

A HARD PILL TO SWALLOW: OPTIONS FOR REDUCING PRESCRIPTION DRUG COSTS

ISSUE BRIEF

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“The U.S. health care system ... is rife with good and bad news, both stemming from the same source: medical innovation. First the good news: Overall life expectancy and health status in the United States are improving; infant mortality is declining; and disability rates among the elderly have been falling Now, the bad news: This medical progress is expensive.”

-- JD Kleinke (3)

The Pharmaceutical Drug Cost Problem

For millions of Americans, prescription drugs save lives, ease suffering, reduce disability, and restore vitality. More than 90% of Americans have taken a prescription drug, half regularly take prescriptions drugs, and one-fourth take three or more drugs regularly. Of persons 65 years old or older, 84% regularly take prescription drugs (1).

Prescription drugs and the miracles they enable come with a hefty price tag. High costs of prescription drugs continue to rise, alarming consumers, motivating payers and purchasers to establish aggressive cost control measures, and stimulating public policy makers to enact major policy changes. As recently summarized, “although the importance of prescription drugs to modern medicine is well established, some critics question whether spending levels and prescribing patterns are an efficient use of the already stretched health care dollar” (2).

State policies that are part of an overall strategy to reduce costs may also help ensure that patients receive appropriate drug therapy consistent with current best-practices and that harmful interactions are minimized. However, policies to control costs may produce significant barriers to access to needed drugs. Thus, the “challenge for policy makers at both the federal and state levels is to recognize the need for a balanced approach to cost-containment as they make changes to this essential benefit” (3).

Achieving this balance will be the focus of this Forum and of this Issue Brief. In this Issue Brief, we will

- present information about the growth of pharmaceutical expenditures in general and in Medicaid programs in particular;
- review the major factors underlying the rise in pharmaceutical expenditures;
- review the options that states can and have utilized to reduce drug expenditures; and
- provide information about the relationship between pharmaceutical costs, cost containment efforts, and health care quality.

The national trend in expenditures for prescription drugs is shown in Figure 1. From 1993 to 2003, overall spending increased from \$51.3 billion to \$179.2 billion (4-7). Annual rates of increase have varied from 10.2% to 16.7% per year, rates considerably higher than the overall rate of increase in total national health care expenditures. The annual price increase for commonly used medications for the 12 months ending September 2004 was 7.4%, or 3.2 times the overall rate of inflation (2.3%) for that period. Projections suggest that drug expenditures will slow somewhat over the next decade but will exceed one-half trillion dollars in ten years.

Data for Tennessee (8) are shown in Table I and in Figure 2. The data illustrate the following points:

- Tennessee ranks among the states with the highest total number of prescriptions and highest drug sales.

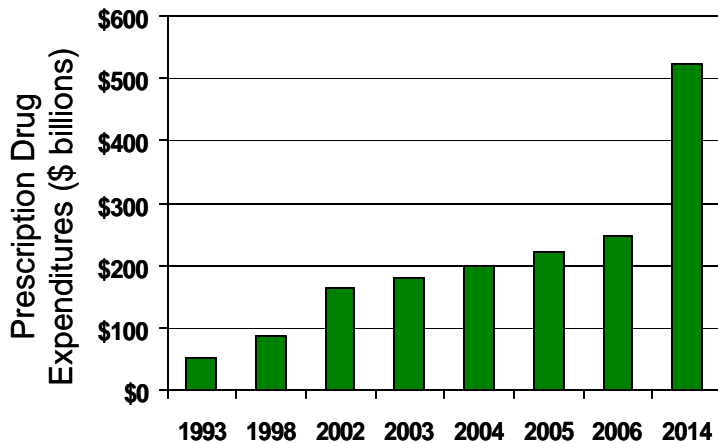


Figure 1: Annual expenditures for prescription medications in the U.S. from 1993 through 2003 and projected to 2014. Source: S Heffler et al (4).

- Tennessee ranks first in the number of prescriptions written per resident, with higher than average numbers in all age groups; and
- Tennessee was among the few states with a decline in retail sales from 2002 to 2003 as a result of a reduced volume but with higher costs per prescription.

Medicaid is the single largest payer for prescription drugs (5,6), paying for 19% of all prescriptions written each year. Even though medication coverage is optional according to federal regulations, all states provide it for categorically needy beneficiaries and 35 states provide it for medically needy beneficiaries. Medicaid, in 2000, paid for at least one drug for 26.6 million Medicaid recipients or about 62% of all Medicaid beneficiaries.

Medicaid prescription expenditures increased from \$4.4 billion in 1990 to \$29.7 billion in 2002 (Figure 3), an average annual rate of growth of 16.2% (Figure 4).

- Medicaid expenditures for drugs have been steadily increasing since 1996, reaching an annual growth rate of 20.8% in 2000. From 2000 to 2002, total expenditures for prescription drugs increased by 18.8% per year (Figure 4).
- The average reimbursement for each Medicaid outpatient prescription increased from \$49 in 2001 to \$57 in 2002, a rise of approximately 8% per year.

What Are Trends in Medicaid Pharmaceutical Expenditures?

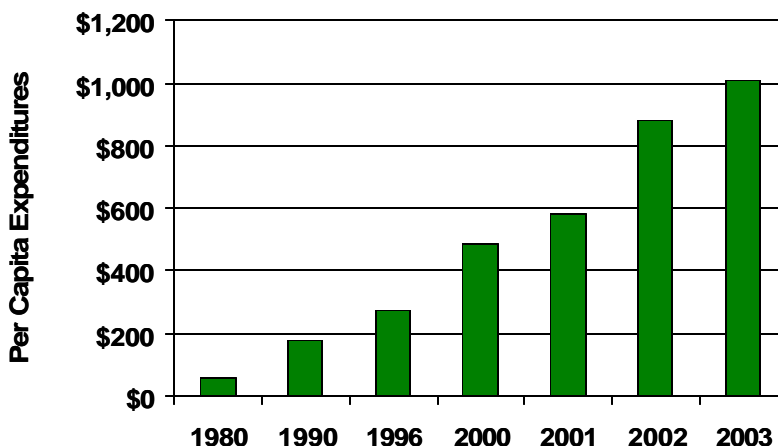


Figure 2: Per capita prescription drug expenditures in Tennessee from 1980 to 2003. Source: Blue Cross/Blue Shield of Tennessee, 2004.

Table I: Prescription Drug Use and Costs in Tennessee

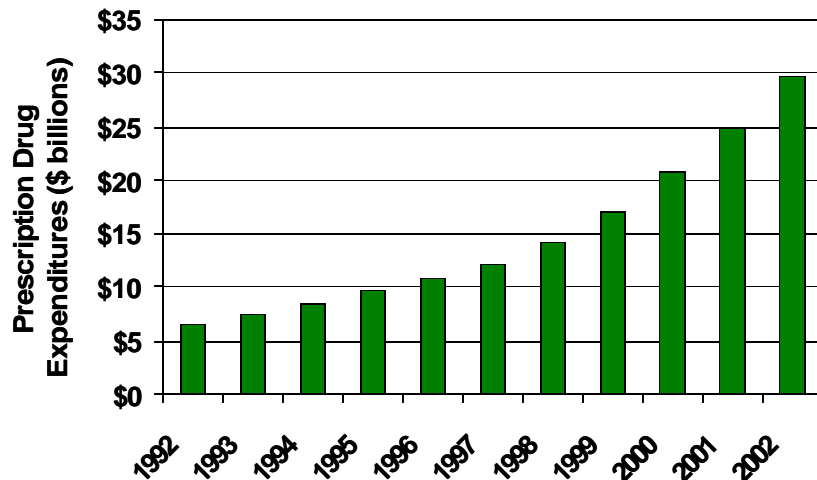
	TN	US	TN Rank
Total Retail Prescriptions Filled (in thousands)	94,440	3,083,903	11
Total Retail Prescription Sales (in thousands of \$)	\$4,603,542	\$163,358,121	12
Average Price of Retail Prescription	\$52.97	\$48.75	44
Retail Prescriptions per Capita	16.5	10.7	1
Age 0-18	5.7	4.2	5
Age 19-64	18.0	10.8	1
Age 65+	31.0	24.3	7
% Change in Retail Prescriptions Filled, 2002-2003	-11.5%	1.5%	51
% Change in Retail Sales, 2002-2003	-1.0%	8.3%	49
% Change in Average Retail Prescription Price	11.9%	6.7%	4
Medicaid Expenditures on Prescription Drugs (in thousands of dollars)	\$1,056,057	\$26,603,237	7
% of Medicaid Expenditures on Prescription Drugs	21.5%	16.8%	16

Source: Kaiser Family Foundation, StateHealthFacts, 2005.

- The rate of increase in spending for drugs has been faster than for other Medicaid services (Figure 5).
- For all Medicaid beneficiaries, the proportion of all Medicaid funds expended on prescription medications increased by 70%, increasing from 6.8% of all expenditures in 1990 to 11.6% in 2002 (7). For the disabled, the increase was from 7.6% to 15.9%.
- In a recent survey by the Kaiser Family Foundation, 36 states identified prescription drugs as the top Medicaid cost driver in 2001.

Data for TennCare are listed in Table I. Tennessee ranks among the states with the highest Medicaid prescription expenditures and among the states with the highest proportion of total Medicaid funds used for prescription medications.

Figure 3: Medicaid expenditures for outpatient prescription drugs from 1992 through 2002. Source: B Bruen and A Ghosh (6).



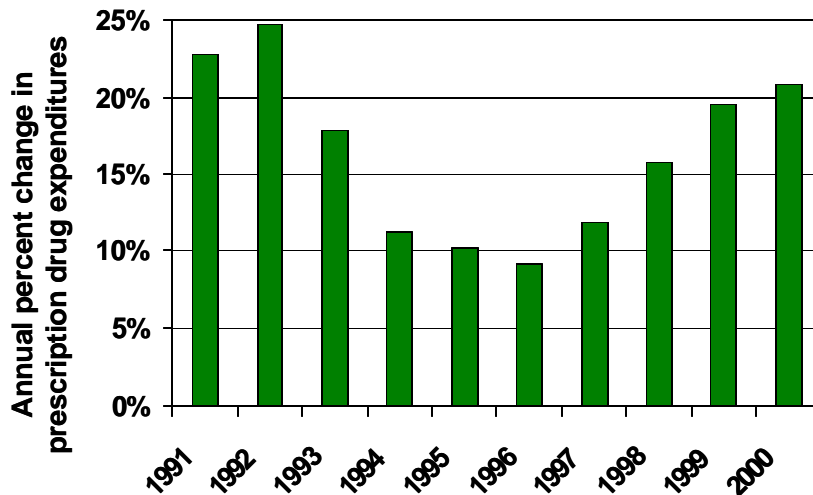


Figure 4: Annual rate of change in Medicaid outpatient prescription drug expenditures. Source: DE Baugh et al, 2004 (5).

These high and rising costs have consequences to both consumers and to payers for health care, including states. Nearly one in eight (8%) Americans report spending more than \$1000 per year out-of-pocket on drugs. Of those 65+ years old, 19% spend more than \$1000 out-of-pocket for drugs. These high costs have negative consequences.

In a survey conducted by the Kaiser Family Foundation in 2000, 29% of adults said that have not filled a prescription because of cost; 25% reported that they had to give up basic necessities (e.g., cutting back on food) because of drug costs or that paying for prescriptions is a 'serious problem'; and 58% were worried that their health plan will not cover the drugs they need.

For states, rising costs impact Medicaid, state employee insurance plans, and other direct institutional purchasing programs (7). State Medicaid programs are the largest single payer for prescription medications, paying for 19% of the total national payment in 2003 and accounting for 17% of overall Medicaid expenditures.

The rate of increase in prescription drug costs exceeds that of other Medicaid services (Figure 5) and is generally considered to be the major cause of the increase in overall Medicaid expenditures by states. Medicaid expenditures consumed 21.4% of all state budgets in 2003,

What are the Consequences of High Prescription Drug Expenditures?

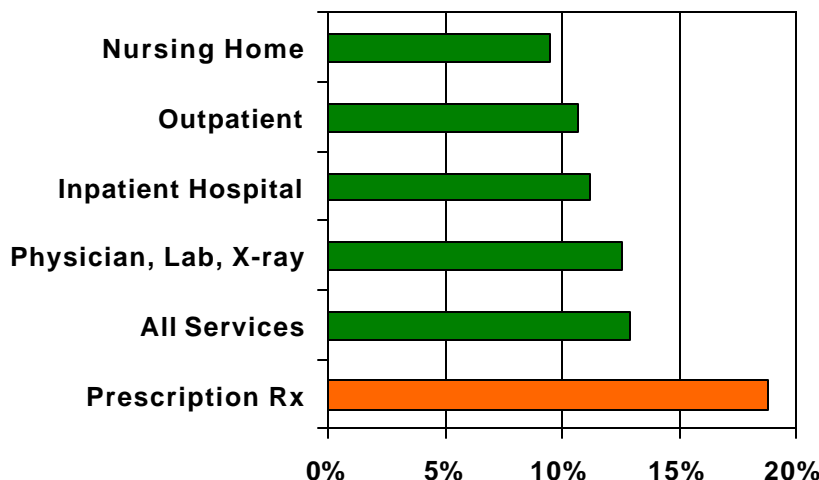


Figure 5: Rates of growth for selected Medicaid services from 2000 through 2002. Source: B Bruen, and A Ghosh (6).

Why are Drug Expenditures Rising?

compared to 14% in 1991. In Tennessee, the percent of the state's budget allocated to Medicaid services in 2003 was estimated to be 33.9%. The rising costs to states for Medicaid drug programs are compounded by rising costs for drugs by other state programs (e.g., for prisons and employees).

Rising drug expenditures may be attributed to a complex mix of three basic causes (7,9,10). These include increases in the volume of medications that are prescribed, increases in the unit price of drugs, and changes in the mix of drugs used.

The volume of medication prescribed. From 1993 to 2003, the number of prescriptions purchased increased 70% - from 2.0 billion to 3.4 billion per year. This increase reflects:

- the overall increase in the population (13% from 1993 to 2002);
- the disproportionate increase in the number of elderly persons who use more drugs than younger persons;
- the rising prevalence of identified and treatable diseases;
- the introduction of new and expensive drugs to treat diseases that previously had no effective treatment and more aggressive recommendations for treating common conditions (e.g., high cholesterol and high blood pressure);
- the aggressive marketing practices of manufacturers, including direct-to-consumer advertising;
- the increasing consumer empowerment and awareness; and
- the increasing demand for lifestyle drugs to, for example, reduce hair loss and wrinkles.

Increases in unit costs of drugs. Manufacturer's unit prices have increased for both existing and new drugs. These price increases are typically passed on directly to the consumer. Prices to wholesalers have increased 7.4% per year from 1993 to 2003 and have exceeded the consumer price index (CPI) during each of the past four years (9). The annual price increase for commonly used medications for the 12 months ending September 2004 (7.4%) was 3.2 times the rate of inflation (2.3%) for that period.

These increases in manufacturer charges have increased the average cost of therapy from \$33.76 in 2000 to \$58.52 in the year from October 2003 to September 2004 (which was down from \$70.64 in 2003). An average older American taking three prescription drugs is likely to have had an average increase in cost of therapy of \$175.56 over this period because of manufacturer price increases, assuming that the full cost increase is passed on to the consumer.

Changes in the mix of drugs. Expenditures have also increased because of changes in types of drugs used. Most top selling drugs are newer, higher-priced brand-name drugs. Advances in medical therapy have produced new and more effective drugs at higher costs, and consumer demands for name-brand and new drugs have increased. The costs of newer drugs have been estimated to be 1.75 times those of older drugs within the same drug group.

The relative proportions that these three factors contribute to the overall increase in drug expenditures are shown in Figure 6. For most

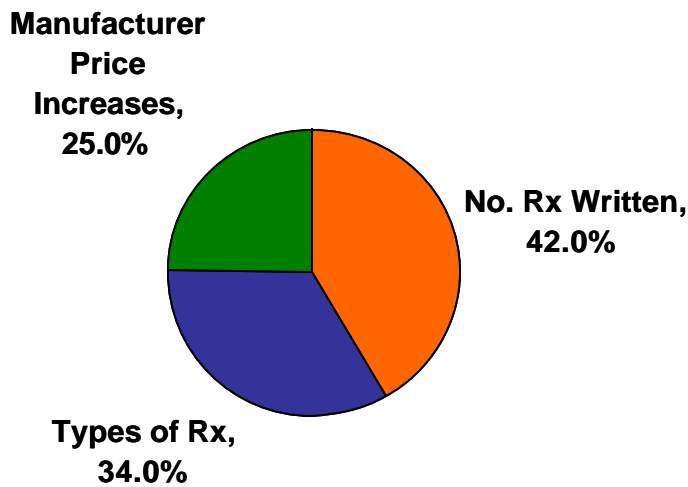


Figure 6: Relative causes of prescription price increases, 1997 through 2002. Source: Kaiser Family Foundation (9).

common medical conditions, the increase in the cost of drug therapy has been driven more by increases in prescription volume than by increases in cost. In one study of seven common conditions, the ratio of the impact of volume to the impact of cost on overall drug expenditures ranges from 2.5 to 1 (for hormone replacement therapy) to 10 to 1 (for gastrointestinal and cholesterol-lowering drugs) (Dubois et al, 2000). That is, for hormone replacement therapy, for every \$1 in increased drug expenditures, an increase in drug costs accounted for only \$0.29 of the change in expenditure; an increase in prescription volume or drug mix accounted for the remaining \$0.71. For lipid-lowering agents, an increase in drug cost accounted for only \$0.09 of each \$1 of increased expenditures.

States have numerous options to mitigate the rise in expenditures for prescription drugs (11-13). In 2003 and in 2004, every state and the District of Columbia implemented at least one new Medicaid cost containment strategy. For 2005, every state and the District of Columbia reported the intent to undertake additional cost reduction strategies (Figure 7). The most common target for cost containment was prescription drugs (Figures 7 and 8).

What are Options for States to Reduce Medicaid Pharmaceutical Expenditures?

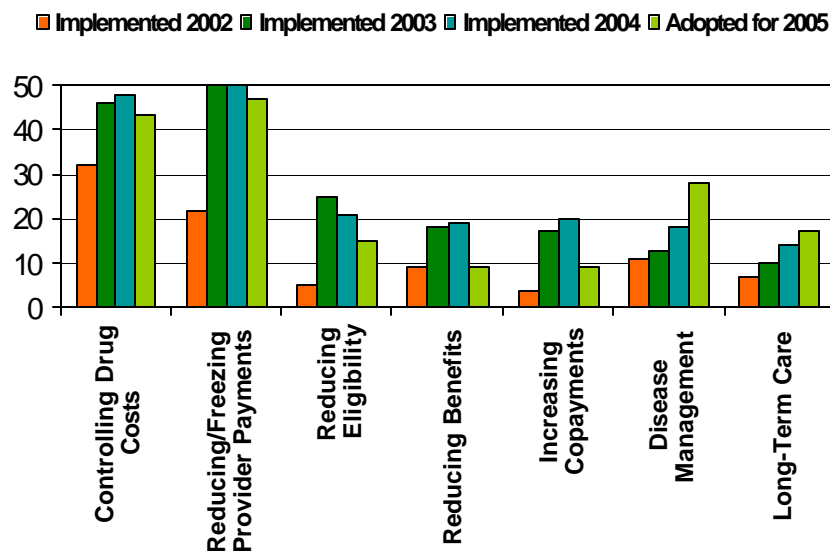


Figure 7: States undertaking new Medicaid cost reduction strategies in 2002 – 2005. Source: Kaiser Commission on Medicaid and the Uninsured, 2004

These actions may be divided into three major groups, representing utilization management, changes in payment or purchasing policies, and expanded utilization review and monitoring.

Utilization management approaches include various actions aimed at reducing the volume of medications consumed by patients. This may be achieved by direct limits on dispensing or by enforcing financial disincentives to consumers for high consumption.

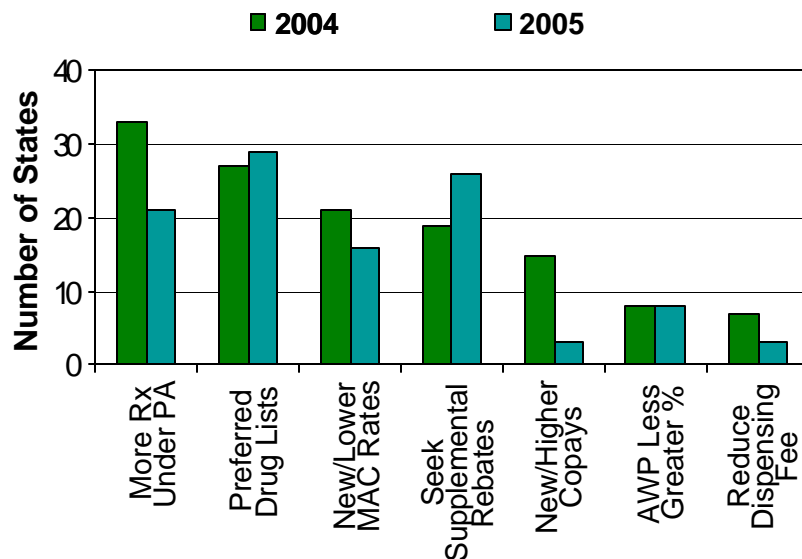
- *Dispensing limits.* These are state policies that directly restrict the quantity of prescription drugs that Medicaid will purchase for a beneficiary, that is, limiting the quantity that can be dispensed. The limits may be based on the quantity per prescription, the number of active prescriptions, the number of refills allowed, or the cost of all active prescriptions.

A 2004 law in Mississippi limits prescription Medicaid coverage to four brand-name drugs and unlimited generic drugs.

Illinois law, signed in 2002, establishes a dispensing limit of four brand-name prescription drugs per month.

- *Excluded drugs policies.* These policies identify specific drugs or drug classes for which a state Medicaid program does not provide coverage. States are permitted to exclude groups of drugs from Medicaid coverage such as drugs not used for medically accepted conditions (e.g., drugs in clinical trials or not FDA approved or not proven to be effective) or drugs in certain classes (such as those used for weight control, fertility enhancement, cosmetic purposes, symptomatic relief of cough and colds, antismoking, vitamins except prenatal, over the counter drugs, barbiturates, and benzodiazepines).
- *Preferred drug lists (PDLs) or formularies.* PDLs are lists of covered prescription drugs that a state Medicaid program agrees to provide without prior authorization. Federal regulations place limits on a state's ability to develop a preferred drug list; for example, a preferred drug list must include all drugs produced by a manufacturer that has a federal rebate agreement unless the drug does not have a clinically significant advantage over other drugs already on the formulary.

Figure 8: States undertaking new Medicaid prescription drug cost reduction strategies, 2004-2005. Source: Kaiser Commission on Medicaid and the Uninsured, 2004.



Mississippi established a preferred drug list in 2004 and required prior authorization for drugs not on the preferred list.

An Oregon law, signed in 2003, requires the development of a preferred drug list for all state agencies that directly or indirectly purchase medications.

- *Prior authorization policies of a state Medicaid program require obtaining approval from the state (or a subcontractor) before dispensing certain drugs.*

Missouri law subjects all new drugs to prior authorization.

Mississippi law requires that all prescriptions over five be subject to prior authorization.

Oklahoma enacted a law that immediately provides coverage under prior authorization for any new drug approved by the FDA if other agents in the same class are subject to prior authorization.

- *Fail first and step-therapy policies.* States may require an individual to use and fail on a particular drug (generally a low-cost alternative) before a state Medicaid program will pay for another (usually higher cost) drug. Usually a physician must demonstrate that the alternative therapy is ineffective or otherwise inappropriate.
- *Generic drug policies.* Policies may encourage or require the use of generic drugs. In 1998, a survey by the Kaiser Family Foundation reported that the average prescription cost for a generic drug was \$19.33 compared to \$65.29 for a name-brand one. Advantages of the full use of generic drugs are substantial; estimates suggests that a fully implemented generic mandate would reduce annual prescription drug expenditures in TennCare by as much as \$44 million.

A Rhode Island law, enacted in July 2004, authorized the state's Medicaid office to authorize generic substitution whenever the generic is less costly than the brand name.

A Maryland law, enacted in May 2003, requires pharmacy staff to advise consumers of available generic equivalents and of the cost difference between the generic and the name-brand drug.

North Carolina reduced dispensing fees for name-brand drugs from \$5.60 to \$4.00 but maintained the prior rate for generic drugs.

Minnesota law requires authorization to dispense a name-brand rather than generic drug even if the practitioner has written "Dispense as Written - Brand Necessary" .

- *Cost-sharing with consumers.* Policies require the beneficiary to pay a portion of the cost of service. In the case of drugs, federal law requires that cost-sharing be "nominal", usually defined as \$0.50 to \$3.00 per prescription, although waivers have permitted rates as high as \$5.00 per prescription. A state cannot, however, deny therapy because of failure to pay the shared amount. The value of cost sharing policies is based on the economic theory that, with "rational economic behavior", people will use fewer services as their cost rises, with the intent that the services that are reduced are of marginal health value. Cost-sharing may take several forms:

- *Co-payments*, representing a fixed amount the beneficiary must pay for each prescription.
- *Co-insurance*, representing a fixed percentage of the cost of the prescription that the beneficiary must pay.
- *Multi-tier plans*, in which different co-payments or coinsurance levels are established for different drug classes. In a single-tier plan, cost-sharing is the same for all drugs. In a two-tier plan, co-payments or coinsurance levels are higher for name-brand than for generic drugs. Three-tier plans add additional cost sharing requirements for selected groups of groups. Multi-tier plans are popular because of the evidence that they can reduce expenditures, especially the part paid for by third-parties; switching from a single- to a two-tier plan reduces mean drug spending in employer covered populations by 6% to 19% (14).
- *Reference pricing* is a cost-sharing model in which the insurer pays only the price of a low-cost option among groups of drugs deemed to be close substitutes; patients pay the full difference between this reference price and the price of the drug actually dispensed.

In one company, changing from a single-tier plan to a three-tier plan with higher copayments resulted in a 58% reduction in plan costs for drugs to treat hypertension and somewhat lesser savings for treatments for peptic ulcer disease and treating high cholesterol levels (15).

In British Columbia, starting a reference pricing for selected drugs for hypertension resulted in 29% reduction in higher priced agents, with a projected savings of \$6.7 million during the first year (16).

Florida, in 2004, increased co-payments for state employees from \$10 to \$80 and required the use of a preferred drug list.

Changes in state payment and purchasing policies include changing the amount the state will pay for specific drugs or the method used to determine the maximum price it will pay; negotiating rebates from manufacturers based on the drugs that are purchased; forming purchasing cooperatives to maximize volume-related discounts; utilizing special rate agreements with the federal government; and facilitating the purchase of drugs from other nations at lower costs.

○ *Reducing payments for the drug itself.* States may reduce the cost of the drugs (the *estimated acquisition cost* or EAC) or the dispensing fee. The EAC is set at average wholesale price (AWP) minus some percentage reduction determined by the state. Most states pay based upon some discount from the AWP, ranging from -4% in Wyoming to -15.1% in Michigan for pharmacy chains with more than five stores. Alternatively, states may reduce the dispensing fee paid to pharmacists. States may also set maximum allowable costs (MAC) for multiple source drugs that limit reimbursement to a set percentage of the cheapest agent.

New Jersey reduced Medicaid reimbursement rates from AWP-10% to AWP-12.5% in 2003.

Connecticut reduced pharmacists' dispensing fees from \$3.60 to \$3.30 in state funded programs and allowed higher dispensing fees to pharmacies enrolled in or under contract with federal 304B programs (see below).

Virginia changed its MAC to be based on costs of available generic drugs.

○ *Negotiating supplemental drug rebates.* The net cost of Medicaid prescriptions to states is reduced by rebates manufacturers pay to states. Federal rebates are negotiated by the Department of Health and Human Services and are standard across all states. For name-brand drugs, the federal rebate is the greater of 15.1% of the average manufacturer's price (AMP) or the difference between the manufacturer's best price and the AMP, with an additional rebate on drugs whose AMP has risen more than the consumer price index (CPI) since 1990. States may also negotiate supplemental rebates directly with manufacturers, and managed care organizations may negotiate their own discounts.

Florida, in 2004, enacted a law requiring that the Medicaid federal and state supplemental rebate be at least 27% of the average manufacturer price.

Texas law (2003) allows only drugs from manufacturers that agree on supplemental rebates to be included on preferred drug lists.

○ *Establishing purchasing pools.* Purchasing pools increase a state's bargaining power with manufacturers, increase the efficiency of pharmacy procurement by lowering administrative costs and facilitating benefits such as drug utilization review and use of evidence-based practice plans. Pools may be formed among various state agencies that buy drugs for different populations (e.g., departments of health and mental health, state employees, teachers, and the state prison system) or between states.

The Minnesota Multi-state Contacting Alliance for Pharmacy includes government groups from 42 states.

Texas implemented a bulk-purchasing system for medications by state agencies including the Departments of Health and Mental Health, programs for state employees and retirees, teachers, prison systems, and any other agency that purchase drugs.

South Carolina law created the Interstate Bulk Prescription Drug Program with neighboring states to provide prescription drugs at lower prices for seniors and disabled residents who do not have prescription drug insurance coverage.

Nevada requires state agencies to purchase drugs only through a centralized Purchasing Division of the Department of Administration.

○ *Implementing pharmacy assessments and surcharges.* States may impose a fee on all retail pharmacy sales, with the revenues being used to subsidize drug benefits.

Alabama imposed a privilege tax of ten cents per prescription on all retail prescription sales regardless of retail price.

Massachusetts instituted a provider fee or assessment on all retail prescription drug sales sufficient to generate at least \$36 million each year (\$1.30 for each nonMedicaid, nonMedicare prescription).

- *Requiring disclosure of drug company marketing activities.* States are limited in their influence on national advertising campaigns, including direct-to-consumer marketing and direct-to-provider marketing. They may implement public disclosure requirements to indirectly limit the influence of companies on prescribing practices by requiring the release of information about these practices.

In Vermont, companies must disclose to the state the value of marketing activities, including offering free samples, gifts, etc. valued at over \$25.

Maine requires that a manufacturer or distributor of drugs within the state who utilizes salespersons to report marketing costs for prescription drugs.

- *Expanding the 340B Drug Pricing Program.* This federal program allows designated health care providers to purchase drugs covered through Medicaid at a substantial discount. The average discount price is \$51 lower than AWP and 19% lower than Medicaid net price. “Covered entities” include community health centers and disproportionate share hospitals.

Vermont required the study of the potential for expanding the 340B purchasing in correctional facilities, state funded managed care organizations, and state bulk purchasing programs.

- *Reimportation of drugs from Canada and other countries.* It is well known that drug prices are substantially lower in other countries, including Canada, than in the United States. In January 2002, Canadian prices were 8% to 29% lower than prices in the U.S. Although there are concerns about the safety of these drugs manufactured or dispensed without U.S. federal supervision and although reimportation is currently against federal law, a recent study of U.S. consumers revealed that 7% have purchased drugs from Canada or another country (Wall Street Journal/Harris Poll). Another poll indicated that 73% of Americans 50+ years old would consider buying drugs from another country if it were feasible (AARP Poll, 2004).

Connecticut enacted a law that required the Commissioner of Social Services to establish a procedure by which certain citizens may obtain covered drugs from Canadian pharmacies.

Rhode Island began a process to license Canadian pharmacies to sell drugs to state residents. A similar bill to license Canadian pharmacies was introduced in Texas in 2005.

- *Single Benefit Waivers.* Medicaid waivers may allow coverage for a single benefit for people with incomes above traditional Medicaid limits. When the benefit is prescription drugs, these waivers are referred to as “Pharmacy Plus” waiver options. As of October 2004, these waivers were approved for five states (IL, WI, SC, FL, MD).

Nevada enacted a law in May 2003 requiring the state to apply for a Medicaid “Pharmacy Plus” waiver to cover persons eligible for Medicare with incomes up to 200% of the poverty level.

New Mexico law required the state to seek a Pharmacy Plus waiver to cover seniors and disabled persons with incomes up to 185% of the federal poverty level.

Utilization review and monitoring options focus on reducing costs by assessing the compliance of individual or groups of patients or providers (e.g., high cost users and high cost prescribers) with regulations and treatment “best practices” and guidelines.

- *Expanding drug utilization monitoring.* Some drug utilization review (DUR) is required by federal law and states may expand the scope and power of utilization review procedures.

Tennessee has established a controlled substance monitoring database to monitor the dispensing of federally regulated Schedule II, III, and IV, and selected V drugs.

- *Using pharmacy benefit management companies (PBMs).* These companies serve as intermediaries between state Medicaid agencies and pharmaceutical companies and can provide expertise in costs and related economic factors; clinical guidelines; educational efforts to consumers and providers; form accessible networks of pharmacies and mail order outlets; have capacity to integrate medical and pharmacy data to manage large populations.

- *Implementing disease management programs, clinical guidelines, evidence-based practice.* Because 80% of Medicaid expenditures for drugs are for patients with chronic diseases, states have attempted to reduce drug costs by implementing a variety of disease management schemes, including the use of clinical guidelines and other forms of evidence-based practice. The goal is to reduce inappropriate use of medications and to increase compliance with best practices to reduce costs of ER visits and hospitalization and to reduce complications of chronic diseases. Numerous studies have documented the common inappropriate overuse as well as underuse of prescription medications.

The annual health care costs generated by inappropriate drug use has been estimated to be \$177.4 billion (17).

The introduction of a community-based diabetes care program in Asheville, NC that was staffed by pharmacists resulted in a \$1200 to \$1872 reduction in overall medical costs and an substantial improvement in quality of care (18).

In one study, over 50% of patients with a common cold were inappropriately treated with broad spectrum antibiotics (19).

A study of older persons in HMOs demonstrated that 28.8% of elderly individuals received at least one of 33 potentially inappropriate medications (20).

Sixteen to thirty-seven percent of patients with acute myocardial infarction in Tennessee did not receive appropriate drug therapy; 34% of patients with heart failure also did not (21).

Oregon initiated a polypharmacy review of Medicaid enrollees with more than six prescriptions or evidence of frequent refills.

What are the Negative Consequences to Efforts to Reduce Prescription Drug Expenditures?

“...high price new drugs may be the cheapest weapon we have in our struggle against rising medical expenses.”

-- JD Kleinke (3)

We have entered “a new era in which it is more difficult to balance the possibilities of medicine and public expectations against the willingness to finance them.”

-- David Mechanic, 1997

Indiana enacted a law implementing an information strategy targeted at high-volume prescribers.

○ *Reducing fraud, waste, and abuse.* It is estimated that fraud, waste and abuse exceed \$1 billion in Medicaid pharmacy costs. Efforts to reduce these costs include enhancing prospective DUR, using technology at point of sale to reduce abuse and errors, using data and education to change provider practices, limiting the supply a patient can get from a pharmacy, and auditing claims to profile providers and clients.

Missouri law requires a drug management program for all beneficiaries who receive more than nine prescriptions per month.

Other actions. States have taken a series of other actions to reduce prescription drug expenditures.

Nebraska established a Cancer Drug Repository for the return and reuse of cancer drugs.

Nevada established procedures for reusing certain medications dispensed but not used by a patient in a mental facility, skilled nursing or intermediate care facility or a jail or prison.

Efforts to reduce prescription drug expenditures are complicated by two factors – prescription drugs may reduce overall health care costs and actions that restrict access to prescription drugs may result in reduced quality of care with deleterious impacts on health outcomes.

First, drugs may reduce overall health care costs. Increasing the number of prescriptions and the use of newer although more expensive prescription drugs may improve health. This will be so if the added prescriptions represent an increase in appropriate care but not if they reflect treatments with marginal or no added health value.

The cost savings resulting from medication use may be quick (as in the use of use of antipsychotic medications) or slow (as for drugs that increase bone mass to reduce osteoporosis and reduce the long-term incidence of costly hip fractures). Savings may occur in only a subset of patients but not in the aggregate (e.g., drugs that lower cholesterol) or in nonmedical sectors (e.g., flu vaccines). Other drugs may reduce short-term costs but increase long-term costs (e.g., treatments for cystic fibrosis) or just improve life but do not save money (e.g., lifestyle drugs) (3).

In one nationwide study, patients treated with drugs approved after 1980 had lower mortality rates, fewer lost days of work, and fewer hospital days than those treated with older drugs approved before 1950. Replacing a 15-year old drug with a 5.5 year old drug increased costs, on average, by \$18 per prescription but reduced medical care costs by \$71 per prescription (22).

Treatment of diabetes with angiotensin converting enzyme (ACE) inhibitors results in a net savings of \$9900 to \$33,350 per patient, or an aggregate savings of \$475 million in 2004 (23).

Use of more expensive drugs such as nonsedating antihistamines may increase work productivity, with a benefit-to-cost ratio of \$5.67 gained for each health care dollar spent (24).

In Florida, expansion of AIDS drug coverage under Medicaid increased drug costs from \$411 per person to \$871 per person, but overall medical expenditures per person fell from \$2848 to \$2005, largely as a reduction in overall inpatient costs. (25).

In addition, cost containment effects may have unintended consequences that reduce quality of care, reduce health outcomes, and, paradoxically, increase overall health care costs. Potential untoward consequences of cost containment efforts include the following:

- Patients may stop taking needed drugs because of increased out-of-pocket costs resulting from cost-sharing or because they do not proceed through the authorization process required by prior authorization and other administrative requirements.

When one company switched from a one-tier to a three-tier plan and increased copayments, there was a 13.7 to 58% reduction in plan cost for three drug groups but a 118 to 148% increase in costs to employees (15).

- Reductions in effective drug therapy may reduce health status.

After New Hampshire imposed a three-prescription limit, the use of essential medication among the elderly fell by 34.4%, with greater changes among those with more medications, more comorbidities, and greater health services utilization (26).

Introduction of cost-sharing in Quebec resulted in a 14.4% reduction in drug use among welfare recipients; adverse events and ER admissions related to stopping essential drugs increased 4.2%. It was estimated that cost-sharing resulted in 7000 additional adverse events per million persons per year (27).

- Reduction in effective therapy may increase the use of physician and hospital services.

Arbitrary limits on number of prescriptions for Medicaid patients reduced, in one study, the use of essential medications (e.g., insulin) by 35% and resulted in a 200% increase in the use of more expensive services (hospitalization, emergency rooms) that exceeded the price of the drugs (28-29).

The imposition of a three-prescription limit in New Hampshire was associated with an increase in visits to community mental health centers and emergency rooms or partial hospitalization programs. The estimated cost of increased mental health services exceeded the cost of prescription drugs by a ratio of 17:1 (28-29).

Nursing home admission rates in New Hampshire before a \$1 copayment for prescriptions was introduced were the same as in New Jersey; 11 months after the copayment, the rate in New Hampshire was twice that of New Jersey (10.6% vs 6.6%) (28-29).

- Excluding certain drugs for payment may lead to substitution with less effective or more expensive agents.

Removal of 40 classes of drugs in New Jersey resulted in minimal reduction in number of prescriptions and no cost savings because the removed agents were replaced with more expensive covered alternatives (29).

“... although the goal of these policies is to reduce costs without reducing appropriate care, there are concerns that when used inappropriately they could result in unintended outcomes, including lower use of essential therapies, declines in health substitution of less effective, more toxic or more expensive medications for nonreimbursed agents; or increased use of more costly physician or institutional care.”

-- S Soumerai (29)

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