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United States Government Accountability Office
Washington, DC 20548

October 31, 2005

The Honorable Edward Whitfield
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Subject: *Medicaid: States' Payments for Outpatient Prescription Drugs*

Dear Mr. Chairman:

Spending on outpatient prescription drug coverage for Medicaid beneficiaries has accounted for a substantial and growing share of Medicaid program expenditures.[1] All states and the District of Columbia have elected to include outpatient prescription drug coverage as a benefit of their Medicaid programs. Total Medicaid expenditures on outpatient prescription drugs grew from $4.6 billion (nearly 7 percent of Medicaid's total medical care expenditures) in fiscal year 1990 to $33.8 billion (13 percent of Medicaid's total medical care expenditures) in fiscal year 2003. This represented more than twice the rate of increase in total Medicaid spending from fiscal year 1990 through fiscal year 2003. Amid concerns about increasing Medicaid drug spending, focus has been drawn to the ways states pay for prescription drugs.

State Medicaid programs pay pharmacies for covered outpatient prescription drugs dispensed to Medicaid beneficiaries. The Centers for Medicare & Medicaid Services (CMS)—the agency of the Department of Health and Human Services (HHS) that oversees states' Medicaid programs—sets maximum payment limits for certain drugs—federal upper limits (FUL)[2]—and provides guidelines regarding drug payment, as defined by regulation.[3] Within these parameters, states may determine their own drug payment methodologies. States are to pay pharmacies the lower of the state's estimate of the drug's acquisition cost to the pharmacy, plus a dispensing fee, or the

[1]Medicaid is a joint federal-state program that finances health insurance for certain low-income adults and children.

[2]See 42 C.F.R. § 447.332 (2004). Federal regulations require CMS to set specific FUL amounts for certain multiple-source drugs that are provided by at least three suppliers. A multiple-source drug is a drug that is either marketed or sold by two or more manufacturers or labelers, or marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name. Payments for these drugs must not exceed, in the aggregate, a reasonable dispensing fee plus an amount that equals 150 percent of the lowest published price of the drug listed in national pricing compendia.

[3]See 42 C.F.R. § 447.331 (2004).

pharmacy's usual and customary charge to the general public; for certain drugs, the FUL or the state maximum allowable cost (MAC) may apply if lower.[4] All states estimate the acquisition cost of drugs using published prices because they do not have access to actual sales price data, which are not publicly available. Most states choose to estimate drug acquisition cost by taking a percentage discount off of Average Wholesale Price (AWP).[5] AWP is a list price that a manufacturer suggests wholesalers charge pharmacies.

Based on concerns about escalating Medicaid drug expenditures, you asked us to review state Medicaid payments for covered outpatient prescription drugs. We reviewed how Medicaid payments for prescription drugs compared across selected states and how these states' Medicaid payments for prescription drugs compared to three market-based prices.

We briefed your staff on the information contained in this report on September 16, 2005. As discussed with your staff at that time, we agreed to issue this report, which officially transmits the briefing slides (see enc. I) and expands on the information provided at the briefing.

Scope and Methodology

To examine state Medicaid payments for outpatient drugs, we analyzed CMS data to develop a basket of 200 drugs that accounted for more than half of Medicaid's national spending on outpatient prescription drugs in 2003.[6] We judgmentally selected five states for review—Mississippi, Montana, Pennsylvania, South Carolina, and Utah; these states utilize a varying percentage discount off of AWP to estimate drug acquisition cost. We interviewed officials from the five states' Medicaid agencies to gather information on each state's pharmacy payment practices. We also obtained the five states' 2003 payment data for each of the 200 drugs in our basket. For every drug, we calculated each state's payment per unit.[7] Using these calculations, we reviewed the variation in the percent difference between the lowest state payment and the highest state payment for each drug. We report our findings

[4]As of December 2003, 38 states had established maximum allowable costs for multiple-source drugs at a rate below an established FUL or for drugs for which CMS had not set an FUL.

[5]States may obtain AWP from one or more national pricing compendia; although multiple sources publish price lists, the prices listed by one source do not necessarily equal the prices listed by other sources.

[6]For the purpose of this report, the term drug refers to a distinct national drug code (NDC). NDCs identify unique formulations of each drug, including the manufacturer, strength, and package size. A single drug may have multiple NDCs. Because our analysis was performed at the NDC level, multiple versions of the same drug are included in our basket.

[7]State's payment per unit was the state's payment to pharmacies as determined by the lowest of: the state's estimate of drug acquisition cost, the pharmacy's usual and customary charge, the FUL, if available, or the state MAC, if available, divided by the number of units dispensed. Our report summarizes results from our analysis of states' payments per unit as calculated without dispensing fees.

based on drug type (brand or generic) and drug therapeutic class based on data we obtained from First DataBank.[8]

To compare state Medicaid payments to selected market-based prices, we reviewed how states' average payments compared to three prices that are based on actual sales transactions—Average Manufacturer Price (AMP), Best Price, and Federal Supply Schedule (FSS) Price. We selected AMP and Best Price because they are currently used in the Medicaid program to calculate drug rebates;[9] FSS Price was selected because it represents prices available to certain federal government purchasers. Table 1 provides descriptive characteristics of these prices. We obtained AMP and Best Price data from CMS and FSS Price data from the Department of Veterans Affairs (VA).[10] We assessed the variation in the percent difference between each state's payment and the states' average payment, to each of the market-based prices.

[8]Drugs that possess similar chemical structures and similar therapeutic effects are grouped into therapeutic classes. Most drugs within a class produce similar benefits, side effects, adverse reactions, and interactions with other drugs and substances.

[9]The Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508 § 4401, 104 Stat. 1388-143–1388-161, established the Medicaid drug rebate program to help control Medicaid drug spending. Under the rebate program, a pharmaceutical manufacturer pays rebates to states in order for federal payments to be available under Medicaid for the manufacturer's outpatient drugs.

[10]AMP and Best Price data are reported quarterly; we obtained data on both prices for all four quarters of 2003 and calculated the average 2003 AMP and Best Price. FSS Price is reported based on a contract period; if more than one contract was in place during calendar year 2003, we averaged the available 2003 FSS Prices for the purposes of our analysis.

Table 1: Characteristics of Selected Market-Based Prices

Price	Definition	Price determination method	Defined by statute or regulation	Data availability
Average Manufacturer Price (AMP)	The average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade.[a]	Manufacturers calculate AMP based on actual sales data and report it to the Centers for Medicare & Medicaid Services (CMS).[b]	Yes	Not publicly available
Best Price	The lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, or nonprofit or government entity, with some exceptions.[c]	Manufacturers calculate Best Price based on actual sales data and report it to CMS.[b]	Yes	Not publicly available
Federal Supply Schedule (FSS) Price	A price that is intended to equal or better the prices charged to a manufacturer's most favored nonfederal customer under comparable terms and conditions. FSS Prices are available to all direct federal purchasers of pharmaceuticals, although other lower prices may be available to the largest federal purchasers.	On behalf of the federal government, the Department of Veterans Affairs (VA) negotiates FSS Prices based on manufacturer-reported data on actual sales to their most favored commercial customers.[d]	Yes	Publicly available

Source: GAO analysis of CMS and VA data.

Note: Retail pharmacies that dispense prescription drugs to Medicaid beneficiaries may be unable to purchase drugs at AMP, Best Price, or FSS Price.

[a]See 42 U.S.C. § 1396r-8(k)(1). According to CMS, transactions used to calculate AMP are to reflect cash discounts and any adjustments that affect the price realized, but are not to include prices to direct federal purchasers based on the Federal Supply Schedule (FSS), prices from direct sales to hospitals or health maintenance organizations, or prices to wholesalers when they relabel drugs they purchase under their own label. There is no definition in the statute for "retail pharmacy class of trade."

[b]The Omnibus Reconciliation Act of 1990 created AMP and Best Price for use in the Medicaid program to calculate drug rebates. As we noted in our February 2005 report, we found considerable variation in the methods manufacturers used to determine AMP and Best Price. See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

[c]See 42 U.S.C. § 1396r-8(c)(1)(C). CMS has further defined Best Price as the lowest price at which the manufacturer sells the drug to any purchaser in any pricing structure, including capitated payments, with some exceptions. Best Price is required to be reduced to account for price adjustments such as discounts and rebates, but is not to include prices charged to certain federal purchasers (including prices to direct federal purchasers based on the FSS) and other select purchasers.

[d]See Pub. L. No. 102-585, § 603, 106 Stat. 4943, 4971-75. The Veterans Health Care Act of 1992 required that drug manufacturers list their brand-name drugs on the FSS in order for purchases of such drugs to be eligible for Medicaid payment. During a multiyear contract period, FSS Prices may not increase faster than inflation.

While we generally relied on and did not independently verify the data provided to us by the states, we reviewed the data for reasonableness and to identify unusual patterns, including outliers. To ensure that state payments and market-based prices were based on the same number of units, we compared the units used to calculate both. Where necessary, we recalculated unit payments to ensure valid per-unit comparisons. We also reviewed the reasonableness of states' payments in comparison to their formulas for estimating acquisition cost. Additionally, we discussed unusual patterns and outliers with state Medicaid officials and as a result of unresolved data reliability concerns, eliminated six drugs from our basket.[11] Our final basket contained 194 drugs, which consisted of 189 brand-name drugs—187 single-source and 2 multiple-source drugs—and 5 generic drugs.[12]

Our results cannot be generalized to states or drugs not included in our analysis. Our work also did not consider other mechanisms state Medicaid programs may use to control the costs of prescription drugs, such as the collection of rebates through federal and state programs and policies on the mandatory use of generic drugs. Furthermore, our analysis did not examine the utilization of drugs and therefore does not estimate cost savings for the Medicaid program. We performed our work from February 2004 through October 2005 in accordance with generally accepted government auditing standards.

Results in Brief

Overall, minimal variation existed among the five states' payments for most drugs. Specifically, the five states' payments for 189 brand-name drugs varied less than 7 percent on average; the five states' payments for the 5 generic drugs we reviewed varied 30 percent on average. States' payment levels aligned with their respective formulas for estimating drug acquisition cost. In particular, states that based their estimates of drug acquisition cost on larger discounts off of AWP often paid the lowest amount for drugs; similarly, states that based their estimates of drug acquisition cost on smaller discounts off of AWP often paid the highest amount for drugs.

The five states' payments exceeded the three market-based prices we reviewed—AMP, Best Price, and FSS Price. Each state's payments exceeded these market-based prices for nearly all of the brand-name drugs we reviewed. On average, each state's payments for brand-name drugs exceeded each market-based price by 10 percent or more. Additionally, states' average payments for brand-name drugs were 12 percent higher than AMP, 36 percent higher than Best Price, and 73 percent higher than FSS

[11]Five of the six excluded drugs were antihemophiliac factor drugs; the sixth drug was an injectable drug used to treat multiple sclerosis. As a result of data reliability concerns, we also excluded data on five drugs from one state, and data on one drug each from two states.

[12]For the purposes of this report, we refer to single-source and multiple-source drugs that are marketed under a registered trade name as brand-name drugs. Single-source drugs are brand-name drugs that have no generic equivalent on the market and are generally available from only one manufacturer.

Price, on average. Our results highlight the differences between states' payments (based on the lower of states' estimates of drug acquisition cost or the pharmacy's usual and customary charge; for certain drugs, the FUL or the state MAC may apply if lower) and market-based prices (based on actual sales transaction data).

Agency and State Comments

We provided a draft of this report for comment to the Administrator of CMS and Medicaid directors in Mississippi, Montana, Pennsylvania, South Carolina, and Utah. CMS comments are included in enclosure II. We received technical comments from some states, which we incorporated as appropriate.

CMS stated that this report makes it clear that the current payment rules result in overpayments for drugs and emphasizes the need for reform. CMS commented that payments should be determined using accurate acquisition cost data, which it said requires congressional action. Our review focused on describing how payments for prescription drugs compared across selected states and how these states' payments compared to three market-based prices. As such, the scope of our work did not include an evaluation of the need to reform the current payment system. CMS also commented that it has encouraged states to review their estimates of drug acquisition cost and that states have submitted to the agency an increased number of amendments to their state Medicaid plans that would lower these estimates. Finally, CMS commented that the report focused solely on states' payment rates for drugs and did not consider a variety of other approaches that states have adopted to control their drug spending. As we noted in our draft report, such consideration was beyond the scope of our work.

One state—Utah—raised concerns that states do not have access to the market-based pricing data we used in our analysis, which makes it difficult for them to accurately estimate the acquisition cost of drugs. Our draft report noted that states do not have access to actual sales price data and that states therefore use published prices, such as AWP, to estimate the acquisition cost of drugs.

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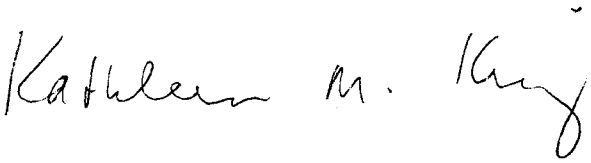
As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this report. At that time, we will send copies to the Administrator of CMS and interested congressional committees. The report will also be available on GAO's home page at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7119 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure III.

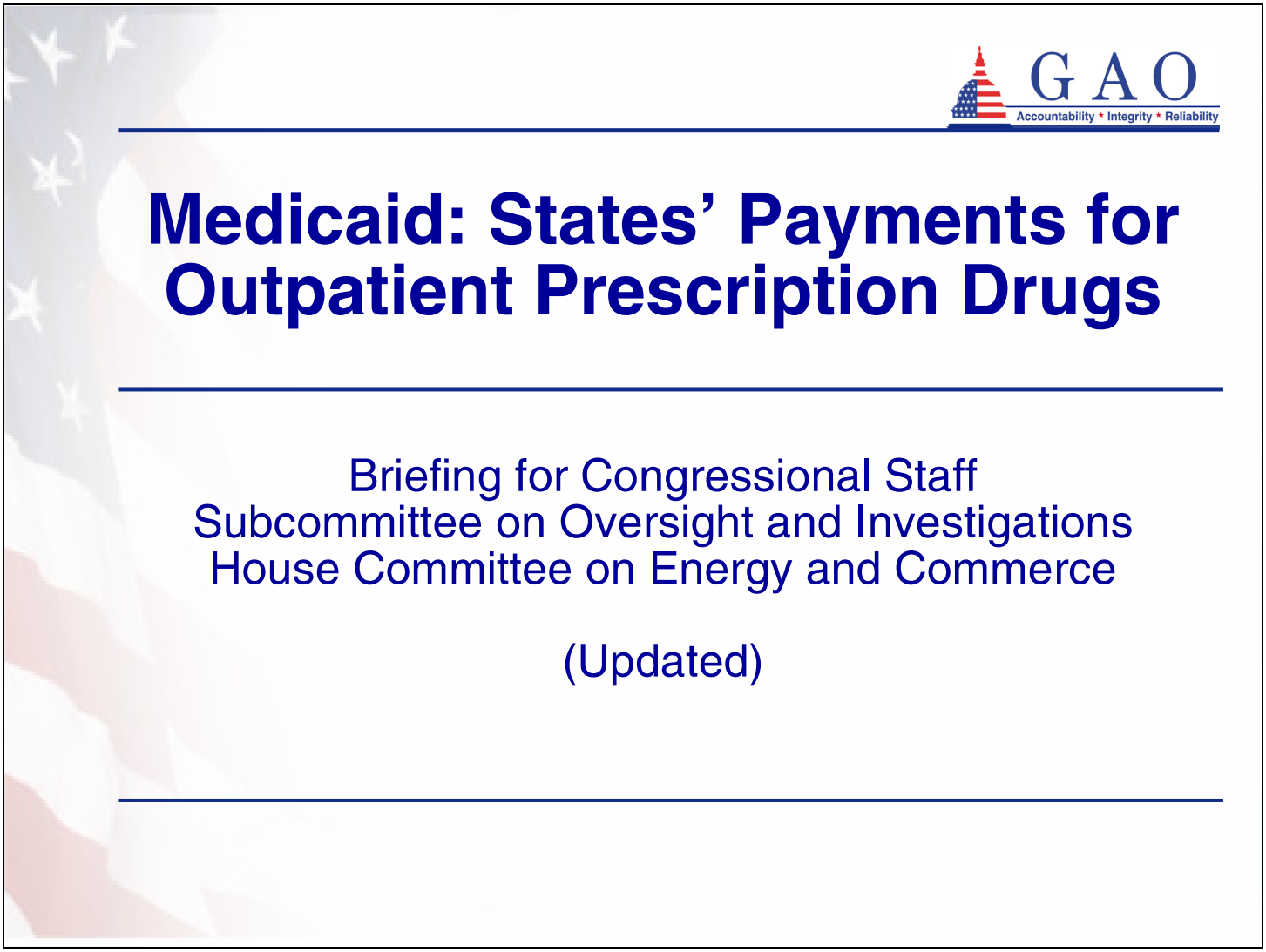
Sincerely yours,



Kathleen M. King
Director, Health Care

Enclosures – 3

Enclosure I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Medicaid: States' Payments for Outpatient Prescription Drugs
Briefing for Congressional Staff
Subcommittee on Oversight and Investigations
House Committee on Energy and Commerce
(Updated)

Enclosure I

Overview

- Introduction
- Objectives
- Scope and Methodology
- Findings

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Enclosure I

Introduction

Overview

- Outpatient prescription drug coverage is an optional Medicaid benefit that all 50 states and the District of Columbia provide.
- Spending on outpatient prescription drugs has been one of Medicaid's fastest growing medical care expenditures.
- Amid concerns about increasing Medicaid drug spending, focus has been drawn to the ways states pay for prescription drugs.

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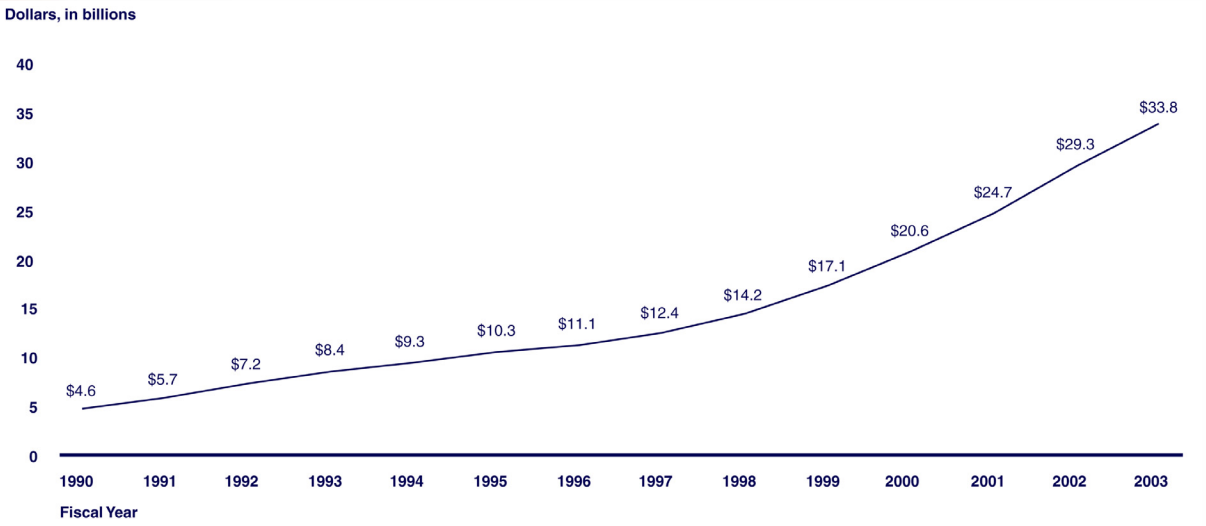
Enclosure I

Introduction

Medicaid Drug Expenditure Growth

Growth in Total Medicaid Outpatient Prescription Drug Expenditures, Fiscal Years 1990 - 2003



Source: GAO analysis of CMS data.

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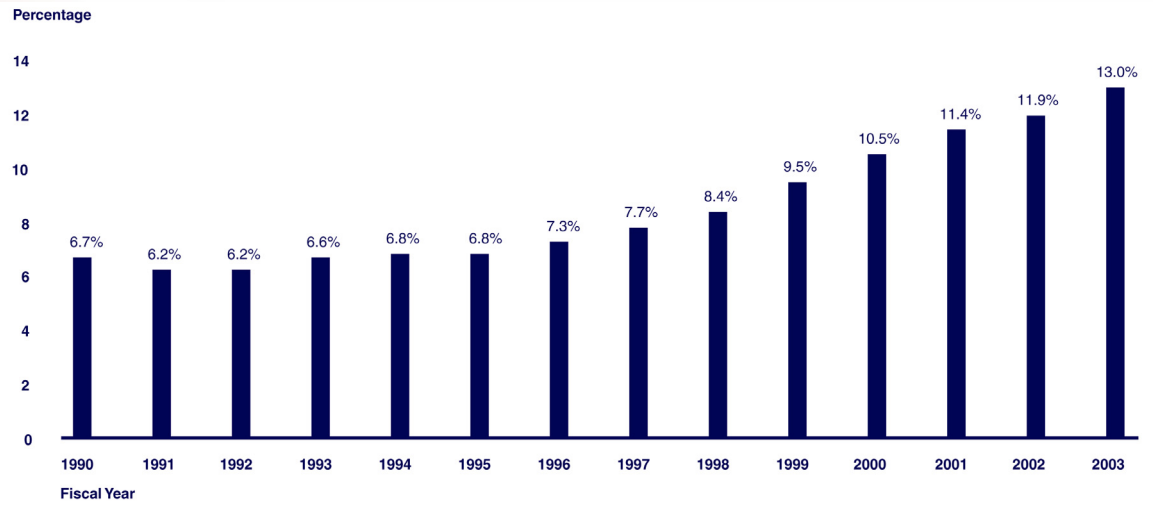
Introduction

Disproportionate Medicaid Drug Expenditure Growth

Total Medicaid Outpatient Drug Spending as a Percentage of Total Medicaid Medical Care Expenditures, Fiscal Years 1990 - 2003



Source: GAO analysis of CMS data.

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Introduction

Medicaid Drug Payment

- State Medicaid programs pay pharmacies for covered outpatient drugs dispensed to Medicaid beneficiaries.
- States are required to pay pharmacies the lower of the state's estimate of the drug's acquisition cost to the pharmacy, based on a state-determined formula, plus a dispensing fee; or the pharmacy's usual and customary charge to the general public. For certain drugs, the federal upper limit (FUL) or the state maximum allowable cost (MAC) may apply if lower.
- All states use published prices, such as Average Wholesale Price (AWP), to estimate the acquisition cost of drugs because they do not have access to actual sales price data, which are not publicly available. AWP is the average list price that a manufacturer suggests wholesalers charge pharmacies.

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Objectives

1. To describe how Medicaid payments for outpatient prescription drugs compare across selected states.

2. To describe how selected states' Medicaid payments compare to market-based prices.

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Enclosure I

Scope and Methodology

Overview

In conducting our work, we:

- Selected 200 prescription drugs that accounted for more than half of 2003 national Medicaid drug spending.
- Grouped drugs into therapeutic classes and by type (brand or generic) using 2005 First DataBank definitions.
- Judgmentally selected 5 states for review.
- Interviewed officials from the 5 state Medicaid agencies.
- Reviewed 2003 drug payment data from the 5 states for the 200 drugs.
- Calculated each state's average payment to pharmacies for each drug.
- Reviewed selected 2003 market-based price data from the Centers for Medicare & Medicaid Services (CMS) and the Department of Veterans Affairs (VA).
- Performed our work from February 2004 through October 2005 in accordance with generally accepted government auditing standards.

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Scope and Methodology

Basket of Drugs

Our initial basket of 200 drugs reflected more than half of Medicaid's national spending on outpatient prescription drugs in 2003.

- We performed data reliability testing on all state drug payment data.
- We recalculated unit payment amounts where necessary to ensure that state payments and market-based prices were based on the same number of units.
- Due to data reliability concerns, we excluded 6 drugs from our basket.[1]

For the 5 selected states, we performed analyses on a final basket of 194 drugs that included:

- 189 brand-name drugs (187 single-source and 2 multiple-source), and
- 5 generic drugs.

[1]We also excluded data on 5 drugs from 1 state and 1 drug each from 2 states due to data reliability concerns.

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Scope and Methodology

Therapeutic Classification of Drug Basket

Therapeutic Classification of Drug Basket

Therapeutic class	Number of drugs	Portion of basket
Psychotherapeutic	47	24%
Anti-infectives/Miscellaneous	18	9%
Central Nervous System	18	9%
Cardiovascular	16	8%
Antiasthmatics	12	6%
Unclassified	11	6%
Hypoglycemics	11	6%
Gastrointestinal	9	5%
Analgesics	8	4%
Antiarthritics	7	4%
Hormones	7	4%
Antihistamines	5	3%
Blood Products	5	3%
Other	20	10%
Total	**194**	**100%**

Source: GAO classification of 2003 CMS data using 2005 First DataBank definitions.

Notes: Therapeutic classes with four or fewer drugs were collapsed into the "Other" class. Percentages do not add to 100 due to rounding.

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Scope and Methodology

Selection of States

We selected 5 states for analysis to include a range of payment levels based on the states' use of a percentage discount off of AWP to estimate drug acquisition cost.

States Selected for Analysis

State	Formula used to estimate drug acquisition cost, as of 2003
Montana	AWP minus 15%
Utah	AWP minus 15%
Mississippi	AWP minus 12%
Pennsylvania	AWP minus 10%
South Carolina	AWP minus 10%

Source: CMS.

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Scope and Methodology

Selection of Market-Based Prices

We selected 3 market-based prices that are based on actual sales transactions.

- Average Manufacturer Price (AMP) and Best Price are currently used by the Medicaid program to calculate drug rebates.[2]
- Federal Supply Schedule (FSS) Price represents prices available to certain federal government purchasers.

[2]To help control Medicaid spending on drugs, the Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program. Under this program, a pharmaceutical manufacturer pays rebates to states in order for federal payments to be available under Medicaid for the manufacturer's outpatient prescription drugs.

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Scope and Methodology

Market-Based Price: Average Manufacturer Price

Average Manufacturer Price (AMP) is the average price paid to a manufacturer by a wholesaler for drugs distributed to the retail pharmacy class of trade. Transactions used to calculate AMP are required to reflect cash discounts and other price adjustments that affect the price actually realized.

- AMP is calculated from actual sales transactions.
- AMP price determination methods vary across manufacturers.
- Manufacturers report AMP data to CMS on a quarterly basis.
- AMP data are not publicly available.
- Retail pharmacies may be unable to purchase drugs at AMP.

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Scope and Methodology

Market-Based Price: Best Price

Best Price is the lowest price the manufacturer sells the drug to any purchaser in any pricing structure, including capitated payments, with some exceptions. Best Price is required to be reduced to account for price adjustments such as discounts and rebates.

- Best Price is calculated from actual sales transactions.
- Best Price determination methods vary across manufacturers.
- Manufacturers report Best Price data to CMS on a quarterly basis.
- Best Price data are not publicly available.
- Retail pharmacies may be unable to purchase drugs at Best Price.

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Scope and Methodology

Market-Based Price: Federal Supply Schedule Price

Federal Supply Schedule (FSS) Price is intended to equal or better the prices manufacturers charge their most favored commercial customers under comparable terms and conditions. On behalf of the federal government, the VA negotiates this price with manufacturers.

- All direct federal purchasers of pharmaceuticals may purchase drugs at the FSS Price, but other lower prices may be available to the largest federal purchasers. Medicaid is not a direct purchaser of drugs.
- FSS Price is negotiated based on actual sales transactions to manufacturers' most favored commercial customers.
- Manufacturers report most favored commercial customer pricing data to VA.
- Manufacturers must list their brand-name drugs on the FSS in order to receive payment for drugs covered by Medicaid.
- FSS Price data are publicly available.
- Retail pharmacies may be unable to purchase drugs at FSS Prices.

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Scope and Methodology

Limitations

- Findings are not generalizable to states or drugs not included in our analysis.
- Analysis did not consider all mechanisms states may use to control the costs of prescription drugs in their Medicaid programs, such as the collection of rebates through federal and state programs and policies on the mandatory use of generics.
- Analysis did not examine drug utilization and therefore does not estimate cost savings for the Medicaid program.

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Summary of Findings

For the 2003 data analyzed, we found that:

- Minimal variation existed among the 5 states' payments for most drugs.
- The 5 states' payments exceeded the 3 market-based prices for the brand-name drugs we reviewed.

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Minimal Variation in States' Payments for Most Drugs

Overview

- Brand-name drug payments varied less than 7 percent across the 5 states on average.
- Generic drug payments varied 30 percent across the 5 states on average.
- Gastrointestinal drug payments varied most across the 5 states on average, among the therapeutic classes.
- State payment levels aligned with their respective formulas for estimating drug acquisition cost.

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Minimal Variation in States' Payments for Most Drugs

Payments for Most Brand-Name Drugs Varied Little

For the 189 brand-name drugs we reviewed,

- The highest state payment exceeded the lowest state payment by 7 percent, on average.
- Payments for 50 percent of these drugs differed by 6 percent or less.
- Payments for 75 percent of these drugs differed by 7 percent or less.
- Payments for 95 percent of these drugs differed by 15 percent or less.
- Payments for 1 drug varied more than 26 percent.

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Minimal Variation in States' Payments for Most Drugs

Payments for Generic Drugs Varied Considerably

For the 5 generic drugs we reviewed,

- The highest state payment exceeded the lowest state payment by 30 percent, on average.

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Minimal Variation in States' Payments for Most Drugs

Payments for Gastrointestinal Drugs Varied Most

Percent Difference in the 5 States' 2003 Drug Payments, by Therapeutic Class

Number of drugs	Therapeutic class	Average difference between states' lowest payment and states' highest payment
9	Gastrointestinal	17%
8	Analgesics	11%
11	Unclassified	10%
12	Antiasthmatics	9%
18	Anti-infectives/Miscellaneous	8%
47	Psychotherapeutic	8%
20	Other	8%
11	Hypoglycemics	7%
18	Central Nervous System	7%
16	Cardiovascular	7%
7	Hormones	6%
5	Blood Products	5%
7	Antiarthritics	4%
5	Antihistamines	4%

Source: GAO analysis of 2003 state data using 2005 First DataBank classifications.

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Minimal Variation in States' Payments for Most Drugs

States' Payment Levels Aligned with their Acquisition Cost Formulas

Level of State Payment for Drugs in 2003, by State

State	Formula used to estimate drug acquisition cost, as of 2003	Number of drugs reviewed	Among the 5 states, the number of drugs for which each state's payment was: *The lowest state payment*	*Less than states' average payment*	*The highest state payment*
Montana	AWP minus 15%	194	112	180	1
Utah	AWP minus 15%	193	28	174	1
Mississippi	AWP minus 12%	193	17	91	22
Pennsylvania	AWP minus 10%	194	7	9	113
South Carolina	AWP minus 10%	189	30	65	57

Source: GAO analysis of 2003 state data.

Note: States with equivalent formulas for estimating drug acquisition cost do not necessarily pay the same amount for each drug because payments are determined by the lower of the state's estimate of drug acquisition cost or the usual and customary charge; for certain drugs, the FUL or the state MAC may apply if lower.

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Minimal Variation in States' Payments for Most Drugs

States' Payment Levels Aligned with their Acquisition Cost Formulas

Variation in State Payment for Drugs in 2003, by State

State	Formula used to estimate drug acquisition cost, as of 2003	Number of drugs reviewed	Among the 5 states, the number of drugs for which each state's payment exceeded the lowest state payment by			
			5% or less	*> 5-10%*	*>10-20%*	*More than 20%*
Montana	AWP minus 15%	194	178	5	6	5
Utah	AWP minus 15%	193	172	8	9	4
Mississippi	AWP minus 12%	193	155	12	21	5
Pennsylvania	AWP minus 10%	194	81	101	5	7
South Carolina	AWP minus 10%	189	117	66	5	1

Source: GAO analysis of 2003 state data.

Note: States with equivalent formulas for estimating drug acquisition cost do not necessarily pay the same amount for each drug because payments are determined by the lower of the state's estimate of drug acquisition cost or the usual and customary charge; for certain drugs, the FUL or the state MAC may apply if lower.

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States' Payments Exceeded Market-Based Prices

Overview

Among the 5 states we reviewed,

- Medicaid payments were the highest for nearly all brand-name drugs in our basket.
- States' 2003 average payments for brand-name drugs were, on average:
  - 12 percent higher than AMP.
  - 36 percent higher than Best Price.
  - 73 percent higher than FSS Price.

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States' Payments Exceeded Market-Based Prices

Each State's Payments Were the Highest for Nearly All Brand-Name Drugs

Among the 5 states we reviewed,

- Each state's payments exceeded market-based prices for nearly all brand-name drugs in 2003.[3]
- Each state's payments exceeded market-based prices for brand-name drugs, on average.

Average Percent by which State Payments Exceeded Market-Based Prices for Brand-Name Drugs in 2003, by State

State	Formula used to estimate drug acquisition cost, as of 2003	AMP	Best Price	FSS Price
Montana	AWP minus 15%	10%	33%	69%
Utah	AWP minus 15%	10%	34%	70%
Mississippi	AWP minus 12%	13%	36%	73%
Pennsylvania	AWP minus 10%	15%	39%	77%
South Carolina	AWP minus 10%	13%	37%	74%

Source: GAO analysis of 2003 state, CMS and VA data.

[3]Specifically, state payments exceeded market-based prices for all drugs we reviewed except for the following cases: Mississippi's payments exceeded AMP for all but 1 drug and exceeded Best Price for all but 1 drug; Pennsylvania's payments exceeded AMP for all but 3 drugs and exceeded Best Price for all but 1 drug; and South Carolina's payments exceeded AMP for all but 2 drugs.

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States' Payments Exceeded Market-Based Prices

States' Average Payments Were the Highest for All Brand-Name Drugs

Among the 5 states we reviewed,

- States' average payments for brand-name drugs exceeded all 3 market-based prices we reviewed.
- AMP, Best Price and FSS Price were lower than states' average payments for brand-name drugs. Among these prices,
  - FSS Price was the lowest price for 164 drugs.
  - Best Price was the lowest price for 25 drugs.

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States' Payments Exceeded Market-Based Prices

States' Average Payments Exceeded AMP

For the 189 brand-name drugs we reviewed,

- States' average payments exceeded AMP by 12 percent, on average.
- States' average payments for 50 percent of these drugs exceeded AMP by 11 percent or less.
- States' average payments for 75 percent of these drugs exceeded AMP by 13 percent or less.
- States' average payments for 1 drug exceeded AMP by more than 30 percent.

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States' Payments Exceeded Market-Based Prices

States' Average Payments Exceeded Best Price

For the 189 brand name drugs we reviewed,

- States' average payments exceeded Best Price by 36 percent, on average.
- States' average payments for 50 percent of these drugs exceeded Best Price by 28 percent or less.
- States average payments for 75 percent of these drugs exceeded Best Price by 36 percent or less.
- States' average payments for 6 drugs exceeded Best Price by more than 100 percent.

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Enclosure I

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States' Payment Exceeded Market-Based Prices

States' Average Payments Exceeded FSS Price

For the 187 brand name drugs we reviewed,[4]

- States' average payments exceeded FSS Price by 73 percent, on average.
- States' average payments for 50 percent of these drugs exceeded FSS Price by 65 percent or less.
- States' average payments for 75 percent of these drugs exceeded FSS Price by 86 percent or less.
- States' average payments for 29 drugs exceeded FSS Price by more than 100 percent.

[4]FSS Prices were only available for 187 of the 189 brand-name drugs in our basket.

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Enclosure II

Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 19 2005

TO: Kathleen M. King
Director, Health Care
U.S. Government Accountability Office

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office's (GAO) Draft Report: *Medicaid: States' Payments for Outpatient Prescription Drugs* (GAO-06-69R)

Thank you for the opportunity to comment on the above-referenced draft report. The report reviews State Medicaid payments for covered outpatient prescription drugs under the Medicaid drug rebate program. Specifically, the report examines (1) how Medicaid payments for outpatient prescription drugs compare across selected States and (2) how selected States' Medicaid payments compare to market-based prices.

As for every major payer in this country, prescription drug costs in Medicaid have increased substantially and account for a growing share of Medicaid program expenditures. The Centers for Medicare & Medicaid Services (CMS) shares the GAO's concerns regarding the increase in Medicaid spending for prescription drugs and the high reimbursement levels paid by States.

Federal regulations at 42 CFR 447.331 require States to pay for prescription drugs at the lower of estimated acquisition cost or usual and customary charges. Absent a more accurate source of price data, States rely on prices published by drug compendia to estimate acquisition costs. The regulations at 42 CFR 447.332 also require CMS to set upper limits for certain multiple source drugs.

The GAO report makes clear that the current payment rules result in overpayments for drugs and emphasizes the need for reform. The President's fiscal year (FY) 2006 budget proposes to solve this problem by basing Medicaid drug payment on average sales prices (ASP). The FY 2006 budget proposal would require drug manufacturers to report the ASP for each drug and would cap Federal payment, in the aggregate, at ASP plus 6 percent. As long as States must rely on prices that are not based on market prices paid to manufacturers, they lack sufficient information to set appropriate payment amounts. Current wholesale acquisition cost (WAC) and average wholesale prices (AWP) are greatly inflated, in part because higher list prices from manufacturers result in greater profits to pharmacies when payment is set in relation to the artificial prices. Requiring manufacturers to report true market based prices and limiting Medicaid payment to a reasonable amount above these prices will eliminate the opportunity for manufacturers and pharmacies to gain through reporting inflated prices, yield substantial State and Federal government savings, and retain flexibility for States to set prices for individual drugs as they find appropriate within the overall cap.

Enclosure II

The GAO report finds that Medicaid payments exceed market based prices, but it provides no new or additional information regarding the true acquisition cost of drugs. CMS continues to believe that an accurate acquisition cost should be used to determine payments. This requires Congressional action to define acquisition cost in statute, require manufacturers to report this cost to the Federal government, and set a cap on Federal reimbursement to States based on this cost. As long as States must rely on data submitted by manufacturers which is inflated, States will continue to pay at rates not reflective of market prices.

Numerous reports and studies on acquisition costs for brand name and generic drugs reimbursed under Medicaid have recommended that CMS require States to bring drug reimbursement more in line with the actual acquisition cost. Absent a change in the law, CMS has encouraged States to review their estimates of acquisition costs in light of those findings. Additionally, CMS continuously monitors States' estimated acquisition costs and provides a quarterly update on the CMS website. These actions have resulted in States submitting an increased number of State plan amendments to lower their estimates of acquisition costs.

This report focused solely on payment rates to compare States drug spending. We note that States have adopted a variety of approaches to reduce prescription drug spending. These include establishing preferred drug lists, negotiating supplemental rebates (either individually or with other States), and expanding prior authorization requirements. The findings did not consider these other mechanisms State Medicaid agencies use to control the costs of prescription drugs.

Thank you again for the opportunity to respond to the report.

Enclosure III

GAO Contact and Staff Acknowledgments

GAO Contact

Kathleen M. King, (202) 512-7119 or kingk@gao.gov

Acknowledgments

In addition to the contact named above, Debra Draper, Assistant Director; Jennie Apter; Robin Burke; Jessica Cobert; Martha R. W. Kelly; Kevin Milne; Daniel S. Ries; and Patricia Roy made key contributions to this report.

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