable to the state.

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Office of
Missouri State Auditor
Claire McCaskill

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YELLOW SHEET

State Medicaid program may pay too much for prescription drugs and reimburse pharmacies more than necessary

Missouri's Medicaid outpatient prescription drug costs have more than doubled in the last 5 years and totaled $770 million in fiscal year 2001. This audit focuses on the Division of Medical Services' efforts to reduce prescription drugs costs. Auditors found Missouri has not been as proactive as other states with certain containment programs, such as preferred drug lists or prior authorization. The following highlights our findings:

Preferred drug lists help other states save money

Many states are now following practices of most employee health insurance plans in using preferred drug lists to reduce costs. Physicians who want to prescribe drugs not on the list have to seek prior approval from the Medicaid program. Michigan and Florida officials estimate these lists will save annually $80 million and $150 million, respectively. Legislation just passed in Missouri's 2002 session allows the division to establish a preferred drug list by January 2003, but division officials predict, in the end, the state rule making process will block its implementation. (See page 5)

State prior authorization rules more complicated then federal

Division officials have not placed many drugs in prior authorization status in the last 5 years, partly due to restrictive state rules which exceed federal requirements. Drugs in this status require a physician seek Medicaid program approval before dispensing them, which often saves costs by resulting in fewer unnecessary prescriptions. State rules require Missouri-specific clinical and therapeutic analysis before placing a drug in prior authorization. Federal law only requires a state plan to respond within 24 hours of a request and dispense a 72-hour emergency prescription. In January 2002, division officials tried to place more drugs in this status, but were blocked from doing so. (See page 6)

Outdated pharmacy reimbursement rates raise costs

Each state Medicaid agency determines how pharmacies are reimbursed for acquiring and dispensing drugs for Medicaid recipients. One way Missouri reaches this price is to use the average wholesale price for a drug less 10.43 percent. But Missouri has not changed this percentage decrease since 1991 and 19 states use a higher percentage decrease than Missouri. For example, a Missouri pharmacy would receive a $119.66 reimbursement from Medicaid for a month's supply for the 20 milligram version of Prilosec®, whereas

pharmacies in a state with a 14 percent decrease would receive $115.05 for dispensing the same supply. Overall, if Missouri changed its percentage decrease from 10.43 percent to 14 percent, division records estimated annual savings of $16.4 million. (See page 7)

Lower reimbursement rate on some drugs could save $1.5 million

Missouri pays more than necessary on 437 drugs dispensed intravenously to at-home or non-hospitalized chronically ill patients. The overpayment occurs because division officials have not timely implemented new dispensing fees for these drugs which would allow providers to be reimbursed using more accurate drug prices. In May 2000, the federal government provided more accurate average wholesale prices for these drugs, with some prices being 80 percent less than previous prices. Our calculations indicate the state could have saved an estimated $1.5 million ($2 million in drugs costs less $500,000 increase in dispensing fees) on the $8.4 million spent on these drugs in fiscal year 2001 if the more accurate prices had been used. Division officials believe any costs savings from the more accurate drug prices would be completely offset by the higher dispensing fees. (See page 9)

State to pay pharmacies the nation's highest dispensing fee to offset new tax

Legislation passed in the 2002 session nearly doubled the dispensing fee paid by the state Medicaid program to pharmacies. The fee increase to $8.04 per prescription from $4.09 would rank as the nation's highest. On average, state Medicaid programs paid a $4.27 fee in 2001. This increase offsets a new 2 percent pharmacy provider tax, also passed in the 2002 session, which would help the state obtain additional federal Medicaid matching funds. Pharmacies would pay about $55.4 million with the new tax, but then receive about $60.4 million from the state in higher dispensing fees. It is uncertain if the federal government will agree to match the tax revenues and the state legislation is not yet signed into law. (See page 10)

New program director appears to have conflict of interest

The Department of Social Services hired a pharmacy program director in October 2001 who previously worked as a lobbyist for the Missouri Pharmacy Association and continues to own at least one pharmacy. Department legal staff determined hiring this person did not violate state conflict of interest laws. However, an appearance of a conflict still exists because of the director's continued financial interests in the pharmacy industry and his new position's influence over policy or legislative changes effecting the industry. (See page 15)

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STATE PRESCRIPTION DRUG EXPENDITURES

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CLAIRE C. McCASKILL
Missouri State Auditor

Honorable Bob Holden, Governor
and
Members of the General Assembly
and
Kathy Martin, Director
Department of Social Services
Jefferson City, MO 65102

The state's Medicaid prescription drug costs have more than doubled since 1997 and account for $660 million of the $770 million spent by the state in fiscal year 2001 on prescription drugs. The objectives of this audit were to (1) determine total direct and indirect cost of prescription drugs for the state, (2) evaluate the effectiveness of some of the state's efforts to reduce Medicaid drug costs, and (3) evaluate the factors leading to increased drug costs in the Medicaid program.

Missouri's current budget problems and legislative mandates have led to cost control initiatives during the last year. Medicaid officials are implementing a pharmacy enhancement program consisting of various cost containment initiatives. While this program focuses on some pharmacy reimbursement issues, other reimbursement issues are not being addressed or do not include the therapeutic benefit and cost effectiveness of prescribed drugs. We recommend changes to help improve the effectiveness of this program. In addition, the Pharmacy Program Director has an appearance of a conflict of interest that should be resolved.

224 State Capitol • Jefferson City, MO 65101

Truman State Office Building, Room 880 • Jefferson City, MO 65101 • (573) 751-4213 • FAX (573) 751-7984

The audit was conducted in accordance with applicable standards contained in *Government Auditing Standards,* issued by the Comptroller General of the United States, and included such tests of the procedures and records as were considered appropriate under the circumstances.

Claire McCaskill
State Auditor

February 19, 2002 (fieldwork completion date)

The following auditors contributed to this report:

Director of Audits:	Kirk Boyer
Audit Manager:	Jon Halwes, CPA, CGFM
In-Charge Auditor:	Christina Davis
Audit Staff:	Shad Becker
	Cindy Elliott
	Andrea Paul
	Lori Melton

RESULTS AND RECOMMENDATIONS

1. Missouri Can Better Contain Medicaid Prescription Drug Costs

Division of Medical Services officials, who run the state's Medicaid program, have not proactively contained drug costs or evaluated pharmacy reimbursements. In the last 5 years, the state's Medicaid outpatient prescription drugs costs have more than doubled. While officials are implementing a pharmacy enhancement program, the program currently does not include establishing a preferred drug list which other states use to lower drug costs. The enhancement initiatives lack emphasis on pharmacy compensation issues. The following concerns were noted:

- Outdated estimated acquisition prices,
- Higher maximum reimbursement rate for insulin drugs,
- More accurate pricing data on home infusion drugs not being used,
- Pharmacies keeping shared dispensing fees, and
- Inadequate monitoring of transactions related to a federal discount program.

In addition, the implemented or planned initiatives to limit prescriptions to a 31-day supply and not pay for over-the-counter products may not be cost effective. As a result, Missouri's Medicaid program may be paying too much for some drugs and reimbursing pharmacies more than necessary.

State prescription drug costs

The state spent approximately $770 million on prescription drugs during fiscal year 2001. Medicaid drug costs[1] made up approximately 85 percent of this total, with the majority for outpatient prescriptions. Table 1.1 shows the prescription drug costs for the state.

[1] Medicaid program expenditures are approximately 60 percent paid for from federal funding. In addition, 60 percent of any Drug Rebates received go to the federal government.

Table 1.1: State Prescription Drug Costs Fiscal Year 2001

Agency or Program Area	Amount Spent
Direct Expenditures:	
Medicaid - Outpatient Services[1]	$ 681,377,799
less Medicaid Drug Rebate[2]	(128,352,149)
Department of Mental Health	7,791,114
Department of Health	2,789,904
Other State Agencies	1,812,943
Total Direct Costs	565,419,611
Indirect[3] Expenditures:	
Employee Health Insurance	91,662,982
Medicaid - Managed Care	62,364,747
Medicaid - Hospital Inpatient[4]	45,000,000
Inmates	5,160,557
Total Indirect Costs	204,188,286
Total Costs	$ 769,607,897

[1] Medicaid program activity is highlighted in yellow.

[2] Federal law requires drug manufacturers to rebate a portion of the drug costs when purchased through state Medicaid programs. The rebate is generally between 15 and 20 percent of the drug's cost.

[3] Costs are built into contract prices.

[4] Estimated based on fiscal year 1999 data.

Source: statewide accounting system, state agency survey and Medicaid records

Medicaid drug costs doubled over 5 years

Between 1997 and 2001, the cost for Medicaid outpatient prescription drugs in the Medicaid program more than doubled, increasing to $553 million from $268 million. This increase has been driven by new drugs, more Medicaid recipients, increased use of maintenance drugs,[2] and higher drug prices. Blind, disabled and elderly Medicaid recipients account for approximately 86 percent of all outpatient prescription drug costs. In fiscal year 2001, the Medicaid program paid $131 million for antipsychotic and antidepressant drugs, before rebates. Twenty-five brand name prescription drugs accounted for nearly 38 percent of all Medicaid outpatient drug expenditures, which are summarized in Appendix III, page 23.

To help control increasing drug costs, the General Assembly mandated various cost containment initiatives. One mandate, in December 2000, targeted the rising costs of antiulcer drugs ($48 million spent in fiscal year 2001) by requiring doctors to receive prior authorization before prescribing these drugs. A second mandate, in fiscal year 2002, required the division to cut pharmacy program expenditures through various division determined initiatives. The division hired a director in October 2001 to manage the Medicaid pharmacy program and oversee the cost

[2] Maintenance drugs are taken daily by patients to treat conditions such as high blood pressure, high cholesterol and anxiety.

cutting initiatives. (See Appendix I, page 19 for a summary of the initiatives and their implementation status as of early 2002.)

Missouri is behind other states in comprehensive cost-containment initiatives

Missouri has not been as proactive as other states in developing preferred drug lists or requiring prior authorization. Both a preferred drug list and prior authorization can help control drug costs while not placing program recipients at risk. These measures would also help program officials better manage use of certain drugs and monitor prescribing practices.

Preferred drug lists could help contain costs

Millions in potential saving available

Recently some Medicaid programs in other states have implemented preferred drug lists, which most employee health insurance plans have used for years. Drugs which are not on these lists may only be prescribed after physicians obtain prior approval from the Medicaid program. Preferred drug lists often take into account the cost and therapeutic value of a drug. Missouri's pharmacy enhancement program does not include plans to implement a preferred drug list. Part of a May 2002 house bill to establish the Department of Social Services budget for fiscal year 2003 would give the Division of Medical Services authorization to establish a preferred drug list prior to January 15, 2003. The Division Director stated that it would be difficult to get such a list approved through the states rule making process and there would be opposition from parties affected by this change.

Since early 2001, Florida and Michigan have joined California[3] in establishing preferred drugs lists. Michigan and Florida officials estimate the lists will save annually $80 million and $150 million, respectively in total state and federal funding. Other states, including Colorado, Louisiana, and Indiana, are also working on similar programs. The Missouri Pharmacy Program Director reported to the legislature an estimated annual savings of $32 million in state funding if a preferred drug list is implemented.

Florida's plan requires drug manufacturers to rebate the state an extra 10 percent of a drug's cost, in addition to the regular federal Medicaid rebate, to place products on the preferred drug list. Drugs from manufacturers unwilling to provide the additional state rebate are only made available to Medicaid recipients on a prior authorization basis. Florida officials allowed two drug manufacturers to guarantee certain costs savings from disease management programs in lieu of paying the rebate.

Michigan, with similar Medicaid prescription drug costs to Missouri, established a state medical panel to analyze cost and therapeutic data and select at least the two best drugs in each of 40 highest cost categories. Other drugs in these categories are placed on prior

[3] California's Medicaid program began using a preferred drug list in 1990. Drug manufacturers provide the state a rebate of 10 to 60 percent of the average manufacturer's price in addition to the federal drug rebate. In fiscal year 2001, California's Medicaid program had $3.2 billion in expenditures for outpatient prescription drugs. The estimated annual saving from using the preferred drug list was $235 million.

authorization status. Drugs already less expensive than the preferred medicines are also placed on the preferred drug list. Manufacturers can also have other products moved to the preferred drug list if they cut prices to match the best-in-class drugs. The program is used for Medicaid and other state funded healthcare programs.

Missouri's prior authorization rules are too complicated

Division officials have not placed many drugs or classes of drugs in prior authorization[4] status in the last five years. The pharmacy enhancement program proposes expanding the number of drugs on the state's prior authorization list, but restrictive state rules hinder this process. A prior authorization process is an integral part of any preferred drug list because drugs not on the list may not be prescribed without prior authorization.

Missouri's rules[5] for placing drugs on prior authorization are more complicated and restrictive than federal government requirements. A division official stated part of the reason the rules are more complicated than necessary is because pharmaceutical industry representatives assisted state officials in drafting the rules 10 years ago. State rules require Missouri-specific data based on medical and clinical criteria, a public hearing, and an annual review of approved drugs. Federal law does not require these procedures. Federal law only requires a state's prior authorization plan respond within 24 hours of a request and allow for dispensing of a 72-hour emergency prescription. As a result, clinical and therapeutic analysis is not required to place drugs on prior authorization under federal law. Missouri has used prior authorization as more of a clinical tool to prevent adverse drug interaction for recipients, while other states such as South Carolina, also used it to contain drug costs.

In January 2002, the division attempted to add some antihistamine and antifungal drugs to the state's prior authorization list. The General Assembly's Joint Committee on Administrative Rules denied this request citing noncompliance with some of the prior authorization requirements. Division officials believe all requirements were met, but withdrew the request with an intent to submit it again. As a result, the state lost potential savings by not placing these drugs into prior authorization status.

Our survey of 20 states indicated that certain drugs or drug classes are frequently placed in a prior authorization program. Product cost was at least one component in the decision to implement prior authorization for the drugs or drug classes in those states. Table 1.2 lists these drugs or drug classes and the amount the Missouri Medicaid program spent on these drugs or drugs classes in fiscal year 2001. As of February 2002, only the antiulcer drug class required prior authorization in Missouri.

Vioxx®, Celebrex®, Claritin®, and OxyContin® are among Missouri's top 25 Medicaid drug costs as noted in Appendix III, page 23. While prior authorization of a drug or drug class

[4] A prior authorized drug will be approved for dispensing if the division's detailed algorithm based on clinical data specific to the drug indicates a patient's therapeutic need for it.

[5] Generally established through state agency developed proposals contingent upon the General Assembly's review of the proposed order of rulemaking through the Joint Committee on Administrative Rules.

may result in some increased costs to manage prior authorization requests, these additional costs are more than offset by fewer unnecessary prescriptions for these drugs.

Table 1.2: Drug or Drug Classes Other States Require Prior Authorization and Missouri's Cost for These Drugs

Drug or Drug Class	Number of States	Missouri's Fiscal Year 2001 Cost
Antiulcer (Prilosec®, Prevacid®, etc.)	8	$ 48,052,775
Cox II Inhibitors (Vioxx® and Celebrex®)	8	22,347,736
Antihistamines (Claritin®, Allegra®, Zyrtec®)	6	13,029,558
OxyContin®	2	9,344,838

Source: State survey results and Medicaid data

Cost containment initiatives lack emphasis on adjusting pharmacy compensation

Most of the pharmacy enhancement program initiatives do not consider pharmacy reimbursement rates or evaluate appropriateness of pharmacy billings to the program. One initiative is to expand the number of drugs on the state upper payment list as generic drugs become available for brand-name drugs.[6] Updating state upper payment limit rates more frequently will help contain the state's drug costs. These updates will have increasing importance as popular brand-name drugs lose patent protection over the next 5 years and more generic alternatives become available. Currently, drugs added to the list and the upper limit reimbursement prices are updated on an irregular basis with a planned goal of updating them at least quarterly. The most recent updates were done in September 2001; and January and May 2002. Some states surveyed revise drugs and rates on upper payment limit lists more than quarterly. For example, Nebraska officials do updates every other month and Illinois officials make changes weekly.

However, approximately 80 percent of the expenditures for outpatient prescription drugs received by Medicaid recipients in fiscal year 2001 were for brand-name and generic drugs not eligible for the state upper payment limit list. Medicaid program officials have not evaluated the pharmacy compensation for these drugs, making it possible the state is paying too much for them.

Pharmacy reimbursement rates are outdated

Each state Medicaid agency determines how much pharmacies are reimbursed for the estimated cost involved in acquiring (estimated acquisition price) and dispensing drugs.[7] This price is based on manufacturers' costs and is generally calculated using two different rates; one rate uses the average wholesale price for a drug less a percentage and the other rate is based on the wholesale acquisition cost plus a percentage. While most states use one or

[6] This is a list of brand-name drugs with expired patents and associated generic drugs for which the division has established a lower reimbursement limit generally close to the lowest cost generic drug.

[7] See Appendix II, page 20, for a more detailed description of pharmacy reimbursement options.

the other rate, Missouri has used both since July 2001. Further, the same rates are used for both brand-name and generic drugs. According to division estimates, each percentage change in these price adjustments impacts expenditures by an estimated $5 million annually.

In addition to using the same price for brand and generic drugs, the average wholesale price percentage decrease used by Missouri may be outdated based on federal reports and discounts used by other states. Missouri's average wholesale price decrease of 10.43 percent is based on a 10-year old (1991) state-sponsored study of pharmacy wholesale prices. Further, the wholesale acquisition cost increase of 10 percent is based on percentages used in other states and not a state study.

A 1997 federal report[8] based on Missouri pharmacy wholesale prices concluded pharmacy discounts from average wholesale prices were 18.5 percent for brand name drugs and 46.4 percent for generic drugs. National figures for other states reviewed at that time indicated similar percentage reductions. A 2001 federal report[9] indicated national pharmacy discounts had increased substantially to 21 percent for brand-name drugs and to 65 percent for generic drugs. While state officials must include other factors beside wholesaler price discounts when setting estimated acquisition prices, 19 states use a higher average wholesale price percentage decrease than Missouri's 10.43 percent. One state uses a 15 percent decrease. If Missouri's percentage decrease was changed from 10.43 percent to 14 percent, division records showed annual savings of $16.4 million.

Reimbursement rates for insulin drugs are also outdated

The state reimbursed pharmacies $320,000 more than necessary in state fiscal year 2001 as the result of using a higher maximum reimbursement rate for insulin drugs.[10] The estimated acquisition price used for pharmacy reimbursements for these products is average wholesale price minus 10.43 percent plus 25 percent which is higher than the estimated price used for most drugs (average wholesale price minus 10.43 percent plus a $4.09 dispensing fee per prescription). Division officials seemed to be unaware of this higher reimbursement rate when we questioned them on the issue. Officials from three states surveyed indicated they used the same reimbursement rate for insulin drugs as other prescription drug products. If the same estimated acquisition price had been used for insulin drugs as other prescription drugs in the Medicaid program, the state would have saved $320,000 on the $7.1 million spent on these drugs in fiscal year 2001.

[8] Department of Health and Human Services Office of Inspector General - *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Missouri Department of Social Services* issued January 1997.

[9] Department of Health and Human Services Office of Inspector General - *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the Washington Department of Social and Health Services* issued November 2001.

[10] Insulin products are considered over-the-counter products for which pharmacies do not receive a dispensing fee.

Lower reimbursement rates for certain home infusion drugs not used

Missouri continues to pay more than it should on home infusion drugs[11] because division officials have not implemented more accurate drug prices. In May 2000, the federal Department of Justice provided all states with more accurate average wholesale prices for 437 primarily home infusion dispensed drugs. Some prices were more than 80 percent less than the average wholesale prices previously reported by pharmaceutical companies. The state could have saved an estimated $1.5 million on the $8.4 million spent on these 437 drugs in fiscal year 2001 if officials used the more accurate average wholesale prices and a dispensing fee structure similar to one implemented in another state.

Within 2 months of Department of Justice notice of the more accurate average wholesale prices, Utah officials began using the lower drug prices with new dispensing fees. With the help of infusion specialty providers, Utah officials categorized the 437 drugs into 5 groups appropriate to the preparation and overhead costs for the product. The new dispensing fees set up for drugs in 4 of the 5 categories ranged from $8.90 to $33.90 per prescription.

The state could save $1.5 million annually

Missouri officials initially implemented the more accurate prices for provider reimbursement using the normal $4.09 dispensing fee, which was not designed to cover these drugs. Division officials reversed this decision after home infusion providers threatened to cease services due to insufficient dispensing fees. Provider personnel admitted the former reimbursement rates exceeded their product acquisition costs, but they used the excess reimbursement to offset the higher dispensing costs of home infusion drugs. Division officials indicated they plan to use these lower prices again after determining adequate compensation for home infusion services. While no implementation date has been set, the Division Director stated the necessary changes to implement these prices would be part of the division's fiscal year 2004 budget proposal.

State is not collecting some pharmacy fees while proposing to increase other fees

For years, division officials have allowed pharmacies to keep some recipient co-payments, known as shared dispensing fees, in lieu of increasing the $4.09 prescription dispensing fee. Pharmacies kept an estimated $3 million to $6 million in shared dispensing fees in fiscal year 2001. Certain Medicaid recipients pay an optional shared dispensing fee for pharmacy transactions ranging from 50 cents to $2 based on the cost of the prescription.[12] However, this compensation is not being considered as part of legislation to establish a pharmacy provider tax and nearly double the dispensing fee to $8.04 per prescription.

Division officials do not maintain any data on the shared dispensing fee amounts kept by pharmacies. They estimate this fee applies to half of all pharmacy transactions, and

[11] Drugs generally dispensed intravenously by health care professionals to patients with chronic illnesses who can live at home or in a non-hospital arrangement.

[12] Children, pregnant women and institutionalized recipients are exempt from paying the shared dispensing fee. However, no Medicaid recipient can be denied a prescription if he/she cannot pay the shared fee amount.

recipients pay the fee about half of the time. During fiscal year 2001, the Medicaid program had more than 13 million pharmacy transactions. We estimate that pharmacies received between $3 million and $6 million based on (1) an average prescription price greater than $10, (2) a shared dispensing fee between $1 and $2 per prescription, and (3) the fee applied to 25 percent of the more than 13 million pharmacy transactions in fiscal year 2001.

$8.04 fee would be nation's highest

The fiscal year 2003 state budget includes a pharmacy provider tax to obtain additional federal Medicaid matching funds although it is uncertain the federal government will match these tax revenues.[13] The budget estimates pharmacies will pay about $55.4 million under a 2 percent tax on their prescription drug business. However, the budget also shows the state will pay pharmacies $60.4 million in additional dispensing fee compensation. The dispensing fee would nearly double from $4.09 to $8.04. If the pharmacy tax is implemented, the state's $8.04 dispensing fee will far exceed fees paid by any other state. During fiscal year 2001, the average dispensing fee for all state Medicaid programs was $4.27, with the highest being $5.77 in Louisiana. The $8.04 fee does not include the shared dispensing fees currently retained by pharmacies. Some states that require recipient co-payments or shared dispensing fees will reduce a pharmacy's transaction reimbursement for the amount the pharmacy receives from a recipient. However, this situation was not considered by the state under this pharmacy tax/increased dispensing fee legislation.

Controls over transactions for a pharmacy discount program need improvement

The state may have lost more than $500,000 in fiscal year 2001 by overpaying some pharmacies or incorrectly billing manufacturers for rebates related to a federal discount drug program. Section 340B of the Public Health Service Act requires drug manufacturers discount the cost of drugs supplied to certain federally covered entities, and that the entities pass on the discounts by billing Medicaid at the discounted prices. We focused on approximately 20 pharmacies that received more than 95 percent of the outpatient pharmacy expenditures paid to program participating providers. The errors occurred because division staff did not determine if program providers billed the state appropriately and did not effectively evaluate the continued participation status of program providers. As a result, the state (1) did not claim some rebates from pharmaceutical manufacturers, (2) claimed some rebates for ineligible transactions, and (3) failed to receive the required discount from at least three program participating providers. Table 1.3 summarizes these results.

According to federal officials, discounted prices through this program generally average about 40 percent less than the manufacturers' average wholesale price. For entities participating in the Section 340B program, the state is not allowed to bill the manufacturer for drug rebates for transactions billed at the discounted rate. The state has established a computer edit to remove transactions for participating providers from the rebate billing process.

[13] The federal matching funds are estimated at $86.5 million. The federal government will have to approve a waiver to the state's Medicaid Plan for this tax revenue to qualify for additional matching funds.

Table 1.3: Fiscal Year 2001 340B Program Provider Errors

Error Type	Number of Providers	Pharmacy Expenditures to Provider	Estimated Value of Errors
Provider failed to bill at discounted rate	3	$ 1,275,651	$ 389,549
Rebate not claimed	7[1]	1,279,297	177,502[2]
Rebates inappropriately claimed[3]	1	1,157,761	(40,169)[2]
Total		$ 3,712,709	$ 526,882

[1] Four of the 7 providers receive only family planning drugs through the 340B program, but all facility transactions are excluded from the rebate process. These providers billed little or no family planning drugs to the Medicaid program.

[2] These errors may be corrected through billing corrections for any rebates not claimed and the manufacturer billing dispute process.

[3] Provider began participating in the 340B program April 1, 2001.

Source: Medicaid data and discussions with providers

Two initiatives may be counter-productive and increase costs

In fiscal year 2001, Medicaid program rule changes limited most prescription drugs to a maximum 31-day supply. Department budget documents also proposed, beginning in fiscal year 2003, not paying for over-the-counter products, except insulin. These changes could cost the program more, particularly with the proposed increase in dispensing fees to $8 or more per prescription.

The 31-day supply limit prevents many recipients from receiving 90-day prescriptions for maintenance drugs which triples the program's dispensing costs for these recipients. According to division officials, the theory behind such a policy change is the increased dispensing costs will be offset by less money spent on unused portions of 90-day prescriptions. Unused drugs may occur if recipients are given 90-day prescriptions for drugs prior to their doctor determining the drug was effective to treat them. The Pharmacy Program Director stated it was inconclusive whether the Medicaid program saved money with the 31-day supply limit during fiscal year 2001. At least three of the states surveyed have monthly supply limits, but make an exception for maintenance drugs. In December 2000, Missouri made this same exception on maintenance drugs for 25,000 Medicaid spenddown[14] recipients.

Missouri and 12 states responding to our survey questions on over-the-counter products currently use payment for these products as a cost containment measure. A Medicaid program would rather have a physician prescribe a less expensive over-the-counter product than a more expensive prescription product if that product could effectively treat the patient. During fiscal year 2001, the Medicaid program paid $6.4 million for non-insulin over-the-counter drugs. Most of these products were for the treatment of lice, indigestion, pain, or iron deficiency. State officials estimate the Medicaid program will save more than $6 million by not paying for over-the-counter products. However, if doctors begin prescribing

[14] Spenddown is a status given to a recipient whose income is too high to qualify for normal Medicaid benefits but can qualify after incurring a determined amount of medical costs during a three-month period.

prescription drugs for Medicaid recipients when an over-the-counter product would suffice, this potential saving is lost by paying higher prices for prescription drugs. This scenario could occur since Medicaid recipients pay little or no cost for prescription drugs and may tell doctors they cannot afford the prescribed over-the-counter product. In addition, recent news that the popular prescription product Claritin® will be converted to over-the-counter status in late 2002 may require this decision to be modified.

Conclusion

Cost containment for Medicaid prescription drug costs must be evaluated on an ongoing basis as changes take place in the pharmaceutical industry and in other state Medicaid programs. The Division of Medical Services has not done all it can to contain Medicaid drug costs. While division officials have faced challenges in restrictive state laws, they have been slow in implementing new cost containment initiatives, updating current initiatives and recommending legislative or rule changes that enhance program effectiveness. Some state Medicaid programs are implementing preferred drug lists which consider therapeutic value and/or cost of drugs being prescribed. Several cost containment measures are currently being implemented with unknown savings. Various pharmacy compensation issues need to be evaluated as part of the pharmacy enhancement program to better contain drug costs.

Recommendations

We recommend the Director, Department of Social Services:

1.1 Develop plans to implement a preferred drug list that considers the therapeutic value and cost of drugs.

1.2 Amend the state's Medicaid prior authorization rules to limit unnecessary issues that delay moving drugs or drug classes to a prior authorization basis.

1.3 Update drugs and reimbursement rates on the state upper payment limit list more frequently.

1.4 Update the current estimated acquisition prices and pharmacy dispensing fees. Separate estimated acquisition price computations for generic and brand name drugs should be established as well as eliminating the current higher maximum reimbursement rate for insulin products.

1.5 Implement the lower average wholesale prices for home infusion products with equitable dispensing fees for home infusion services.

1.6 Improve procedures to ensure (1) 340B program providers pass on appropriate discounts to the state and (2) drug rebates are received for all appropriate pharmacy transactions including eligible transactions for providers only receiving some discounted drugs through the program.

1.7 Adjust pharmacy reimbursements for shared dispensing fees retained by pharmacies if the planned pharmacy tax/increased dispensing fee is implemented.

1.8 Closely monitor the cost effectiveness of (1) eliminating 90-day prescription authorization for maintenance drugs and (2) not paying for over-the counter drugs.

Department of Social Services Responses

1.1 Consistent with the mandates of the General Assembly, the Division of Medical Services plans to begin work on a preferred drug list in FY 03.

1.2 The Division concurs with the SAO recommendation. Consistent with the opportunities and constraints of the rulemaking process, the Division is amending the prior authorization rules to make the process more streamlined.

1.3 The Division is presently updating the upper payment information globally on a quarterly basis and as needed on an individual product basis. This is more frequently than other third party payers. The Division feels it would be impractical to update these limits more frequently.

1.4 The Division pointed out to the SAO the pharmacy reimbursement regarding the acquisition prices and the dispensing fees are set through the appropriation process by the General Assembly. The Division continues to collect information regarding these reimbursement issues for use by the General Assembly in their deliberations.

With regard to the insulin products, they are presently subject to the "lower of" test with the AWP plus 25% reimbursement being the maximum allowable reimbursement. The Division has found few pharmacies billing at this ceiling rate. However, the Division will change the insulin reimbursement to the standard pharmacy reimbursement methodology approved by the General Assembly.

1.5 The Division agrees a change in the reimbursement methodology should occur with respect to the home infusion services. The Division continues to work on this process and will develop a decision item for consideration in the SFY04 budget. When implemented, the resulting changes are expected to be revenue neutral for the state and the providers.

1.6 The Division has accepted the recommendation of the SAO and is developing guidelines for 340B program providers.

The Division policy is to place providers that purchase products through 340B in a system edit (Parm) so claims will not enter the Medicaid rebate system. When a provider is added to the Parm, all their products are exempt from reporting to Drug Rebate. The Division will research a system modification to resolve the issue of providers purchasing specific products only through 340B.

Any uncollected rebates noted in the review are recoverable and overpayments of rebates will be resolved with the manufacturers during the dispute resolution process.

1.7 The shared dispensing fee collection is not required of the recipient to receive services. Federal law will not allow the assessment of the fee as a prerequisite for receiving services. Pharmacy providers in various areas of the state collect the fee at a different rate. The Division will consider the impact and the collection rate when providing information to the General Assembly for future changes in the pharmacy dispensing fee.

1.8 The 30-day prescription limit and limited payment for over-the-counter drugs were mandated by the General Assembly during the appropriation process. The Division will monitor both for fiscal impact to the state.

2. Pharmacy Program Director Appears to Have a Conflict of Interest

Prior to being hired by the Department of Social Services in October 2001, the Pharmacy Program Director served as a registered lobbyist for the Missouri Pharmacy Association and continues to own at least one pharmacy. Division of Medical Services officials did not consult the Missouri Ethics Commission concerning potential conflicts, although they were aware of his business relationships. The Division Director stated the department's legal staff evaluated the hiring and determined there would be no conflict of interest problem if the hiring took place. Nevertheless, the pharmacy program is managed by someone with a financial interest in the same industry on which he can influence policy decisions made by his department and the legislature. Department officials have no assurance that such influence is unbiased or in the state's best interest.

The Pharmacy Program Director said his business interests do not create a conflict of interest because he lacks rule-making authority and does not qualify as a "decision-making public servant" under state law. However, this Director is in a position to influence program decisions and legislative changes that may impact the profitability of pharmacies, such as proposing changes to pharmacy reimbursement rates. He needs to be free of unintentional or intentional bias towards the industry. The Division Director stated the Pharmacy Program Director is providing the state needed expertise to get the pharmacy program in the right direction.

Conclusion

Department officials should ensure conflicts of interest do not occur. Issues regarding potential conflicts of interest should be resolved before employees are hired.

Recommendation

The Director, Department of Social Services:

2.1 Resolve the appearance of a conflict of interest for the Pharmacy Program Director.

Department of Social Services Responses

2.1 The Division consulted with the Department's Division of Legal Services regarding the issue of conflict of interest of the Pharmacy Program Director. The Pharmacy Program Director has filed a full disclosure with the Ethics Commission and has made his holdings clear to all interested parties. Additionally, the Pharmacy Program Director obtained a legal opinion from his legal counsel and has shared that opinion with the Department and Division. The opinion indicates no conflict of interest exists.

The results of the pharmacy program operations, the decline in industry reimbursement, and the program management statistics all support the fact the Pharmacy Program Director is fulfilling his job requirements without bias or regard to pharmacy or pharmaceutical industry outcomes. The Pharmacy Program Director has been forthcoming in all recommendations and has delivered on all Division requests with

balanced recommendations, which allowed appropriate decisions to be made by the Division and Department administration.

OBJECTIVES, SCOPE AND METHODOLOGY

Objectives

The objectives of this audit were to (1) determine total direct and indirect cost of prescription drugs for the state, (2) evaluate the effectiveness of some of the state's efforts to reduce Medicaid drug costs, and (3) evaluate the factors leading to increased drug costs in the Medicaid program.

Scope and Methodology

To accomplish the objectives, we:

- Reviewed applicable state and federal laws related to outpatient prescription drug benefits in the state's Medicaid program.

- Reviewed the state's Medicaid pharmacy enhancement program current and planned initiatives. These initiatives and the implementation or planned implementation dates are summarized in Table I.1. Due to delays in implementation of some initiatives, and the timing of our audit, our review focused on the items discussed in the report.

- Interviewed the Pharmacy Program Director and other responsible officials to determine the status of the pharmacy enhancement program initiatives and pharmacy reimbursement processes, and obtained necessary documentation.

- Interviewed officials responsible for various state employee health plans (Missouri Consolidated Health Plan, Department of Conservation, Department of Transportation and the University of Missouri) to determine the total cost of prescription drugs to the state, and to compare the pharmacy benefits of the employee plans.

- Contacted Medicaid program officials of 20 states to determine how Missouri compares to other states in implementing cost containment initiatives.

- Analyzed Missouri Medicaid pharmacy claims for fiscal years 2000 and 2001 to determine the most prescribed and most expensive drugs to the program, and the reasons for the increase in prescription drug costs.

- Reviewed average wholesale prices, wholesale acquisition costs, and federal and state upper payment limits for selected drugs to understand the pharmacy reimbursement process and how Missouri's reimbursements compare to other states.

- Analyzed pharmacy claims for selected Medicaid providers participating in a federal prescription drug discount program. We identified approximately 20 pharmacies that handled the majority of the program's transactions. For each pharmacy we selected 5 brand-

name drugs and compared the reimbursed rate to a computation of the average wholesale price less 10.43 percent plus the $4.09 pharmacy fee. If the reimbursed rate was 25 to 40 percent less than the estimated normal reimbursement we concluded the pharmacy billed the state at an appropriate discounted rate. For any other results, we contacted representatives of the pharmacy to determine program participation status. To evaluate if rebates were correctly billed, we obtained a listing of all providers in Missouri participating in the program. This listing was compared to a listing of providers in the program maintained by the division whose transactions are not included in drug rebate billings. The estimates for potential overpayments or rebate over or under billings were adjusted for dispensing fee compensation received by pharmacies.

- To determine the amount potentially overpaid for 51 insulin drugs, we obtained all transactions for these products for fiscal year 2001. We compared the amount paid for each transaction to a computation of the average wholesale price less 10.43 percent plus the $4.09 pharmacy fee.

- To determine the potential saving for the 437 home infusion products, we obtained the spring 2000 wholesale prices submitted to states by the Department of Justice. For these 437 drugs in fiscal year 2001, we compared the pharmacy reimbursement for each transaction using the wholesale prices submitted by the Department of Justice to the prices currently being used by the state. To determine the potential increase in dispensing fee costs, we obtained the dispensing fee structure for these drugs used by Utah, and multiplied that rate less $4.09 times the number of transactions for each drug. The estimated drug cost savings was $2 million with additional dispensing costs estimated at no more than $500,000.

We conducted our fieldwork between August 2001 and February 2002.

Table I.1: Medicaid Prescription Drug Cost Containment Initiatives

Initiative	Implementation or Planned Implementation Date
31-day maximum supply	December 2000
Expansion of state upper payment limit list	December 2000; September 2001; and January and May 2002[1]
Eliminate pay and chase	March 2001 - Halted due to litigation
Nursing home credits for returned drugs	July 2001[2]
Unique prescriber number	January 2002
Prior authorization expansion	January 2002 - Withdrawn due to rule compliance issues
Dose optimization	April 2002
Edits-max quantity/hard edits	June 2002[3]
Physician education components	June 2002[3]
Disease management	June 2002[3]
Patient profiling	June 2002[3]
Enhanced retrospective drug utilization	June 2002[3]
Additional justification on overrides	March 2002
Provider audits	Fiscal Year 2003
Prior authorization of all new drugs	Fiscal Year 2003
Eliminate over-the- counter, except insulin	Fiscal Year 2003
Pharmacy provider tax	Fiscal Year 2003
Pill splitting	unknown - Reassessing based on fewer products being eligible for splitting than originally planned

[1] Division officials estimate this initiative saved the program $4.28 million through December 31, 2001.

[2] Division officials estimate this initiative saved the program $100,000 through December 31, 2001.

[3] The initiative is pending installation of Medicaid computer system enhancements which are expected in the fourth quarter of fiscal year 2002.

Source: Department of Social Services budget documents, discussions with Division of Medical Services officials

BACKGROUND

The Department of Social Services - Division of Medical Services is responsible for administering the state's Medicaid program. The program is authorized under Title XIX of the federal Social Security Act,[15] and is jointly funded by state and federal funds. Services provided by the program include those required by federal regulations such as hospital, physician, and skilled nursing home care. The state's Medicaid program also provides optional services such as dental, prescription drugs, and personal care as authorized by the General Assembly.

The state's Medicaid program provides eligible Missouri residents prescription drug services at nominal or no cost. The cost for Medicaid outpatient prescription drugs increased $285 million between fiscal year 1997 and 2001 as shown in Table II.1. These costs are estimated to be $744 million during fiscal year 2002.

Table II.1: Medicaid Outpatient Prescription Drug Costs
Fiscal Years 1997 to 2001 (in millions)

		Fiscal Year				
		1997	**1998**	**1999**	**2000**	**2001**
Expenditures	$	321	374	469	581	681
Less rebates		(53)	(64)	(84)	(110)	(128)
Net expenditures	$	268	310	385	471	553
Change from prior year			16%	24%	22%	17%

Source: Medicaid records

Pharmacy reimbursement options

Medicaid regulations provide for the pharmacy reimbursement of outpatient drugs using two methods (multiple source and single source).

If a drug is a multiple source drug (brand-name drug and 3 or more generic versions of the drug), then reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public or a federal upper limit amount plus a dispensing fee. The federal upper limit amounts are established by the Department of Health and Human Services - Centers for Medicare and Medicaid Services. The reimbursed amount for the brand-name and associated generic drugs will be the federal upper payment limit amount no matter what the billed cost of the drug. The rate is set based on the prices for each product and normally set near the lowest price for any of the products. Missouri also has established another option (state upper payment limit) which is similar to the federal upper payment limit, but may be set once a brand-name drug

[15] Laws governing the Medicaid prescription drug programs are 42 United States Code (USC) Section 1396r-8 (Payment for covered outpatient drugs) and 13 Code of State Regulation (CSR) 70-20 (Pharmacy Program).

has at least 1 but generally 2 or more generic versions verses the federal criteria of 3 or more versions. Pharmacy reimbursement is based on the lower of the pharmacist's usual and customary charge to the general public, the state upper payment limit plus a dispensing fee or the federal upper limit amount plus a dispensing fee (if applicable).

If a drug is a single source drug (brand-name drug), or a generic drug for which a state or federal upper limit amount has not been established, then the reimbursement is the lower of the pharmacist's usual and customary charge to the general public or the estimated acquisition cost plus a dispensing fee. Effective July 1, 2001, Missouri uses two potential estimated acquisition prices:

- Average wholesale price (AWP) minus 10.43 percent
- Wholesale acquisition cost (WAC) plus 10 percent

Tables II.2 and II.3 illustrate the reimbursement options and decision process for a one month prescription for two drugs.

Table II.2: Pharmacy Reimbursement Options

		Estimated Acquisition Price		Upper Payment Limit	
Drug Type	**Drug Name**	**AWP-10.43%**	**WAC+10%**	**State**	**Federal**
Brand	Prilosec	$ 115.57	118.27	N/A	N/A
Generic	Amoxapine	$ 70.05	68.82	23.40	31.72

Table II.3: Pharmacy Reimbursement Decision

Drug Name	**Lowest Option + Dispensing Fee[1]**	**Billed Amount**	**Reimbursement[2]**
Prilosec	$ 119.66	115.00	115.00
Amoxapine	$ 27.49	35.85	27.49

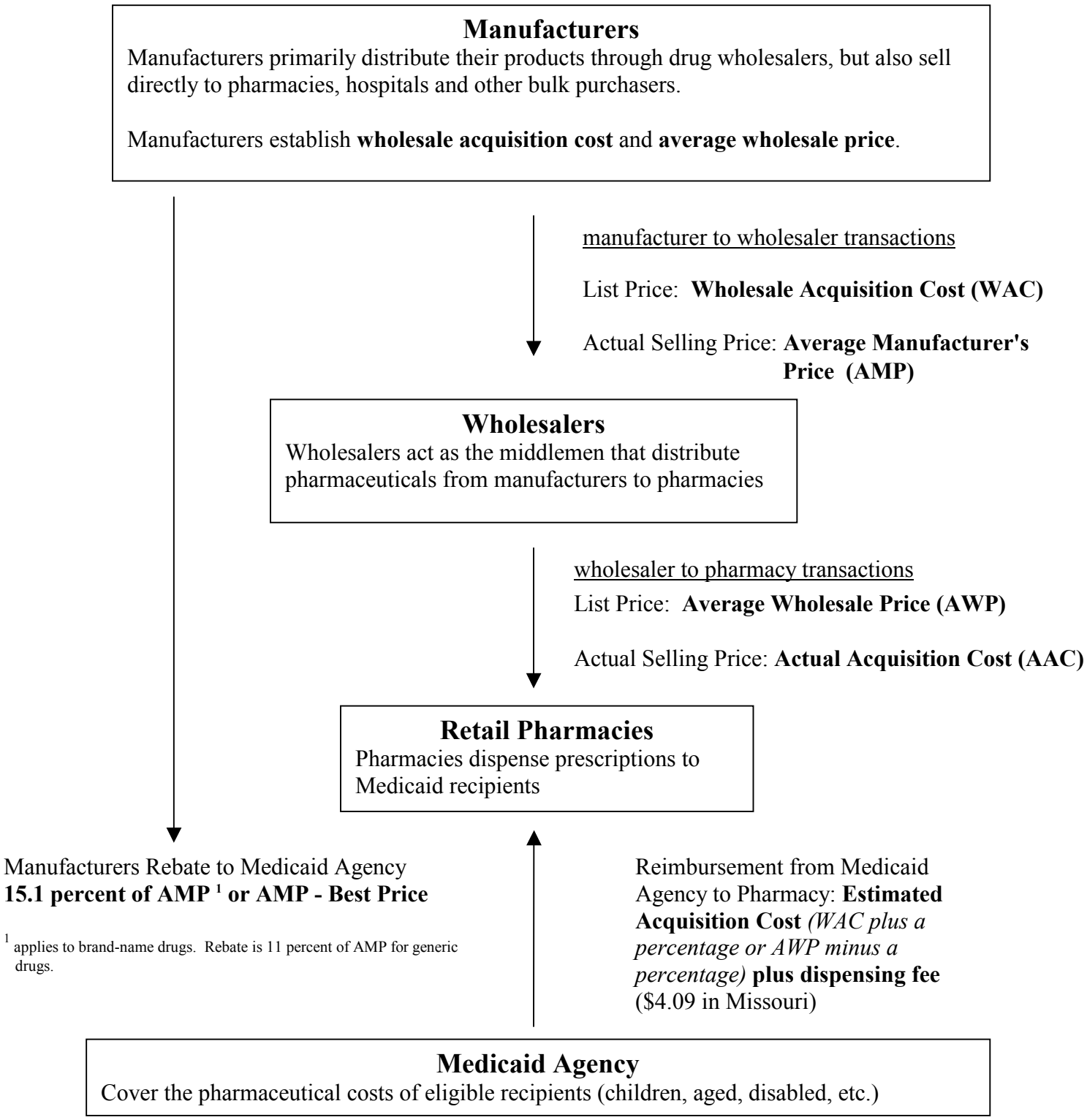
[1] The lowest cost of the 4 options is chosen and the $4.09 dispensing fee is added to determine the maximum reimbursement amount.

[2] The lower of the amount billed or the maximum reimbursement amount.

Source: Medicaid drug price data

Figure II.1 describes the reimbursement process to pharmacies for drugs received by Medicaid recipients and the rebate provided by manufacturers to state Medicaid agencies.

Figure II.1: Description of the Medicaid Reimbursement Process



Source: Department of Health and Human Services - Office of Inspector General; SAO compiled data

APPENDIX III

TOP 25 MEDICAID OUTPATIENT PRESCRIPTION DRUGS - FISCAL YEAR 2001

Table III.1 lists the 25 outpatient prescription drugs the Missouri Medicaid program spent the most for in fiscal year 2001. These drugs represent nearly 38 percent of the $681,377,799 spent on outpatient prescription drugs that year.

Table III.1: Top 25 Medicaid Prescription Drugs - Fiscal Year 2001

Brand Name		Amount Spent	Use
Zyprexa®	$	35,910,411	Antipsychotic
Risperdal®		22,991,612	Antipsychotic
Prilosec®		18,806,905	Stomach Acid Blocker
Prevacid®		14,432,770	Stomach Acid Blocker
Celebrex®		13,197,253	Arthritis Treatment
Prozac®		11,847,723	Antidepressant
Zoloft®		10,886,247	Antidepressant
Depakote®		10,767,140	Anticonvulsant
Paxil®		10,420,245	Antidepressant
Lipitor®		10,022,348	Cholesterol Lowering Agent
Neurontin®		9,895,260	Anticonvulsant
Oxycontin®		9,344,838	Narcotic Pain Reliever
Vioxx®		9,150,483	Arthritis Treatment
Seroquel®		9,100,210	Antipsychotic
Norvasc®		6,852,602	Blood Pressure Reducer
Buspar®		6,436,251	Antianxiety
Claritin®		6,160,792	Antihistamine
Glucophage®		6,136,640	Lowers Blood Sugar
Zocor®		5,294,398	Cholesterol Lowering Agent
Celexa®		5,200,362	Antidepressant
Ultram®		5,092,688	Analgesic Pain Reliever
Remeron®		5,077,321	Antidepressant
Pepcid®		5,007,771	Stomach Acid Reducer
Zithromax®		4,926,713	Antibiotic
Effexor®		4,899,261	Antidepressant
Total	$	257,858,244	

Source: Medicaid program expenditure data