



Continuing Education



Pharmaceutical affordability and value

Learning Objectives

Explain the reasons for increased spending on prescription drugs.

Describe the major programs providing prescription drug coverage.

Explain the pros and cons of price controls.

Describe other cost-control proposals.

Explain how pharmaceutical companies can help pharmaceutical products achieve their complete value.

This third article in a three-part series discusses the issues behind drug affordability and the challenge of demonstrating the value of pharmaceuticals. Topics include: prescription drug spending, prescription drug coverage, price controls and other cost-control proposals, and achieving complete value.

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Many factors have converged to increase the amount individuals are spending on prescription drugs. For example, newer drugs are more costly, and many patients require several medications to manage their diseases. In addition, many individuals have inadequate insurance coverage and must pay for most or all of their prescription drugs out of their own pockets.

It is important to realize that the expanding use of medications, not rising drug prices, accounts for most of the increase in pharmaceutical expenditures. Several major reasons for this are:

- An increasing number of new breakthrough drugs to treat conditions for which there previously was no effective therapy.
- A dramatic rise in pharmaceutical use as an aging population develops more chronic conditions.
- A shift to a disease management approach to medicine that emphasizes preventive care; drug therapy often plays a key role in this approach.

Prescription drug affordability has been a major issue for older Americans. Individuals aged 50 years and older are more likely to be on chronic medica-

tion for conditions such as hypertension, congestive heart failure, diabetes or high cholesterol. One survey predicts that the average annual number of prescriptions per senior citizen will grow from 28.5 in 2000 to 38.5 in 2010. To offset the cost of multiple medications, patients may forgo one medication to pay for another, take their medication every other day or take a reduced dose. When patients do not properly comply with their medication regimen, their diseases worsen, leading to higher medical spending.

Prescription drug coverage

Millions of Americans with and without insurance do not have coverage for medications. The major prescription drug insurance options available in the United States are described below.

Private insurance. Private insurance programs do not always provide coverage for prescription drugs, and those that do typically require some form of copayment that may be higher for brand-name drugs than for generic drugs. Growth in private health insurance spending for prescription drugs (16.1%) slowed while growth in out-of-pocket spending (14.4%) accelerated in 2002; this was an effect of

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Note: The Continuing Education quizzes are not part of CMR Institute's certification program and do not count as credits toward the CMR® designation.

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tiered drug formularies shifting more of the cost to consumers. Businesses faced with increased health insurance costs will likely reduce health benefits for their employees or shift more of the costs to them.

Medicaid. Medicaid is a federally funded, state-managed insurance program for the poor, currently providing coverage for prescription drugs in all 50 states. Federal law requires that all pharmaceutical manufacturers who sell products to Medicaid patients provide a minimum discount of approximately 15% off the average selling price or match the lowest price charged to any nongovernment customer, whichever results in a lower price. In this program, state governments reimburse retail pharmacies for prescriptions purchased by Medicaid patients and then submit documentation for purchases to the pharmaceutical companies to receive their discounts via a rebate system.

Medicare. Medicare is a federally regulated program that provides healthcare coverage to Americans over age 65 and those with certain disabilities. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 will add prescription drug benefits for those on Medicare beginning in 2006. However, Medicare-approved drug discount cards that offer savings of 10% to 25% became available in 2004.

The Department of Veterans Affairs and the Department of Defense. These federal departments also provide prescription drug coverage to qualified citizens with prior or active military service. They contract with pharmaceutical companies to receive deep discounts and offer prescription drugs for a small copayment. These agencies purchase products directly from pharmaceutical companies.

State assistance programs. State assistance programs are now beginning to provide assistance with prescription drug payments for citizens who do not qualify for Medicaid – typically, disabled and lower-income senior citizens. As of January 1, 2004, at least 38 states have established or authorized some type of program to provide pharmaceutical coverage or assistance for these individuals. Most programs use state funds to subsidize a portion of the costs, but others use discounts or bulk-purchasing approaches.

Price controls

The public perceives the increasing costs of pharmaceutical products to be excessive, and consumers want help from national policymakers to determine how to pay for prescription drugs. One response from U.S. policymakers has been consideration of various price-control plans, modeled after those used in other countries.

One proposal would require pharmaceutical companies to charge prices similar to those in the Federal Supply Schedule (FSS) for the VA and other government agencies. According to one analysis, this would cut prescription prices by over 40%. Some say this would lead to an increase in prescription drug use. However, others suggest that it is very unlikely that any increase in volume would make up

Figure 1

Proposals for lowering pharmaceutical costs

- **Price controls** similar to those used by foreign countries.
- **Reimportation** of drugs from countries where they are less expensive.
- **Group discounts** for Medicare patients or low-income residents of certain states.
- **Patient assistance** programs offered by pharmaceutical companies.
- **Increased coverage** for the underinsured.



for such a drastic cut in prices.

Another proposal suggests selling products to Medicare patients at an “average foreign price” based on the average prices manufacturers charge in Canada, France, Germany, Italy, Japan and the United Kingdom. Those backing this plan suggest it would lower prices for brand-name drugs by an average of 40%. However, this would trigger an automatic reduction in Canadian prices, which must be lower than U.S. FSS prices – leading to an impractical downward spiral in drug prices.

Critics of price controls note that countries that have adopted price regulation have experienced a gradual reduction in competitiveness, both in their ability to develop new products and in their ability to enter international markets. Pharmaceutical companies warn that without adequate return on their investment in research and development, they may not have enough funding for continuing innovation and research into new medicines.

Price-control opponents also point out that Canadians wait an average of seven months longer for approval of new medications in their country. Canada ranks third from the last in the developed world in the availability of medical technology, and polls show that Canadians pay approximately \$1 billion annually out-of-pocket for access to American healthcare. Throughout the European Union, price controls have resulted in rationing of drugs and a lack of access to new products.

Individual states have attempted to mandate price controls for prescription drugs. For example, the Maine legislature passed a bill in 2000 that included a price regulation measure; the bill was overturned later that year by a federal lawsuit brought by pharmaceutical companies. The court found that while the state has an interest in assisting its citizens, price controls are an unconstitutional means of achieving this end.

Other cost-control proposals

Reimportation. This is a plan to reduce pharmaceutical prices by importing U.S.-manufactured drugs from Mexico or Canada, where these agents are often less expensive. The Food and Drug Administration and the Washington-based Pharmaceutical Research and Manufacturers of America state that if reimportation were put into effect, the biggest safety threat would be the importation of drugs that are counterfeit, illegal, unapproved, expired, subpotent, superpotent or contaminated. Additional safety concerns stated by the FDA include: The labeling may not be in English, information regarding adverse effects may not be available, drugs may not have been packaged or stored properly to avoid degradation, and there is no guarantee of use of good manufacturing practice standards. PhRMA further states that “importation is tantamount to importing foreign price controls ... [and] these policies will limit patient choices and stifle the incentives for research and development of the innovative medicines patients need.”

Group discounts. At present, consumers who are not part of large groups such as managed care organizations and pharmacy benefit management companies often find they are paying much more for drugs than other consumers. One government report noted that consumers with no insurance coverage pay an average of 15% more for prescriptions than those with coverage. Consequently, an increasing number of groups are forming to negotiate discounts.

A drawback to this approach is that a buying group requires an administrative infrastructure, particularly if it only benefits a particular segment of the population, such as those without prescription drug insurance. Also, many buying group proposals require retail pharmacists to sell medicines at greatly discounted prices and then get reimbursed by pharmaceutical companies. This arrangement would likely create an unacceptable financial and administrative cost for the retail pharmacy sector. For example, one proposal stipulated that retail pharmacies would absorb the entire price discount; some pharmacists believe this requirement might put some pharmacies out of business.

Patient assistance programs. Most major pharmaceutical companies offer some type of patient assistance program to provide prescription medicines to patients who cannot afford them. More than 80% of these programs provide assistance to patients who have exhausted their insurance coverage for medications. These voluntary programs have been growing by over 30% annually and provide over \$500 million in prescription drugs each year.

Increased coverage for the underinsured. Perhaps the most widely discussed means for making prescription drugs more affordable has been to increase insurance coverage for medications. To this end, Washington-based AARP launched an advocacy and education campaign in 2004, which included the following elements:

- Advocating lower prescription drug prices through federal legislative initiatives.
- Seeking ways to improve the benefits in the Medicare Act.
- Protecting and improving Medicaid coverage, supporting state pharmaceutical assistance programs, and aiding states' efforts to negotiate lower prescription drug prices for their residents.
- Educating beneficiaries and their families on how to make the most of the new Medicare coverage.

Achieving complete value

Politicians, the media, consumer groups and even some physicians are criticizing the pharmaceutical industry for the prices of prescription drugs in this country. Increasing attempts are being made to force pharmaceutical companies to contain the costs of drugs, which are often examined in isolation from other healthcare costs. To address this issue, pharmaceutical companies and their representatives need to encourage prescribers and the general public to consider the value of pharmaceuticals rather than just the price. Value can be assessed in terms of economic, clinical and humanistic outcomes.

A number of factors hinder pharmaceuticals from achieving their complete value, such as: adverse events, drug-related morbidity and mortality, drug overdosage, failure to receive the appropriate drug or adequate dosage, drug interactions, lack of patient compliance, drug administration or prescription

Article Summary

- **Many factors have converged to increase the amount individuals are spending on prescription drugs.**
 - Expanding use of medications, not rising drug prices, accounts for most of the increase in pharmaceutical expenditures.
 - Prescription drug affordability has been a major issue for older Americans.
- **Millions of Americans without insurance, as well as many with health insurance, do not have coverage for medications.**
 - Prescription drug coverage is provided in varying degrees by private insurance companies and several major government insurance programs.
- **Consumers want help from national policymakers to determine how to pay for prescription drugs.**
 - Responses have included proposals for price-control plans, modeled after those used in other countries.
 - Other cost-control proposals include reimportation, group discounts, patient assistance programs and increased insurance coverage for the underinsured.
- **Pharmaceutical companies and their representatives need to encourage prescribers and the general public to consider the value of pharmaceuticals rather than just the price.**
 - A number of factors hinder pharmaceuticals from achieving their complete value.
 - Pharmaceutical companies can take proactive steps toward addressing these factors.

errors, and untreated conditions.

Pharmaceutical companies can take proactive steps toward addressing these and other factors by:

- Gathering and distributing complete pharmacoeconomic and safety data.
- Supporting evidence-based medicine.
- Helping design disease management programs for patients with chronic conditions to increase patient compliance.
- Developing educational materials for patients and healthcare professionals to help prevent medication misuse and reduce adverse events.
- Facilitating the use of information technology (such as personal digital assistants and computerized monitoring systems) by healthcare professionals to prevent, identify and report drug administration and prescription errors.

There are a number of other ways pharmaceutical companies can demonstrate the value of pharmaceuticals to physicians and other healthcare providers. Their top priority should be educating managers and healthcare representatives so that they:

- Are knowledgeable about pricing issues, but when necessary, have the ability to shift the topic of conversation to the value of prescription drugs and remind physicians of the overall benefits their drugs have to offer both physicians and patients.
- Can demonstrate the economic value of their products by presenting pharmacoeconomic and safety data.
- Use selling practices that are based upon the individual needs of physicians in their districts and territories.
- Are familiar with the educational programs available for healthcare professionals.
- Pass information on to physicians about prescription drug assistance programs offered by the government or their pharmaceutical company.
- Comply with the new PhRMA guidelines on interactions with healthcare professionals.

The next series will focus on the 21st century physician.