kaiser commission on medicaid and the uninsured

THE HENRY J. KAISER FAMILY FOUNDATION

POLICY BRIEF

JANUARY 2002

Medicaid: Purchasing Prescription Drugs

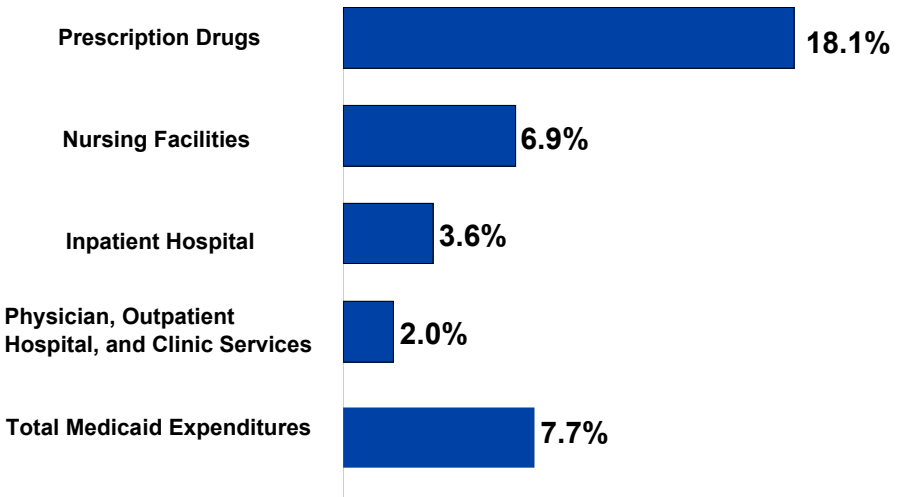
Introduction

Medicaid spending on prescription drugs is an issue of considerable interest to state and federal policymakers. A recent survey of state Medicaid officials found that spending on prescription drugs was one of the most frequently cited reasons for overall Medicaid spending growth.[1] Nationally, prescription drug spending accounted for nearly nine percent of all Medicaid spending on benefits in 2000.[2]

Between 1997 and 2000, Medicaid spending on prescription drugs grew at an average annual rate of 18.1 percent, over two times the 7.7 percent annual growth in Medicaid spending (Figure 1), and accounting for nearly 20 percent of the increase in total spending in this period. The Congressional Budget Office (CBO) expects that Medicaid spending on prescription drugs will "continue to rise as demand for and the prices of current and new high-cost products increases."[3]

Figure 1

Average Annual Growth in Medicaid Expenditures for Selected Services, 1997 - 2000



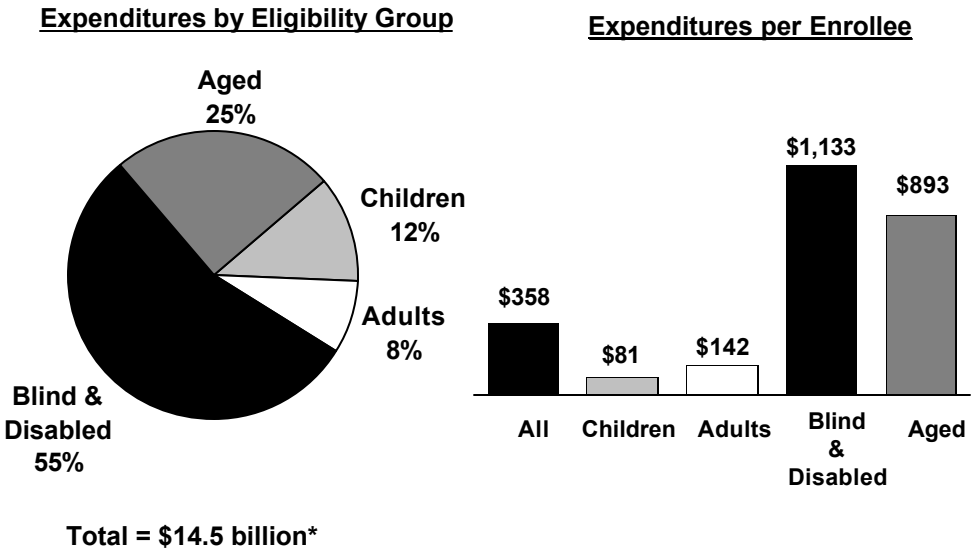
Source: CMS, CMSO, Financial Management Reports (HCFA-64 data).
All growth rates shown represent changes in total fee-for-service expenditures for the types of services listed, except prepaid/managed care. Prepaid/managed care expenditures cover a wide range of medical services. Data are for federal fiscal years (October - September).

[1] Smith, Vernon K. "Medicaid Budgets Under Stress: A Survey of State Medicaid Programs for State Fiscal Year 2001 and 2002." (October 2001). Kaiser Commission on Medicaid and the Uninsured.
[2] Spending refers to Medicaid outpatient, fee-for-service drug spending, net of rebate.
[3] CBO, *The Budget and Economic Outlook: Fiscal Years 2002-2011* (January 2001), p. 81, www.cbo.gov/.

Of course, access to prescription drugs is of particular importance to Medicaid beneficiaries, who by definition are unable to afford the costs of needed prescription drugs. Individuals with disabilities and the elderly, who represent about 27 percent of all Medicaid beneficiaries, account for about 80 percent of all Medicaid spending on prescription drugs (Figure 2). Medicaid beneficiaries with disabilities often need effective but costly new drugs, such as antiretroviral therapies for HIV/AIDS and psychotropic medications for mental health conditions. Moreover, Medicaid beneficiaries tend to have poorer health status and greater health needs than the general population.

Figure 2

Medicaid Prescription Drug Spending, 1998



Total = $14.5 billion*

* 8.2% of total Medicaid spending on services. Includes both fee-for-service expenditures and estimated drug spending by managed care organizations
SOURCE: Urban Institute Estimates, 2000.

The data in the figures presented above are largely drawn from a recent Urban Institute analysis that presents national data on Medicaid expenditures for prescription drugs, the utilization of prescription drugs by Medicaid enrollees, and the growth in per enrollee spending on prescription drugs.[4] The purpose of this Policy Brief is to explain the way in which the Medicaid program purchases outpatient drugs on behalf of its beneficiaries, as well as the policy tools available to states to limit the rate of growth in spending on prescription drugs. The paper relies heavily on the results of an extensive survey undertaken for prepared for

[4] Bruen, B., Urban Institute, *Medicaid and Prescription Drugs: An Overview* (October 2000), and 2001 update (forthcoming), Kaiser Commission on Medicaid and the Uninsured, www.kff.org

the Kaiser Commission on Medicaid and the Uninsured by Health Systems Research, Inc. [5]

State Medicaid programs have substantial flexibility in purchasing prescription drugs. In fact, there is no requirement that states include prescription drugs in their Medicaid benefit packages, although all have elected to do so.[6] Each state's Medicaid expenditures for prescription drugs are matched by the federal government on an open-ended basis at between 50 and 77 percent, depending upon the state. Because states have substantial flexibility in the coverage and purchase of prescription drugs, it is not surprising that there is large variation from state to state in policies and procedures. This paper describes the federal statutory and regulatory framework within which states design and implement their Medicaid prescription drug benefits, but it does not review the specific policies and procedures in effect in each state.

This paper begins by summarizing the flexibility available to state Medicaid agencies in designing a prescription drug benefit, controlling utilization, and paying for drug products. It then describes the program under which drug manufacturers provide rebates to both the federal and state governments for the products that Medicaid buys. In addition, the paper reviews efforts in Maine and Vermont to extend the price discounts achieved by the rebate program to non-Medicaid populations. Finally, the paper discusses two recent settlements between the federal government, states, and pharmaceutical manufacturers that have resulted in significant payments to state Medicaid programs in satisfaction of excess Medicaid payments for certain drug products.

The focus of this Policy Brief is on the purchase of outpatient prescription drugs by Medicaid[7] on a fee-for-service basis. The paper does not address the purchase of drugs on behalf of Medicaid beneficiaries institutionalized in hospitals, nursing facilities, or intermediate care facilities for the mentally retarded (ICFs/MR). Nor does it discuss the purchase of drugs by managed care organizations (MCOs) that have contracted with states to cover drugs for their Medicaid enrollees.[8] Finally, it does not discuss Medicaid policy relating to vaccines.

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[5] Schwalberg, R., et al., Health Systems Research, and Elam, L., Kaiser Commission on Medicaid and the Uninsured, *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights* (October 2001), www.kff.org.

[6] For an overview of state options with respect to Medicaid benefits, see Schneider, A., and Garfield, R., *Medicaid Benefits* (revised, December 2001), Kaiser Commission on Medicaid and the Uninsured, www.kff.org.

[7] For an overview of other federal drug purchasing programs, see von Oehsen, W., Ashe, M., and Duke, K., *Pharmaceutical Discounts under Federal Law: State Program Opportunities* (May 2001), Public Health Institute, http://www.picprogram.org.

[8] See GW Center for Health Services Research and Policy, *Optional Purchasing Specifications: Pharmaceutical Benefits and Services in Medicaid Managed Care* (December 2001), www.gwhealtpolicy.org.

State Flexibility in Prescription Drug Benefit Design

In general, states that elect to cover outpatient prescription drugs under their Medicaid programs must cover all FDA-approved drugs of every manufacturer that has entered into an agreement with the Secretary of HHS to pay rebates to states for the products they purchase.[9] Within this general framework, states have considerable flexibility to design their outpatient prescription drug benefit.

Allowable Exclusions. States may exclude a prescription drug from Medicaid coverage if it falls into one of the following eight categories: (1) anorexia, weight loss, or weight gain drugs; (2) fertility drugs; (3) cosmetic or hair growth drugs; (4) drugs for symptomatic relief of cough and colds; (5) smoking cessation drugs; (6) prescription vitamins and mineral products (other than prenatal vitamins and fluoride preparations); (7) barbiturates; and (8) benzodiazepines.[10] As of 2000, 40 of 44 Medicaid programs surveyed excluded one or more of these categories from their Medicaid prescription drug benefit[11] (Table 1). In addition, states may exclude a drug from coverage if the prescribed use is not for a medically accepted indication. [12]

Formularies. States may adopt formularies, or lists of drugs, that exclude from Medicaid coverage prescription drugs other than those in the eight categories above. The formulary must be developed by a committee of physicians, pharmacists, and others appointed by the Governor, and it must meet certain substantive requirements. First, a drug may only be excluded from a formulary if the drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome" over other drugs covered under the formulary with respect to the treatment of a specific disease or condition for an identified population.[13] Second, any drug excluded from a state's Medicaid formulary (other than a drug in one of the eight categories) must be covered through a prior authorization program described below.[14]

On September 18, 2001, the Secretary of HHS approved an amendment to Florida's state Medicaid plan to enable it to establish a formulary that excludes prescription drugs on a basis other than the absence of a "clinically meaningful therapeutic advantage." Instead, Florida may exclude from its formulary prescription drugs of manufacturers that do not agree to pay the state a

[9] Section 1902(a)(54) of the Social Security Act, 42 U.S.C. 1396a(a)(54).
[10] Section 1927(d)(1)(B)(ii) of the Social Security Act, 42 U.S.C. 1396r-8(d)(1)(B)(ii).
[11] Schwalberg, *op. cit*., Table 2. The programs include 43 states and the District of Columbia.
[12] Section 1927(d)(1)(B)(i) of the Social Security Act, 42 U.S.C. 1396r-8(d)(1)(B)(i).
[13] Section 1927(d)(4)(C) of the Social Security Act, 42 U.S.C. 1396r-8(d)(4)(C).
[14] Section 1927(d)(4)(D) of the Social Security Act, 42 U.S.C. 1396r-8(d)(4)(D).

Table 1

Specific Formulary Exclusions by State

State	Any Formulary Exclusions	Cosmetic and Hair-loss Drugs	Fertility/ Sexual Dysfunction Drugs	Anorexants/ Weight Control Drugs	Smoking Cessation Drugs	Investiga-tional Drugs	Other
United States Total	**40**	**36**	**30**	**32**	**18**	**22**	**15**
Alabama							
Alaska							
Arizona							
Arkansas	✔	✔	✔	✔	✔		Barbiturates, Benzodiazepines, Compounded
California							
Colorado							
Connecticut	✔	✔		✔	✔	✔	
Delaware	✔	✔	✔			✔	
District of Columbia	✔	✔	✔	✔			
Florida	✔			✔	✔	✔	
Georgia	✔	✔	✔	✔			
Hawaii	✔	✔	✔		✔	✔	
Idaho	✔	✔	✔	✔	✔	✔	
Illinois	✔	✔		✔			Biologicals and drugs available from Department of Health
Indiana	✔	✔	✔	✔		✔	
Iowa	✔	✔	✔	✔	✔		
Kansas	✔		✔				Benzodiazepines
Kentucky	✔	✔	✔	✔	✔		
Louisiana	✔	✔		✔		✔	
Maine	✔	✔		✔			Amphetamines
Maryland	✔	✔		✔			
Massachusetts	✔	✔	✔	✔	✔	✔	Vaccines from DPH
Michigan	✔	✔		✔		✔	
Minnesota	✔	✔	✔	✔			Amphetamines
Mississippi	✔	✔		✔	✔	✔	Barbiturates, Benzodiazepines
Missouri	✔	✔	✔	✔	✔		Benzodiazepines, Hemorrhoidal products, Oral analgesics
Montana	✔	✔	✔			✔	
Nebraska	✔	✔	✔	✔	✔	✔	
Nevada	✔		✔	✔		✔	Radiographic adjuncts, Radiopaque agents
New Hampshire	✔	✔	✔	✔			
New Jersey	✔	✔		✔		✔	Methadone
New Mexico	✔	✔	✔			✔	Barbiturates, Treatment of Tuberculosis
New York							
North Carolina	✔	✔	✔			✔	Vaccines
North Dakota	✔	✔	✔	✔			
Ohio							
Oklahoma							
Oregon	✔	✔	✔	✔		✔	
Pennsylvania	✔	✔	✔	✔	✔		
Rhode Island	✔	✔	✔		✔		
South Carolina	✔	✔	✔	✔	✔	✔	Injectables, Vaccines
South Dakota	✔	✔	✔	✔	✔	✔	
Tennessee							
Texas							
Utah	✔	✔	✔	✔	✔	✔	Cosmetic drugs, amphetamines
Vermont	✔			✔			
Virginia	✔	✔	✔			✔	
Washington	✔	✔	✔	✔	✔		
West Virginia	✔	✔	✔	✔			
Wisconsin							
Wyoming	✔	✔	✔	✔	✔	✔	Anabolic steroids

*SOURCE: Schwalberg, R., et al., Health Systems Research, and Elam, L., Kaiser Commission on Medicaid and the Uninsured, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights (KCMU, October 2001)

Notes Shaded states did not respond to survey

✔ *=product is excluded*

"supplemental" rebate in addition to the rebate required under the manufacturer's agreement with the Secretary. The drugs of manufacturers that do not agree to pay the additional rebate will be subject to prior authorization. Some manufacturers have negotiated rebate agreements with the state under which the manufacturer will, in lieu of paying the "supplemental" rebate, fund disease management and health literacy programs designed to generate a specified amount of Medicaid savings for the state.[15] The Pharmaceutical Research and Manufacturers of America (PhRMA) challenged Florida's formulary in federal court as a violation of federal Medicaid law.[16] According to PhRMA, as of August 2001, Florida's formulary includes only 821 of 1827 brand-name prescription drugs sold by manufacturers that have entered into rebate agreements with the Secretary of HHS; the remaining 1006 brand-name drugs are subject to prior authorization.[17]

Generic Substitution. As discussed above, federal Medicaid law generally prohibits states from excluding from coverage the brand name drugs of a manufacturer that has entered into a rebate agreement, regardless of the cost of those drugs. Federal Medicaid law does not, however, preclude states from requiring or encouraging the use of generic drugs covered under a state's Medicaid program in lieu of covered brand-name drugs. In 2000, 16 of 44 programs surveyed had in effect state legislation or regulations requiring pharmacists to substitute a generic drug for a prescribed brand-name drug when a generic equivalent is available (Table 2). In 7 of these states, the prescriber may override this substitution by writing "brand medically necessary" on the prescription.[18] In addition, as discussed below, states have the flexibility to encourage the use of generic drugs through differential copayments, differential dispensing fees, and differential payment rates.

Cost-sharing. States have the option of imposing "nominal" copayments on certain groups of Medicaid beneficiaries with respect to certain types of services.[19] Among the groups of Medicaid beneficiaries upon which states may impose copayments are elderly and disabled individuals who are not inpatients in hospitals or nursing facilities. Among the services to which copayments may be applied are prescription drugs. Under CMS regulations, a "nominal" copayment may range from 50 cents to $3.00, depending upon the cost of the item or service. In 2000, 28 of 44 Medicaid programs surveyed imposed copayments on prescription drugs; in 5 states, copayments imposed on brand-name drugs were higher than those imposed on generic drugs [20] (Table 3). Because providers that

[15] The development of the Florida Medicaid formulary is the subject of a forthcoming KCMU report based on case study research conducted by The Health Strategies Consultancy, LLC.
[16] *PhRMA v. Medows* (N.D. Fl., August 7, 2001).
[17] *PhRMA Backgrounder*, http://www.phrma.org/press/newsreleases//2001-08-07.255.phtml.
[18] Schwalberg, *op. cit*., Table 6.
[19] For a summary of Medicaid cost-sharing rules, see Hudman J. and O'Malley, M., *Cost Sharing and Premiums in Medicaid and CHIP Programs*, Kaiser Commission on Medicaid and the Uninsured (forthcoming).
[20] Schwalberg, *op. cit*., Table 7.

Table 2

State Medicaid Policies Regarding Use of Generics

State	Generics Required			Generics Encouraged				
	By State Law	May be Overridden With BMN	PA Required for BMN	Differential Copays	Differential Dispensing Fees	State Pays Generic Rate	Preferred Drug List	Provider Education
United States Total	**16**	**9**	**7**	**5**	**2**	**13**	**2**	**3**
Alabama							✔	
Alaska	✔	✔						
Arizona								
Arkansas						✔		
California	✔*							
Colorado								
Connecticut					✔			
Delaware						✔		✔
District of Columbia	✔		✔					
Florida	✔**							
Georgia			✔			✔		
Hawaii			✔			✔		
Idaho			✔					
Illinois								
Indiana	✔	✔		✔				
Iowa			✔					
Kansas								✔
Kentucky	✔	✔						
Louisiana							✔	
Maine				✔				
Maryland						✔		
Massachusetts								
Michigan						✔		
Minnesota	✔							✔
Mississippi								
Missouri			✔					
Montana		✔		✔		✔		
Nebraska								
Nevada	✔							
New Hampshire	✔			✔				
New Jersey	✔							
New Mexico						✔		
New York				✔	✔			
North Carolina	✔							
North Dakota								
Ohio								
Oklahoma								
Oregon								
Pennsylvania			✔			✔		
Rhode Island	✔	✔						
South Carolina	✔	✔†						
South Dakota		✔				✔		
Tennessee								
Texas								
Utah						✔		
Vermont	✔	✔						
Virginia						✔		
Washington						✔		
West Virginia	✔							
Wisconsin								
Wyoming	✔	✔						

*SOURCE: Schwalberg, R., et al., Health Systems Research, and Elam, L., Kaiser Commission on Medicaid and the Uninsured, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights (KCMU, October 2001)

Notes *BMN=brand medically necessary*

PA=prior authorization

** An exception may be made if a patient is allergic to the generic drug.*

*** Recipients are limited to four brand name drugs per month, with no limit on generics*

† The physician must write "substitution permitted" and the pharmacist must dispense the generic equivalent.

Table 3

Amount of Drug Copayments for Medicaid

State	Amount of Copayment
Alabama	Drug cost $0-$10 then $0.50 copay; $10.01-$25 then $1.00 copay; $25.01-$50.00 then $2.00 copay; >$50.00 then $3.00 copay
Alaska	$2.00
Arizona	
Arkansas	Drug cost $0-$10 then $0.50 copay; $10.01-$25 then $1.00 copay; $25.01-$50.00 then $2.00 copay; >$50.00 then $3.00 copay
California	Voluntary copay of $1.00
Colorado	
Connecticut	No copay
Delaware	No copay
District of Columbia	$1.00
Florida	No copay
Georgia	$0.50
Hawaii	No copay
Idaho	No copay
Illinois	No copay
Indiana	$0.50 to $3.00 for branded drugs and $0.50 for generic drugs
Iowa	$1.00
Kansas	$2.00
Kentucky	No copay
Louisiana	$0.50 to $3.00 depending on cost of drug
Maine	Sliding scale based on cost and brand vs. generic- $0.50 to $3.00
Maryland	$1.00
Massachusetts	$0.50
Michigan	$1.00
Minnesota	No copay
Mississippi	$1.00
Missouri	Drug cost $0-$10 then $0.50 copay; $10.01-$25 then $1.00 copay; >$25.00 then $2.00 copay
Montana	$1.00 for generic drugs and $2.00 for all others
Nebraska	$1.00
Nevada	No copay
New Hampshire	$0.50 for generic drugs and $1.00 for brand name drugs
New Jersey	No copay.
New Mexico	No copay
New York	$2.00 for brand-name drugs, $0.50 for generics and OTCs
North Carolina	$1.00
North Dakota	No copay
Ohio	
Oklahoma	
Oregon	No copay
Pennsylvania	$1.00
Rhode Island	No copay
South Carolina	$2.00
South Dakota	$2.00
Tennessee	
Texas	
Utah	$1.00 per prescription and a $5.00/month limit
Vermont	$1.00 for prescriptions under $30.00 and $2.00 for prescriptions over $30.00
Virginia	$1.00.
Washington	No copay
West Virginia	$0.50 for drugs under $10.00; $1.00 for drugs $10.01-$25; $2.00 for drugs >$25.00
Wisconsin	
Wyoming	$2.00

*SOURCE: Schwalberg, R., et al., Health Systems Research, and Elam, L., Kaiser Commission on Medicaid and the Uninsured, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights (KCMU, October 2001)

Notes *Shaded states did not respond to survey*

emergency services, family planning products and for categorically needy HMO enrollees.

elect to participate in Medicaid may not withhold an item or service from a beneficiary due to failure to pay a required copayment,[21] the imposition of copayments on low-income Medicaid beneficiaries for prescription drugs is often the functional equivalent of a reduction in reimbursement to the pharmacist.

State Flexibility in Utilization Management

States have broad flexibility under federal law in controlling the use of prescription drugs by Medicaid beneficiaries. In the case of beneficiaries enrolled in managed care organizations (MCOs) with which a state has contracted to provide prescription drugs, the MCO is essentially being paid to manage utilization of drugs and other covered services. In the case of beneficiaries on whose behalf Medicaid buys prescription drugs on a fee-for-service basis, states have a number of tools at their disposal to manage utilization. Not only may they impose nominal copayments on certain groups of beneficiaries, as discussed above, but they may also limit the number of prescriptions per month and impose prior authorization and "fail first" requirements. In addition, states are required to have in place drug utilization review (DUR) systems. Many states apply several of these tools simultaneously.

Amount, Duration and Scope Limitations. Federal Medicaid law gives states discretion to limit the amount, duration, and scope of any of the benefits they cover, so long as each benefit is "sufficient" to "reasonably achieve its purpose." States may also place "appropriate" limits on a service based upon "medical necessity."[22] And, in the case of prescription drugs, states may impose limits on the quantities per prescription or on the number of refills "if such limitations are necessary in order to discourage waste."[23] A 2000 survey found that, of 44 Medicaid programs responding, all but one imposed one or more limits on prescriptions (Table 4). The most common limitations were on the amount of medication per prescription (e.g., 30 or 34 day supply), the number of refills (e.g., 5 within 6 months), and the number of prescriptions (e.g., 6 per month).[24]

Prior Authorization and "Fail First" Requirements. States may require prescribers to obtain approval from the state Medicaid agency (or a subcontractor) prior to the dispensing of the drug by a pharmacist. States may impose such prior authorization requirements on one or more individual drug or on all drugs in one or more therapeutic classes. (As discussed above, if a state elects to establish a formulary, any drug product excluded from the formulary must be available through prior authorization).

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[21] Section 1916(e) of the Social Security Act, 42 U.S.C. 1396o(e).
[22] 42 C.F.R. 440.230.
[23] Section 1927(f)(6) of the Social Security Act, 42 U.S.C. 1396r-8(f)(6).
[24] Schwalberg , *op. cit*., Table 5.

Table 4

State Medicaid Programs' Limits on Prescriptions

State	Limits on Prescriptions	Amount of medication per prescription	Number of refills	Number of prescriptions	Total expenditure
United States Total	**41**	**40**	**24**	**12**	**1**
Alabama	✔	30 days	5		
Alaska	✔	30 days	not before 23 days		
Arizona					
Arkansas	✔	30 days	5 within 6 months	3/month	
California	✔	100 days or 100 units		6/month w/o PA	
Colorado					
Connecticut	✔	240 units	5 or 6 mo for controlled subs		
Delaware	✔	34 days or 100 units			
District of Columbia	✔	30 days for maintenance drugs	3 within 4 months for maintenance drugs		$1500 limit for 30-day supply
Florida	✔	1 therapeutic class/month*	1 year's worth	4 for brand, unlimited for generic	
Georgia	✔	30-31 days		5/month w/o PA	
Hawaii	✔	30 days or 100 units			
Idaho	✔	34 days***			
Illinois	✔		11	varies by drug	
Indiana					
Iowa					
Kansas	✔	34 days	1 year's worth		
Kentucky	✔	30 days	5 within 6 months		
Louisiana	✔	30 days or 100 units	5 within 6 months	limit on Viagra only (6/month)	
Maine	✔	30 days	12 within 12 months		
Maryland	✔	34 days***	2 on one script		
Massachusetts	✔	30 days **	5 within 6 months		
Michigan	✔	100 days			
Minnesota	✔	3 months			
Mississippi	✔	34 days or 100 units	5	10/month	
Missouri	✔	90 days			
Montana	✔	34 days or 100 units			
Nebraska	✔	90 days			
Nevada	✔	34 days		6/month	
New Hampshire	✔	34 days or 100 units	once every 34 days		
New Jersey	✔	34 days or 100 units	5 within 6 months		
New Mexico	✔	34 days	3 within 70 days		
New York	✔	varies by drug	5 within 6 months	43/year	
North Carolina	✔	100 days		6/month	
North Dakota	✔	34 days			
Ohio					
Oklahoma					
Oregon	✔	34 days			
Pennsylvania	✔	34 days or 100 units	5 within 6 months		
Rhode Island	✔	1 month or 100 units	5 for maintenance drugs		
South Carolina	✔	100 days for maintenance drugs		4/month	
South Dakota					
Tennessee					
Texas					
Utah	✔	1 month			
Vermont	✔	60 days	5		
Virginia	✔	30 days or 100 units			
Washington	✔	34 days	2 within 30 days, with exceptions		
West Virginia	✔	varies by drug	1 for specific drug types	10/month w/o PA	
Wisconsin					
Wyoming	✔	30 days (90 for maintenance)	One year's worth		

*SOURCE: Schwalberg, R., et al., Health Systems Research, and Elam, L., Kaiser Commission on Medicaid and the Uninsured, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights (KCMU, October 2001)

Notes *Shaded states did not respond to survey*

**For anti-ulcer, anti-anxiety, and sedative hypnotic drugs.*

***For controlled substances (schedule II and III) only.*

**** 100 days for maintenance drugs*

This flexibility is subject to two statutory requirements. First, a state's prior authorization system must provide for a response, by telephone or otherwise, within 24 hours of a request. Secondly, the system must make at least a 72-hour supply of the requested drug available in an emergency situation.[25] A 2000 survey found that, of 44 programs responding, 36 imposed prior authorization requirements on one or more types of drugs, most commonly on growth hormone, impotence treatments, Retin-A and Accutane, amphetamines, anorexants, and non-steroidal anti-inflammatory drugs [26] (Table 5).

One variant of prior authorization controls is known as "fail first," also referred to as "step therapy." Under this control, a physician must demonstrate that the alternative therapy is ineffective for a patient before a prescription for a newer, more costly drug will be approved. As in the case of other prior authorization programs, these "fail first" requirements can be applied to one or more individual drugs and to one or more classes of drugs. Of the 44 Medicaid programs responding to the 2000 survey, 11 and the District of Columbia reported imposing "fail first" requirements on one or more drugs (Table 6).

Drug Utilization Review (DUR). All states are required to have drug utilization review (DUR) programs for outpatient drugs to ensure that prescriptions paid for by Medicaid are appropriate, medically necessary, and not likely to result in adverse medical outcomes. DUR programs must include both prospective and retrospective review. Prospective DUR involves a review of each prescription before it is filled to screen for potential drug therapy problems, including drug-drug interactions and clinical abuse. Retrospective DUR involves as review of claims data to identify fraud, abuse, or inappropriate or medically unnecessary care among physician prescribing patterns.[27] States report that DUR programs can produce significant savings: 10 of the 44 programs responding to the 2000 survey cited prospective DUR as a major cost containment strategy.[28]

State Flexibility in Payment

In the case of outpatient prescription drugs that a state purchases on a fee-for-service basis, the price that the state pays is determined by three amounts: (1) the amount the state pays the pharmacist for the drug product itself; (2) the fee the state pays the pharmacist for dispensing the drug; and (3) the rebate the state receives from the manufacturer for purchasing the drug. States have considerable discretion in determining the amounts they pay pharmacists for individual drug products as well as the dispensing fees. This state flexibility is the subject of this section. The rebate amount that each state receives for the

[25] Section 1927(d)(5) of the Social Security Act, 42 U.S.C. 1396r-8(d)(5).
[26] Schwalberg , *op. cit*., Table 3.
[27] Section 1927(g)(2) of the Social Security Act, 42 U.S.C. 1396r-8(g)(2).
[28] Schwalberg, op.cit., p. 11.

Table 5
Prescription Drugs Requiring Prior Authorization by State

State	Any prior author-ization	Growth Hormones	Impotence Agents	Retin-A/ Accutane	Anor-exants	Amphet-amines	NSAIDs	OTCs	Anti-ulcer/-reflux	Vita-mins	Antihist-amines	Smoking Cessa-tion	Dipyrid-amole	Benzo-diaze-pines	Other
United States Total	**36**	**17**	**18**	**12**	**14**	**10**	**9**	**8**	**13**	**7**	**7**	**8**	**5**	**4**	**27**
Alabama	✔	✔	✔	✔			✔		✔		✔		✔		Synagis, Enbrel, renal dialysis products, drugs for which OTC exists, nutritional supplements, anabolic steroids, stool softeners/laxatives, Persantine, Tranxene
Alaska	✔	✔													Clozapine, Lupron-depot, Panretin, Actiq, calcium, naltrexone
Arizona															
Arkansas	✔		✔				✔		✔		✔				Toradol, Cataflam
California															
Colorado															
Connecticut															
Delaware	✔	✔			✔										Regranex
District of Columbia	✔						✔		✔						
Florida	✔														Various chemotherapy agents
Georgia	✔			✔		✔			✔		✔				All brand name drugs, anabolic steroids, duplicate therapies for antidepressants, drugs for renal disease, interferons
Hawaii	✔	✔			✔		✔	✔	✔	✔	✔				Clozaril, Procardia XL, Norvasc, Various chemotherapy agents, Betaseron
Idaho	✔	✔		✔		✔									Amphetamines, retinoids, brands when generic is available
Illinois															
Indiana															
Iowa	✔	✔	✔	✔		✔	✔			✔	✔		✔		Ergotamine derivatives, anti-fungal, vasopressin derivatives, serotonin agonists, epoetin, filgrastim
Kansas	✔	✔	✔	✔	✔	✔			✔ *					✔	Synagis, Regranex, tuberculosis agents, decubitis/wound care products
Kentucky	✔				✔			✔							Cough and cold, controlled substances, injectables, topicals
Louisiana															
Maine	✔							✔							Controlled substances
Maryland	✔														Any prescription exceeding $400, early refills, excessive quantities, and nutrition supplements
Massachusetts	✔	✔	✔		✔			✔	✔			✔		✔	Ritalin, Enbrel, Synagis, epoetin, filgrastim, Botox, Synvisc, Hyalgan, Zyvox, alglucerace, a-1 proteinase inhibitor, nutritional supplements, Herceptin, immune globulins, Remicade, alosetron
Michigan	✔	✔	✔	✔	✔	✔ **			✔ †			✔	✔		Addeall, methylphenidate (Ritalin)
Minnesota	✔								✔						Epoetin, filgrastim, interferons, Declomycin, granisetron, Saranostim, alglucerase, botulinum toxin
Mississippi	✔	✔	✔				✔							✔	Sandimmune, Clozaril, Humatrope
Missouri	✔		✔	✔											
Montana	✔	✔	✔	✔	✔		✔		✔		✔	✔	✔	✔	Migraine drugs, Aggrenox, Trental, Isoetherine, isoproterenol, Ambien, Sonata, Arava, Enbrel, thalidomide, Zoloft, Remicade
Nebraska	✔	✔	✔												Sunscreens, modified versions of allowed drugs, erythropoietin, convenience drugs/supplies, respiratory syncytial virus prophylaxis

Table 5
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United States Total	**36**	**17**	**18**	**12**	**14**	**10**	**9**	**8**	**13**	**7**	**7**	**8**	**5**	**4**	**27**
Nevada	✔	✔				✔				✔		✔	✔		Stool softeners/laxatives, Ritalin, aspirin, Betaseron, chorionic gonadotropin, Cognex, egoloid meslates, Ethatab, glucose blood test strips, papaverine, Pemoline, Pulmozyme, Quinine, Aricept
New Hampshire															
New Jersey	✔				✔										Methadone, nutritional supplements
New Mexico	✔				✔	✔		✔							
New York	✔		✔									✔			
North Carolina	✔		✔												
North Dakota	✔				✔							✔			Nutritional supplements
Ohio															
Oklahoma															
Oregon	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔				Stool softeners/laxatives, anti-fungal, cosmetic indications, nasal inhalers
Pennsylvania	✔		✔						✔						
Rhode Island	✔		✔		✔					✔					Hematinics
South Carolina	✔		✔	✔		✔		✔		✔					
South Dakota	✔	✔													Clozapine
Tennessee															
Texas															
Utah	✔	✔		✔	✔	✔									Enbral, Regranex, Aggrenox, Cerezyme, Darvocet, Lovenox, Lufyllin, Oxandrin, Prolastin, Relenza, Tamiflu, Zofran
Vermont	✔		✔					✔		✔		✔			
Virginia	✔				✔										
Washington															
West Virginia	✔	✔	✔	✔			✔		✔			✔			Most injectables
Wisconsin															
Wyoming															

*SOURCE: Schwalberg, R., et al., Health Systems Research, and Elam, L.,
Kaiser Commission on Medicaid and the Uninsured, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights (KCMU, October 2001)

Notes *Shaded states did not respond to survey*

a=product requires prior authorization

**PA required after 60 days of continuous use*

***PA required for patients under age 6 or over age 18*

†PA required for acute dosing greater than 102 days

dipyridamole is an oral anticoagulant

Table 6

Fail-First Requirements for Drugs and/or Classes of Drugs by State

State	Fail-First Requirement?	Drug and/or Class of Drug
United States Total	**12**	
Alabama		
Alaska		
Arizona		
Arkansas	✔	Rogaine; Apligraf; Xenical; Remicade; Enbrel; Zyvox
California		
Colorado		
Connecticut		
Delaware		
District of Columbia	✔	Brand medically necessary
Florida		
Georgia		
Hawaii		
Idaho		
Illinois		
Indiana		
Iowa	✔	NSAIDs; antihistamines; proton pump inhibitors;Tretinoin
Kansas		
Kentucky	✔	All non-prior authorization drugs and antihistamines
Louisiana		
Maine	✔	Controlled substances
Maryland		
Massachusetts		
Michigan		
Minnesota	✔	Proton-pump inhibitors (must try H2 blocker first)
Mississippi	✔	NSAIDs
Missouri		
Montana	✔	Benzodiazepines; NSAIDs
Nebraska		
Nevada		
New Hampshire		
New Jersey		
New Mexico		
New York		
North Carolina		
North Dakota		
Ohio		
Oklahoma		
Oregon		
Pennsylvania		
Rhode Island		
South Carolina		
South Dakota		
Tennessee		
Texas		
Utah	✔	Growth hormones; Xenical
Vermont		
Virginia	✔	Anti-ulcer drugs
Washington	✔	List not provided
West Virginia	✔	NSAIDs
Wisconsin		
Wyoming		

*SOURCE: Schwalberg, R., et al., Health Systems Research, and Elam, L., Kaiser Commission on Medicaid and the Uninsured, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights (KCMU, October 2001)

purchase of a particular drug is determined by a statutory formula under federal law that is the subject of the next section.

Payment Ceilings. Federal Medicaid law does not impose a "floor" or minimum payment standard that states must follow in paying pharmacists for the prescription drugs they dispense to Medicaid beneficiaries. Federal law does, however, impose ceilings on the payment amounts that the federal government will match. There are two ceilings: Estimated Acquisition Cost (EAC) and Federal Upper Limit (FUL). The former applies to brand name drugs and drugs with less than 3 generic versions rated therapeutically equivalent; the latter applies to drugs with 3 or more generic versions. Both ceilings apply in the aggregate, not on a drug-by-drug basis.

Estimated Acquisition Cost (EAC). In the case of brand-name drugs (e.g., drugs that are still under patent) and multiple source drugs (e.g. drugs with expired patents) that are not subject to the FUL described below, Medicaid payment may not exceed the lesser of:

(1) The drug's estimated acquisition cost (EAC) plus a dispensing fee; or

(2) The provider's usual or customary charges to the general public.[29]

In almost all cases the ceiling amount is the EAC plus dispensing fee.

The EAC for a particular drug is "the agency's best estimate of the price generally and currently paid by providers for the drug … in the package size of drug most frequently purchased by providers." A 2000 survey found that of 44 programs responding, all but three used the Average Wholesale Price (AWP) of a drug to determine its EAC. As explained by the Government Accounting Office (GAO), the AWP of a drug is essentially the price the manufacturer suggests that wholesalers charge retail pharmacists: "The term AWP is not defined in law or regulation, so the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers. Manufacturers periodically report AWPs to publishers of drug pricing data, such as the Medical Economics Company, Inc., which publishes the Red Book, and First Data Bank, which compiles the National Drug Data File."[30]

Because the actual acquisition costs incurred by pharmacists or physicians in purchasing a drug are often substantially below AWP, most states pay at a percentage discount from listed AWPs. Table 7 shows the payment methodologies used by the 44 responding programs, ranging from AWP minus 4 percent in Wyoming to AWP minus 15.1 percent in Michigan.[31] Because the

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[29] 42 C.F.R. 447.331(b).

[30] GAO, *Medicare Part B Drugs: Program Payments Should Reflect Market Prices* (September 21, 2001), GAO-01-1142T, p. 4.

[31] The three responding states that do not use a drug's AWP to determine the EAC for the drug use Wholesale Average Cost (WAC), which reflects the average price that wholesalers pay manufacturers for the product. A drug's WAC, like its AWP, is determined by the manufacturer. See General Accounting Office, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost* (September 2001), GAO-01-1118, p. 23.

Table 7

Medicaid Payment Rates for Five Commonly Prescribed Drugs by State (2000)

State	Formula	Premarin 00046-0867-81	Prilosec 00186-0743-31	Trimox 00003-0101-50	Zocor 00006-0735-61	Prozac 00777-3105-02
Alabama	WAC+9.2%*	$49.59	$155.03	$20.78	$113.83	$229.75
Alaska	AWP-5	$54.15	$169.29	$22.70	$124.35	$250.88
Arizona						
Arkansas	AWP-10.5	$51.02	$159.49	$21.38	$117.15	$236.35
California	AWP-5	$54.15	$169.29	$22.70	$124.35	$250.88
Colorado						
Connecticut	AWP-12	$50.16	$156.82	$21.02	$115.18	$232.39
Delaware	AWP-12.9	$49.65	$155.21	$20.81	$114.01	$230.01
District of Columbia	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Florida	AWP-11.5	$50.45	$157.71	$21.14	$115.84	$233.71
Georgia	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Hawaii	AWP-10.5	$51.02	$159.49	$21.38	$117.15	$236.35
Idaho	AWP-11	$50.73	$158.60	$21.26	$116.49	$235.03
Illinois	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Indiana	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Iowa	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Kansas	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Kentucky	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Louisiana	AWP-10.5	$51.02	$159.49	$21.38	$117.15	$236.35
Maine	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Maryland	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Massachusetts	WAC+10*	$49.60	$155.01	$20.78	$113.87	$229.74
Michigan	AWP-15.1	$48.39	$151.29	$20.28	$111.13	$224.20
Minnesota	AWP-9	$51.87	$162.16	$21.74	$119.11	$240.31
Mississippi	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Missouri	AWP-10.43	$51.05	$159.61	$21.40	$117.24	$236.54
Montana	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Nebraska	AWP-8.71	$52.04	$162.68	$21.81	$119.49	$241.08
Nevada	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
New Hampshire	AWP-12	$50.16	$156.82	$21.02	$115.18	$232.39
New Jersey	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
New Mexico	AWP-12.5	$49.88	$155.93	$20.90	$114.53	$231.07
New York	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
North Carolina	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
North Dakota	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Ohio						
Oklahoma						
Oregon	AWP-11	$50.73	$158.60	$21.26	$116.49	$235.03
Pennsylvania	AWP-10	$51.30	$160.38	$21.50	$117.80	$237.67
Rhode Island	WAC+5*	$47.87	$149.71	$20.07	$109.95	$221.83
South Carolina	AWP-13	$49.59	$155.03	$20.78	$113.87	$229.75
South Dakota	AWP-10.5	$51.02	$159.49	$21.38	$117.15	$236.35
Tennessee						
Texas						
Utah	AWP-12	$50.16	$156.82	$21.02	$115.18	$232.39
Vermont	AWP-11.9	$50.22	$156.99	$21.05	$115.31	$232.65
Virginia	AWP-9	$51.87	$162.16	$21.74	$119.11	$240.31
Washington	AWP-11	$50.73	$158.60	$21.26	$116.49	$235.03
West Virginia	AWP-12	$50.16	$156.82	$21.02	$115.18	$232.39
Wisconsin						
Wyoming	AWP-4	$54.72	$171.07	$22.93	$125.65	$253.52

*SOURCE: Schwalberg, R., et al., Health Systems Research, and Elam, L., Kaiser Commission on Medicaid and the Uninsured, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights (KCMU, October 2001)

Notes *Rates are estimates based on equivalent AWP-based formula

n/a=information not available

AWP - Average Wholesale Price

WAC - Wholesale Acquisition Cost

Shaded states did not respond to survey

federal government matches the state payment regardless of the amount of the discount from AWP used by the state, the Medicaid price paid by the federal government for the same drug can vary from state to state. For example, the cost of Zocor to Medicaid in Michigan (AWP-15.1 percent) is $111.13; the price in Wyoming (AWP-4 percent) is $125.65. The Office of Inspector General has estimated that in 1999, the average state discount from AWP was 10.31 percent, compared with an actual acquisition cost to pharmacies of 21.84 percent below AWP.[32] The difference is retained by pharmacies.

Federal Upper Limit (FUL). There is a group of multiple source drugs to which a payment ceiling different from the EAC applies. These drugs, referred to as Federal Upper Limit, or FUL drugs, are available in at least three therapeutically equivalent generic versions. The payment ceiling for each drug is set at 150 percent of the published price for the least costly therapeutic equivalent that can be purchased by pharmacists in quantities of 100 tablets or capsules.[33] CMS periodically revises the list of FUL drugs.[34] The FUL payment ceiling does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular patient by using a notation like "brand necessary."[35] Examples of FUL drugs include furosemide, a diuretic used in the treatment of edema and hypertension; albuterol, a treatment for asthma and other obstructive lung diseases; and amoxicillin, an antibiotic. States have the flexibility to establish their own payment ceilings for multiple source drugs, so long as these do not exceed the federal payment ceiling for FUL drugs. A 2000 survey by the National Pharmaceutical Council found that 23 states applied their own Maximum Allowable Cost (MAC) limits to multiple source drugs.[36]

Dispensing Fees. Both of the drug-specific payment ceilings described above expressly allow for (but do not require) the payment to the pharmacist of a "reasonable" dispensing fee established by the state Medicaid agency. CMS regulations do not define "reasonable" for this purpose. A 2000 survey found wide variation among the states in the amount of dispensing fees and the

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[32] The OIG estimated that if all states paid AWP minus 21.84 percent on average for the 200 drugs most commonly purchased by Medicaid in 2000, the savings to federal and state governments would exceed $1 billion per year. Office of Inspector General, *Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products* (August 10, 2001) (A-06-00-00023) http://oig.hhs.gov/oas/reports/region6/60000023.htm

[33] 42 C.F.R. 447.332(b).

[34] The most recent version of the FUL Price List (April 2000) is published as Addendum A to Part 6 (Payment for Services) of the *State Medicaid Manual*,www.hcfa.gov/medicaid/drugs/drug10.htm

[35] 42 C.F.R. 447.331(c).

[36] The state MAC limits vary from state to state and do not necessarily apply to the same drugs as those listed by CMS for purposes of the FUL limits. See *Pharmaceutical Benefits Under State Medical Assistance Programs* (2001) National Pharmaceutical Council, pp. 4-16, 4-52. An example of a state MAC limit is Maryland's, which applies to a brand name drug with at least two therapeutic equivalents. The state pays the lesser of EAC, the FUL, or its state MAC, which is set at the higher of the two lowest wholesale average costs paid by the two largest wholesalers in the state. Maryland Regulations Code Title X, section 10.09.03.01(18).

manner in which they are determined (Table 8). Fees in the 44 reporting Medicaid programs ranged from $2.50 to $15.70 per prescription. States may negotiate these fees with providers as part of the budget process (e.g. Illinois).[37]

Manufacturer Rebates

The price that a state Medicaid program pays for a prescription drug on a fee-for-service basis is effectively reduced by a rebate that the manufacturer of the drug is required to pay to the state. (Manufacturers are not required to pay rebates to Medicaid MCOs that cover prescription drugs, as it is assumed they can obtain their own discounts). State Medicaid programs only receive federal matching payments for the costs of those drugs produced by manufacturers that have entered into an agreement with the Secretary of HHS to provide rebates to states for the drugs they purchase on an outpatient basis.[38] In exchange for agreeing to give rebates, manufacturers are guaranteed that state Medicaid programs will cover their drug products. The states and the federal government share in the rebates in proportion to their share of the cost of the drug product.[39]

As discussed above, states can exclude certain categories of drugs (e.g., barbiturates) from coverage altogether; however, any drug of a participating manufacturer not in one of these categories must be covered (although it may be subjected to a prior authorization requirement). About 500 manufacturers have entered into master agreements with the Secretary covering some 56,000 drug products.[40]

As shown in Figure 4, the Medicaid rebate program returned $19.8 billion to federal and state treasuries between its inception in 1991 and 2000. The Urban Institute reports that the rebate program has reduced Medicaid fee-for-service drug spending by about 17 percent each year since 1996.[41]

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[37] Schwalberg, *op cit*., Table 14.

[38] The manufacturer is also required to (1) enter into an agreement with the Secretary of HHS to provide rebates on covered outpatient drugs to community health centers funded under the Public Health Service Act and other specified providers and (2) to enter into a master agreement with the Secretary of Veterans Affairs to furnish discounted prices on its products to the VA. Section 1927(a)(1) of the Social Security Act, 42 U.S.C. 1396r-8(a)(1).

[39] Participating manufacturers pay the rebates to the states; the rebate payments received by a state in a quarter are treated as a reduction in the Medicaid spending for which the state claims federal matching funds for that quarter. Section 1927(b)(1)(B) of the Social Security Act, 42 U.S.C. 1396r-8(b)(1)(B). In some states, the rebate payments are credited to the state's Medicaid program, in others to other accounts.

[40] http://www.hcfa.gov/medicaid/drugs/drughmpg.htm.

[41] Bruen, *op. cit*., p. 6.

Table 8

Dispensing Fees by State

State	Dispensing Fee 1	Dispensing Fee 2	Notes
Alabama	$5.40 for retail	$3.99 for institutions	
Alaska	$3.45 - $11.46		
Arizona			
Arkansas	$5.51		
California	$4.05		State law subtracts $0.25 from every claim, so the fee becomes $3.80
Colorado			
Connecticut	$4.10 for brand	$4.60 for voluntary generic substitution	
Delaware	$3.65		
District of Columbia	$3.75		
Florida	$4.23		
Georgia	$4.63	$4.33 for non-profit health systems	
Hawaii	$4.67		Fee-for-service
Idaho	$4.94 for regular dose	$5.54 for unit dose	
Illinois	$3.69 to $15.40 for brand	$3.69 to $15.70 for generic	Fees are negotiated with providers as part of the budget process
Indiana	$3.92		$3.92 represents the average fee; $4.00 is the maximum
Iowa	$4.13 for generics	$6.42 for brand	
Kansas	$4.95		This figure represents an average fee; a flat fee of $4.50 was instituted on 8/1/00
Kentucky	$4.75 for outpatient	$5.75 for LTC patients	
Louisiana	$5.77		
Maine	$3.35 to $5.35		Fee ranges depending on whether it is a single-ingredient or compound drug
Maryland	$4.21		
Massachusetts	$3.00		
Michigan	$3.72		
Minnesota	$3.65	$8.00 for compound drugs	$30 for TPN 1L bag; $44 for 2L or more; $14 for IV chemotherapy compound preparation
Mississippi	$4.91		
Missouri	$4.09	$4.24 for long term care	
Montana	$2.00-$4.20		An additional $.75 paid to pharmacies if they dispense in a unit
Nebraska	$2.85	$5.05	
Nevada	$4.76		
New Hampshire	$2.50		
New Jersey	$3.73 to $4.07		Base is $3.73. Pharmacists can add $0.15 for regression, $0.08 for pharmaceutical consultation (now mandatory by state law) and $0.11 for 24-hour availability. Most pharmacies qualify for the $4.07 fee.
New Mexico	$4.00		
New York	$3.50 for brand	$4.50 for generic	
North Carolina	$5.60		Pharmacists can only bill this dispensing fee once a month for each prescription.
North Dakota	$4.60		
Ohio			
Oklahoma			
Oregon	$3.91-$4.28		
Pennsylvania	$4.00		
Rhode Island	$3.40	$2.85 for nursing home patients	
South Carolina	$4.05		
South Dakota	$4.75 to $5.55		
Tennessee			
Texas			
Utah	$3.90 in urban areas	$4.40 in rural areas	
Vermont	$4.25		
Virginia	$4.25		
Washington	$3.90 to $4.82		Fee depends upon the number of prescriptions filled annually by pharmacy
West Virginia	$3.90 for single-ingredient	$4.90 for compound prescriptions	
Wisconsin			
Wyoming	$4.70		

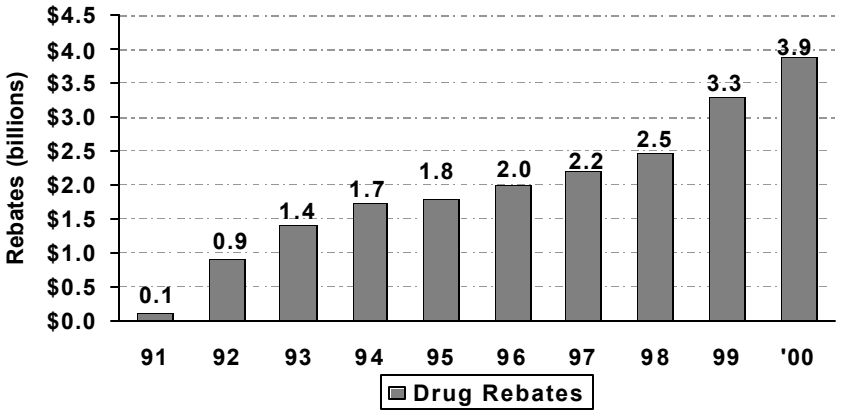
*SOURCE: Schwalberg, R., et al., Health Systems Research, and Elam, L., Kaiser Commission on Medicaid and the Uninsured, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights (KCMU, October 2001)

Notes n/a=information not available

Shaded states did not respond to survey

Figure 4

Medicaid Drug Rebates, 1991-2000



Source: Urban Institute estimates (2000) based on data from HCFA-64 reports.
Note: Rebates for fee-for-service, outpatient drugs only.

The rebate amount owed by a manufacturer on any given drug is determined by a federal statutory formula. Each state that purchases the manufacturer's drug gets the same rebate amount on each unit of the drug it purchases, regardless of the price that the state pays the pharmacist for the drug. Thus, even after the rebates are taken into account, the net prices paid by states for the same drug will vary whenever the prices that states pay pharmacies for the products vary. The rebate amount for each drug is calculated based upon pricing data reported to CMS on a confidential basis by each manufacturer every quarter. This pricing data relates to average manufacturer price (AMP) and "best price," discussed below. States report to the manufacturers the number of units of each of the manufacturer's drugs that the state purchases on an outpatient basis during the quarter; manufacturers are then required to remit the appropriate rebate amounts to each state.

Generic Drugs. In the case of generic ("non-innovator multiple source") drugs, the rebate amount is determined by multiplying the average manufacturer price (AMP) for the drug by 11 percent. The AMP is the average price paid to the manufacturer for the drug by wholesalers for distribution to the retail pharmacy class of trade, after deducting customary prompt payment discounts. Thus, AMP is almost always lower than AWP, which approximates the retail price that the manufacturer suggests. (As discussed above, the pricing information used to determine AMP is confidential.)

Brand-Name Drugs. The rebate formula for brand-name drugs is far more complex. It has two elements: (1) a basic rebate, which is intended to secure for Medicaid the same price discounts as many (but not all) other large purchasers receive; and (2) an additional rebate, which is intended to protect Medicaid against price increases that exceed the rate of increase in the consumer price index (CPI-U).

Basic Rebate. The basic rebate for a "single-source" or "innovator multiple source" drug is the greater of:

(1) 15.1 percent of the AMP for the drug; or

(2) the difference between the AMP for the drug and the manufacturer's "best price" for the drug.

The manufacturer's "best price" for the drug is the lowest price at which the manufacturer will supply the drug to any wholesaler, retailer, provider, HMO, or nonprofit or governmental entity in the U.S. "Best price" does not include prices at which the manufacturer sells the drug to the Department of Veterans' Affairs (the Federal Supply Schedule, or FFS price)[42], the Indian Health Service, state pharmaceutical assistance programs, community health centers, and certain other purchasers. The purpose of excluding these prices from the "best price" calculation is to enable these purchasers to obtain more favorable prices from manufacturers than Medicaid receives.[43] For example, the AWP for Prilosec, an anti-ulcer drug, is $124.18 for 30 capsules (20-mg.); the FSS price, which is excluded from the "best price" calculation, is $60.75.[44] The AMP is confidential.

Additional Rebate. The additional rebate for a "single-source" or "innovator multiple source" drug is the amount by which:

(1) the manufacturer's AMP for the drug in the calendar quarter for which the rebate is being calculated exceeds:

(2) the AMP for the drug for the July 1, 1990 calendar quarter increased by the percentage increase in the consumer price index (CPI-U) since that time. (For new drugs, the AMP for this portion of the calculation is the AMP during the first calendar quarter after the drug was first marketed).

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[42] The FSS price, administered by the Department of Veterans Affairs, is the price available to VA, I.H.S., and other federal entities that purchase prescription drugs. The FFS price is equal to or better than the price offered by the manufacturer to it most-favored nonfederal customer under comparable terms and conditions. 48 C.F.R. 538.270.

[43] "The significance of the 'best price' exemptions under OBRA '90 cannot be overstated. Without the exemption, a purchaser cannot hope to negotiate a price better than Medicaid 'best price.' If the purchaser could, its discounted price would, by definition, become the new Medicaid 'best price.' The manufacturer would then have to pay larger rebates to the entire Medicaid program. The net effect is that, for each brand name drug marketed in the U.S., 'best price' becomes a floor on price negotiations for every purchaser save those whose prices have been statutorily excluded from 'best price.'" von Oehsen, *op. cit.*, page 21.

[44] Special Investigations Division, Minority Staff, House *Committee on Government Reform, Prescription* Drug Pricing in the 37th Congressional District in California (May 2001), Appendix B.

Note that for drugs approved by the FDA for marketing on or before October 1, 1990, the additional rebate captures price increases above CPI in the AMP for each drug for the calendar quarter beginning July 1, 1990. However, for "new" drugs – i.e., those first approved by the FDA after October 1, 1990 -- increases in the AMP are measured from the "launch price" set by the manufacturer, which is not constrained in any manner by the rebate formula.

How Medicaid Gets Its Price: An Example

The following example illustrates the interaction between the price a state decides to pay the pharmacist for a covered outpatient drug and the rebate that the federal government commands from manufacturers on behalf of all states. In this simplified example, which involves a brand name drug, the state pays AWP-10 percent, and the manufacturer discounts the drug fairly steeply to certain purchasers, resulting in a "best price" that is $45 below the AWP. The Medicaid program receives more than the minimum rebate (15.1 percent of AMP or $11) but even after the rebate pays $70 (not including the dispensing fee), or $15 more than the "best price" of $55 paid by more favored purchasers.

Medicaid's Purchase of a Brand Name Drug

Average Wholesale Price (AWP).....$100

Average Manufacturer Price (AMP)... $ 80

Best Price..... $ 60

State Purchase Price (AWP-$10).....$ 90

Less: Manufacturer's Rebate ($20) *...$ 70

Plus: Dispensing Fee ($3) ..... $ 73

If the state's federal matching rate is 50 percent, the state and the federal government each pay $36.50.

*Rebate amount is greater of:
(1) 15.1 percent of AMP ($16.61), or
(2) difference between AMP and Best Price ($20).

Example assumes AMP did not increase faster than CPI-U.

Estimates by Stephen Schondelmeyer at the University of Minnesota are that, based on price data for 1996, the AMP averages 80 percent of AWP, and the minimum rebate (15.1 percent of AMP) is 67.9 percent of AWP. The Medicaid net price – i.e., the price effectively paid by Medicaid programs after taking into account "best price" (in cases where that is deeper than 15.1 percent of AMP) and the adjustment for inflation at a rate of increase faster than CPI-U which is estimated at 60.5 percent of AWP.[45]

State Supplemental Rebates. The federal Medicaid statute allows states to maintain rebate agreements with manufacturers in effect as of the enactment of the federal rebate program in 1990, if those rebates are "at least as large" as the federally prescribed rebates.[46] This exemption allows California to continue to operate its supplemental rebate program, under which manufacturers pay rebate amounts in addition to those required under federal Medicaid law in order to keep their drugs off the state's prior authorization list.[47] Federal law does not expressly authorize or prohibit states that do not have pre-1990 rebate agreements to negotiate supplemental rebates with manufacturers. As discussed above, Florida has received approval from the Secretary to implement a supplemental rebate program, and the matter is in litigation.

Extending Medicaid Purchasing Leverage to Other Populations. Although the discounts Medicaid achieves from its rebate program are not as deep as those of other large public or private purchasers, they result in prices that are significantly lower than those paid by individual consumers on a retail basis. Two states, Maine and Vermont, have obtained section 1115 demonstration waivers[48] from the Secretary of HHS in order to give non-Medicaid beneficiaries access to the same price reductions that Medicaid obtains. The Pharmaceutical Research & Manufacturers Association (PhRMA) has sued to block the implementation of both waivers as well as a related prescription drug discount program in Maine. As of November 26, 2001, the Maine 1115 waiver program is operational, the Vermont 1115 waiver has not been implemented, and the U.S. Supreme Court is considering whether to review PhRMA's challenge to the related Maine discount program.

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[45] Schondelmeyer S., PRIME Institute, University of Minnesota (2001) in von Oehsen, *op. cit.*, Chart 4, p. 10.

[46] Section 1927(o)(4) of the Social Security Act, 42 U.S.C. 1396r-8(o)(4).

[47] "The success of the California supplemental rebate program may be based in large part on the fact that Medi-Cal has the largest Medicaid enrollment in the country and that, because of this volume, manufacturers are willing to pay supplemental rebates to keep their drugs off the state's prior authorization list." von Oehsen, *op cit.*, p. 27.

[48] See Lambrew, J., *Section 1115 Waivers in Medicaid and the State Children's Health Insurance Program: An Overview* (July 2001), www.kff.org.

Maine. Maine has two drug discount programs: the Healthy Maine Prescription Drug Program and the Maine Rx Program. The former is a section 1115 waiver program, the latter is not. Both programs are linked to the Medicaid rebate program. PhRMA has challenged both in federal court.

In January 2001, the Secretary of HHS granted the state a section 1115 waiver to implement the Healthy Maine Prescription Drug Program. Under this waiver, which is similar to Vermont's section 1115 waiver discussed below, people with incomes between 185 and 300 percent of the Federal poverty level who are not otherwise eligible for Medicaid can pay a $25 annual enrollment fee to purchase prescription drugs at a discounted price. The discounted price is the price that the state Medicaid program pays the pharmacist for the drug, less the average manufacturer's rebate to Medicaid. The state reimburses the pharmacist for the rebate amount (estimated at 15 percent of the Medicaid price) and then collects the rebate from the manufacturer on a quarterly basis along with the rebates owed on drugs purchased for Medicaid beneficiaries. PhRMA has brought suit to enjoin the waiver, citing the decision of the D.C. Circuit Court of Appeals invalidating a similar section 1115 waiver granted to Vermont (discussed below).

The Maine Rx program allows any resident of the state who enrolls in the program to purchase prescription drugs from participating pharmacies in the state at a discounted price. There are no income limitations and no enrollment fee. The State will collect rebates from participating manufacturers in amounts that it will negotiate with them. From these rebates, the State will reimburse the pharmacies for the discounts they give to residents enrolled in the program. The drugs of manufacturers that do not participate in the Maine Rx program are subject to prior authorization requirements in Maine's Medicaid program. A District Court enjoined the program but the First Circuit Court of Appeals reversed this order.[49] The First Circuit Court decision was appealed to U.S. Supreme Court, which asked the Solicitor General for an opinion on its constitutionality. As of November 26, 2001, the program has not been implemented.

Vermont. In November 2000, the Secretary of HHS approved Vermont's request for a section 1115 waiver to enable it to implement its Pharmacy Discount Program. This program makes discounts available on prescription drugs to individuals who are either (1) eligible for Medicare with incomes above 150 percent of the Federal poverty level and have no supplemental coverage for drugs; or (2) adults with incomes at or below 300 percent of the poverty level who do not have insurance coverage that pays for prescription drugs. Those Vermont residents eligible to participate in the program purchase drugs at a discounted price (about 82.5 percent of the price that the state Medicaid program pays the pharmacist for the drug). The State of

[49] *Pharmaceutical Research and Manufacturers of America v. Maine*, No. 00-2446 (1st Cir., May 16, 2001).

Vermont pays the pharmacy the remaining 17.5 percent of the drug's price to Medicaid. Vermont then bills the manufacturers on a quarterly basis to collect the rebates on these drugs in the same manner as it does for drugs it purchases for Medicaid beneficiaries. Under the terms of the waiver, the manufacturers must pay the rebates attributable to drugs purchased by this demonstration population, who are not otherwise eligible for Medicaid. In June 2001, the U.S. Court of Appeals for the D. C. Circuit ruled that the Secretary does not have the authority under section 1115 to grant Vermont a waiver that would enable the state to implement this program.[50] The state has requested the Supreme Court to overturn the Circuit Court's decision.

False Claims Act Settlements

The Federal False Claims Act imposes significant financial penalties on contractors that submit false or fraudulent claims to the federal government in programs ranging from defense to energy to health care. Two recent False Claims Act cases involving drug manufacturers have resulted in $31.7 million in payments to states for losses incurred by their Medicaid programs, and $567.3 million to the federal government for both its Medicaid and Medicare losses. Additional settlements with other manufacturers that could generate more direct and indirect savings to Medicaid prescription drug costs are reported to be under negotiation.

The first of these cases involves the marketing and sale of certain biologic products manufactured by the Bayer Corporation and used in treating hemophilia and immune deficiency diseases. The government alleged that Bayer inflated the AWPs for these products and then "marketed the spread" by selling them to physicians at a dramatic discount in order to induce the to use its products in treating their patients. Because Medicaid and Medicare payments to physicians for the products were linked to the AWP and not the actual discounted price paid by each physician, the physician could profit from the differential. The government also alleged that Bayer did not accurately report to the Secretary of HHS the extent of the discounts it gave to the physicians on these products. Because the Secretary did not have accurate "best price" information, the Medicaid rebate amounts owed by the manufacturer on these products were understated.[51]

The other case involved TAP Pharmaceutical Products, a joint venture between Abbott Laboratories and a Japanese firm, and its prostate cancer drug, Lupron. The government alleged that TAP inflated the AWP for Lupron and sold

[50] *Pharmaceutical Research and Manufacturers of America v. Thompson*, 2001 U.S. App. LEXIS 11850 (D.C. Cir., June 8, 2001).

[51] Department of Justice, "Bayer to Pay $14 Million to Settle Claims for Causing Providers to Submit Fraudulent Claims to 45 State Medicaid Programs" (January 23, 2001), http://www.usdoj.gov/opa/pr/2001/January/039civ.htm. The state share of the settlement was $6.7 million.

it to physicians at sharply discounted prices to enable them to profit on the difference between their acquisition cost and the Medicare and Medicaid payment amounts linked to the inflated AWP. The government also alleged that TAP did not report to the Secretary of HHS the "best price" at which it sold the drug to physicians, thereby reducing the amount of the Medicaid rebate it otherwise would have owed.[52]

The tens of millions in Medicaid drug expenditures these cases have returned directly to state and federal treasuries are of obvious significance. Yet these cases may have even greater indirect benefits. First, they will deter future AWP manipulation by these manufacturers and, presumably, their competitors. Second, these cases have also produced agreements by the manufacturers involved to submit accurate pricing data on all their products to the Secretary of HHS for purposes of calculating the Medicaid rebate amounts. This is likely to generate additional Medicaid savings for the state and federal governments on the purchase of these manufacturers' products (and perhaps those of competitors) through the collection of larger rebate amounts.

Conclusion

Medicaid, no less than other public or private purchasers, is facing sharp increases in the prices drug manufacturers charge for prescription drugs. This price inflation creates particular problems for a payer like Medicaid, which is responsible for financing coverage for millions of low-income elderly and individuals with disabilities who have high levels of need for prescription drugs. The states have substantial flexibility in discounting from the manufacturers' suggested prices the amounts they pay for particular drugs. States also benefit from the rebates that the federal government commands from manufacturers as a condition of federal Medicaid matching payments for the purchase of their products. In addition, states have considerable discretion in managing fee-for-service beneficiary use of outpatient drugs through limitations on the number of prescriptions, imposition of copayments, use of formularies, imposition of prior authorization and "fail first" requirements, and application of prospective as well as retrospective drug utilization review. Finally, anti-fraud prosecutions against certain drug manufacturers are producing more accurate pricing information that should improve the effectiveness of the rebate mechanism.

These various flexibilities do not enable Medicaid programs to dampen the high rates of drug price inflation; Medicaid as a payer does not have sufficient purchasing leverage to accomplish this. The flexibilities do, however, have the potential to enable states to limit their rates of increase in Medicaid spending for prescription drugs without seriously compromising beneficiary access to

[52] Department of Justice, "TAP Pharmaceutical Products, Inc., and Seven Others Charged with Health Care Crimes; Company Agrees to Pay $875 million to Settle Charges," (October 3, 2001), www.usdoj.gov/opa/pr/2001/October/513civ.htm. The state share of the settlement was $25.5 million.

appropriate needed medicines. Given the health status and low incomes of Medicaid beneficiaries, the impact of cost containment tools must be closely monitored. Research on the cost-effectiveness and access implications of these various policy tools would benefit state purchasers, the federal government, and program beneficiaries alike.

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