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**NATIONAL
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Providing Outpatient
Prescription Drugs
through Medicare:
Can We Afford To?
Can We Afford Not To?



In the Spring 1994 issue of *Health Affairs*, Stephen H. Long, Ph.D., senior economist at RAND and the executive director of the short-lived Prescription Drug Payment Review Commission, raised the following questions in his article “Prescription Drugs and the Elderly: Issues and Options.”

- Whose responsibility is it to provide coverage?
- Who should be covered?
- What should be covered?
- Who should pay for prescription drug coverage?
- How to control costs?

These questions remain relevant today and form the framework for this paper. In addition, the paper contains a section on options for structuring a Medicare outpatient prescription drug benefit as well as a glossary.

WHOSE RESPONSIBILITY IS IT TO PROVIDE COVERAGE?

Many believe that it is the government’s responsibility—through Medicare and Medicaid—to provide an outpatient prescription drug benefit. Others, however, argue that the private market should be the vehicle for expanding drug benefits—through supplemental plans such as Medigap, through retiree health plans, and through Medicare risk plans, as they do now to a limited degree.

The Federal Government: Medicare Prescription Drug Coverage

In 1969, a task force headed by Philip Lee, M.D., was created to study the issue of providing a drug benefit for beneficiaries of the newly created Medicare program. While the task force pushed for a Medicare drug benefit, concerns about associated costs, industry opposition, and congressional inaction resulted in the death of that proposal. The 1972 Social Security Act amendments sparked renewed interest in the notion of a Medicare prescription drug benefit. Again, the idea fizzled. While the concept has come and gone throughout the intervening years—during the 1970s talk of a national health insurance benefit package; during the 1980s passage and subsequent repeal of the Medicare Catastrophic Coverage Act; during the 1990s defeat of President Clinton’s health reform movement; and most recently during the deliberations of the National Bipartisan Commission on the Future of Medicare—the Medicare drug benefit has remained elusive. According to the *Wall Street Journal*, when asked whether this

Medicare commission will change the course of a Medicare drug benefit, Lee predicted it would not. “It is destined to fail,” he replied.¹ Time will tell.

The Role of the States

Medicaid coverage of outpatient prescription drugs. Medicaid provides medical assistance to certain categories of low-income people, including the aged and disabled. Under this state-federal program, each state designs and administers its own program, subject to federal guidelines. Although they are not required to do so, all states currently offer outpatient prescription drug coverage through their Medicaid plans. As a result, Medicaid provides outpatient prescription drug coverage to Medicare beneficiaries who also qualify for some category of Medicaid benefits. These beneficiaries are referred to as “dual eligibles.”

Under the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Congress enacted several provisions designed to reduce drug expenditures under Medicaid, including institution of the Medicaid Drug Rebate Program and mandatory drug utilization review (DUR) systems. These initiatives are described more fully in the section entitled “How to Control Costs?”

QMB and SLMB coverage of outpatient prescription drugs. Certain low-income Medicare beneficiaries (qualified Medicare beneficiaries, or QMBs), receive assistance from Medicaid for payment of Medicare cost-sharing charges, such as premiums, deductibles, and coinsurance. These beneficiaries include the elderly with incomes below the federal poverty line who are not Medicaid beneficiaries. In some states, however, QMBs could be full Medicaid beneficiaries; it depends on where the state sets its income limits.

For Medicare beneficiaries with incomes between 100 percent and 120 percent of poverty (specified low-income Medicare beneficiaries, or SLMBs), Medicaid pays only the Part B Medicare premium. Therefore, although Medicaid will pay the coinsurance charges for the limited outpatient drugs covered by Medicare (for QMBs), as well as Part B premiums for both QMBs and SLMBs, most QMBs and SLMBs do not have access to Medicaid’s outpatient drug benefit.

State pharmaceutical assistance programs. Since 1975, a number of states have developed drug coverage programs for low-income elderly or disabled persons not covered by Medicaid. Currently, 13 states have such programs (Table 1). These programs are each funded and operated differently. For example, while several states use state general funding (Connecticut and

Table 1
State Pharmaceutical Assistance Programs

	Program Name	Recipients	Enacted
Connecticut	ConnPACE	33,798	1986
Delaware	Nemours Health Clinic Pharmaceutical Assistance Program	9,335	1981
Illinois	Pharmaceutical Assistance Program (PAP)	53,555	1985
Maine	Low-Cost Drugs for the Elderly Program	22,000	1975
Maryland	Maryland Pharmacy Assistance Program	27,786	1979
Massachusetts	Senior Pharmacy Program	65,000 (estimated)	1997
Michigan	Michigan Emergency Pharmaceutical Program	10,000	1988
Minnesota	Senior Drug Program	4,500 in 1999, 11,600 in 2000 (estimated)	January 1999
New Jersey	Pharmaceutical Assistance for the Aged and Disabled (PAAD)	214,018	1975
New York	Elderly Pharmaceutical Insurance Coverage (EPIC)	107,767	1987
Pennsylvania	PACE	305,102	1984
Pennsylvania	PACENET	1,522	1984
Rhode Island	Rhode Island Pharmaceutical Assistance for the Elderly (RIPAE)	16,000	1985
Vermont	Vermont Health Access Program (VHAP)	6,283	1996
Vermont	VSCRIP	4,306	1989

Source: National Pharmaceutical Council, Inc., "Pharmaceutical Benefits under State Medical Assistance Programs," December, 1998, 5-3.

Maryland), others rely on foundations (Delaware), on cigarette tax revenues (Massachusetts), casino revenue funds (New Jersey), and state lottery monies (Pennsylvania). Most of these programs also receive some type of manufacturer rebate.

The Private Marketplace

Given the lack of an outpatient prescription drug benefit under Medicare, it is not surprising that the majority of the elderly with drug coverage obtain their

coverage in the private market. Seniors obtain supplemental coverage for prescription drugs through Medigap policies, retiree health plans, or Medicare risk plans.

The Medigap market. Beneficiaries have purchased supplemental insurance (referred to as Medigap policies) since the inception of the Medicare program as a way to protect themselves against costs not covered by the program (for example, outpatient drugs, routine physicals, and podiatric care). Medigap insurance is specifically designed to supplement Medicare's benefits

and is regulated by federal and state law. Until the passage of OBRA 1990, however, the Medigap market lacked standardization among the benefits sold, creating confusion among consumers. The Medigap provisions in OBRA 1990, which became effective on July 30, 1992, required all new Medigap policies to conform to one of ten standardized sets of benefits, or plans. These range from Plan A, the basic benefit package, to Plan J, which provides the greatest coverage.

Among other things, OBRA 1990 enabled beneficiaries to make informed choices about the benefits they were purchasing. One of those benefits was outpatient prescription drug benefits. Plans H, I, and J offer prescription drug benefits. Plans H and I are structured with a \$250 deductible. After the deductible is met, the policy covers 50 percent of prescription drug costs to a maximum benefit of \$1,250. Plan J also has a \$250 deductible but covers 50 percent of prescription drug costs to a maximum benefit of \$3,000. The costs of these plans are high in comparison to the other plans (in part, to compensate for adverse risk selection), and the coverage is quite limited.

Access to individually purchased Medigap policies can, in some cases, be limited. Elderly Medicare beneficiaries are guaranteed a six-month open-enrollment period when they first enroll in Part B at age 65 or older.

Under federal law, at any time after the open-enrollment period, insurers can refuse to issue Medigap policies on the basis of age or health status and can impose preexisting condition exclusion periods or refuse to cover certain conditions at all. Even insurers that have "guaranteed issue" for Medigap policies without drug coverage underwrite drug coverage purchased outside of the open-enrollment period.²

Retiree health plans. Many employers provide health insurance benefits to their Medicare-eligible retirees as part of their company retirement package. This insurance is typically more generous and less costly for the beneficiary than Medigap. Most employer-provided retiree benefits include outpatient prescription drug coverage.

While the vast majority of retiree health plans offer outpatient prescription drug coverage, benefit analysts report that, as a result of changing accounting requirements and rising health care costs, the number of employers offering retiree health coverage is diminishing. In particular, employers have expressed concern over the rising cost of providing prescription drug coverage.

Consequently, employers are reconsidering the package they are willing to offer employees. According to the recent Mercer/Foster Higgins National Survey of Employer-Sponsored Health Plans 1998:

Some employers keep the cost of their retiree medical plans down by excluding prescription drug coverage. In 1998, 24 percent of retiree plan sponsors did not provide prescription drug coverage to pre-Medicare retirees; 28 percent did not provide it to Medicare-eligible retirees. This exclusion is rare among the largest employers; fewer than 10 percent of employers with 10,000 or more employees refuse to cover prescription drugs for their retirees. Among those sponsors providing drug coverage to pre-Medicare retirees, half provide a card plan or mail-order plan (51 and 50 percent, respectively). Among sponsors who provide drug coverage to Medicare-eligible retirees, 56 percent offer a mail-order plan and 50 percent offer a card plan.

In response to increasing cost pressures, many employers are moving their Medicare-eligible retirees into Medicare managed-care plans, thus reducing premium and claim costs and allowing companies to more accurately predict retiree health costs.

Medicare risk plans. Prescription drug coverage is a key benefit that greatly influences a Medicare beneficiary's decision to join an HMO. Although not obligated to do so, many of the Medicare health maintenance organizations (HMOs) were quick to offer outpatient prescription drug coverage in an attempt to gain market share. While this strategy may have yielded the desired results initially, much has happened in the marketplace that will change how Medicare HMOs do business in the future. Analysts warn that the likelihood of HMOs offering unrestricted drug coverage in the future is questionable.

Especially problematic for Medicare risk plans, they maintain, is their attractiveness for patients with a high number of prescriptions. Further disadvantaging these plans are the current Medicare rules which allow beneficiaries to leave a plan with only 30 days notice. Many beneficiaries exhaust their drug benefits and then switch to another Medicare risk plan, thus taking advantage of the new plan's drug coverage. Beneficiaries will be able to move from plan to plan until 2002, when the rules stipulate a longer commitment. In 2003, the lock-in period is one year, with an initial three-month window for beneficiaries to switch plans.

By the end of 1998, some Medicare HMOs withdrew from the market in part because, according to plan executives, medical costs were higher than expected (particularly in the area of prescription drugs), Medicare payments were lower than expected, and plans were unable to raise premiums or cut prescription drug coverage for the elderly once initial benefit packages were filed with the Health Care Financing Administration (HCFA). The pull-out was estimated to affect over 400,000 beneficiaries. These beneficiaries had the option of going back

into the traditional fee-for-service Medicare program, with or without supplemental insurance to cover extra items (such as outpatient prescription drugs), or of enrolling in another HMO, if available in their market.

Beneficiaries choosing among Medicare HMOs and other plan options may find the plans difficult to compare. As explained in the Forum's Issue Brief No. 723, *Communicating to Beneficiaries about Medicare+Choice: Opportunities and Pitfalls*, written by Nora Super Jones,

The value of plans' prescription drug coverage may be the most difficult to compare. GAO [the General Accounting Office] found that plans differ in how they calculate the dollar amounts of drugs used by beneficiaries. For example, some plans use retail prices, while others use average wholesale prices (AWP) or a lower price discounted from AWP to calculate a member's total drug usage in dollars. Therefore, a beneficiary comparing one plan with an annual cap on prescription drug coverage of \$1,200 with another offering coverage up to \$1,000 may incorrectly assume the first plan is more generous. In fact, the consumer value of the drug benefit could vary substantially, depending on how the HMOs compute the drug cost.

WHO SHOULD BE COVERED?

Despite the absence of a specific Medicare drug benefit, supplemental coverage does exist for the majority of the nearly 40 million Medicare-eligible beneficiaries. Among those covered, there exists a great deal of variation among the types and level of coverage. When considering the addition of a Medicare outpatient drug benefit, policy analysts and legislators will need to distinguish between anecdotal and statistical reality:

- Who is already covered?
- Is that coverage adequate?
- Is that coverage affordable?
- Will that coverage be there in the long-term?
- Who is not covered?
- Will a Medicare drug benefit duplicate or substitute for existing coverage?
- Should a Medicare benefit be designed to cover only those without coverage?

Who Is Covered?

The most recent estimates appeared in the January/February 1999 issue of *Health Affairs*, in a Datawatch piece entitled "Prescription Drug Coverage, Utilization, and Spending among Medicare Beneficiaries," by Mar-

garet Davis, et al. Using data from the 1995 Medicare Current Beneficiary Survey (MCBS), the authors describe the sources and extent of drug coverage among non-institutionalized Medicare beneficiaries.

The data show that 65 percent of Medicare beneficiaries have some level of drug coverage—a figure much higher than previous published numbers—and that 95 percent of Medicare health maintenance organization enrollees have drug coverage.

Table 2 summarizes the distribution of prescription drug coverage among Medicare beneficiaries based on the 1995 MCBS data.

Analysts urge caution when citing this 65 percent number, primarily because of the unevenness of the coverage. Some of the Medicare beneficiaries counted in the 65 percent have robust drug coverage through generous employee retiree plans and Medicare HMOs, while others—also included in this 65 percent—have meager coverage and high deductibles through Medigap policies. Further, beneficiaries were considered to have drug coverage in this study if they had it at any point during their eligible months.

Who Is Not Covered?

Most of the Medicare eligible beneficiaries without supplemental coverage are those with incomes too high to qualify for Medicaid or other state assistance programs, those with incomes too low to afford the purchase of supplemental coverage, or those who did not work for an employer who sponsors retiree coverage.

Many of these elderly cannot afford the out-of-pocket expenses needed to pay for drugs. According to data from the American Association of Retired Persons (AARP):

Fee-for-service beneficiaries with annual incomes below \$10,000—who are less likely to have prescription drug coverage—were estimated to have spent an average of 8 percent of their income out-of-pocket for prescription drugs. By contrast, beneficiaries with annual incomes above \$25,000 were estimated to have spent an average of 2 percent of income on prescription drugs.

Average out-of-pocket payments for drug expenses for beneficiaries without any form of drug coverage were \$432 in 1995, compared with \$232 for those with drug coverage, according to the HCFA data.

Beneficiaries without prescription drug coverage are disadvantaged further. Unlike individuals in employer-sponsored and managed care plans who enjoy volume discounts, most individuals without drug coverage must pay retail price for their prescription drugs. These

individuals can, however, take advantage of competition at the retail level by shopping around to get a better price. Also, even without drug coverage, a person can access a mail-service pharmacy (for example, through AARP) which generally offers competitive prices, particularly for chronic condition medications.

WHAT SHOULD BE COVERED?

Under traditional fee-for-service Medicare, coverage of outpatient prescription drugs is limited. As legislators

consider broadening this benefit, they will have to consider how generous a benefit to design.

Current Medicare Outpatient Prescription Drug Coverage

Currently, payment will be made only when a drug or biologic cannot be self-administered. In other words, Medicare coverage is generally limited to drugs or biologics administered by injection. If the injection is self-administered, as in the case of insulin, for example, it is not covered under Medicare.

Table 2
Outpatient Drug Coverage among Noninstitutionalized Medicare Beneficiaries, 1995
(by type of supplemental insurance)

	Percent of Beneficiaries with Specified Type of Supplemental Insurance	Percent of Beneficiaries with Each Type of Supplemental Insurance Who Have Drug Coverage	Percent of All Beneficiaries with Drug Coverage
Employer Sponsored^a	33%	86%	28%
Medicaid^b	12%	90%	11%
Medicare Risk HMO	7%	95%	7%
Individually Purchased (Medigap)	29%	29%	8%
All Other^c	3%	89%	3%
Switched Coverage during the Year^d	8%	80%	6%
No Supplemental Insurance	8%	0%	0%
Total	100%	N/A	65% ^e

Key: N/A—Not Applicable

Notes: Data are based on noninstitutionalized, community-based population and include those who were enrolled in Medicare at some point during the year. Each person has been assigned to one supplementary insurance category, but may or may not obtain his or her drug insurance coverage from that source.

^aIncludes those who had only employer-sponsored supplemental insurance and those who had both employer-sponsored and individually purchased supplemental insurance.

^bIncludes beneficiaries receiving full Medicaid benefits, as well as qualified Medicare beneficiaries (QMBs) and specified low-income Medicare beneficiaries (SLMBs).

^cIncludes other public programs such as Veterans Affairs, Department of Defense, and State Pharmaceutical Assistance Programs for low-income elderly, as well as nonrisk HMOs (cost and health care prepayment plans).

^dIncludes beneficiaries who did not spend 100 percent of their Medicare-eligible months in one insurance category.

^eColumn does not add up to total due to rounding error.

Source: Michael E. Gluck, Ph.D., "A Medicare Prescription Drug Benefit," National Academy of Social Insurance White Paper (forthcoming). Data from M. Davis et al., "Prescription Drug Coverage, Utilization, and Spending among Medicare Beneficiaries," Health Affairs 18, no. 1 (January/February 1999): 231-243, and from the Medicare Current Beneficiary Survey.

Despite these limitations, Medicare law specifically authorizes coverage for a number of drugs, such as immunosuppressive drugs following a covered organ transplant (for 36 months), some vaccines, erythropoietin, and oral cancer drugs used in cancer chemotherapy when identical to drugs that would be covered if not self-administered.

As of January 1, 1998, the Medicare payment amount for covered drugs is the lesser of (a) the actual charge or (b) 95 percent of the average wholesale price. For most of these drugs, Medicare pays 80 percent of its recognized payment amount once the beneficiary meets the deductible for Medicare Part B services. With few exceptions, the beneficiary is responsible for the remaining 20 percent. The president's fiscal year 2000 budget proposes to change the payment amount to 83 percent of average wholesale price.

Because of the way Medicare has historically paid HMOs, prescription drug coverage under these plans varies significantly by geographic region. Areas with high payment rates generally have generous prescription drug coverage, while Medicare HMOs in low payment areas offer no additional benefits beyond what Medicare traditionally covers. Benefit packages can also vary markedly within a given region. For example, on the San Diego area (zip code 92014), Aetna U.S. Healthcare provides Medicare beneficiaries with an unlimited generic drug benefit, but brand-name prescription drugs are covered only up to \$2,000 per year; UCSD Health Plan covers generic and brand-name drugs up to \$2,500 per year; and Kaiser Foundation Health Plan and PacifiCare provide an unlimited prescription drug benefit. In addition, each of the plans has a different copayment schedule.³

Future Medicare Outpatient Prescription Drug Coverage

Not all drugs are created equal. In fact, the very definition of a "drug" may change.

We live in an era where the line is blurring between ethical drug products and biotechnology, as well as drug-device combination products. Determining (a) What is a drug? (b) Should it be covered? Under what conditions(s)? (c) How should it be reimbursed? are all important questions."⁴

Presently, analysts are faced with the same set of questions for today's breakthrough drugs, which represent a significant advance over existing therapies, as well as for "me-too" drugs, which represent slight variations of existing products.

In addition to determining coverage of breakthrough and me-too drugs, further consideration will have to be given to expanding coverage not only to life-extending products but also to those pharmaceuticals, "recroceuticals," "cosmeceuticals," and "nutraceuticals" that may not extend life but certainly enhance it. For example, should Medicare pay for every product approved by the FDA? Should off-label use be covered? Are nutrition supplements and vitamins to be part of this benefit? Who should decide what gets covered?

WHO SHOULD PAY FOR PRESCRIPTION DRUG COVERAGE?

Steve Long's caution in his 1994 *Health Affairs* article still holds:

Many a meeting on health policy is yet brought to a pause by the call to "remember the lesson of the Medicare Catastrophic Coverage Act." One lesson clearly pertains to the difficulty of financing coverage expansions that will benefit only some people, while using taxes that would be paid by all Medicare enrollees. Many people who now have coverage for prescription drugs are reluctant to depart from premium-financed approaches that would closely match incremental contributions to incremental benefits. On the other hand, many of those without coverage do not have the means to pay for its full cost. This argues for broad-based taxes levied on those who are able to pay, regardless of their current benefits.

The Mechanics of Part B Financing

Should an outpatient prescription drug benefit be added to Medicare's core benefit package, it would fall under what is referred to as Part B. Medicare, a federal health insurance program, is divided into three parts: Part A, which, with few exceptions, covers inpatient care; Part B, which covers outpatient services, such as physician office visits and medical equipment; and Part C, the Medicare+Choice program, the most recent addition.

Currently, Medicare Part B, also known as Supplementary Medical Insurance, or SMI (which is different from Medigap supplemental insurance), is financed by a combination of beneficiary premiums and general federal revenues collected from workers, retirees, corporations, and other federal taxpayers. For 1999, the Part B premium is \$45.50 per month and the annual deductible is \$100. Although Part B is voluntary, virtually all Medicare-eligible beneficiaries have Part B coverage.

Beneficiary premiums cover about 25 percent of program costs, while general federal revenues finance the remaining 75 percent through the Part B Trust

Fund. In addition to having paid income taxes during their younger years, it is estimated that people age 65 and older will pay about 9 percent of federal personal income taxes in 1997. Personal income taxes represent about 70 percent of general revenues.⁵

HOW TO CONTROL COSTS?

The issues of pharmaceutical cost and price are complicated and have become highly politicized over the past decade. On the one hand, while headlines—such as the one in a January 25, 1999, *New York Times* article—cry out that “Patients Are Facing Sharp Rise in Costs for Drug Purchases,” other articles, reports, and analysts caution that short-term cost hikes should be weighed against the fact that pharmaceuticals in many cases provide long-term value and, often, cost-effective care.

Nevertheless, retail prescription drug sales grew 14.1 percent in 1997—faster than other types of health care spending and the greatest growth since 1990, when it reached 14.6 percent—according to HCFA data released in November 1998. HCFA data further revealed that retail prescription drug expenditures rose from about \$5.5 billion in 1970 to some \$12 billion in 1980, \$37.7 billion in 1990, and \$78.9 billion in 1997.⁶

By all accounts, double-digit pharmaceutical budget increases are forecast annually for the next three to five years. Three factors have contributed to the recent increases in pharmaceutical budgets: unit cost inflation; utilization (that is, increases in the absolute number of prescriptions); and intensity (that is, new drug technologies becoming available). Fueling the increase in utilization is the explosion of direct-to-consumer advertising by the pharmaceutical companies, with some estimates reaching as high as \$917 million for 1998.⁷ The technological explosion that enabled the extraordinary growth of electronic prescription claims processing has also contributed to the increase.

In a December 21, 1998, special report on pharmaceuticals, *BNA* reporters pointed out that “an emerging new mix of drivers—demographic, scientific, economic, and regulatory—is helping to engineer the recent increasing double-digit growth rates in retail prescription drug sales.”⁸

Cost Drivers

Demographic. The Council on the Economic Impact of Health System Change held a conference on “Health Status, Technological Innovation, and Health Care Expenditures” on February 9 and 10, 1999, in Washing-

ton, D.C. In the background paper of the same title, prepared by Cindy Parks Thomas, David Shactman, and Stuart H. Altman, Ph.D., the authors pointed out the following:

Indicators typically used to gauge the health of the population—longevity, mortality, disability, and disease incidence and prevalence—reveal several demographic and health trends relevant to health care utilization and expenditures. They include:

- A growing elderly population, increasing both in absolute terms and as a proportion of the overall population;
- Decreasing mortality rates for several high-prevalence, high cost diseases such as cardiovascular disease and stroke;
- Changing patterns of chronic disease prevalence;
- Decreasing disability rates among several segments of the older population; and
- Improving health-risk behaviors among the elderly (decreased smoking; better education).

The magnitude and sustainability of each of the above trends will have direct bearing on health expenditures over the next decades.

The economic burden resulting from a growing elderly population will depend upon the extent of disease and disability among this age group (Table 3). This will be particularly relevant to the Medicare program should an outpatient prescription drug benefit be added.

Scientific. Over the years, Americans have benefitted from the advances in pharmaceutical research. Leading causes of death have been eliminated, treatments for many diseases are taken for granted, vaccines preventing diseases are commonplace, and life expectancy has increased. Scientists have come a long way since the development of penicillin. Today’s pharmaceutical research has entered the biotechnology era. The Pharmaceutical Research and Manufacturers of America (PhRMA) has indicated that, today, over 350 biotechnology medicines produced by 140 pharmaceutical and biotechnology companies, for a variety of diseases, are in development (that is, in human clinical trials or at the FDA for approval).

Indeed, the face of pharmaceutical research is changing (Figure 1). Steve Arlington and Simon Hughes, authors of a recent PriceWaterhouseCoopers article, “The Pharmaceutical Industry 2005—A Window onto the Future,” explain that

discovery throughput has been revolutionized through extensive investment in new technologies—genomics, combinatorial chemistry, high throughput screening.

Table 3
Selected Major Chronic Conditions by Age Group, 1995
(per 1,000 persons in each age group)

	Prevalence in Age Group under 45	Prevalence in Age Group 45-64	Prevalence in Age Group over 65
Arthritis	29.2	232.9	489.5
Hypertension	32.2	222.7	403.4
Cardiac disease	29.0	120.8	307.7
Diabetes	7.9	63.8	126.4
Cerebrovascular disease (Stroke)	1.7	14.9	71.3

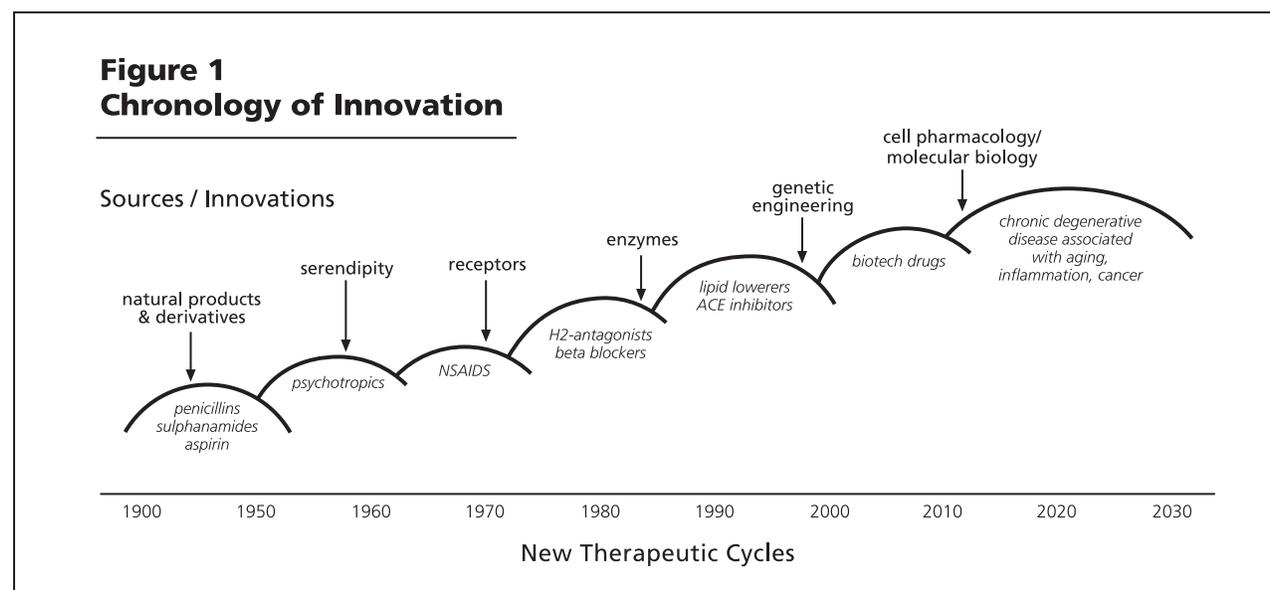
Source: National Center for Health Statistics, 1998.

Meanwhile, productivity and speed continue to be transformed through increasing use of CROs (contract research organizations), massive investment in IT (information technology) and the setting up of virtual development organizations or “skunk works.”

Economic. Despite the promising advances in drug innovation, it is a long and risky undertaking for pharmaceutical research and manufacturing companies. It has been estimated that drug companies will invest \$24 billion in drug discovery this year. According to

PhRMA, only three out of ten approved drug products recover their research and development (R&D) costs. “Companies must rely on these highly successful products to fund R&D.” Industry critics point out, however, that “drug company profits are enormous. The annual profits of the 10 leading drug companies were nearly \$20 billion last year, according to *Fortune* magazine.”⁹

According to manufacturers, patent protection is critical for the continuation of pharmaceutical innovation. Patents provide research-based pharmaceutical



Source: Lehman Brothers Pharmaceutical Research

companies with a period of market exclusivity, during which time they have the opportunity to recoup their R&D investments. During the mid-1980s, passage of the Drug Price Competition and Patent Term Restoration Act—also referred to as the Hatch-Waxman Act—made it easier for generic drugs to enter the market. Sales of generic drugs result in a reduction of returns that pharmaceutical companies earn from developing brand-name drugs. Generic drugs cost less than brand-name drugs, largely because the manufacturers do not carry the financial burden of R&D costs.

As a July 1998 Congressional Budget Office study explained:

The Hatch-Waxman Act aimed to limit that effect by extending the length of time that a new drug is under patent—and thus protected from generic competitors. Those extensions compensate for the fact that part of the time a drug is under patent it is being reviewed by the FDA rather than being sold. The act tried to balance two competing objectives: encouraging competition from generic drugs while maintaining the incentive to invest in developing innovative drugs.¹⁰

According to PhRMA, “In the United States, despite 20 year patent terms, the average period of useful (post-FDA approval) patent life for new drugs introduced in the 1990s has been only 11-12 years.”

Regulatory. One of the results of the passage of the FDA Modernization Act of 1997 was the extension of the 1992 Prescription Drug User Fee Act, otherwise known as PDUFA. Among other things, one of the primary objectives of PDUFA is to streamline the amount of time required for drug development and approval. Between 1985 and 1990, for example, the average number of new product approvals per year was 23. That number jumped to 50 between 1995 and 1998. It is estimated that by 2002 new products will account for 41 percent of total sales.

Cost Control Tools

While the clinical benefits of many of these new products are significant, their high costs place a heavy burden on payers and patients. As new products make their way into the market, the market has responded with new tools to control drug costs. One of the most dramatic responses has been the growth of pharmacy benefit managers, or PBMs.

PBMs. The past decade has witnessed the proliferation of pharmacy benefit managers. PhRMA reports that “these companies evolved from insurance claim-processing and mail-order prescription companies. PBMs now provide managed pharmacy benefits for approximately half the

insured population in the United States.” The relationships between PBMs and pharmaceutical companies as well as between PBMs and pharmacies are shifting. Recently, there has been a lot of activity in the buying and selling of PBMs. Some question whether PBMs, especially those owned by drug companies or by drug store chains, are necessarily freestanding companies.

Using purchasing techniques such as pharmacy networks, negotiated discounts and rebates, lists of preferred drugs, and online utilization review, PBMs enhance the ability of employers and health plans to contend with pharmaceutical prices, physician prescribing practices, and rising drug expenditures. Leading firms are also pioneering new methods of disease management.¹¹

Many of the cost-saving tools used by PBMs are not new. Copays and deductibles, for example, are standard fare among health plans. In response to rising drug costs, insurers, such as Cigna Corp., began a three-tiered copay arrangement in 1998: \$5 for generics, \$15 to \$20 for preferred brand-name drugs, and \$35 to \$40 for nonpreferred brand-name drugs. In 1995, Cigna members paid only a \$5 copay for preferred drugs—generic or brand-name.

Similarly, most plans and PBMs have instituted many of the following cost-control tools (all of which are defined in the glossary at the end):

- formulary;
- generic substitution;
- drug utilization review;
- step-care therapy;
- therapeutic substitution;
- prior approval;
- mail-order pharmacies; and
- disease management.

Negotiated discounts. Negotiating discounts for pharmaceuticals is a common practice. PBMs and managed care plans negotiate discounts in exchange for the ability to move market share, while the federal government (for example, the Veterans Health Administration, the Public Health Service, and the Indian Health Service) mandates discounts.

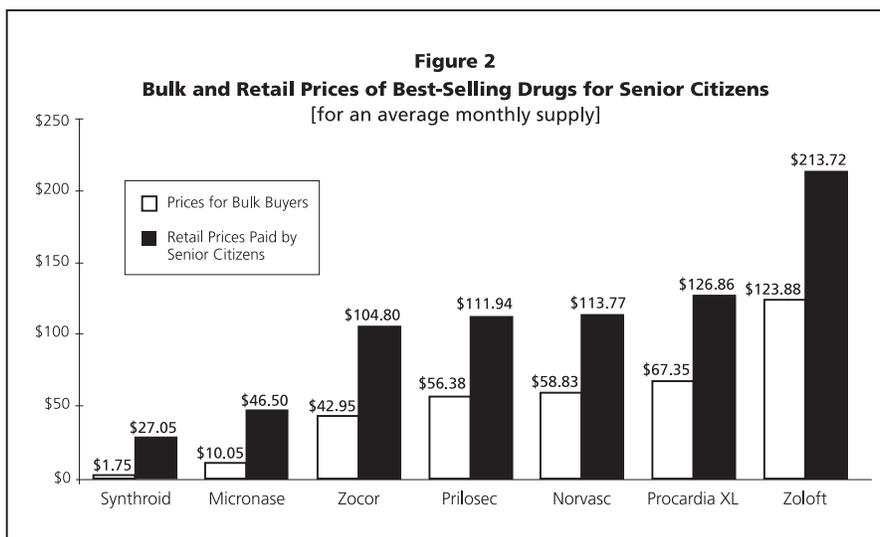
Senior citizens without drug coverage generally do not enjoy the benefits of “preferred pricing.” During the summer of 1998, minority staff of the House Government Reform and Oversight Committee conducted 20 studies around the country to monitor the prices of best-

selling drug products for the elderly. Staff analysis found that elderly individuals paying cash (as opposed to using a discount drug card) paid significantly more money for the same medication than drug manufacturers' most favored customers. However, some analysts have questioned aspects of the study's methodology (that is, base prices used for comparison). Figure 2 highlights findings from the study.

A new congressional Prescription Drug Task Force was created in response to the price discrimination found by minority committee staff. Rep. Marion Berry (D-Ark.) and Rep. Tom Allen (D-Maine) serve as co-chairs of the task force. On September 25, 1998, the co-chairs introduced H.R. 4627, the Prescription Drug Fairness Act of 1998, which would allow pharmacies that serve Medicare beneficiaries to purchase prescription drugs at the low prices available to federal agencies under the Federal Supply Schedule. Nothing in the bill requires the pharmacy to pass its savings on to the Medicare beneficiaries, however, although a bill summary estimates that this legislation could reduce prices for seniors by over 40 percent. Others point out that, as a result of these savings, prescription drug prices could go up elsewhere—the classic balloon phenomenon.

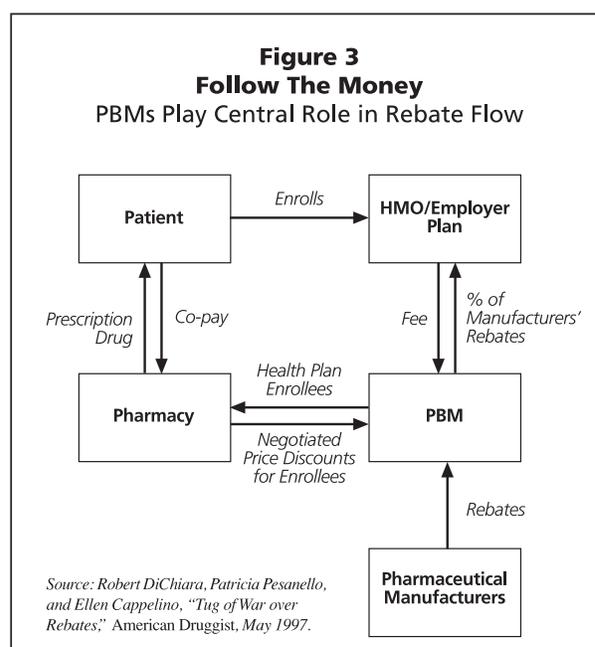
Rebates. OBRA 1990 established the Medicaid rebate program. The basic formula requires that, in exchange for having their product(s) reimbursed (that is, on the formulary), pharmaceutical manufacturers rebate to the states the greater of (a) 15.1 percent of the average manufacturer price (AMP) paid by wholesalers for brand-name drugs that Medicaid beneficiaries purchase as outpatients or (b) the manufacturer's "best price." The best price is the lowest price offered to any other customer, excluding Federal Supply Schedule prices and prices to state pharmaceutical assistance programs. Similarly, manufacturers pay a rebate equal to 11 percent of the AMP on generic and over-the-counter drugs.

If a brand-name drug's AMP increases faster than the inflation rate, an additional rebate is imposed so that manufacturers cannot offset the basic rebate by raising their AMP. The additional rebate is equal to the difference between the current AMP and a base-year AMP increased by the inflation rate as measured by the consumer price index.¹²



Source: House Government Reform and Oversight Committee, Democratic Staff Report

Medicaid—which accounted for over \$2.2 billion worth of pharmaceutical manufacturer rebates in 1997—is not alone in its use of rebates. As the number of HMOs and PBMs increased, manufacturers began to offer rebates in an effort to gain access to managed care patients. According to a May 1997 *American Druggist* article, "Tug-of-War over Rebates," by Robert DiChiara, Patricia Pesanello, and Ellen Cappelino, rebates flow from the manufacturer through the PBM and are split with the benefit plan of the HMO or employer (Figure 3).



When considering the use of PBMs, rebates, and best price for a Medicare benefit, it is important for policy and legislative analysts to note that each pharmaceutical company is structured differently and prices its products differently. Thus, the effects of such policies vary widely from company to company.

OPTIONS FOR STRUCTURING A MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT

The following components are all considerations in the design of a Medicare outpatient prescription drug benefit. These categories are merely representative of the elements involved in designing such a benefit, and are not meant to be exhaustive. Depending upon how the debate unfolds and how a benefit might be designed, issues of adverse risk selection, income distribution, locus of control, interface with existing drug benefits, as well as long-term implications of future pharmaceutical research and development investment will be paramount. Each option is associated with trade-offs—political, financial, competitive, and practical:

Type of Benefit

- Standard, broad-scale benefit for all beneficiaries (with or without cap)
- Catastrophic coverage only
- Targeted benefit for those without any other coverage (For example, the federal government could require prescription drug coverage for QMBs and SLMBs or encourage state pharmaceutical assistance programs by offering matching grants)
- Voluntary, supplemental coverage

Benefit Structure

- Amended Medicare Part B (traditional fee-for-service Medicare beneficiaries)
- Mandated drug benefit for all standard Medigap plans
- Federal government financial contribution to help Medicare beneficiaries purchase a health plan (Beneficiaries would be free to select from a range of private-sector options the plan that best meets individual needs. [This option represents the PhRMA proposal])

Eligibility Criteria

- Age
- Disability

- Income level/wealth (single, married)
- Preexisting conditions

Type of Insurance

- Community rating
- Experience rating
- Age rating

Market Structure

- Universal or voluntary coverage
- Plan choices
- Basis of competition
- Risk adjusters
- Market rules
- Benefit design
- Flexibility or standardization

Financing

- Beneficiary premiums
- Federal general revenues
- Payroll or other targeted tax
- Government surpluses
- Savings from competition (or other reforms)

Beneficiary Cost-sharing

- Additional drug deductible
- Increased deductible
- Co-pays or coinsurance (differential, based upon generic, preferred, or brand name product)
- Out-of-pocket limits (individual/couple)

Reimbursement

- Pharmacy Payment
 - Dispensing fee
 - Ingredient reimbursement basis
 - Cognitive services
- Drug Price
 - Manufacturer rebates
 - Best price
 - Price negotiated by HCFA directly with manufacturer

Benefit Administration

- Pharmacy Benefit Management (many technical operational questions to resolve)

- Capitated or noncapitated basis
- Carve-out program for drugs
- Government-administered benefit

Cost/Utilization Management

- Formulary (open, closed, national)
- Use of generics
- Prior authorization
- Therapeutic substitution
- Disease management
- Mail service
- Price controls
- Prescribing/dispensing limits
 - Quantity (that is, limited to 30-day supply or 100-unit dosage, whichever is greater)
 - Dollar limits

Quality Assurance

- Drug utilization review
- Cognitive services

estimates as well, but show generally similar growth trends.” See Jennifer Kalms, “Special Report: Pharmaceuticals,” *BNA’s Health Care Policy Report*, 6, no. 49.

7. See “Direct-to-Consumer Advertising of Prescription Drugs,” National Health Policy Forum Background Paper, April 1998, for a thorough discussion of the complex issues related to direct-to-customer advertising.

8. Kalms, “Special Report: Pharmaceuticals,” 2019.

9. Marilyn Werber Serafini, “Bitter Pills,” *National Journal*, 30, no. 44 (October 31, 1998), 2557.

10. Congressional Budget Office, “How Increased Competition for Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry,” CBO Study, July 1998.

11. Lynn Etheredge, “Pharmacy Benefit Management: The Right Rx?” Health Insurance Reform Project Research Agenda Brief, April 1995.

12. Congressional Budget Office, “How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry,” CBO Papers, January 1996, xi.

ENDNOTES

1. Lucette Lagnado, “Medicare Reformers Seek, Once Again, to Implement Drug Benefits for Elderly,” *Wall Street Journal*, November 17, 1998.

2. M.. Davis et al., “Prescription Drug Coverage, Utilization, and Spending among Medicare Beneficiaries,” *Health Affairs* 18, no. 1 (January/February 1999): 232.

3. Health Care Financing Administration, “Medicare Compare,” accessed at <http://32.97.224.58/comparison>, March 11, 1999.

4. Sing-huen Morgan, “Gene Therapy: The Beginning Payoffs,” *Inside Medical Technology*, 2, no 1 (January 1999).

5. David J. Gross and Normandy Brangan, “The Medicare Program,” Public Policy Institute, American Association of Retired Persons, April 1998.

6. According to a December 12, 1998, *BNA* article, “Estimates of annual retail sales levels vary by organization. HCFA and the National Association of Chain Drug Stores (NACDS), for example, define retail sales similarly but differ in their figures by up to \$10 billion. HCFA estimates about \$78.7 billion in retail sales for 1997 and NACDS figures about \$89.1 billion for that year. Other health care research organizations such as IMS and Scott Levin, which, unlike HCFA and NACDS, do not include mail service sales in retail sales, have their own

Glossary

Unless otherwise indicated, these terms were taken from the December 1998 National Pharmaceutical Council's (NPC's) *Pharmaceutical Benefits under State Medical Assistance Programs* and a CBO study, "How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," July 1998.

Actual Acquisition Cost: The pharmacist's net payment made to purchase a drug product, after taking into account items such as purchasing allowances, discounts, and rebates. (NPC)

Average Manufacturer Price (AMP): The average price paid by wholesalers for products distributed to the retail class of trade. (NPC)

Average Wholesale Price (AWP): The published suggested wholesale price of a drug. It is often used by pharmacies as a cost basis for pricing prescriptions. (NPC)

Best Price: For purposes of Medicaid rebate calculations, lowest price paid for a product by any purchaser other than federal agencies and state pharmaceutical assistance programs. (NPC)

Brand-Name Drug: See *Innovator Drug*.

Card Programs: The use of a drug benefit identification card which, when presented to a participating pharmacy by employees or their dependents, usually entitles them to receive the medication for a copay. (NPC)

Carve Out: A decision to purchase separately a service that is typically a part of an indemnity or HMO plan. Example: an HMO may "carve out" the behavioral health benefits and select a specialized vendor to supply these services on a stand-alone basis. (NPC)

Compliance: The degree to which patients follow treatment recommendations. (NPC)

Concurrent Drug Evaluation: An electronic assessment of claims at the point of service to detect potential problems that should be addressed prior to dispensing drugs to patients. (NPC)

Contract Pharmacy System: Pharmaceutical benefit delivery arrangement in which an HMO contracts with community pharmacies (chain or selected independents) to provide medications to members. Reimbursement may be by fee-for-service, capitation, or some other arrangement. (NPC)

Counter Detailing: A process of re-educating or influencing prescribers in a closed or controlled HMO plan. Usually done in order to gain more compliance with a formulary. In a counter-detailing program, techniques used by pharmaceutical sales representatives are adapted to a "counter" objective, that is, to provide doctors with basic pharmacological information designed to influence their prescribing habits. (NPC)

Disease Management: An effort to improve patient outcomes and lower costs by organizing managed care initiatives around patients with a particular disease or condition. (NPC)

Day Supply Maximum: The maximum amount of medication a person may receive at one time, usually the amount needed for 30 (acute) or 90 (maintenance) days of therapy, as defined by the drug benefit. (NPC)

Dispense as Written (DAW): A prescribing directive issued by physicians to indicate that the pharmacy should not in any way alter a prescription. Such alterations are usually done in order to substitute a generic drug for the brand-name drug ordered. (NPC)

Dispensing, Fill, or Professional Fee: The amount paid to a pharmacy for each prescription, in addition to the negotiated formula for reimbursing ingredient cost. (NPC)

Drug Detailing: Presenting information about a brand-name drug product to prescribers to educate them about its activity, uses, side effects, proper dosage and administration, etc. (NPC)

Drug Formulary: A listing of prescription medications which are preferred for use by a health plan and which may be dispensed through participating pharmacies to covered persons. This list is subject to periodic review and modification by the health plan. A plan that has adopted an "open or voluntary" formulary allows coverage for both formulary and nonformulary medications. A plan that has adopted a "closed, select or mandatory" formulary limits coverage to those drugs in the formulary. (NPC)

Drug Use Evaluation (DUE): Evaluations of prescribing patterns of prescribers to specifically determine the appropriateness of drug therapy. There are three forms of DUE: prospective (before or at the time of prescription dispensing), concurrent (during the course of drug therapy), and retrospective (after the therapy has been completed). Same as Drug Utilization Review. (NPC)

Drug Utilization: The prescribing, dispensing, administering, and ingestion or use of pharmaceutical products. (NPC)

Drug Utilization Review (DUR): A quantitative evaluation of prescription drug use, physician prescribing patterns, or patient drug utilization to determine the appropriateness of drug therapy. Most often focuses on overutilization. (NPC)

Estimated Acquisition Cost (EAC): An estimate of the price generally, and currently, paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers. (NPC)

Fixed Fee: An established “fee” schedule for pharmacy services allowed by certain government and private third-party programs in lieu of cost-of-doing-business markups. (NPC)

Formulary: *See Drug Formulary.*

Generic Drug: a copy of an innovator drug, containing the same active ingredients, that the FDA judges to be comparable in terms of such factors as strength, quality, and therapeutic effectiveness. Generic copies may be sold after the patent on a brand-name drug has expired. Generic drugs are generally sold under their chemical name rather than under a brand name. (CBO)

Generic Substitution: Dispensing a generic drug in place of a brand-name medication. (NPC)

Innovator Drug: A drug that receives a patent on its chemical formulation or manufacturing process, obtains approval from the FDA after extensive testing, and is sold under a brand name. Also known as Brand-Name Drug. (CBO)

Legend Drug: A drug that, by law, can be obtained only by prescription and bears the label, “Caution: federal law prohibits dispensing without a prescription.” *See Prescription Medicine.* (NPC)

Maximum Allowable Cost (MAC), or “Reasonable Cost Range”: A maximum cost is fixed for which the pharmacist can be reimbursed for selected products, as identified in a formulary. (NPC)

Me-Too Drug: A brand-name drug that uses the same therapeutic mechanism as a breakthrough drug and therefore competes with it directly. (CBO)

Most Favored Nations Discount or Clause: A contractual arrangement that stipulates that a vendor must provide to a particular payor the lowest prices that would be available to any purchaser. The federal government often invokes most favored nation clauses for healthcare contracts. (NPC)

Multiple-Source Drug: A drug available in both brand-name and generic versions from a variety of manufacturers. (CBO)

National Drug Code (NDC): A national classification system for identification of drugs. Similar to the Universal Product Code (UPC). (NPC)

Over-the-Counter (OTC): A drug product that does not require a prescription under federal or state law. (NPC)

Pharmacy and Therapeutics (P&T) Committee: An organized panel of physicians and pharmacists from varying practice specialties, who function as an advisory panel to the plan regarding the safe and effective use of prescription medications. Often comprises the official organizational line of communication between the medical and pharmacy components of the health plan. A major function of such a committee is to develop, manage and administer a drug formulary. (NPC)

Prescribed Drugs: Prescribed drugs are drugs dispensed by a licensed pharmacist on the prescription of a practitioner licensed by law to administer such drugs, and drugs dispensed by a licensed practitioner to his own patients. This item does not include a practitioner’s drug charges that are not separable from his other charges, or drugs covered by a hospital bill. (NPC)

Prescription Medication: A drug which has been approved by the Food and Drug Administration and which can, under federal and state law, be dispensed only pursuant to a prescription order from a duly licensed prescriber, usually a physician. (NPC)

Prior Approval or Prior Authorization: The process of obtaining prior approval as to the appropriateness of a service or medication. Prior authorization does not guarantee coverage. (NPC)

Rational Drug Therapy: Prescribing the right drug for the right patient, at the right time, in the right amount, and with due consideration of relative cost. (NPC)

Rebate: A monetary amount that is returned to a payer from a prescription drug manufacturer based upon utilization by a covered person or purchases by a provider. (NPC)

Restrictive Formulary: A term often used synonymously with closed formulary. *See Drug Formulary.* (NPC)

Single-Source Drug: A brand-name drug that is still under patent and thus is usually available from only one manufacturer. (CBO)

Step-Care Therapy: Requires that physicians follow a sequence of treatments for a given condition, usually starting with the lowest-cost treatment and progressing to higher-cost treatments only if previous treatments are not effective. (PhRMA 1998 Industry Profile)

Therapeutic Alternatives: Drug products containing different chemical entities but which should provide similar treatment effects, the same pharmacological action or chemical effect when administered to patients in therapeutically equivalent doses. (NPC)

Therapeutic Substitution: Dispensing by a pharmacist of a product different from that which was prescribed, but which is deemed to be therapeutically equivalent. In most states, such a practice requires the prescribing physician's authorization before the substitution may occur. A pharmacy and therapeutics committee most often approves the rationale for therapeutic equivalency prior to such practice. (NPC)