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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 is prescription drug coverage. As of January 2006, many of Medicaid's elderly and disabled beneficiaries began receiving their drug coverage under Medicare. Nonetheless, Medicaid continues to be an important source of funding in the nation's pharmaceutical markets, and Medicaid drug coverage an important source of drugs for many low-income and disabled Medicaid beneficiaries.

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 groups. 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. Thirty-three states and the District of Columbia provide prescription drug coverage to all Medicaid beneficiaries.

Prescription drug benefits under Medicaid are very broad. States can create formularies, or lists of preferred benefits, but certain federal rules keep actual coverage very comprehensive. Even in Medicaid managed care organizations, which are not subject to those rules, current practice ensures a generous drug benefit. There are 11 categories of prescription drugs that states are allowed to exclude from coverage.

Based on state financial reports for 2005, payments for Medicaid outpatient prescription drugs, net of all rebates (federally required rebates plus state supplemental rebates), were $30.7 billion, accounting for just over 10% of payments for all Medicaid services. 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 of $11.1 billion in federal rebates and an additional $1.3 billion in state supplemental rebates on prescription drugs in 2005. On average, in 2005, per-person spending for Medicaid drugs was just over $1,500.

The Deficit Reduction Act of 2005 made a number of changes to the program's rules, primarily relating to the financing of drugs, the definition of average manufacturer's price (AMP), and the cost sharing amounts that states are able to require Medicaid beneficiaries to pay for these drugs. CMS regulations providing instructions to states on implementing the new AMP, however, have been enjoined from being implemented while awaiting the outcome of a lawsuit brought by associations of pharmacists.

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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 FY2005 for benefits and administration is estimated to have been $180 billion[1]; states are estimated to have spent an additional $136 billion, for a total program cost of $316 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 number of 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 FY2005 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. (See **Table 1**.)

Several recent laws have had and will continue to have a major impact on Medicaid prescription drug benefits. While specific provisions will be discussed in detail below, a summary of those major changes that affect prescription drugs for Medicaid beneficiaries are as follows.

The Deficit Reduction Act of 2005 (DRA 2005, P.L. 109-171)

- changed the federal upper limit applying to payments for most generic drugs under the Medicaid program;
- required that manufacturer-reported average manufacturer prices be publically available;
- included provisions intended to improve states' ability to collect drug rebates for physician-administered and authorized generic drugs; and
- liberalized states' ability to establish co-payments on prescription drugs for Medicaid beneficiaries.

The Medicare Prescription Drug, Improvements, and Modernization Act of 2003 (MMA, P.L. 108-173)

- established the Part D Medicare benefit. Effective January 1, 2006, all beneficiaries who are eligible for both Medicaid benefits and Medicare benefits will receive their drug coverage under the new Medicare Part D; and
- established a formula to continue the states' contribution for the cost of prescription drugs provided to dually eligible beneficiaries whose drug coverage moved from Medicaid to Medicare upon implementation of Part D.

Other recent activity includes a provision passed in P.L. 110-28 (The U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007) that would require all paper Medicaid prescriptions to be written on "tamper-resistant" pads. Subsequent legislation (P.L. 110-90, TMA, Abstinence Education, and QI Programs Extension Act of 2007), however, delayed

its implementation through March 31, 2008. In addition, CMS rules[4] intended to define the way the AMP is to be calculated under DRA have been challenged,[5] and CMS has been enjoined from implementing the changed rules until the court's deliberation is complete.

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 2005, all states covered outpatient prescription drugs for at least some Medicaid beneficiaries; well 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, 2005

State	Categorically needy	Medically needy
Alabama	X	
Alaska	X	
Arizona	X	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
Maine	X	X
Maryland	X	X

[4] Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicaid Program; Prescription Drugs," 72 *Federal Register* 39142, July 17, 2007.

[5] National Association of Chain Drug Stores v. HHS, D.D.C., No. 07-02017.

State	Categorically needy	Medically needy
Massachusetts	X	X
Michigan	X	X
Minnesota	X	X
Mississippi	X	
Missouri	X	
Montana	X	X
Nebraska	X	X
Nevada	X	
New Hampshire	X	X
New Jersey	X	X
New Mexico	X	
New York	X	X
North Carolina	X	X
North Dakota	X	X
Ohio	X	
Oklahoma	X	
Oregon	X	
Pennsylvania	X	
Rhode Island	X	X
South Carolina	X	
South Dakota	X	
Tennessee	X	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: *Medicaid At-a-Glance, 2005; A Medicaid Information Source, Centers for Medicare and Medicaid Services*, Department of Health and Human Services, Publication No. CMS-11024-05.

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 11 specific categories — see below)

that is specifically requested and approved through a prior authorization process.[6] 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[7]; (j) drugs requiring tests or monitoring that can only be provided by the drug manufacturer, and (k) for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration. Formularies may also 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.[8] 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.[9] 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;

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[6] 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.

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

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

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

smoking deterrents; digestive products; H2 antagonists (drugs used to treat ulcers and other stomach conditions); feminine products; and topical products. In 2005, all but one state reported covering some OTC drugs, in most cases limited coverage or coverage with restrictions.[10] Thirty states reported covering at least some OTC drugs in seven or more of the following categories: allergy, asthma, and sinus; analgesics; cough and cold; smoking deterrents; digestive products; H2Antagonists; feminine products; and topical products.[11]

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 have undergone major changes in their drug coverage policies over the past few years in response to the implementation of Medicare prescription drug coverage (Part D). Under the provisions of the MMA 2003, and as of January of 2006, Medicare Part D replaced Medicaid as the primary insurer for most drugs for dual eligible beneficiaries. Medicaid programs are specifically prohibited from continuing to cover drugs offered under the Medicare plans, but may, however, cover those drugs not included in Part D coverage. State Medicaid programs will continue to be required to contribute to the cost of drugs now covered under Medicare Part D, however, based on a formula specified in MMA 2003. The formula requires states to contribute an amount equal to 90%, declining to 75%, 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.[12] In addition, Medicaid administrations are required to conduct eligibility determinations for individuals qualifying for assistance with co-pays under Part D.

Prescription Drugs: Pricing Policies and Rebates

Medicaid Drug Payments and Federal Upper Limits

Medicaid's payments to pharmacies for outpatient prescription drugs have 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

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[10] One state, Arizona, reports that managed care plans make such coverage decisions independently.

[11] Pharmaceutical Benefits Under State Medical Assistance Programs 2005/2006, National Pharmaceutical Council at [http://www.npcnow.org/resources/PDFs/medicaid2005/05-06 Section4.pdf].

[12] See CRS Report RL32902, *Medicare Prescription Drug Benefit: Low-Income Provisions* by Jennifer O'Sullivan for more details.

the prescription (the dispensing fee). Medicaid law requires the Secretary to establish upper limits on the federal share of payments for acquisition costs that are designed to encourage the substitution of lower-cost generic equivalents for more costly brand-name drugs. Those limits apply separately to multiple source drugs — defined to include any drug for which there is at least one other drug sold and marketed during the period that is rated as therapeutically equivalent and bioequivalent to it — and to all other drugs.

FULs for Multiple Source Drugs. When applied to multiple source drugs, the limits are referred to as the FULs — which stands for federal upper limits. The FULs 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 DRA 2005, signed by the President on February 8, 2006, made several significant changes to the FUL policy for multiple source drugs. The provision of law became effective on January 1, 2007 — new FULs, however, have not yet been issued by CMS. As a result, the FULs in effect today are based on formulas in prior law.

The FULs are calculated by the Centers for Medicare and Medicaid Services (CMS) and are periodically published in the state Medicaid Manual.[13] Under the Deficit Reduction Act of 2005, new FULs issued after January 1, 2007, are required to be equal to 250% of the "average manufacturer price" (AMP) of the least costly therapeutic equivalent computed without regard to prompt pay discounts.[14] The AMP is reported to CMS by manufacturers, and is defined in statute to be the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade.[15]

Under the FUL policy, 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 least costly alternative even if the brand-name drug is actually furnished. The Medicaid program, as well as the pharmacy supplying the drug, therefore, has a financial incentive to see that lower-cost generic equivalents are substituted for their brand-name counterparts.

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[13] 42 CFR 447.331-447.332

[14] The FULs in effect today, as calculated under prior law, are equal to 150% of the published price for the least costly therapeutic equivalent. CMS uses average wholesale prices (AWPs) as the basis for the formula. Those figures are published annually in compendia by the pharmaceutical industry.

[15] New FULs taking into account changes passed in DRA are not likely to be issued soon. This is because regulations issued in July of 2007 describing the methodology for calculating AMP, an important component of the FULs as required by DRA, have been enjoined from being implemented pending a legal challenge brought by the National Association of Chain Drug Stores and the National Community Pharmacists Association. They contend that the regulation goes beyond congressional intent and would cause harm if implemented.

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.

Upper Limits for all Other Drugs. All "other" drugs include single source or brand-name drugs and multiple source drugs for which a specific FUL limit has not yet 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 state Medicaid agency's best estimate of the price generally paid by pharmacies and other providers to acquire the drug. States may use any payment method as long as, in the aggregate, a state's payments for "other" drugs are below the payment levels determined by applying the upper limit for other drugs.

States' Payment Formulas

While states must ensure that federal matching funds do not pay for drug prices that exceed the upper limits described above, there are no other rules on how states set their payment formulas for drugs. For most Medicaid drugs, many states use payment formulas that are based on published retail prices — known as "average wholesale prices" (AWPs)[16] — less some percentage (**Table 2**), although this may change following the full implementation of DRA 2005. The formulas below 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, it is believed that the published AWPs are more like manufacturers' suggested wholesale prices rather than a true measure of the average costs to pharmacies of 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.[17]

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[16] AWPs are intended to represent the average price at which wholesalers sell a drug product to retail pharmacies. They are compiled annually in industry compendia including First DataBank's *Annual Directory of Pharmaceuticals* (Blue Book) and National Drug Data Files, Medi-Spans' *Price Alert* and Master Drug Data Base, and Thomson PDR's *2006 Redbook: Pharmacy's Fundamental Reference.*

[17] 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.

Table 2. States' Payment Formulas as of March 2007 (for acquisition costs)

State	Amount for each prescription
Alabama	WAC+9.2%; AWP-10%
Alaska	AWP - 5%
Arizona	AWP - 15%
Arkansas	AWP - 20% (generic); AWP-14% (brand)
California	AWP - 17%
Colorado	AWP - 35% (generic) or AWP - 13.5% (brand)
Connecticut	AWP - 40% (generic); AWP - 14% (brand)
Delaware	AWP - 14% (retail); AWP - 16% (LTC and specialty pharmacies)
District of Columbia	AWP - 10%
Florida	Lowest of AWP - 15.45% or WAC + 5.75%; FUL or SMAC
Georgia	AWP - 11%
Hawaii	AWP - 10.5%
Idaho	AWP - 12%
Illinois	AWP - 25%, (generic); AWP - 12% (brand)
Indiana	AWP - 20% (generic); AWP - 16% (brand)
Iowa	AWP - 12%
Kansas	AWP - 27% (generic); AWP - 13% (single source, brand)
Kentucky	AWP - 12%
Louisiana	AWP - 13.5%; AWP - 15% for chains
Maine	AWP - 15%; AWP - 17% or usual and customary plus professional fee or FUL/MAC plus professional fee for direct supply drug list; Lower of AWP-20% plus professional fee, usual and customary, or FUL or MAC plus professional fee for mail order*
Maryland	Lower of AWP - 12% or WAC+8%, direct price+8% or distributor price when available.
Massachusetts	WAC + 5%
Michigan	AWP - 13.5% (1-4 stores); or AWP - 15.1% (5+ stores)
Minnesota	AWP - 11.5%
Mississippi	Lower of FUL, AWP-12%, and WAC+9% (brand); lower of FUL, and AWP-25% (generic.)
Missouri	Lower of AWP - 10.43% or WAC + 10%
Montana	AWP - 15%
Nebraska	AWP - 11%

State	Amount for each prescription
Nevada	AWP - 15%
New Hampshire	AWP - 16%
New Jersey	AWP - 12.5%
New Mexico	AWP - 14%
New York	AWP - 13.5% (brand); lower of AWP-20% and MAC (generic); AWP-12%for specialized HIV pharmacies.
North Carolina	AWP - 10%, ASP +6%
North Dakota	Lower of WAC + 12.5% or AWP - 10%
Ohio	WAC+7% or its equivalent, AWP-14.4%
Oklahoma	AWP - 12%
Oregon	AWP - 11% (institutional), or AWP - 15% (non-institutional)
Pennsylvania	Lower of WAC +6%, AWP - 15%
Rhode Island	WAC
South Carolina	AWP - 10%
South Dakota	AWP - 10.5%
Tennessee	AWP - 13%
Texas	Lower 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 - 15% (brand), AWP-30% (generic)
Wisconsin	AWP - 11.25%
Wyoming	AWP - 11%

Source: [http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/RxReimbursementRate March2007Qtr.pdf].

Notes: * For other exceptions see state plan.
ASP: Average sales price
AWP: Average wholesale price
WAC: Wholesaler acquisition cost
SMAC: State maximum allowable cost

Another provision in DRA 2005 requires the Secretary of HHS to make manufacturers' reported AMP data available on a monthly basis to states and to post those amounts, with at least quarterly updates, on a website accessible to the public. The availability of such data, which CMS plans to make available in the spring of 2007, may encourage states to make changes to their drug reimbursement formulas based on AMPs instead of AWPs. There are a few reasons why states may want to make this change. First, basing reimbursements on the same measure of price that the FULs are based on could help to ensure that the ceilings are not exceeded. Second, the AMPs, unlike the AWPs, will presumably be calculated in a consistent

fashion once proposed regulations defining those calculation become finalized.[18] In addition, AMPs are subject to the oversight and review of the Secretary of HHS.

Dispensing Fees

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." Most such fees generally range from around $3.50 per prescription to $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, the fees 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 11 categories of drugs that states are allowed to exclude from coverage). In 2003 there were reported to have been more than 550 manufacturers participating in the Medicaid drug rebate program.[19]

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.[20] 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

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[18] Proposed rules were published on Friday, December 22, 2006: 42 CFR 447; Medicaid Program; Prescription Drugs.

[19] Testimony of Dennis Smith, Director, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, before the Energy and Commerce Committee, Subcommittee on Oversight and Investigations, December 7, 2004.

[20] 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.

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 AMP for a drug 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.[21] 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 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.[22]

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[23] 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 reduced Medicaid savings from the rebate program, so Congress responded with an offset. Rebate percentages were increased to those

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[21] 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.

[22] U.S. Department of Health and Human Services, Office of the Inspector General, *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices*, OEI-05-05-00240, June 2005. Other comparative pricing analyses can be found in U.S. Government Accountability Office (GAO), *States' Medicaid Payments for Prescription Drugs*, GAO-06-69R, October 2005, and U.S. Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, January 1996.

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

amounts shown in **Table 3**. MMA 2003 further excludes the prices of drugs provided under Medicare Part D from best price. That legislation, however, did not include an offsetting rebate adjustment.

The Veteran's Health Care 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.[24]

"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.

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: 42 USC Sec. 1396r-8.

In 2005, the total amount of federally required drug rebates was reported by states to be $11.1 billion. (States also reported collecting more than $1.3 billion in supplemental rebates not required by the federal government, although there is reason to believe that reported amounts for state supplemental rebates are too low. See the discussion on page 16.) On average, federal rebates represented about 26% of Medicaid spending on outpatient prescription drugs. Rebates for 2005 by state are reflected in **Table 4**.

[24] 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 4. Medicaid Total Drug Spending and Rebates by State, 2005

(in millions of dollars, includes state and federal shares)

	Total Spending on Prescription Drugs	All Rebates Collected	Spending Net Rebates	Rebates as a Percentage of Drug Spending
Alabama	606.6	145.2	461.3	24%
Alaska	127.3	27.5	99.8	22%
Arizona	-	-	-	-
Arkansas	419.4	93.6	325.7	22%
California	5,187.3	2,056.5	3,130.8	40%
Colorado	285.4	74.6	210.7	26%
Connecticut	496.7	109.4	387.3	22%
Delaware	122.0	35.4	86.6	29%
District of Columbia	105.9	24.7	81.2	23%
Florida	2,503.2	728.6	1,774.6	29%
Georgia	1,184.9	336.3	848.6	28%
Hawaii	119.9	25.1	94.7	21%
Idaho	168.8	48.5	120.3	29%
Illinois	1,716.4	575.5	1,140.9	34%
Indiana	751.5	204.4	547.2	27%
Iowa	412.3	90.1	322.2	22%
Kansas	296.3	93.1	203.2	31%
Kentucky	794.5	217.3	577.2	27%
Louisiana	1,082.6	278.8	803.8	26%
Maine	282.0	99.8	182.2	35%
Maryland	578.2	154.1	424.2	27%
Massachusetts	1,067.4	281.5	785.9	26%
Michigan	965.4	325.1	640.2	34%
Minnesota	441.9	118.0	323.9	27%
Mississippi	665.5	180.1	485.4	27%
Missouri	1,246.1	300.3	945.9	24%
Montana	105.2	25.2	80.0	24%
Nebraska	228.6	68.4	160.1	30%
Nevada	134.6	34.1	100.5	25%
New Hampshire	133.3	37.6	95.7	28%
New Jersey	1,158.6	261.6	897.0	23%
New Mexico	116.3	25.4	90.8	22%
New York	5,253.7	1,300.1	3,953.5	25%
North Carolina	1,790.4	452.7	1,337.7	25%
North Dakota	64.2	15.3	48.8	24%
Ohio	1,981.2	591.9	1,389.3	30%
Oklahoma	500.4	103.4	397.0	21%
Oregon	261.4	60.5	200.9	23%
Pennsylvania	1,009.8	253.7	756.1	25%
Rhode Island	173.9	44.7	129.2	26%
South Carolina	716.7	217.0	499.7	30%
South Dakota	89.0	22.1	66.9	25%
Tennessee	2,344.4	768.9	1,575.5	33%

	Total Spending on Prescription Drugs	All Rebates Collected	Spending Net Rebates	Rebates as a Percentage of Drug Spending
Texas	2,416.9	736.8	1,680.1	30%
Utah	221.9	39.9	182.0	18%
Vermont	184.7	45.1	139.7	24%
Virginia	634.7	174.0	460.7	27%
Washington	682.6	176.8	505.8	26%
Wisconsin	759.7	202.8	556.9	27%
West Virginia	431.6	114.3	317.3	26%
Wyoming	51.2	13.7	37.6	27%
National Total	43,084.3	11,102.2	30,662.5	26%

Source: Table prepared by Congressional Research Service (CRS) based on tabulations of 2005 CMS Financial Management Reports.

* Arizona has a statewide managed care waiver in place. Under the waiver, all Medicaid services are provided through capitated arrangements. Since drugs are included in the capitation payment to MCOs, rebates do not apply.

Drug Pricing and Rebate Issues

Average Wholesale Prices. The DRA 2005 addressed concerns that had been raised repeatedly in the last several years regarding the AWPs and the states' and HHS's reliance on those prices for setting pharmaceutical payment levels and FULs. Today, FULs are calculated based on the published AWPs. However, Congressional hearings and investigations by the General Accounting Office, and the office of the Inspector General (IG) of Health and Human Services (HHS) found that the AWPs do not reflect the intended wholesale prices, and that some manufacturers manipulated the published AWPs to offer discounts to certain purchasers without offering those prices to Medicaid.[25] By replacing the FUL computation with a formula based on AMPs, the use of AWPs for setting Medicaid drug prices may become a thing of the past. In addition, DRA 2005 allows the Secretary to gather data on retail drug prices. Once implemented, DRAs data reporting provisions may prove to be useful for determining whether the upper limits on drug prices are too high, too low, or adequate.

Circumventing the Best Price or Rebate Policies. A second area that has raised concerns relates to the best prices that are reported by manufacturers to CMS and are used by CMS to calculate rebates. There have been cases in which manufacturers sell drugs or report drug prices in ways that circumvent Medicaid's rebate requirement or minimize rebates to be paid. For example, manufacturers could skirt 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 sold by repackagers or redistributors are not subject to

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[25] 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, November 22, 1999.

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.[26] In addition, recently, Schering Plough Corporation agreed to pay $293 million to resolve its liabilities in connection with fraudulent pricing of its allergy drug Claritin under the Medicaid drug rebate program. Schering Plough allegedly failed to include the value of certain incentives offered to two managed care organizations in the best price reported for purposes of the Medicaid drug rebate program. The resulting charge was that Medicaid rebates were underpaid, and other entities (such as community health centers) that purchase drugs at ceiling prices that are based on Medicaid drug rebate prices were overcharged.[27]

DRA 2005 intervened to address another concern related to the collection of rebates on certain drugs. The IG and CMS have both raised the concern that some rebates have gone unpaid for certain drugs administered by physicians in their offices (or in another outpatient setting), such as chemotherapy, simply due to operational gaps. This is because providers use Healthcare Common Procedure Coding System (HCPCS) J-codes to bill the Medicaid program for injectible prescription drugs, including cancer drugs. The HCPCS J-codes do not, however, provide states with the specific manufacturer information necessary to enable them to seek rebates. In a letter to state Medicaid directors, CMS requested that states identify Medicaid drugs, specifically those using HCPCS J-codes, by their NDC codes so that rebates can be collected for these drugs (SMDL #03-002, dated March 14, 2003). Nonetheless, DRA 2005 stepped in to require, as a condition of receiving Medicaid payments, that states submit to the Secretary of HHS utilization data and coding information for certain physician-administered outpatient drugs. Such data would be required initially for all single source drugs administered by physicians. Later, the same data would be required for the 20 physician-administered multiple source drugs with the highest dollar volume as determined by the Secretary.

Finally, the DRA included a provision intended to improve best price reporting for authorized generic drugs. Sometimes manufacturers produce both a brand-name version of a prescription drug and also sell or license a second manufacturer (or a subsidiary) to produce some of the same product to be sold or re-labeled as a generic. Concerns have been raised by two Senators, both in a letter to the Chairman of the Federal Trade Commission[28] and at a hearing on Medicaid fraud[29] that there may be problems collecting rebates on these generic products, referred to as "authorized generics." One potential problem is that the reported best prices for the brand-name

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[26] Correspondence from the Office of the Inspector General, November 1999.

[27] Testimony of George M. Reeb, Assistant Inspector General for the Centers for Medicare and Medicaid Audits, Office of Inspector General, U.S. Department of Health and Human Services before the Energy and Commerce Committee, Subcommittee on Oversight and Investigations, December 7, 2004.

[28] Letter dated May 9, 2005 from Senators Grassley and Rockefeller to Federal Trade Commission Chairman Deborah Platt Majoras posted at [http://www.Grassley.Senate.Gov].

[29] U.S. Congress, House Committee on the Energy and Commerce, Subcommittee on Oversight and Investigations, *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*, hearings, 108th Cong., 2nd sess., December 7, 2004, H.Rept. 108-126 (Washington: GPO, 2004).

product do not properly account for prices at which the authorized generics are sold. A second potential problem is that the rebates for the authorized generics are calculated using the wrong rebate formula. DRA 2005 modified the existing drug price reporting requirements to ensure, effective January 1, 2007, that the manufacturer-reported prices, including both the average manufacturer's price and the manufacturer's best price, include the price of the authorized generic.[30]

Supplemental Rebates. In addition to the rebates required under federal law, a number of states charge certain pharmaceutical manufacturers additional rebates. In 2005, 22 states reported collecting a total of $1.3 billion in supplemental rebates (federal share of $719 million).[31] California collected 50% of the reported amounts. But reported collections are likely to be too low. In information provided by CMS to the Committee on Energy and Commerce in 2004, 33 states were noted to have supplemental rebates in effect. If those programs remained in effect in 2005, supplemental rebate collections may well exceed the amounts reported in the 2005 CMS Financial Management Reports.[32]

Policies to Control 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. Under a prior authorization requirement, only those pharmaceutical products that have been approved in advance by a designated individual or entity are 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 2005, all (including the District of Columbia) but one state reports 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.[33]

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

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[30] The bill language doesn't use the term "authorized generic." Instead it requires the reported prices to include the price of any drug sold under a new drug application approved (under Section 505c of the Federal Food, Drug and Cosmetic Act, FFDCA) by FDA.

[31] Supplemental rebates are required to be shared by states and the federal government in the same way that federally required rebates are shared.

[32] Prepared Statement of Dennis Smith, Director of Center for Medicaid and State Operations of CMS, submitted for the record in U.S. Congress, House Committee on Energy and Commerce; Subcommittee on Oversight and Investigations, *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*, 108th Cong., 2nd sess., December 7, 2004, 2004, 108-126 (Washington: GPO, 2004)

[33] National Pharmaceutical Council, 2005/2006. South Dakota reports having no prior authorization procedure. Arizona reports that such policies are left to individual managed care organizations.

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.

Prescribing/Dispensing Limitations. States may also restrict the quantity of prescription drugs available to beneficiaries. Such prescribing and dispensing limits are ubiquitous. All but three 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, 2005

State	Limits on number, quantity, and refills of prescriptions
Alabama	34-day supply per Rx, 5 refills per Rx, 4 brand limit per month
Alaska	30-day supply per Rx, other ceilings on certain classes of drugs
Arizona	**
Arkansas	31-day supply per Rx, 3 Rx per month (extension to 6), five refills per Rx within 6 months
California	6 Rx per month, maximum 100 day supply for most meds, 3 claims per drug w/in 75 days.
Colorado	30-day supply per Rx, 100 days for maintenance medication, other limits may apply
Connecticut	240 units or 30-day supply, 5 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, 3 refills per Rx within 4 months, other limits specific to certain medications
Florida	Vary according to drug
Georgia	34-day supply per Rx, 5 Rx per month (adult), 6 Rx per month (child); $2999.99/Rx limit (potential override)
Hawaii	30-day supply or 100 unit doses per Rx, maximum quantities for some drugs.
Idaho	34-day supply (with exceptions), 3 cycles birth control, limits on refills
Illinois	Medically appropriate monthly quantity, 3 brand Rxs per month, 11 refills per Rx
Indiana	—
Iowa	Maximum 30-day supply except oral contraceptives (90 days)
Kansas	31 day supply per Rx, 5 Rx per month, other limitations specific to certain medications
Kentucky	32 day supply, Maximum 5 refills in 6 months, 92 days/100 units per month for maintenance medication, 4 Rxs per month.

State	Limits on number, quantity, and refills of prescriptions
Louisiana	Greater of 30-day supply per Rx or 100 unit doses, 5 refills per Rx within 6 months, max 8 Rx per recipient per month
Maine	34-day supply (brand), 90-day supply (generic), maximum 11 refills per Rx, 5 brand Rx per month
Maryland	34-day supply per Rx, 11 refills per Rx, refills cannot exceed 360-day supply
Massachusetts	30-day supply, 5 refills per Rx, per month limits on some drugs
Michigan	100-day supply, quantity limits for certain drugs
Minnesota	34-day supply, quantity limits for selected drugs
Mississippi	Greater of 31-day supply or 100 unit doses per Rx, 5 Rx per month, 11 refills maximum
Missouri	—
Montana	34-day supply
Nebraska	Greater of 90-day supply or 100 dosage units per Rx, 5 refills per Rx, 6 mo. for controlled substances, 31 days for injectibles
Nevada	34-day supply per Rx, 100 day supply for maintenance medications, 5 refills within 6 months
New Hampshire	34-day supply, 90-day supply on maintenance medications
New Jersey	34-day supply or 100-unit dosage per Rx, 5 refills within 6 months
New Mexico	34-day supply except contraceptives (100 days) and maintenance drugs (90 days)
New York	5 refills per Rx, annual limits on number of Rx and OTC drugs available (with exceptions)
North Carolina	34-day supply per Rx, with exceptions, 8 Rx per month
North Dakota	34-day supply per Rx
Ohio	34-day supply; 102 day supply for maintenance, 5 refills per Rx
Oklahoma	34-day supply or 100 unit doses per Rx, 6 Rx per month (age 21 and over, under 21 unlimited)
Oregon	34-day supply, 100 days for mail order and maintenance drugs
Pennsylvania	Greater of 34-day supply or 100 unit, 5 refills within 6 months, 6 Rx per month
Rhode Island	30-day supply per Rx (non-maintenance), 5 refills per Rx
South Carolina	34-day supply w/ unlimited Rx (children), 4 Rx per month (adult) with exceptions, other limits may apply
South Dakota	Varies by drug
Tennessee	Varies by basis of eligibility
Texas	3 Rx per month, unlimited Rxs for nursing home residents and children, max 5 refills or 6 months per Rx
Utah	31-day supply per Rx, max 5 refills per Rx, other limits on specific drugs
Vermont	34-day supply per Rx, 102-day supply for maintenance medications, 5 refills per Rx
Virginia	34-day supply per Rx
Washington	34-day supply per Rx, 2 scripts per month except for antibiotics or scheduled drugs, 4 brand cap

State	Limits on number, quantity, and refills of prescriptions
West Virginia	34-day supply except antibiotics (14 days and 1 refill)
Wisconsin	34-day supply per Rx with exceptions, maximum 11 refills during 12-month period for non-schedule drugs, 5 refills for Schedule III, IV, V drugs
Wyoming	Quantity limits on some medications as deemed clinically appropriate

Source: National Pharmaceutical Council, Pharmaceutical Benefits Under State Medical Assistance Programs 2005/2006.

Notes: Rx: Prescription.

** Individual managed care and pharmacy benefit management organizations make formulary/drug decisions.

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.

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. Cost sharing is another area that DRA 2005 made significant changes to that could impact prescription drug benefits for Medicaid beneficiaries. Pre-DRA 2005 cost sharing limitations prohibited states from requiring copayments on services provided to children under age 18, pregnant women for any services that relate to the pregnancy or to any medical condition that may complicate pregnancy; and people who are hospitalized or residing in a long-term care facility. In addition, copayments could not be charged for people receiving hospice, emergency[34] and family planning services. Any copayments charged for other beneficiaries or benefits were limited to "nominal" amounts.[35]

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[34] 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.

[35] Nominal amounts are defined in 42 CFR 447.52 - .54. DRA 2005 changed the definition of "nominal" amounts so that beginning with FY2006, those amounts will be indexed by inflation (as estimated using the medical care component of the consumer price index).

DRA 2005 created two optional cost sharing plans that states could choose to implement as alternatives to the cost sharing limitations described above. Under the new cost sharing options, both of which became effective on March 31, 2006, states are prohibited from requiring cost sharing for certain Medicaid beneficiaries. The list of those that must remain exempt from cost sharing is slightly different from the list of those exempt under prior law. States will be prohibited from imposing cost sharing for (1) services provided to mandatory children who are under age 18 or are in foster care under Part B of Title IV, or are receiving adoption or foster care assistance under Title IV-E regardless of age; (2) preventive services provided to children under 18 regardless of family income; (3) services provided to pregnant women that relate to pregnancy or to other medical conditions that may complicate pregnancy; (4) services provided to terminally ill individuals receiving Medicaid hospice; (5) services provided to individuals in medical institutions who are required to spend their income down to qualify for Medicaid; (6) emergency services; (7) family planning services and supplies; and (8) services provided to women qualifying for Medicaid under the breast and cervical cancer eligibility group.

The first new cost sharing option under DRA 2005 allows states to establish cost sharing amounts that exceed nominal amounts and to vary those amounts among classes or groups of individuals or by types of services. The second option, which applies specifically to outpatient prescription drugs, allows states to establish a cost sharing plan under which beneficiaries are charged higher cost sharing amounts for state-identified non-preferred drugs, and no or reduced cost sharing amounts for preferred drugs.

The two new options come with additional limitations. Besides the groups that are specifically exempted, as described above, the DRA 2005 cost sharing amounts cannot exceed 10% of the cost of the item or service for individuals with income between 100% and 150% of poverty, and 20% of the cost of the item or service for individuals with an income over 150% of poverty. In addition, an aggregation of all cost sharing amounts cannot exceed 5% of family income.

Table 6 shows co-payment requirements as of March of 2007. These amounts are not likely to reflect the full impact of the DRA flexibilities, since those provisions became effective at the end of that month. 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. Cost Sharing Requirements for Medicaid Pharmaceuticals as of March 2007

State	Amount for each prescription
Alabama	$.50 to $3.00
Alaska	$2.00
Arizona[a]	—
Arkansas	$.50 to $3.00
California	$1.00
Colorado	$.75 (generic); $3.00 (brand)
Connecticut	$1.00
Delaware	None
District of Columbia	$1.00
Florida	2.5% of payment up to $300
Georgia	$.50 (generic and preferred brand); $.50 to $3.00 (brand)
Hawaii	None
Idaho	None
Illinois	none for generic; $3.00 (brand)
Indiana	$3.00
Iowa	$1.00 (non-preferred brand up to $25); $2.00 (non-preferred brand between $25 and $50), $3.00 (non-preferred brand, $50 and more)
Kansas	$3.00
Kentucky	$1.00
Louisiana	$.50 to $3.00
Maine	$2.50 (generic and brand); $3.00 per day in rural health clinics-All subject to ceilings; Mail order not subject to copay
Maryland	$1.00 (generic, preferred brand), $3.00 (non-preferred brand)
Massachusetts	$1.00 (multi-source &non-legend OTC) - $3.00
Michigan	$1.00 (generic); $3.00 (brand)
Minnesota	$1.00 (generic); $3.00 (brand)
Mississippi	$3.00
Missouri	$.50 to $2.00
Montana	$1.00
Nebraska	$2.00
Nevada	$1.00 (generic); $2.00 (brand)
New Hampshire	$1.00 (generic); $2.00 (brand & compound)
New Jersey	$2.00
New Mexico	None
New York	$1.00 (generic); $3.00 (brand); $.50 (OTC)
North Carolina	$1.00 (generic); $3.00 (brand)
North Dakota	$3.00 (brand)
Ohio	$3.00 (non-preferred), $2.00 (preferred brand)
Oklahoma	$1.00 to $2.00
Oregon	$2.00 (generic); $3.00 (brand)
Pennsylvania	$1.00
Rhode Island	None
South Carolina	$3.00

State	Amount for each prescription
South Dakota	$2.00
Tennessee[a]	—
Texas	None
Utah	$3.00
Vermont	$1.00 to $3.00
Virginia	$1.00
Washington	None
West Virginia	$.50-$3.00
Wisconsin	$.50 (over the counter); $1.00 (generic) $3.00 (brand)
Wyoming	$2.00

Source: [http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/RxReimbursementRateMarch2007Qtr.pdf].

Notes:
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.[36] 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.

Purchasing Pools. Seventeen states participate in multi-state bulk purchasing pools for outpatient prescription drugs. Those states partner together to negotiate on prices and rebates for drugs required by the multiple Medicaid programs. Three states have established intra-state pools that negotiate on prices for Medicaid drugs combined with those needed for other in-state agencies such as state employees' plans and local governments. Nine of those states have reported modest savings from those activities.[37]

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

[37] National Association of State Medicaid Directors and Avalere Health LLC, *State Perspectives on Emerging Medicaid Pharmacy Policies and Practices*, November 2006.

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 2005, total payments for Medicaid outpatient prescription drugs, net of all rebates — federal and state — was $30.7 billion, accounting for about 10.2% of payments for all Medicaid services.[38] The average annual growth in drug spending under Medicaid over the 15- year period from 1990 to 2005 was about 13.1% 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.

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%
2005	$300.7	9.0%	$30.7	13.1%

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

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 federal and state rebates have been subtracted from totals.

Spending by Eligibility Group. The Medicaid Statistical Information System (MSIS) identifies Medicaid spending for prescription drugs by eligibility group and, to date, includes data from 49 states plus the District of Columbia. (Data for Maine are not yet included). Based on this data, of total Medicaid spending for

[38] CRS tabulation of 2005 Medicaid Financial Management Reports.

prescription drugs, about 81% is for individuals qualifying for Medicaid on the basis of being elderly, blind, or having a disability (about 56% for blind and disabled individuals and 25% for elderly beneficiaries). About 10% of drug spending is for non-disabled and foster care children, and an additional 9% is for adults in families with dependent children and women with breast or cervical cancer.[39]

Table 8 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.[40] Among all Medicaid prescription drug users in FY2005, the average Medicaid prescription drug spending amount was $1,510. 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 almost $3,795. Among children with prescription drug spending, the average amount was about $357.

Table 8. Average Medicaid Prescription Drug Spending Among Medicaid Prescription Drug Users by Basis of Eligibility, FY2005

	Percentage of Medicaid enrollees with prescription drug Spending	Average Medicaid drug spending per Medicaid prescription drug user
Aged	68%	$2,944
Blind/Disabled	71%	$3,795
Child[a]	40%	$357
Adult	38%	$622
BCCA women	70%	$2,124
Total[b]	**48%**	**$1,510**

Source: Congressional Research Service (CRS) tabulations of data from CMS MSIS State Summary Datamart.

Notes: Does not include data for Maine. Also 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.

a. Includes foster care children.
b. Includes enrollees for whom basis of eligibility was unknown.

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[39] Expenditures in this paragraph are those reported by states through the Medicaid Statistical Information System (MSIS) for FY2005. MSIS expenditures are different from expenditures reported in Tables 4 and 8 (based on CMS-64 reports) because data reported on form CMS 64 are for slightly different time periods and for different purposes.

[40] 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.

Number and Cost of Prescriptions Filled. In 2005, Medicaid agencies reported processing more than 595 million prescriptions. The average cost of a prescription for the same year was about $66.84.[41]

Some studies have found large variations in drug use patterns among states. Among the many reasons for such variation differences in health care needs and the composition of Medicaid enrollment, drug policies in effect in the state, and/or different physician prescribing behaviors.[42]

Spending on Top Five Therapeutic Categories. The National Pharmaceutical Council (NPC) reported that, in 2005, over 65% of Medicaid drug spending was for drugs in five categories: central nervous system drugs; cardiovascular drugs; psychotherapeutic agents; hormones; and anti-infective agents.[43] While state-by-state variation is large, spending on psychotherapeutic drugs is by far the largest category for which Medicaid drug spending occurs. On average, spending for this class of drugs comprises about 24% of states' total drug spending.

Current Issues

Impact of DRA 2005

Federal Upper Limits. The DRA provision instructing CMS to use the AMP for the purpose of calculating FULs instead of the AWP was intended to eliminate some of the opportunities for drug manufacturers to inflate Medicaid reimbursements as well as to simply reduce spending for Medicaid's generic prescription drugs. Indeed, the CBO estimated federal budgetary savings for this provision to be substantial; totaling $3.6 billion for 2006 through 2010 and almost $12 billion over 10 years. The AMPs, as submitted by the manufacturers to CMS, are generally lower than any of the published AWPs and as yet, remain confidential. Until the passage of DRA, CMS was prohibited from making those prices publically available and could only share them with the U.S. General Accounting Office and the Congressional Budget Office. Upon full implementation of the DRA provisions, AMPs are to become publically available.

Retail pharmacies have responded to DRA's FUL formula change with concerns that the lower FULs will push Medicaid reimbursements for multiple source drugs to amounts below pharmacies' acquisition costs. Small community pharmacies that buy smaller quantities of drugs than the big chain pharmacies are particularly concerned, since they have less price negotiating power and almost always purchase through third-party wholesalers.

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[41] Pharmaceutical Benefits Under State Medical Assistance Programs 2005/2006.

[42] 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.

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

GAO was asked to examine the estimated FULs using AMP and compare those amounts to pharmacy acquisition prices. In a memorandum dated December 22, 2006 addressed to Representative Joe Barton, the GAO compared 250% of the lowest AMP with acquisition costs for a sample of frequently used and high expenditure Medicaid drugs. GAO found that the estimated FULs were below average retail pharmacy acquisition costs for 59 of the 77 drugs examined.[44] These findings potentially provide support for the concerns raised by the retail pharmacies and may raise other concerns as well. For example, if the FULs, when finally implemented, turn out to be below acquisition costs, Medicaid beneficiaries could suffer reduced access to such products since pharmacies might be disinclined to do business with Medicaid programs.

Proposed regulation. In December 2006, CMS issued a proposed rule to implement the DRA provisions pertaining to prescription drugs under Medicaid. The rule, which was issued in final form in July of 2007 (72 *Federal Register* 39142), defines a number of important terms related to drug pricing under Medicaid, including definitions impacted by DRA provisions such as AMP, multiple source drugs, and nominal prices.

The rule has elevated the concerns of pharmacy groups. Some of those concerns were expressed in letters from members of the U.S. House of Representatives and the Senate to the acting CMS administrator in February and March of 2007. One of the issues identified in the letters was about CMS's[45] inclusion of prices that are not available to retailers in calculating AMP. According to the pharmacy groups, by including those prices in AMP — prices and rebates that community pharmacists do not have access to — the FULs would be lowered, as would Medicaid reimbursements, potentially making their Medicaid business unsustainable.[46] This has prompted a pending lawsuit brought by the National Association of Chain Drug Stores and the National Community Pharmacists Association to halt the implementation of this rule. At this time, the rule has been prohibited from being implemented while the court case proceeds.

Cost sharing and Other Flexibility Enabled by DRA. As summarized above, the DRA gave states several new cost sharing options, although the outcome of these new options on beneficiaries' copayments is not yet clear. A survey of state Medicaid Directors conducted during the summer of 2006 suggests that only a handful of states consider it likely or were certain to make changes based on the DRA options. Thirty states, however responded that they didn't know or had not yet determined whether such changes would be forthcoming.[47]

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[44] Letter from John E. Dicken, Director of Health Care at U.S. Government Accountability Office to Representative Joe Barton, December 22, 2006, GAO-07-239R.

[45] Letters from Senators and Representatives and statement of the National Community Pharmacists Association at [http://www.ncpanet.org/leggovaffairs/medicaid.php].

[46] See complaint for National Association of Chain Drug Stores v. HHS, D.D.C. No. 07-02017.

[47] National Association of State Medicaid Directors and Avalere Health LLC, *State Perspectives on Emerging Medicaid Pharmacy Policies and Practices*, November 2006.

In addition to cost sharing flexibility, Section 6081 of the Deficit Reduction Act (DRA) authorized "transformation grants" to States for the adoption of innovative methods to improve effectiveness and efficiency in providing medical assistance under Medicaid. A number of activities were named as potential projects that would qualify for such funds, including increasing the utilization of generic drugs through education programs and other incentives and implementing a medication risk management program as part of a drug use review program. During the first round of grants, three states; Florida, New Mexico, and North Dakota were provided funds to implement electronic prescribing programs.

Impact of MMA 2003

Drug Coverage. State Medicaid programs are undergoing major 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. As of the start of 2006, Medicaid eligibles who also qualify for Medicare receive their outpatient prescription drugs under Medicare Part D instead of under Medicaid. While this law doesn't affect eligibility for Medicaid programs, it does, however, affect the benefits that Medicaid programs will cover. Under MMA 2003, state Medicaid programs are prohibited from covering drugs that are to be provided under Part D, and cannot pay cost sharing amounts for those drugs.

Additional Administrative Responsibilities. States have both new administrative and financial obligations under MMA 2003. States are required to conduct eligibility determinations for the low-income subsidies and cost sharing assistance for the Medicare program. This is 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 qualify for low-income subsidies under Medicare Part D is similar to the QMB eligibility group, except that the Part D group allows for somewhat higher income financial standards.

Maintenance of Effort Payments. Finally, MMA requires states to continue to pay part of the cost of the Medicare Part D drug benefit based on a formula that projects what they would have paid for pharmacy benefits for the dual eligible population in the absence of Medicare Part D. Beginning in 2006, each state must 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[48] trended forward to the current year, multiplied by the total number of such dual eligibles in the state for the month, and multiplied again by the "factor" for the year. The "factor" was 90% in 2006, and will phase down to 75% over 10 years.

This provision has proven to be controversial. Some states claim that the payments for Part D exceed what they would have had to pay under Medicaid because the formula doesn't account for cost cutting activities that would have occurred under Medicaid. Five states were party to an action, filed directly with the Supreme Court challenging the constitutionality of the so-called "clawback"

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[48] Including the estimated actuarial value of prescription drug benefits provided under Medicaid HMOs.

payments. Ten other states signed on as amici curiae, literally 'friends of the court,' in support of the five states.[49] The Supreme Court, however, declined to hear the action and also declined a separate request to block CMS from collecting the payments. States would need to take the actions to federal district courts, which may yet happen, but to date, have not.

[49] Texas v. Leavitt, U.S., Original Action 135, filed March 3, 2006. The action was brought by Texas, Kentucky, Maine, Missouri, and New Jersey. Ten states signing as amici curiae were Alaska, Arizona, Connecticut, Kansas, Mississippi, New Hampshire, Ohio, Oklahoma, South Carolina, and Vermont.

Glossary

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

Average wholesale price (AWP) — Intended to reflect the average price at which pharmaceutical products are purchased from wholesalers. In reality, it is more like a 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). A proposed definition has been promulgated and is to be finalized by July 1, 2007. In addition, reported AMP are to become publically available some time during 2007.

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 and more recently applied to Medicare products paid under Part B of the program. 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 covered outpatient drug for which there is at least one other drug product rated as therapeutically equivalent (under the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence

Evaluations") and is pharmaceutically equivalent and bioequivalent, as determined by the FDA, and is sold or marketed in the State during the period. *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, April 2000; Federal Regulations.