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Prescription Drug Coverage Under Medicaid

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Summary

Medicaid is a joint federal-state entitlement program that pays for services on behalf of certain groups of low-income persons. One of its most important benefits, especially for the elderly and disabled, is prescription drug coverage. Medicare, the nation's health insurance program for the elderly and disabled, does not cover most prescription drugs but will begin doing so beginning January 1, 2006 as a result of the passage of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 (P.L. 108-173, MMA 2003) as signed into law on December 8, 2003. Outpatient prescription drug coverage under Medicaid is an optional benefit. If states choose to cover prescription drugs, they must be provided to Medicaid enrollees who are categorically needy, that is, to individuals who qualify for Medicaid on the basis of being in certain categories that were traditionally tied to the receipt of cash assistance. In addition, states have the option of choosing to provide prescription drug coverage to medically needy individuals, persons who are not poor by cash welfare standards, but who require help with medical expenses. Forty-four states and the District of Columbia provide prescription drug coverage to all Medicaid beneficiaries.

Prescription drug benefits under Medicaid are very broad. States may create formularies, or lists of preferred benefits, but several coverage rules keep actual coverage very comprehensive. Even in Medicaid managed care organizations, which are not subject to those rules, current practice combined with a directive from the Center for Medicare and Medicaid Services (CMS) ensures that drugs made available to fee-for- service enrollees must also be available to managed care enrollees. Most states also cover some categories of non-prescription drugs. There are only 10 categories of prescription drugs that states are allowed to exclude from coverage.

In 2002, total payments for Medicaid outpatient prescription drugs, net of rebates, were $23.4 billion, accounting for about 9.5% of payments for all Medicaid services. On average, per person annual spending for Medicaid drugs was $335. The per person spending for outpatient prescription drugs for blind and disabled Medicaid enrollees was 10 times the amount spent for children enrolled in Medicaid. Since 1990, pharmaceutical manufacturers whose drugs are covered by state Medicaid programs are required to rebate a portion of states' payments for their products. States reported collecting a total $5.9 billion in rebates on prescription drugs in 2002.

State Medicaid programs will be undergoing major changes in their drug coverage policies over the next few years in response to the creation of a Medicare drug benefit under MMA 2003. While specific information about the coverage under the new Medicare Part D is not available at this time, it is likely that Medicaid prescription drug coverage for dually eligible individuals will be considerably reduced. Under MMA 2003 state Medicaid programs will continue to pay for drugs offered to the dually eligible population under Medicare, however, based on a specified formula. In addition, Medicaid administrations will be required to conduct eligibility determinations for individuals qualifying for low-income assistance for the new program.

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Introduction

Medicaid is a joint federal-state entitlement program that pays for medical services on behalf of certain groups of low-income persons. It is the third largest social program in the federal budget, exceeded only by Social Security and Medicare and is typically the second largest spending item for states. The federal share of Medicaid costs in FY2002 for benefits and administration is estimated to have been $146 billion[1] and states are estimated to have spent an additional $112 billion, for a total program cost of $ 258 billion.

Medicaid programs are administered and designed by the states under broad federal guidelines. States must provide Medicaid to certain population groups and have the option of covering others. Similarly, a state must cover certain basic services and may cover additional services if it chooses. States set their own payment rates for services, with some limitations. There is, thus, considerable variation in Medicaid programs with some relatively limited and others very generous in terms of eligible populations, covered benefits and payments for services.

Medicaid is a means-tested program. Enrollees' income and other resources[2] must be within program financial standards. These standards vary among states, and among different population groups within a state. With some exceptions, Medicaid is available only to persons with very low incomes — most Medicaid enrollees have income that is below the poverty level.

With a few narrow exceptions, Medicaid is available only to children, adult members of families with children, pregnant women, and to persons who are aged, blind, or disabled. Persons not falling into those categories — such as single adults and childless couples — generally cannot qualify no matter how low their income is.[3] The various eligibility groups have traditionally been divided into two basic classes, the "categorically needy" and the "medically needy." The two terms once distinguished between welfare-related (categorically needy) beneficiaries and those qualifying only under special Medicaid rules which allow states to cover persons whose income is too high to qualify for cash welfare support but who nevertheless need help with medical bills (medically needy). However, non-welfare groups have

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[1] Preliminary FY2002 CMS Form 64 Financial Reports.

[2] "Resources" include bank accounts and similar liquid assets, as well as real estate, automobiles, and other personal property whose value exceeds specified limits and usually exclude an individual's primary residence.

[3] Several states use special waivers of Medicaid's eligibility rules to extend coverage to other groups of individuals not traditionally eligible.

been added to the "categorically needy" list over the years. As a result, the terms are no longer especially helpful in sorting out the various populations for whom mandatory or optional Medicaid coverage has been made available. However, the distinction remains important when considering certain benefits. Some benefits are considered mandatory for categorically needy individuals; that is, states must cover those benefits for the categorically needy but they are optional for medically needy individuals. Other benefits, including prescription drugs, are optional for both groups of beneficiaries. Some states provide those optional benefits only to categorically needy individuals, some states provide those benefits to both groups, and some provide those benefits to certain subcategories of medically needy as well as categorically needy.

Prescription Drug Benefits

Coverage of outpatient prescription drugs is optional for state Medicaid programs. States choose whether or not to include coverage of outpatient drugs in their Medicaid benefit package. In 2002, all states covered outpatient prescription drugs for at least some Medicaid beneficiaries; more than half of the states reported covering outpatient drugs for all Medicaid beneficiaries. The remaining states covered drugs for at least categorically needy individuals (**Table 1**) and sometimes for other specified groups in addition to the categorically needy. Prescription drug coverage is one of the few optional Medicaid services provided by all states. This is in part due to the belief that coverage of prescription drug benefits is a "good deal" — that the provision of this benefit can help to keep enrollees healthier and potentially prevent more serious and/or costly medical interventions.

Table 1. Medicaid Coverage of Outpatient Prescription Drugs, 2002

State	Categorically needy	Medically needy
Alabama	X	
Alaska	X	
Arizona	X	
Arkansas	X	X
California	X	X
Colorado	X	
Connecticut	X	X
Delaware	X	
District of Columbia	X	X
Florida	X	X
Georgia	X	X
Hawaii	X	X
Idaho	X	
Illinois	X	X
Indiana	X	
Iowa	X	X
Kansas	X	X
Kentucky	X	X
Louisiana	X	X

State	Categorically needy	Medically needy
Maine	X	X
Maryland	X	X
Massachusetts	X	X
Michigan	X	X
Minnesota	X	X
Mississippi	X	
Missouri	X	
Montana	X	For Aged, Children and Adults in Families
Nebraska	X	X
Nevada	X	
New Hampshire	X	X
New Jersey	X	For Aged, Blind and Disabled, and Children
New Mexico	X	
New York	X	X
North Carolina	X	X
North Dakota	X	X
Ohio	X	
Oklahoma	X	X
Oregon	X	For Aged, and Blind and Disabled
Pennsylvania	X	X
Rhode Island	X	X
South Carolina	X	
South Dakota	X	
Tennessee	X	
Texas	X	For Children and Adults in Families
Utah	X	X
Vermont	X	X
Virginia	X	X
Washington	X	X
West Virginia	X	X
Wisconsin	X	X
Wyoming	X	

Source: Table prepared by Congressional Research Services (CRS) based on analysis from Pharmaceutical Benefits Under State Medical Assistance Programs 2002, National Pharmaceutical Council at [http://www.npcnow.org/resources/issuearea/medicaidpharmaceutical.asp]

Note: Arizona and Tennessee provide pharmaceutical coverage to all beneficiaries through programs operated under Section 1115 demonstration waivers. These programs do not recognize the federal distinction between categorically and medically needy.

Fee-for-Service Coverage. For Medicaid beneficiaries who are not enrolled in Medicaid managed care plans, federal statute allows states to establish formularies. "Formularies" are lists of preferred pharmaceuticals. When health care insurers or providers cover only those drugs on the list and deny payment for others, the list is referred to as a "closed formulary." Medicaid formularies are seldom as restrictive as the closed formularies found in the private market for insurance because of two

statutory requirements. The first requirement is that states must cover any non-formulary drug (with the exception of drugs in 10 specific categories — see below) that is specifically requested and approved through a prior authorization process.[4] The second requires states to cover all drugs offered by manufacturers entering into rebate agreements with the Secretary of Health and Human Services (HHS).

While ensuring that Medicaid formularies are not too restrictive, federal statute does (Section 1927(d) of Medicaid law), on the other hand, clearly allow states to exclude the following categories of drug products from Medicaid coverage: drugs used (a) to treat anorexia, weight loss or weight gain; (b) to promote fertility; (c) for cosmetic purposes or hair growth; (d) for the relief of coughs and colds; (e) for smoking cessation; and (f) prescription vitamins and mineral products (except prenatal vitamins and fluoride preparations; (g) non-prescription drugs; (h) barbiturates; (i) benzodiazepines[5]; and (j) drugs requiring tests or monitoring that can only be provided by the drug manufacturer. In addition, formularies may exclude a drug for which there is no significant therapeutic advantage over other drugs that are included in the formularies as long as there is a written explanation of the reason for its exclusion and the explanation is available to the public.

Managed Care Coverage. For Medicaid beneficiaries who are enrolled in managed care plans, plans to which states pay a fixed monthly payment in exchange for the provision all or some subset of covered services, Medicaid statute includes a broad exception to the drug coverage rules described above.[6] The law allows the enrolling managed care organization to develop and administer its own formulary. In practice, however, when prescription drugs are covered under the managed care arrangement, states enforce limitations on the formularies of managed care entities similar to those imposed on states by the federal government. This policy was initiated in correspondence from the Secretary of Health and Human Services (HHS) to State Medicaid Directors[7]. This letter notified states that drugs covered under the state plan must also be made available in Medicaid managed care formularies for Medicaid managed care enrollees. States generally establish contract clauses in their agreements with Medicaid health maintenance organizations (HMOs) and other managed care organizations (MCOs) that allow such entities to establish formularies but also require them to meet all of the fee-for-service coverage rules.

Over-the-counter (OTC) medications. Many state Medicaid programs also cover OTC medications — or those medications that can be purchased without a prescription. A survey conducted by the National Pharmaceutical Council (NPC) questions states about Medicaid coverage of eight categories of non-prescription drugs: allergy, asthma, and sinus medications; analgesics; cough and cold medicines; smoking deterrents; digestive products; H2 antagonists (drugs used to treat ulcers and

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[4] Prior authorization is a process whereby a patient's provider requests approval for coverage from the Medicaid agency or its contractor of a specific drug before dispensing that drug.

[5] Barbiturates and benzodiazepines are drugs generally used as sedatives and tranquilizers.

[6] Section 1927(j) of the Social Security Act.

[7] Coverage of Protease Inhibitors — June 19, 1996.

other stomach conditions); feminine products; and topical products. Thirty-three states reported covering some drugs in at least five of the eight categories while 13 reported covering some drugs in all eight categories.[8]

In general, Medicaid pharmaceutical benefits are very broad, encompassing most prescription drugs and many non-prescription drugs. Medicaid beneficiaries receiving care in the fee-for-service sector are assured of broad pharmaceutical coverage due to statutory requirements that prohibit states with closed formularies from denying drugs requested and approved in the prior authorization process and those offered by manufacturers that have rebate agreements in effect. The benefits provided to Medicaid managed care enrollees tend to be similarly broad because of administrative policies.

State Medicaid programs will be undergoing major changes in their drug coverage policies over the next few years in response to the recent passage of H.R. 1, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The new law (P.L. 108-173), signed by President Bush on December 8, 2003. The law provides for a Medicare drug benefit for Medicaid beneficiaries who also qualify for Medicare. While specific information about the drugs that will be covered under Medicare is not available at this time, it is likely that Medicaid prescription drug coverage for dually eligible individuals will be considerably reduced since Medicaid programs are specifically prohibited from continuing to cover drug offered under the Medicare plans. State Medicaid programs will continue to be required to pay for drugs offered to the dually eligible population under Medicare, however, based on a formula specified in MMA 2003. The formula requires states to contribute an amount equal to 90% (declining to 75% over several years) of the per capita cost of states' drug spending under Medicaid in 2003 multiplied by the number of dual eligibles enrolling in the new Medicare benefit. In addition, Medicaid administrations will be required to conduct eligibility determinations for individuals qualifying for low-income assistance for the new program.

Prescription Drugs — Pricing Policies and Rebates

Medicaid Drug Payment Methods

Medicaid reimbursement for outpatient prescription drugs has two components: an amount to cover the cost of the ingredients (the acquisition cost) and an amount to cover the pharmacist's professional services in filling and dispensing the prescription (the dispensing fee). Medicaid regulations establish upper limits on federal payments for acquisition costs (42 CFR 447.331-447.332) that are designed to encourage the substitution of lower cost generic equivalents for more costly brand name drugs. Two separate ceilings on acquisition costs are used, one for certain

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[8] Pharmaceutical Benefits Under State Medical Assistance Programs 2002, National Pharmaceutical Council at [http://www.npcnow.org/resources/issuearea/medicaidpharmaceutical.asp]

multiple source drugs[9] and one for all other drugs. Multiple source drugs are those 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 under a proprietary name and without such a name. The limits do not apply to individual claims for prescription drugs. Rather, the limits are applied in the aggregate to each state's spending for a particular drug.

The federal upper payment limits for multiple source drugs are calculated by the Centers for Medicare and Medicaid Services (CMS) and are periodically published in the state Medicaid Manual. The upper limits are equal to 150% of the published price for the least costly therapeutic equivalent. The published prices that CMS uses as a basis for calculating upper payment limits are the lowest of the "average wholesale prices" for each group of drug equivalents. Average wholesale prices (AWPs) are published annually in compendia by the pharmaceutical industry.[10] Each state must assure the Secretary that its Medicaid spending for multiple-source drugs is in accordance with the upper limits plus reasonable dispensing fees. The effect of this requirement is that, when a lower cost "generic" equivalent exists for a brand-name drug, a pharmacy will be paid at a price tied to the generic price even if the brand-name drug is actually furnished. The pharmacy, therefore, has a financial incentive to substitute the lower cost generic equivalent for the brand-name drug.

The upper limit for multiple source drugs does not apply if a physician provides handwritten certification on the prescription that a specific brand is medically necessary for a particular recipient. The brand name would then be dispensed subject to the limits applicable to "other" drugs.

"Other" drugs include brand name drugs and multiple-source drugs for which a specific limit has not been established. The upper limit that applies to "other" drugs is the lower of the estimated acquisition cost (EAC) plus a reasonable dispensing fee or the provider's usual and customary charge to the general public. The EAC is the Medicaid agency's best estimate of the price generally paid by pharmacies and other providers to acquire the drug. States may use another payment method as long as, in the aggregate, a state's payments for "other" drugs is below the payment levels determined by applying the upper limit for other drugs.

While states must meet the overall requirement that federal spending falls below the "upper payment limits," there are no other rules on how states set their payment formulas for drugs. Most states use payment formulas that are based on the AWP less some percentage (**Table 2**) for most covered drugs. The formulas represent states' attempt to estimate the true acquisition costs that retailers pay to wholesalers to obtain the pharmaceuticals they sell. While AWPs are used by the states to estimate those acquisition costs, those prices are more like manufacturers' suggested wholesale prices rather than a true measure of the average costs to pharmacies of

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[9] A multiple-source drug is a covered outpatient drug for which there are two or more drug products which are therapeutically, pharmaceutically and bio-equivalent and are sold or marketed in the state (1927(k)(7)(A)(i)).

[10] American Druggist First DataBank Annual Directory of Pharmaceuticals (Blue Book), and *Medi-Span's Pricing Guide*, and Medical Economic's *Drug Topics Redbook.*

obtaining pharmaceuticals. In reality, many drug wholesalers compete with each other by offering pharmacies different discounts from AWP, and some pharmacies purchase their drugs directly from the manufacturers, skipping wholesalers entirely.[11]

Table 2. States' Payment Formulas

State	Amount for each prescription
Alabama	WAC+9.2%; AWP-10%
Alaska	AWP - 5%
Arizona	AWP - 15% + $2
Arkansas	AWP - 20% (generic); AWP-14% (brand)
California	AWP - 5%
Colorado	AWP - 35% (generic) or AWP - 13.5%
Connecticut	AWP - 40% (generic); AWP - 12%
Delaware	AWP - 14% (traditional); AWP - 16% (non-traditional)
District of Columbia	AWP - 10%
Florida	Lowest of AWP - 13.25%, WAC + 7%,FUL, or SMAC
Georgia	AWP - 10%
Hawaii	AWP - 10.5%
Idaho	AWP - 12%
Illinois	AWP - 25%, (generic); AWP - 12% (brand)
Indiana	AWP - 20% (generic); AWP - 13.5% (brand)
Iowa	AWP - 10%
Kansas	AWP - 27% (generic); AWP - 13% (single source)
Kentucky	AWP - 12%
Louisiana	AWP - 13.5%; AWP - 15% for chains
Maine	AWP - 13%
Maryland	AWP - 10% or WAC+10%, direct price+10% or distributor price when available.
Massachusetts	WAC + 6%
Michigan	AWP - 13.5% (1- 4 stores); or AWP - 15.1% (5+ stores)
Minnesota	AWP - 14%
Mississippi	AWP - 12%
Missouri	AWP - 10.43% or WAC + 10%
Montana	AWP - 15%
Nebraska	AWP - 11%
Nevada	AWP - 15%
New Hampshire	AWP - 12%

[11] E.K. Adams, D.H. Kreling, and K. Gondek, State Medicaid Pharmacy Payments and Their Relation to Estimated Costs, *Health Care Financing Review*, vol. 15, no. 3, spring 1994, p. 27.

State	Amount for each prescription
New Jersey	AWP - 10%
New Mexico	AWP - 12.5%
New York	AWP - 10%
North Carolina	AWP - 10%
North Dakota	AWP - 10%
Ohio	WAC + 9% or AWP - 12.8%
Oklahoma	AWP - 12%
Oregon	AWP - 11% (institut), or AWP - 15% (non-institut)
Pennsylvania	AWP - 10%
Rhode Island	WAC + 5%
South Carolina	AWP - 10%
South Dakota	AWP - 10.5%
Tennessee	AWP - 13%
Texas	lowest of AWP - 15% or WAC + 12%
Utah	AWP - 15%
Vermont	AWP - 11.9%
Virginia	AWP - 10.25%
Washington	AWP - 14% (single source and multiple source (1-4 manuf.)), AWP - 50% (multiple source, 5+), AWP - 19% (brand-mail order), AWP - 15% (generic-mail order)
West Virginia	AWP - 12%
Wisconsin	AWP - 11.25%
Wyoming	AWP - 11%

Source: [http://www.cms.hhs.gov/medicaid/drugs/prescriptions.asp]

Note: AWP: Average Wholesale Price
WAC: Wholesalers Acquisition Cost

Dispensing fees, the amounts paid to pharmacies to cover the cost of dispensing the prescription medication are only limited insofar as they must be "reasonable." Such fees generally range from under $3.00 per prescription to over $5.00 per prescription, although fees may be higher in states that do not use a flat fee. Until only recently, few states varied professional dispensing fees. Today dispensing fees in many states vary, most often with higher fees paid for generics than for single source drugs. In a few states they vary by urban/rural location or based on the pharmacy's historical operating cost and volume.

Medicaid Drug Rebates

An important feature of Medicaid's "best price" drug payment policy was created in the Omnibus Budget Reconciliation Act of 1990. That law requires drug manufacturers that wish to have their drugs available for Medicaid enrollees to enter into rebate agreements with the Secretary of HHS, on behalf of the states. Under the agreements, pharmaceutical manufacturers must provide state Medicaid programs with rebates on drugs paid for Medicaid beneficiaries. The formulas used to compute the rebates are intended to ensure that Medicaid pays the lowest price that the manufacturers offer for the drugs. In return for entering into agreements with the

Secretary, state Medicaid programs are required to cover all of the drugs marketed by those manufacturers (with possible exceptions for the 10 categories of drugs that states are allowed to exclude from coverage). In 1999 there were reported to have been more than 500 manufacturers with Medicaid rebate agreements with the federal government. Those agreements cover more than 55,000 drug products.[12]

Rebate requirements do not apply to drugs dispensed by Medicaid managed care organizations when the drugs are paid as part of the MCOs capitation rate, and to drugs provided in hospitals, and sometimes in physicians', or dentists' offices, or similar settings.[13] Rebate requirements, on the other hand, do apply to prescription drugs provided on a fee-for-service basis as well as to nonprescription items, such as aspirin, when they are prescribed for a Medicaid beneficiary and covered under the state's Medicaid plan.

The rebates are computed and remitted by pharmaceutical manufacturers each quarter based on utilization information supplied by the state programs. States collect the rebates from the manufacturers. The federal share of the rebates are subtracted from states' claims for their federal share of program costs.

In setting the amount of required rebates, the law distinguishes between two classes of drugs. The first includes single source drugs (generally, those still under patent) and "innovator" multiple source drugs (drugs originally marketed under a patent or original new drug application (NDA) but for which generic competition now exists). The second class includes all other, "non-innovator" multiple source drugs (generics). **Table 3** shows the requirements applicable to the two different classes of drugs. These are discussed in further detail below.

Single Source and "Innovator" Multiple Source Drugs. Manufacturers are required to pay state Medicaid programs a basic rebate for single source and innovator multiple source drugs. Basic rebate amounts are determined by comparing the average manufacturer price (AMP) for a drug (the average price paid by wholesalers) to the "best price," which is the lowest price offered by the manufacturer in the same period to any wholesaler, retailer, nonprofit, or public entity.[14] The basic rebate is the greater of 15.1% of the AMP or the difference between the AMP and the best price.

Additional rebates are required if the weighted average prices for all of a given manufacturer's single source and innovator multiple source drugs rise faster than inflation as measured by the consumer price index for all urban consumers. Prices

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[12] D.K. Baugh, P.L. Pine, and S. Blackwell, Trends in Medicaid Prescription Drug Utilization and Payments, 1990-97, *Health Care Financing Review*, vol. 20, no. 3, spring 1999. Reported as personal communication with S. Gaston (HCFA), Baltimore, MD, Mar. 11, 1999.

[13] The general rule here is that rebates apply to drugs when they are billed separately, and not when their costs are embedded in a claim for another service.

[14] For the purposes of determining Medicaid rebates, prices paid by a number of federal and state entities are excluded from the definition of the "best price." These are discussed in further detail below.

in effect on October 1, 1990 are used as a base and are compared with prices in the month before the start of the period for which the rebate is to be issued to determine if current prices have risen faster than inflation.

The AMP, used to calculate rebates, and the AWP, used by states to set prices for drugs and by the federal government to calculate upper payment limits, each measure pharmaceutical prices but at different stages of the journey from manufacturing plant to individual drug user. The AMP measures prices charged by manufacturers when selling to wholesalers. The AWP measures the prices charged by wholesalers when selling the products to retail pharmacies. The AMP was created in Medicaid statute for the purpose of calculating rebates. The statute further requires that those prices remain confidential. The AWPs are figures that are developed and used by manufacturers and retailers and are shared in the industry in several annual publications. While the numbers are not overtly linked by formula or derivation, economists would assume similar forces would impact the prices at each stage. In 1996, the Congressional Budget Office (CBO) estimated the AMP to be about 20% less than AWP for more than 200 drug products frequently purchased by Medicaid beneficiaries.[15]

Since 1990 there have been a few changes to the Medicaid drug rebate policy. Before 1992 "best price" was defined to exclude drugs sold to federal agencies at depot prices[16] and single award contract prices. Under the Veterans Health Care Act of 1992 (P.L. 102-585) prices charged by manufacturers to certain federal agencies were also excluded from the determination of "best price." These agencies include the Department of Veteran's Affairs (DVA), the Department of Defense (DOD), the Public Health Service (PHS) and various PHS-funded health programs, and state (non-Medicaid) pharmaceutical assistance programs. The exclusion of those prices from the "best price" potentially reduces Medicaid savings from the rebate program. To offset this, minimum rebates were increased to the percentages shown in **Table 3**. The Act also provides, as a condition of Medicaid reimbursement for a manufacturer's drugs, that the manufacturer enter into a separate agreement with the Secretary to provide discounts and rebates to certain PHS-funded entities with public disproportionate share hospitals, as well as a new discount agreement with DVA.[17]

"Non-Innovator" Multiple Source Drugs. For non-innovator multiple source drugs, basic rebates are equal to 11% of the AMP. Prices offered to other payers are not considered, nor is there any additional rebate for excess price increases.

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[15] How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry, Jan. 1996, p. 20.

[16] Depot prices are the prices paid for drugs procured through federal distribution systems and warehoused at federal facilities (depots).

[17] Even before the Veterans Health Care Act of 1992, the DVA had been negotiating discounted prices with manufacturers for drugs provided at DVA and other military facilities.

Table 3. Medicaid Rebate Formulas

	Single source and "innovator" multiple source drugs	"Non-innovator" multiple source drugs
Basic rebate	The greater of: 15.1% of the AMP or AMP minus best price	11% of the AMP
Additional rebate	Required if the drug product price rises faster than inflation as measured by the CPI-U	N/A

Source: Section 1927(c) of the Social Security Act.

In 2002, the total amount of federally required drug rebates was reported by states to be $5.6 billion. (States also collected about $.3 billion in supplemental rebates not required by the federal government.) On average, those rebates summed to 19% of Medicaid spending on outpatient prescription drugs. Rebates for 2002 by state are reflected in **Table 4**.

Table 4. Medicaid Total Drug Spending and Federal Rebates by State, 2002

(in millions of dollars)

State	Total drug spending	Federal rebate	Supplemental rebate	Spending net of rebates	Rebates as percentage of drug spending
Alaska	70.7	14.3	—	56.4	20.3%
Alabama	452.3	85.0	—	367.3	18.8%
Arkansas	273.3	56.7	—	216.6	20.7%
Arizona	3.7	— [a]	—	3.7	0.0%
California	3,591.5	695.1	251.6	2,644.9	26.4%
Colorado	189.7	39.1	—	150.7	20.6%
Connecticut	357.9	62.6	—	295.3	17.5%
District of Columbia	66.1	11.4	—	54.7	17.3%
Delaware	97.8	17.0	—	80.8	17.4%
Florida	1,717.7	301.5	52.2	1,364.0	20.6%
Georgia	873.7	205.5	—	668.2	23.5%
Hawaii	88.3	15.3	—	73.0	17.3%
Iowa	285.5	50.1	—	235.4	17.5%
Idaho	119.2	22.9	—	96.2	19.2%
Illinois	1,293.4	190.3	—	1,103.1	14.7%
Indiana	631.6	126.5	—	505.1	20.0%
Kansas	213.8	29.8	—	184.0	13.9%
Kentucky	652.9	133.3	—	519.6	20.4%
Louisiana	714.1	113.7	—	600.4	15.9%
Massachusetts	959.0	191.1	—	767.9	19.9%
Maryland	297.3	53.8	0.4	243.0	18.3%

Maine	220.4	47.4	—	173.0	21.5%
Michigan	674.2	172.5	—[b]	501.7	25.6%
Minnesota	310.2	62.7	—	247.5	20.2%
Missouri	790.9	147.3	—	643.6	18.6%
Mississippi	567.3	115.2	—	452.1	20.3%
Montana	83.6	16.0	—	67.6	19.1%
North Carolina	1,100.8	207.1	—	893.8	18.8%
North Dakota	52.5	11.7	—	40.8	22.2%
Nebraska	207.8	47.9	—	159.9	23.0%
New Hampshire	99.7	20.9	—	78.8	21.0%
New Jersey	694.7	127.4	—	567.3	18.3%
New Mexico	73.9	13.3	—	60.6	18.0%
Nevada	86.9	13.5	—	73.4	15.6%
New York	3,660.4	664.0	—	2,996.5	18.1%
Ohio	1,334.0	263.3	—	1,070.7	19.7%
Oklahoma	285.1	51.5	—	233.6	18.1%
Oregon	279.0	54.5	—	224.6	19.5%
Pennsylvania	718.2	154.3	—	563.9	21.5%
Rhode Island	125.2	26.2	—	99.0	20.9%
South Carolina	451.8	98.3	—	353.6	21.7%
South Dakota	62.4	12.1	—	50.3	19.3%
Tennessee[a]	905.4	180.6	—	724.8	19.9%
Texas	1,591.1	305.1	—	1,286.0	19.2%
Utah	140.3	36.8	—	103.5	26.2%
Virginia	459.0	76.8	—	382.2	16.7%
Vermont	114.2	24.5	—	89.7	21.5%
Washington	542.0	100.9	—	441.1	18.6%
Wisconsin	442.7	89.2	—	353.5	20.2%
West Virginia	277.0	49.0	—	228.1	17.7%
Wyoming	39.1	8.7	—	30.4	22.2%
National Totals	29,345.4	5,613.3	304.2	23,427.8	20.2%

Source: Table prepared by Congressional Research Service (CRS) based on tabulations of CMS form 64 data.

a. A number of states, including Arizona and Tennessee have statewide managed care waivers. In Arizona, all Medicaid services are provided through capitated arrangements. Since drugs are included in the capitation payment to MCOs, rebates do not apply. Tennessee provides most services through capitated arrangements, but "carves out" certain pharmaceutical products. Drugs that are not included in capitation rates are paid on a fee-for-service basis, and rebates apply.

b. Amount less than $50,000.

Drug Pricing and Rebate Issues

Average Wholesale Prices. Over the last several years, a number of concerns have been raised about the AWPs and the states' and HHS' reliance on those prices for setting pharmaceutical payment levels and federal upper payment levels. In addition to concerns that the AWPs do not reflect wholesale prices, claims have been raised that manufacturers purposely manipulate the published AWPs to offer discounts to certain purchasers without offering those prices to Medicaid. Upon prompting by individual Members of Congress, the Inspector General (IG) of Health

and Human Services (HHS) explored those concerns.[18] Her inspection could not determine how often such practices occur, but indicated that some gaming of Medicaid's best price rules does occur. In at least one case she found that a pharmaceutical manufacturer sold products to a Health Maintenance Organization (HMO) without the manufacturer's label. The HMO then re-labeled the drug. By claiming that the drug had been sold to a "repackager," instead of a wholesaler, the manufacturer was able to offer a discount to the HMO that was not available to Medicaid. In addition, a report issued by the IG in May 1998 explored the idea that Medicaid drug prices are not adequately related to Medicaid drug rebates because prices are set using the AWP and rebates are calculated using a different measure of price.[19] Since Medicaid drug rebates are not based on the AWP, manufacturers may have an incentive to raise AWPs, to obtain higher payments for Medicaid drugs without triggering higher rebates for those same drugs.

In response to criticism about the AWP, H.R. 1, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, establishes a new price setting construct for certain prescription drugs currently covered and paid under the Medicare program. Medicare drugs covered under Medicare Part B and furnished after January 1, 2005 will be paid based on the average sales price. A manufacturer's average sales price will be calculated for each calendar quarter by dividing a manufacturer's total sales of each drug by the total number of units sold in that quarter. Certain sales will be exempted from the calculation, including sale of drugs exempted from Medicaid best price determination and sales that are nominal in amount.

Circumventing the Best Price or Rebate Policies. In addition, some critics have suggested that manufacturers sometimes sell drugs in ways that circumvent the rebate requirement. For example, in November 1999, Representative Henry Waxman wrote a letter to the Inspector General (IG) of HHS claiming that manufacturers are increasingly skirting the best price requirement by selling finished drugs to certain favored HMOs at large discounts and claiming that they have been sold to "repackagers" or "redistributors." Since drugs that are sold by repackagers or redistributors are not subject to Medicaid's rebate requirements, rebates are avoided. In 1999, the Inspector General estimated the lost rebate for one repackaged drug at over $25 million in one year and is considering conducting a study to further examine these practices.[20] Medicaid programs may also not be receiving rebates for drugs that are provided to physicians for direct physician-to-patient dispensing although it is not clear how often this occurs or if it results in a large amount of lost rebate.

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[18] U.S. Congress, House Committee on Government Reform, Correspondence to Representative Henry A. Waxman, Ranking Minority member, from June Gibbs Brown, Inspector General, Dept. of Health and Human Services, Nov. 22, 1999.

[19] U.S. Dept. of Health and Human Services, Office of the Inspector General, *Need to Establish Connection Between the Calculation of the Medicaid Drug Rebates and Reimbursement for Medicaid Drugs,* A-06-97-00052, May 1998.

[20] Correspondence from the Office of the Inspector General, Nov. 1999.

Supplemental Rebates. In addition to the rebates required under federal law, a few states charge certain pharmaceutical manufacturers additional rebates. In 2002, four states claimed a total of $304 million in supplemental rebates (federal share of $159 and state share of $145).[21] Those rebates were reported in four states; Michigan, Maryland, Florida, and California. California collected 82% of the total.

Two states have approved new supplemental rebate programs that will be combined with prior authorization requirements. Under the two programs, neither of which has been implemented yet, drug manufacturers that agree to pay new supplemental rebates would be exempted from certain prior authorization procedures. A program of this type, MaineRx, was the subject of legal challenges brought by the Pharmaceutical Research and Manufacturers of America (PhRMA) whose attorneys argued that the Medicaid Act pre-empts MaineRx insofar as it threatens to coerce manufacturers into reducing their prices on non-Medicaid sales and interferes with Medicaid benefits without serving any Medicaid purpose. The case went to the U.S. Supreme Court, which ruled in favor of the state, thereby clearing the way for MaineRx to be implemented.[22]

Controlling Drug Cost and Use

Prior Authorization. States use a number of techniques to control cost and/or use of pharmaceuticals. One of those techniques is prior authorization. Prior authorization is the requirement that only pharmaceutical products for which advance approval is sought and received from a designated individual or entity are to be covered. States may establish prior authorization programs under Medicaid for all drugs or for certain classes of drugs, as long as these programs meet two criteria: (1) they must respond within 24 hours to a request for approval, and (2) they must dispense at least a 72-hour supply of a covered drug in emergency situations. In 2002, all (including the District of Columbia) but four states report having a prior authorization procedure for at least some covered drugs, but little information is available describing the number or types of drugs those states require to undergo such review.[23]

Some pharmaceutical industry representatives and consumer advocates have voiced opposition to states' use of prior authorization programs. They claim such programs are burdensome, are not cost effective, and are becoming increasingly restrictive. In addition, there are concerns that states are adding more and more drugs to lists of those that require prior authorization and that such requirements are particularly problematic for individuals who need newly developed drugs, possibly because reviewers are less familiar with those drugs. Prior authorization is reportedly particularly problematic for persons needing psychotherapeutics, a population for whom compliance with drug therapies is often challenging to achieve even without additional administrative barriers.

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[21] Supplemental rebates are shared by states and the federal government in the same way that federally-required rebates are shared.

[22] Pharmaceutical Research and Manufacturers of America v. Walsh., U.S. Supreme Court No. 01-188 (May 19, 2003).

[23] National Pharmaceutical Council, 2003.

Prescribing/Dispensing Limitations. States may also restrict the quantity of prescription drugs available to beneficiaries. Such prescribing and dispensing limits are ubiquitous. All but four states surveyed for the National Pharmaceutical Council (NPC) indicated the use of prescribing or dispensing limits (**Table 5**). The most common type of constraint is on the quantity of drug that may be made available for each prescription. Almost all of the states routinely limit the amount of certain drugs dispensed to a 30 to 34-day supply.

Table 5. Medicaid Drug Prescription or Dispensing Limits, 2002

State	Limits on number, quantity, and refills of prescriptions
Alabama	30-day supply per Rx, five refills per Rx
Alaska	30-day supply per Rx
Arizona	0
Arkansas	31-day supply per Rx, three Rx per month (extension to six); five refills per Rx within six months
California	Six Rx per month, maximum 100 day supply for most meds.
Colorado	30-day supply per Rx, 100 day supply for maintenance medication, other limits for stadol & oxycontin
Connecticut	240 units or 30 day supply, five refills except for oral contraceptives
Delaware	34-day supply or 100 unit doses per Rx (whichever is greater)
District of Columbia	30-day supply per Rx, three refills per Rx within four months, other limits specific to certain medications
Florida	Four brand name Rxs per month (with exceptions)
Georgia	31-day supply per Rx, five Rx per month (adult), six Rx per month (child); $2999.99/Rx limit
Hawaii	30-day supply or 100 unit doses per Rx
Idaho	34-day supply (with exceptions)
Illinois	One month supply, 11 refills per Rx
Indiana	Medically appropriate monthly quantity
Iowa	34 day supply except select maintenance drugs (90 days)
Kansas	31 day supply per RX, five Rx per month, other limitations specific to certain medications
Kentucky	30 day supply, Maximum five refills in six months; one dispensing fee per month for maintenance meds.
Louisiana	Greater of 30-day supply per Rx or 100 unit doses; five refills per Rx within six months, max eight Rx per recipient per month
Maine	34-day supply per Rx; 90 day supply (generic), maximum 11 refills per Rx
Maryland	34-day supply per Rx; two refills per Rx
Massachusetts	five refills per Rx.
Michigan	100 day supply, No refills for Schedule II drugs, five refills per 180 days for Schedule III & V drugs
Minnesota	Max three month supply
Mississippi	Greater of 34-day supply or 100 unit doses per Rx; five Rx per month; five refills maximum
Missouri	34-day supply or 100 unit doses per Rx; up to 90 day Rx maximum
Montana	Greater of 34-day supply or 100 unit doses per Rx
Nebraska	Greater of 90-day supply or 100 dosage units per Rx, five refills per Rx, six mo. Fo controlled substances, 31 days for injectibles

State	Limits on number, quantity, and refills of prescriptions
Nevada	34-day supply per Rx; 100 day supply for maintenance medications
New Hampshire	30-day supply 90 day supply on maintenance medications
New Jersey	34-day supply or 100 unit dosage per Rx; five refills within six months
New Mexico	34 day supply; except contraceptives (100 days)
New York	Five refills per Rx; annual limits on number of Rx and OTC drugs avail (with exceptions)
North Carolina	34-day supply per Rx, with exceptions; six Rx per month
North Dakota	34-day supply per Rx, max 12 refills per script; one refill on PPIs
Ohio	34-day supply (acute) and 102 unit doses (chronic)
Oklahoma	34-day supply or 100 unit doses per Rx; three Rx per month (21+)
Oregon	15-day supply for initial Rx for chronic conditions
Pennsylvania	Greater of 34-day supply or 100 unit; five refills within six months; six Rx per month
Rhode Island	30-day supply per Rx (non-maintenance); five refills per Rx
South Carolina	34-day supply w/ unlimited Rx (children); four Rx per month (adult).
South Dakota	None
Tennessee	0
Texas	Three Rx per month; unlimited Rxs for nursing home residents and children; max five refills
Utah	31-day supply per Rx; max five refills per Rx, other limits on specific drugs
Vermont	60 day supply for maintenance medications, five refills per Rx
Virginia	34-day supply per Rx
Washington	34-day supply per Rx; usually two refills per month; four refills for antibiotics or scheduled drugs
West Virginia	34-day supply; five refills per Rx with quantity limits on some drugs
Wisconsin	34-day supply per Rx with exceptions, maximum 11 refills during 12 month period
Wyoming	Quantity limits on some medications as deemed clinically appropriate

Source: Table prepared by Congressional Research Service (CRS) based on analysis from Pharmaceutical Benefits Under State Medical Assistance Programs 2002.

Note: Rx: Prescription
Schedule II: Drugs with high potential for abuse and/or severe dependence
Schedule III: Drugs with some potential for abuse and/or moderate or low dependence
Schedule IV: Drugs with low potential for abuse and/or limited dependence relative to II
Schedule V: Drugs with low potential for abuse and/or limited dependence relative to Schedule IV

Currently, individual managed care and PBM organizations make decisions, but this policy may be changing. First, the state is reportedly phasing in a single, uniform preferred drug list, and second, a U.S. District Court recently cleared the way for the TennCare program to fill only a three day supply of certain new medications. The pharmacy would be required to seek the doctor' permission to switch to a drug on the TennCare formulary, after which a 14 day supply would become available. (**Source**: B. de la Cruz, www.Tennessean.Com, Sept. 26, 2003.)

Drug Use Review. All states use policies to control the use of outpatient prescription drugs and all have programs in place to assess the quality of their pharmaceutical programs. The Omnibus Budget Reconciliation Act of 1990 included a requirement that all states implement drug use review (DUR) programs, and provided for enhanced federal matching payment to cover the costs of conducting those DUR activities. DUR programs are aimed at both improving the quality of pharmaceutical care and assisting in containing costs. The major features of DUR programs are: enhanced communication between pharmacists and beneficiaries upon dispensing prescriptions; ongoing retrospective review of prescribing practices; educational outreach for pharmacists, physicians, and beneficiaries; and pharmacy counseling. Nationally, states reported spending a total (federal and state share) of about $5.8 million on Medicaid drug use review practices in 2002, although some states reported zero for spending in that category.[24]

Cost Sharing Requirements for Medicaid Prescription Drugs. In addition to prior authorization and utilization review, many Medicaid programs impose cost sharing requirements on enrollees to control drug use and spending. The Medicaid statute prohibits states from requiring copayments on services provided to children under age 18, pregnant women, institutionalized individuals, and certain enrollees in HMOs. In addition, copayments cannot be charged for emergency[25] and family planning services. Within those guidelines, states may, and most do, impose "nominal" cost sharing amounts on other users of drug benefits. States that require copayments for covered outpatient drugs generally charge between $.50 and $3.00 per prescription — most falling at about $1.00 per prescription (**Table 6**).

Table 6. Cost Sharing Requirements for Medicaid Pharmaceuticals, 2002

State	Amount for each prescription
Alabama	$.50 to $3.00
Alaska	$2.00
Arizona[a]	—
Arkansas	$.50 to $5.00
California	$1.00
Colorado	G: $.75, B.$3.00
Connecticut	None
Delaware	None
District of Columbia	$1.00
Florida	None
Georgia	G/P: $.50, B/NP: $.50 to $3.00
Hawaii	None
Idaho	None

[24] Preliminary FY2002 CMS Form 64.

[25] States may obtain a waiver of this rule to impose up to twice the nominal amount established for outpatient services for services received at a hospital emergency room, if the services are not emergency services, as long as they have established to the satisfaction of the Secretary that beneficiaries have alternative sources of non-emergency, outpatient services that are available and accessible.

State	Amount for each prescription
Illinois	$1.00
Indiana	$.50 to $3.00
Iowa	$1.00
Kansas	$3.00
Kentucky	$1.00
Louisiana	$.50 to $3.00
Maine	$.50 to $3.00
Maryland	$1.00
Massachusetts	$2.00
Michigan	$1.00
Minnesota	None
Mississippi	$1.00 to $3.00
Missouri	$.50 to $2.00, $5.00 for some waiver populations
Montana	$1.00 to $5.00
Nebraska	$2.00
Nevada	None
New Hampshire	G: $.50, B.$1.00
New Jersey	None
New Mexico	None (except for SCHIP and certain working disabled)
New York	G: $.50, B: $2.00
North Carolina	$1.00 to $3.00
North Dakota	B: $3.00
Ohio	None
Oklahoma	$1.00 to $2.00
Oregon	None
Pennsylvania	$1.00 to $2.00
Rhode Island	None
South Carolina	$3.00
South Dakota	$2.00
Tennessee[a]	—
Texas	None
Utah	$3.00 to $5.00 per month
Vermont	$1.00 to $2.00
Virginia	G: $1.00, B: $2.00
Washington	None
West Virginia	$.50 - $2.00
Wisconsin	$1.00, max $5 per recip per month
Wyoming	$2.00

Source: Pharmaceutical Benefits Under State Medical Assistance Programs 2002.

Note: G: Generic
P: Preferred
B: Brand name
NP: Not preferred

a. Within federal and state guidelines, individual managed care and pharmacy benefit management organizations make formulary/drug decisions.

Other Cost Containment Strategies. Some states are attempting to manage drug costs through the use of pharmaceutical benefits managers (PBMs). Many private insurers, including those that provide coverage to federal employees under the Federal Employees Health Benefits Program (FEHBP), contract with PBMs for drug benefits management and claims payment. PBMs enable insurers to obtain discounts for pharmaceuticals that would not otherwise be available to single insurers because the PBMs administer multiple insurers' covered populations. In addition, PBMs provide a variety of administrative services intended to improve quality and control costs, such as retail pharmacy network development, mail order pharmacy operation, formulary development, manufacturer rebate negotiation and prescription checks for adverse drug interactions.[26] While PBMs have begun to administer a significant portion of the market for private prescription drug benefits, they are not broadly used by states in administering Medicaid drug benefits.

Bulk Purchasing Programs. A number of states have considered establishing bulk purchasing programs for outpatient prescription drugs. Bulk purchasing can be used to obtain those drugs required by state Medicaid agencies combined with those needed by other in-state agencies such as state employees' plans and local governments or could combine the prescription drug needs of two or more states together. While many states are considering such programs, few have actually been implemented and evidence of savings based on these purchasing arrangements among the few implemented purchasing arrangements are scarce. This is because most programs are implemented along with other changes to the formularies and/or the management of pharmaceutical benefits, making isolating the impact of the bulk negotiating power very difficult.

Two Medicaid purchasing pools are in place today. Administrators of one of those, established by Michigan and Vermont, claims to have reduced the rate of growth of drug spending in states by 11%.[27] Other states reportedly plan to join that pool. Georgia established a purchasing program for its state prescribing needs that combines Medicaid outpatient drugs with those needed for public employees and university employees. The program which combines bulk purchasing with plan design changes and a preferred drug list, is claimed to have reduced "pharmacy cost trends" by 18 to 25%.[28] While relatively little bulk purchasing is under way today, it is likely that this approach will continue to gather attention in the coming years as states seek ways to control Medicaid costs.

Importing Lower Priced Drugs from Canada. Several state and local governments are currently considering plans to reimport prescription drugs from Canada in order to save money on medicines that they reimburse for or provide to residents and/or employees. For example, states such as California, Iowa, Illinois,

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[26] GAO/HEHS-97-47; Pharmacy Benefit Managers; FEHBP Plans Satisfied With Savings and Services, but Retail Pharmacies Have Concerns, Feb. 1997.

[27] "Multi-State Medicaid Pooling Program Generates Significant Cost Savings for Michigan and Vermont," *The First Bulletin* published by First Health Services Corporation, Oct. 30, 2003.

[28] "Aggregate Purchasing of Prescription Drugs: The Massachusetts Analysis," Heinz Family Philanthropies, Sept. 11, 2001.

Minnesota, and New Hampshire have begun exploring the prospect of drug importation, and at least two localities, Springfield, Massachusetts and the city of Montgomery Alabama, have already begun to import drugs for employees and retirees.[29] These states or other units of government argue that they have a duty to explore innovative methods for providing more affordable prescription drugs to their residents, even at the risk of violating federal law. Each state and local importation plan varies in their details — at least one includes pharmaceuticals for Medicaid recipients, but most do not. At this time there are no reimportation programs in operation for Medicaid beneficiaries, although this may change. A provision in MMA 2003 requires the Secretary of HHS to promulgate regulations allowing pharmacists and wholesalers to reimport pharmaceutical products once the Secretary certifies to Congress that such reimported drugs provide no risk to the public's health and safety and will result in a significant reduction in cost to the American consumer (MMA 2003, Section 1121).

Medicaid Spending for Outpatient Prescription Drugs

Total Medicaid payments for outpatient prescription drugs represent a growing portion of Medicaid spending. In 1990, states reported total payments for outpatient prescription drugs of about $4.6 billion, or just over 6% of total program spending. In 2002, total payments for Medicaid outpatient prescription drugs, net of rebates, were $23.4 billion, accounting for about 9.5% of payments for all Medicaid services.[30] The average annual growth in drug spending under Medicaid over the eight year period was a substantial 15% per year.

Despite the large and growing share of Medicaid spending on drugs, those numbers represent only a portion of true Medicaid drug spending. States do not include the cost of outpatient prescription drugs provided through capitated arrangements in their reports. In 1990, this probably did not present a major gap in the available information about Medicaid drug spending since only about 10% of Medicaid enrollees received coverage through capitated managed care arrangements. Today, however, well over one-half of Medicaid's enrollees receive some or all of their benefits through Medicaid managed care organizations or prepaid health plans. In addition, other prescription drug payments for products purchased directly from physicians or included in claims for other services, such as institutional and home health care, are not reported as outpatient drug spending.

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[29] Gloria Gonzalez, "Cities Vow to Maintain Canadian Rx Reimports," *Business Insurance*, Feb. 2, 2004, vol. 38, issue 5.

[30] Preliminary 2002 CMS 64.

Table 7. Total Medicaid Spending and Medicaid Prescription Drug Spending and Percentage Change in Spending for Selected Years

(in billions of dollars)

Year	Total Medicaid benefits spending[a]	Average annual percentage change	Medicaid prescription drug spending[b]	Average annual percentage change
1990	$ 72.5	—	$ 4.6	—
1995	$ 151.8	15.9%	$ 8.4	12.7%
2000	$195.5	5.2%	$16.6	14.7%
2002	$246.3	12.2%	$23.4	18.8%

Source: Table prepared by Congressional Research Service (CRS) based on tabulations from HCFA Form 64/ CMS Form 64 data.

a. Does not include administrative costs.
b. Does not include prescription drugs paid through capitated arrangements, obtained directly from physicians or bundled in claims for other services, and rebates have been subtracted from totals.

Medicaid Drug Spending by State. **Table 8** shows 2002 Medicaid spending for prescription drugs by state in order, beginning with the state with the largest percentage of program spending for prescription drugs. (Amounts in **Table 8** are total reported payments for outpatient prescription drugs minus rebates.) Medicaid drug spending as a percentage of total Medicaid medical assistance spending varies widely. About 15.7% of Medicaid spending in Mississippi is attributed to outpatient prescription drugs. New Mexico spends the smallest percentage of program spending on outpatient drugs — about 3.4%. While wide variation in drug spending exists across states, in the past Medicaid was claimed to be the single largest payer for outpatient prescription drugs within each state.[31]

New York reported spending the largest amount on Medicaid outpatient prescription drugs — almost $ 3 billion dollars in 2002. Wyoming, the state with the smallest Medicaid enrollment, reported the lowest amount of outpatient prescription drug spending — $30.4 million, in 2002.

[31] Institute for Health Services Research, Apr. 1995.

Table 8. Total Medicaid Spending and Outpatient Drug Spending, 2002

(payments in millions of dollars)

State	Drug spending as percentage of all medical assistance	Outpatient drug spending	Medical assistance spending
Mississippi	15.7%	452.1	2,877.0
West Virginia	14.4%	228.1	1,584.2
Florida	13.8%	1,364.0	9,871.5
Kentucky	13.8%	519.6	3,763.2
Vermont	13.6%	89.7	660.7
North Carolina	13.3%	893.8	6,723.6
Delaware	12.7%	80.8	634.0
Tennessee	12.5%	724.8	5,787.1
Illinois	12.5%	1,103.1	8,809.1
Idaho	12.4%	96.2	773.5
Louisiana	12.3%	600.4	4,886.0
Maine	12.1%	173.0	1,430.1
Missouri	12.0%	643.6	5,360.6
Nebraska	11.9%	159.9	1,339.1
Alabama	11.9%	367.3	3,093.3
Montana	11.8%	67.6	571.5
Indiana	11.4%	505.1	4,448.3
Ohio	11.1%	1,070.7	9,658.0
Wyoming	11.1%	30.4	274.6
South Carolina	10.7%	353.6	3,292.9
Georgia	10.7%	668.2	6,241.2
Utah	10.5%	103.5	984.2
Oklahoma	10.3%	233.6	2,260.4
Virginia	10.0%	382.2	3,812.2
Kansas	10.0%	184.0	1,836.7
Hawaii	9.9%	73.0	740.0
California	9.8%	2,644.9	26,890.5
Arkansas	9.7%	216.6	2,237.8
Massachusetts	9.5%	767.9	8,063.0
Texas	9.5%	1,286.0	13,523.5
South Dakota	9.2%	50.3	549.9
Iowa	9.1%	235.4	2,575.1
Nevada	9.1%	73.4	808.2
North Dakota	8.9%	40.8	461.4
Oregon	8.7%	224.6	2,571.6
Connecticut	8.5%	295.3	3,456.3
Washington	8.5%	441.1	5,168.5
Wisconsin	8.4%	353.5	4,193.2
New York	8.3%	2,996.5	36,295.1
Alaska	8.2%	56.4	685.8
New Hampshire	7.8%	78.8	1,016.1
New Jersey	7.3%	567.3	7,745.9
Rhode Island	7.3%	99.0	1,358.5
Maryland	6.7%	243.0	3,613.5

State	Drug spending as percentage of all medical assistance	Outpatient drug spending	Medical assistance spending
Michigan	6.6%	501.7	7,562.1
Colorado	6.5%	150.7	2,323.1
Minnesota	5.6%	247.5	4,414.5
District of Columbia	5.4%	54.7	1,021.8
Pennsylvania	4.6%	563.9	12,130.9
New Mexico	3.4%	60.6	1,776.8
Arizona	n/a	n/a	3,541.6
Total	**9.5%**	**23,427.9**	**246,283.9**

Source: Table prepared by Congressional Research Service (CRS) based on tabulations preliminary CMS Form 64 data.

Note: Does not include outpatient drug spending for Medicaid beneficiaries enrolled in some managed care organizations, payments for products purchased directly from physicians, or payments included in claims for other services such as institutional care.

Spending by Eligibility Group. In 2000, the most recent year for which state Medicaid statistical reports link expenditures to enrollees, states reported a total of just over $20 billion spending for outpatient prescription drugs. Of those funds, almost 58% ($11.6 billion)of that amount went to individuals qualifying for Medicaid on the basis of being blind or having a disability, almost 27% ($5.4 billion) for elderly individuals, almost 8% ($1.6 billion) on non-disabled children and an additional 7% ($1.4 billion) on adults in families with dependent children.[32, 33]

Table 9 shows average Medicaid prescription drug spending among Medicaid prescription drug users by eligibility group. The data do not reflect spending for those who receive prescription drugs through managed care only, but they do provide a general idea of the relative spending among different groups of beneficiaries.[34] Among all Medicaid prescription drug users in FY2000, the average Medicaid

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[32] Expenditures in this paragraph are those reported by states through the Medicaid Statistical Information System (MSIS) for FY2000. Those data do not match expenditures reported above in Tables 4 and 8 (based on CMS-64 reports) for two reasons; because Tables 4 and 8 are for fiscal year 2002; and because data reported on form CMS 64 have always varied slightly from the MSIS reported totals. Because the CMS 64 reports are filed for financial accounting purposes, they are generally considered to be a more accurate accounting of total outlays, and are preferred when examining state and/or federal totals. Those data, however do not allow for analysis of spending and use of services for individual and groups of individuals. For those kind of analysis, data from the MSIS system are used.

[33] For additional state-by-state data on Medicaid prescription drug spending for dual eligibles, see CRS Report RL31987, *Dual Eligibles: Medicaid Expenditures for Prescription Drugs and Other Services*, by Karen Tritz and Megan Lindley.

[34] If per-person drug spending under managed care (which is not shown separately in MSIS data) differs significantly from per-person drug spending under FFS (which is shown separately in MSIS data), the estimates provided here could be somewhat distorted. Since Medicaid HMOs enroll many more children and adults than aged or disabled individuals, the exclusion of managed care drug payments might have a greater relative impact on estimates of average spending among children and adults.

prescription drug spending amount was $992. Children had the lowest average spending, while blind and disabled enrollees had the highest. Among blind and disabled enrollees with prescription drug spending, the average amount was $2,316. Among children with prescription drug spending, the average amount was $188.

Table 9. Average Medicaid Prescription Drug Spending Among Medicaid Prescription Drug Users by Basis of Eligibility, FY2000

	Number of Medicaid enrollees	Percentage of Medicaid enrollees with prescription drug spending	Average Medicaid drug spending per Medicaid prescription drug user
Aged	4,294,972	67.3%	$1,853
Blind/Disabled	7,474,028	67.0%	$2,316
Child	21,762,670	37.9%	$188
Adult	10,669,462	37.0%	$366
Total	**44,201,132**	**45.5%**	**$992**

Source: Table prepared by Congressional Research Service (CRS) based on tabulations of CMS MSIS data.

Note: HI data are FY1999, all other states are FY2000. Enrollee counts exclude MSIS records with missing/unknown eligibility status. Medicaid prescription drug users are defined as enrollees with non-zero Medicaid prescription drug spending. Does not include drug rebates or payments for drugs purchased directly from physicians or included in claims for other services such as institutional care. Since it is generally included in the capitation payment for managed care (not broken out separately), figures on prescription drug users and spending do not include those who receive prescription drugs through managed care only (see Appendix Table A-1 for a state-by-state comparison of the percentage of enrollees with drug spending and the percentage of enrollees with managed care).

Table 10. Distribution of Medicaid Prescription Drug Spending Among Medicaid Prescription Drug Users by Basis of Eligibility, FY2000

	Medicaid enrollees with drug spending	Percentiles				
		10th	25th	50th	75th	90th
Aged	2,888,919	$156	$512	$1,309	$2,582	$4,197
Blind/ Disabled	5,005,036	$64	$278	$1,103	$2,909	$5,651
Child	8,258,635	$9	$22	$66	$169	$381
Adult	3,949,947	$12	$34	$100	$275	$775
Total	**20,102,537**	**$14**	**$45**	**$173**	**$927**	**$2,862**

Source: Table prepared by Congressional Research Service (CRS) based on tabulations of CMS MSIS data.

Note: HI data are FY1999, all other states are FY2000. Enrollee counts exclude MSIS records with missing/unknown eligibility status. Does not include drug rebates or payments for drugs purchased directly from physicians or included in claims for other services such as institutional care. Since it is generally included in the capitation payment for managed care (not broken out separately), figures on prescription drug users and spending do not include those who receive prescription drugs through managed care only (see Appendix Table A-1 for a state-by-state comparison of the percentage of enrollees with drug spending and the percentage of enrollees with managed care).

Table 10 shows the distribution of Medicaid prescription drug spending among Medicaid prescription drug users by eligibility group. Among all Medicaid prescription drug users in FY2000, the bottom 25% had $45 or less in Medicaid prescription drug spending, and the top 25% had more than $927. Those in the middle had prescription drug spending amounts between $45 and $927. The bottom half of aged prescription drug users had $1,309 or less in prescription drug spending, while the bottom half of children with drug spending had $66 or less.

As noted earlier, the average Medicaid prescription drug spending amount was $992 among Medicaid prescription drug users in FY2000. However, **Table 10** shows that 50% of prescription drug users had amounts of $173 or less, and more than 75% had amounts below the $992 average. This indicates that prescription drug spending amounts are not evenly distributed among users, and that a relatively small proportion of users have very high prescription drug spending.

Number and Cost of Prescriptions Filled. In 2001, Medicaid agencies reported processing over 478 million prescriptions. Not all states reported this information, but among those that did, the average cost of a prescription was about $52.82.[35]

Some studies have found large variations in drug use patterns among states. The reasons for such variation may reflect differences in composition of Medicaid enrollment, drug policies in effect in the state, and/or different physician prescribing behaviors.[36]

Spending on Top Five Therapeutic Categories. In 2001, the National Pharmaceutical Council (NPC) reported over one-third (76.9%) of Medicaid drug spending was for drugs in five categories: central nervous system drugs;[37] cardiovascular drugs; anti-infective agents; gastrointestinal drugs; and hormones and synthetic substitutes. While state-by-state variation is large, spending on central nervous system drugs is by far the largest category for which Medicaid drug spending occurs. On average, spending for this class of drugs comprises about 37.6% of states' total drug spending.

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[35] Pharmaceutical Benefits Under State Medical Assistance Programs 2002.

[36] B. Stuart, B.A. Briesacher, F. Ahern, D. Kidder, C. Zacker, G. Erwin, D. Gilden, and C. Fahlman "Drug Use and Prescribing Problems in Four State Medicaid Programs," *Health Care Financing Review*, vol. 20, no. 3, spring 1999.

[37] A large classification of drugs that includes psychotherapeutics, treatments for seizure disorders and Parkinson's, and drugs for pain, among others.

Current Issues

Impact of H.R. 1

State Medicaid programs will experience significant changes in response to the implementation of the provisions of the Medicare Prescription Drug, Improvements and Modernization Act of 2003 (MMA 2003, P.L. 108-173) signed in December of 2003. The new law provides that, beginning in 2006, Medicaid eligibles who are also eligible for Medicare will receive outpatient prescription drug coverage through the new Medicare prescription drug benefit instead of through Medicaid. While this bill doesn't affect eligibility for Medicaid programs, it does, however, affect the benefits that Medicaid programs will cover. Under MMA 2003, state Medicaid programs will be prohibited from covering any drugs that are to be provided through the Medicare benefit, and cannot pay cost sharing amounts for those drugs.

States will have both administrative and financial obligations under MMA 2003. States will be required to conduct eligibility determinations for the low-income subsidies and cost-sharing assistance for the program. This makes sense because the assistance for low-income Medicare Part D beneficiaries is based on the statutory description for a Medicaid coverage group — Qualified Medicare Beneficiaries (QMBs). QMBs are a group of dual eligible enrollees for whom Medicaid pays Medicare's cost sharing requirements. The group of individuals who will qualify for low-income subsidies under Medicare Part D will look just like QMBs but with higher financial standards.

In addition, states will share in the cost of the new Medicare program based on a formula that projects what they would have paid for pharmacy benefits for the dual eligible population had the Medicare benefit not passed. Beginning in 2006, each state will be required to make a monthly payment to the Secretary of HHS equal to the product of the state's share of 2003 Medicaid per capita spending for drugs for all full-benefit dual eligibles[38] trended forward to the current year, multiplied by the total number of such dual eligibles for such state for the month, and multiplied again by the "factor" for the month. The "factor" is 90% in 2006, and will phase down to 75% over 10 years. The formula ensures that states continue to fund a significant share of the cost of the new Medicare drug benefit for those individuals who would have otherwise been eligible for Medicaid prescription drugs. A state's failure to make the required payments will result in interest charges and in an offset to amounts otherwise payable under Medicaid.

An indirect impact of MMA 2003 on Medicaid programs will be that the rebate programs and collections will shrink considerably, since a large portion of Medicaid's prescription drugs will shift to being offered and covered through the Medicare program.

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[38] Including the estimated actuarial value of prescription drug benefits provided under a capitated care.

Pharmacy Plus

Federal law gives states the flexibility to conduct demonstration projects as long as those projects promote the objectives of the Medicaid program. Under these demonstrations, states can waive many statutory eligibility and/or benefits rules. The current Administration has encouraged states to pursue targeted policies under a number of "waiver initiatives." One of those initiatives, called *Pharmacy Plus* waivers, encourages states to provide only pharmacy benefits to low-income seniors and individuals with disabilities who do not otherwise qualify for Medicaid drug coverage. These demonstrations provide comprehensive pharmacy benefits for low-income seniors and individuals with disabilities with income at or below 200% FPL. In fiscal year 2002, there were four approved Pharmacy Plus waivers. Two states reported waiver data in fiscal year 2002. In that year 193,574 individuals received pharmacy benefits at a federal cost of approximately $169 million. Features of those programs are in **Table 11** below. These program are expected to undergo significant changes as the Medicare prescription drug benefit becomes implemented.

Table 11. Pharmacy Plus Programs, 2003

	Florida	Illinois	South Carolina	Wisconsin
Enrollees	Age 65 and over with income below 120% FPL	Age 65 and over with income below 200% FPL	Age 65 and over with income below 200% FPL	Age 65 and over with income below 200% FPL including spend-down.
Benefit	Medicaid Rx benefit	Medicaid Rx benefit	Medicaid Rx benefit	Medicaid Rx benefit
Limits	$160 per month	After annual cap of $1,750, then 20% copay	None	None
Other	68,149 enrollment ceiling	Monthly "rebate" check of $25 for individuals with employer provided drug benefits	Enrollees pay $500 fee to have access to Medicaid prices during "deductible period". After that, $10 per generic/$21 per name brand copays apply 50,000 enrollment ceiling	Participants with income between 160% and 200% pay $500 deductible

Source: Based on information from CMS website at [http://www.cms.hhs.gov/medicaid/1115/pharmacyplus.asp]

Glossary

Actual Acquisition Cost (AAC) — Pharmacist's or provider's net payments made to purchase a drug from any source (e.g., manufacturer, wholesaler) net of discounts, rebates, etc.

Average wholesale price (AWP) — The manufacturer's suggested wholesale price to the retailer, listed in any of the published compendia of cost. In 2003 the compendia include the *American Druggist First DataBank Annual Directory of Pharmaceuticals (Blue Book)*, and *Medi-Span's Pricing Guide*, and Medical Economic's *Drug Topics Redbook*.

Average manufacturers price (AMP) — the average price paid to a manufacturer by wholesalers for a drug. AMP was created as a benchmark for the purpose of calculating Medicaid rebates (OBRA 1990) and is not publically available.

Average Sales Price (ASP) — A new system created by federal and state prosecutors in settlements with pharmaceutical manufacturers TAP and Bayer to ensure more accurate price reporting. ASP is the weighted average of all non-federal sales to wholesalers and is net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer.

"Best price" — with respect to single source and innovator multiple source drugs, the lowest price at which the manufacturer sells the covered outpatient drug to any purchaser (excluding depot prices and single award contract prices of any federal agency, prices charged by manufacturers to DVA, DOD, PHS and various PHS-funded health programs, and state (non-Medicaid) pharmaceutical assistance programs) in the United States. Used to calculate rebates due for those drugs.

Dispensing fee — a payment to cover the cost of the pharmacist's professional services in filling and dispensing a prescription.

Estimated acquisition cost (EAC) — the Medicaid agency's best estimate of the price paid by pharmacists or providers.

Formulary — a list of drug products that may be dispensed or reimbursed. Insurers or states may create a "closed" (or "restricted") formulary where only those drug products listed will be reimbursed by that plan or program. Other formularies may have no restrictions ("open" formularies) or may have certain restrictions such as higher patient cost-sharing requirements for off-formulary drugs.

Maximum allowable cost (MAC) — A maximum dollar amount the pharmacist is paid for selected products.

Multiple source drug — a drug that is made available by at least three different suppliers, and the FDA has determined that at least three approved formulations of the drug are "therapeutically equivalent" that is, contain identical doses of the active ingredient and have the same biological effects. *Innovator multiple source drugs* are

those that are marketed under an original new drug application (NDA) approved by the FDA. *Non-innovator multiple source drugs* are all other multiple source drugs.

Original new drug application — an FDA-approved drug or biological application that received one or more forms of patent protection, patent extension or marketing exclusivity rights granted by the FDA.

Pharmaceutical benefit managers (PBMs) — Entities that contract with health insurers to manage pharmaceutical benefits. Activities provided by PBMs could include claims payment; administrative services, such as retail pharmacy network development; mail order pharmacy operation; formulary development; manufacturer rebate negotiation and prescription checks for adverse drug interactions; and negotiating discounts on pharmaceuticals products.

Single source drug — A covered outpatient drug that is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA.

Stop-loss — A specified annual threshold for medical services to be paid by an insured person. Once the threshold is reached, the insurance coverage commences.

Wholesale acquisition cost (WAC) — The wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts.

Sources: E.K. Adams, Emory University School of Public Health, Atlanta, GA and K. Gondek, HCFA as published in the *Health Care Financing Review*, vol. 15, no. 3, spring 1994, p. 26; State Medicaid Manual, Part Six, Transmittal 36, Apr. 2000; Federal Regulations.

Appendix A

The following **Table A-1** shows Medicaid program enrollment by state, the percentage of program enrollment with prescription drug spending, and the percentage with managed care spending. The table is intended to help identify states with large managed care enrollment, and thus low or no prescription drug spending reported for those enrollees. (Since capitated payments for managed care organizations (MCOs) often cover prescription drug costs, states with lots of managed care enrollment often under report prescription drug spending.) For example, Arizona's enrollment is almost entirely in managed care arrangements, as suggested by 94.2% of enrollees in Table A-1 with managed care spending. As suspected, very few enrollees are reported to have prescription drug spending — only 1%. Tennessee reports no prescription drug spending outside of managed care payments.

Most of the states with a low percentage of program enrollment in MCOs (based on having few enrollees with managed care spending) show on average 60 to 70% of all enrollees have prescription drug spending. This would suggest that **Table 9** underestimates the percentage of children and adults on Medicaid who use prescription drug services. Since Medicaid data cannot provide us with any information about their use of prescription drug services, it is not known if the average per capita spending amounts in that table, and in **Table 10** reflect the spending patterns of those managed care enrollees or if their use of drug services is somehow fundamentally different from those who are not in MCOs.

Appendix Table A-1. Percentage of Medicaid Enrollees with Prescription Drug and Managed Care Spending by State, FY2000

State	Number of enrollees	Percentage with prescription drug spending	Percentage with managed care spending
Alaska	109,457	54.7%	0.0%
Alabama	665,767	65.5%	0.0%
Arkansas	504,284	57.4%	0.0%
Arizona	683,224	1.0%	94.2%
California	8,063,639	29.5%	62.6%
Colorado	377,590	40.0%	85.9%
Connecticut	417,682	26.7%	68.4%
District of Columbia	150,767	25.0%	66.3%
Delaware	124,327	62.6%	79.9%
Florida	2,236,955	47.2%	33.7%
Georgia	1,238,794	65.2%	1.8%
Hawaii	202,912	17.1%	80.6%
Iowa	316,425	66.2%	77.7%
Idaho	150,817	61.0%	0.0%
Illinois	1,733,578	57.9%	13.3%
Indiana	753,597	54.9%	23.0%
Kansas	267,812	57.7%	20.5%
Kentucky	718,058	58.4%	94.3%
Louisiana	827,413	66.5%	0.0%
Massachusetts	1,090,300	60.0%	68.6%
Maryland	721,762	54.6%	69.5%
Maine	211,318	68.1%	1.5%
Michigan	1,360,613	31.4%	73.1%
Minnesota	596,726	29.8%	62.7%
Missouri	991,428	44.4%	39.2%
Mississippi	595,813	69.6%	1.4%
Montana	96,268	60.0%	3.1%
North Carolina	1,201,882	67.1%	4.6%
North Dakota	62,213	62.2%	1.8%
Nebraska	237,333	69.5%	72.5%
New Hampshire	110,155	66.2%	6.6%
New Jersey	847,717	34.7%	64.2%
New Mexico	398,498	16.8%	73.6%
Nevada	158,527	30.9%	40.4%
New York	3,401,448	63.6%	28.8%
Ohio	1,420,230	54.4%	25.4%
Oklahoma	584,620	37.7%	65.2%
Oregon	549,294	34.2%	89.8%
Pennsylvania	1,767,817	23.4%	56.4%
Rhode Island	182,149	27.3%	67.3%
South Carolina	775,396	60.9%	5.6%
South Dakota	98,572	54.0%	100.0%
Tennessee	1,535,081	0.0%	97.9%
Texas	2,706,974	67.8%	26.8%
Utah	198,097	64.9%	85.5%

State	Number of enrollees	Percentage with prescription drug spending	Percentage with managed care spending
Virginia	668,842	50.1%	31.3%
Vermont	146,200	68.9%	44.7%
Washington	916,837	35.1%	65.3%
Wisconsin	619,128	42.5%	54.8%
West Virginia	354,326	73.1%	0.0%
Wyoming	52,470	62.8%	0.0%
Total	**44,201,132**	**45.5%**	**45.4%**

Source: Table prepared by Congressional Research Service (CRS) based on tabulations of CMS MSIS data.

Note: HI data are FY1999, all other states are FY2000. Enrollee counts exclude MSIS records with missing/unknown eligibility status. Drug spending does not include drug rebates, payments for drugs purchased directly from physicians or included in claims for other services such as institutional care, or drugs included in the capitation payment for managed care. Managed care spending includes capitated payments for enrollment in an HMO, HIO, or prepaid health plan.