

Prescription Drugs: Issues of Cost, Coverage, and Quality

by Craig Copeland, EBRI

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- This *Issue Brief* closely examines expenditures on prescription drugs, and discusses their potential to substitute for other types of health care services. In addition, it describes employer coverage of prescription drugs, direct-to-consumer advertising of prescription drugs, and potential legislation affecting the prescription drug market.
- Prescription drug expenditures grew at double-digit rates during almost every year since 1980, accelerating to 14.1 percent in 1997. In contrast, total national health expenditures, hospital service expenditures, and physician service expenditures growth rates decreased from approximately 13 percent in 1980 to less than 5 percent in 1997.
- Private insurance payments for prescription drugs increased 17.7 percent in 1997, after growing 22.1 percent in 1995 and 18.3 percent in 1996. This growth in prescription drug payments compares with 4 percent or less overall annual growth in private insurance payments for each of those three years.
- From 1993 to 1997, the overwhelming majority of the increases in expenditures on prescription drugs were attributable to increased volume, mix, and availability of pharmaceutical products. In 1997, these factors accounted for more than 80 percent of the growth in prescription drug expenditures.
- A leading explanation for the sharp growth in drug expenditures is that prescription drugs are a substitute for other forms of health care. While it is difficult to determine the extent to which this substitution occurs, various studies have associated cost savings with the use of pharmaceutical products in treating specific diseases.
- Evidence suggests that more appropriate utilization of prescription drugs has the potential to lower total expenditures and improve the quality of care. Also, some studies indicate the U.S. health care system needs to improve the way patients use and physicians prescribe current medications.
- Prescription drug plans offered by employers are likely to undergo changes to ensure that only the most efficacious drugs are covered. Anecdotal evidence suggests that copayments for prescriptions are going to increase. Some health plans are including prescription drug costs in their capitated payments to physicians. Furthermore, prescription drug plans are expected to use formularies more aggressively.
- In 1996, an average 5.47 outpatient prescriptions were written for those ages 55–64, compared with more than eight for those age 65 and older. Inevitably, this translated to significantly more spending for prescription drugs by the elderly. In 1994–1995, the average elderly individual (age 65 or older) spent \$558 on prescription drugs, while the average 55–64-year-old spent \$355.
- While prescription drugs are showing sharp price increases, they are also becoming more important in the treatment of many diseases. Consequently, both employers and policymakers must carefully balance the design and cost of a drug benefit so that continual innovation is preserved and the benefit can remain affordable and effective.

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Introduction

Employers' health insurance costs in 1998 increased slightly over 6 percent, after

remaining relatively flat for the previous five years (William M. Mercer, 1999). This has generated much speculation that the substantial cost increases experienced in the early 1990s could be returning.

There are a number of reasons cited for the recent rise in health plan costs, with prescription drugs receiving a growing level of attention. According to the latest national health expenditures compiled by the Health Care Financing Administration (HCFA), prescription drugs accounted for just 7 percent of total health care expenditures in 1997. However, prescription drug expenditures did have the highest growth rate of any of the health services and supplies categories in 1997: 14.1 percent compared with the overall health care expenditure growth rate of 4.8 percent. Consequently, despite prescription drug expenditures representing a relatively small percentage of total health care expenditures, their sharply escalating growth has drawn much attention.

This *Issue Brief* provides a closer examination of the expenditures on prescription drugs, in particular the level and growth of these expenditures. A major topic of interest is whether the increases in expenditures are purely inflationary or result from improved or new products. Another topic discussed is the potential for prescription drugs to be substitutes for other types of health care services. In addition, the methods by which employers implement their coverage of prescription drugs is described. Lastly, this *Issue Brief* explores the issues of direct-to-consumer advertising and potential legislation affecting the prescription drug market, including proposals for a Medicare outpatient prescription drug benefit.

Expenditures: A Closer Look

National health expenditures increased from \$26.9 billion in 1960 to \$1.09 trillion in 1997,

while prescription drug expenditures increased from \$2.7 billion to \$78.9 billion over the same period. In comparison, hospital services expenditures increased from \$9.3 billion in 1960 to \$371.1 billion in 1997, and physician service expenditures increased from \$5.3 billion to \$217.6 billion during the period (table 1). In 1960, nearly 35 percent of national health expenditures were for hospital services, almost 20 percent were for physician services, and 10 percent were for prescription drugs. These percentages of national health expenditures were virtually identical for hospital and physician services in 1997, but the share spent on prescription drugs actually decreased between 1960 and 1980 before subsequently increasing.¹ However, this share of national health expenditures has yet to rebound to its 1960 percentage.

While prescription drug expenditures have been substantially smaller than both hospital and physician service payments, in recent years the growth rate of prescription drug expenditures has been significantly larger. Prescription drug expenditures have grown at double-digit rates every year since 1980, with the exception of 1993 and 1994, but they have accelerated since then to 14.1 percent in 1997. Total national health, hospital service, and physician service expenditure growth rates decreased to less than 5 percent annually from 1995 through 1997 (table 2). Consequently, if the present growth rates continue, prescription drug expenditures could reach approximately 16 percent of national

¹ This decline for prescription drugs was mainly due to the tremendous growth in hospital and physician payments after the introduction of Medicare and Medicaid in 1965. That growth continued until the mid-1990s, when the expansion of managed care plans by employers reduced the growth rate of hospital and physician costs.

Table 1
National Health Expenditures: Totals, Various Years 1960–1997

	1960	1970	1980	1990	1994	1995	1996	1997
Total (\$ Billions)	\$26.9	\$73.2	\$247.3	\$699.4	\$947.7	\$993.7	\$1,042.5	\$1,092.4
Hospital	9.3	28.0	102.7	256.4	335.7	347.2	360.8	371.1
Physician	5.3	13.6	45.2	146.3	193.0	201.9	208.5	217.6
Nursing home	0.8	4.2	17.6	50.9	71.1	75.5	79.4	82.8
Prescription drugs	2.7	5.5	12.0	37.7	55.2	61.1	69.1	78.9
Percentage of Total								
Hospital	34.6%	38.3%	41.5%	36.7%	35.4%	34.9%	34.6%	34.0%
Physician	19.7	18.6	18.3	20.9	20.4	20.3	20.0	19.9
Nursing home	3.0	5.7	7.1	7.3	7.5	7.6	7.6	7.6
Prescription drugs	10.0	7.5	4.9	5.4	5.8	6.1	6.6	7.2

Source: Katherine R. Levit et al., "National Health Expenditures in 1997: More Slow Growth," *Health Affairs* (November/December 1998): 99–110.

health expenditures by 2008.² However, in projections from HCFA's Office of the Actuary, prescription drug expenditures are expected to increase to only 8 percent of total national health expenditures by 2007 (Smith et al., 1998).³

Sources of Prescription Drug Expenditures

Private fund payments⁴ of prescription drugs increased from \$31.2 billion in 1990 to \$62.9 billion in 1997. The two private fund sources of prescription drug payments—out-of-pocket and private health insurance payments—saw expenditures increase from \$18.2 billion in 1990 to \$23.0 billion in 1997 for out-of-pocket payments, and from \$13.0 billion to \$39.9 billion for private health insurance payments over the same period (table 3). The percentage of all private payments for prescrip-

tion drugs increased from 9.1 percent to 13.5 percent during this time frame, while the percentage of out-of-pocket payments accounted for by prescription drugs held virtually constant at about 12.5 percent from 1990 through 1997. However, the percentage of private health insurance payments going toward prescription drugs more than doubled, from 5.4 percent in 1990 to 11.5 percent in 1997.

Furthermore, private fund payments of prescription drugs accounted for 79.7 percent of all prescription drug payments in 1997. This percentage has been relatively constant (at around 80 percent) since 1990. In contrast, the breakdown of these private sources of payments has changed dramatically since 1990, when out-of-pocket payments accounted for 58.3 percent of the private fund payments for prescription drugs and private health insurance payments represented 41.7 percent. By

² Specifically, the assumptions are that total national health expenditures (exclusive of prescription drug payments) increase at 5 percent annually, while prescription drug expenditures increase at 14 percent annually.

³ The baseline numbers for these projections have been subsequently updated to a higher level, so the projected prescription drug expenditure percentage will likely be higher for 2007, when revised numbers are released by HCFA.

⁴ Private fund payments are expenditures that do not arise from a government-sponsored program, and include those payments made by individuals directly out of their own pockets and those made by private health insurers. Thus, any payments made by private individuals or by individual and group coverage by private insurers are included in this category.

Table 2
National Health Expenditures: Average Annual Percentage Growth From Prior Year Shown, 1960–1997

	1960	1970	1980	1990	1994	1995	1996	1997
Total	n/a	10.6%	12.9%	11.0%	7.9%	4.9%	4.9%	4.8%
Hospital	n/a	11.7	13.9	9.6	7.0	3.4	3.9	2.9
Physician	n/a	9.9	12.8	12.5	7.2	4.6	3.3	4.4
Nursing home	n/a	17.4	15.4	11.2	8.7	6.2	5.2	4.3
Prescription drugs	n/a	7.5	8.2	12.1	10.0	10.6	13.2	14.1

Source: Katherine R. Levit et al., "National Health Expenditures in 1997: More Slow Growth," *Health Affairs* (November/December 1998): 99–110.

Table 3
National Health Expenditures and Prescription Drugs, by Private Sources, 1990–1997

	1990	1991	1992	1993	1994	1995	1996	1997
All Private Funds (\$ Billions)	\$416.2	\$448.9	\$483.6	\$513.2	\$524.9	\$538.5	\$561.1	\$585.3
Consumer payments	384.6	415.1	447.2	473.9	483.6	495.3	515.2	535.6
out-of-pocket payments	145.0	153.3	161.8	167.1	168.5	171.0	178.1	187.6
private health insurance	239.6	261.7	285.5	306.8	315.1	324.3	337.1	348.0
Prescription Drugs	37.7	42.1	46.6	50.6	55.2	61.1	69.1	78.9
Private funds	31.2	34.5	38.3	41.3	44.8	49.4	55.7	62.9
Consumer payments	31.2	34.5	38.3	41.3	44.8	49.4	55.7	62.9
out-of-pocket payments	18.2	19.3	20.4	21.2	21.4	20.7	21.8	23.0
private health insurance	13.0	15.2	17.9	20.1	23.5	28.6	33.9	39.9
Prescription Drugs—Percentage of Source								
All private funds	9.1%	9.4%	9.6%	9.9%	10.5%	11.3%	12.3%	13.5%
Out-of-pocket payments	12.5	12.6	12.6	12.7	12.7	12.1	12.2	12.3
Private health insurance	5.4	5.8	6.3	6.6	7.4	8.8	10.1	11.5

Source: Health Care Financing Administration, Office of Actuary, nhe97.txt, available at www.hcfa.gov, 1998.

1997, private health insurance had grown to account for 63.4 percent of the private fund payments for prescription drugs, while the out-of-pocket percentage had fallen to 36.6 percent.

In terms of percentage growth, all private fund health payments increased 4.3 percent in 1997. Private fund payments for prescription drugs grew 13 percent, which was lower than the overall growth rate for prescription drug expenditures. However, private insurance payments for prescription drugs increased 17.7 percent in 1997, after 22.1 percent growth in 1995 and 18.3 percent growth in 1996 (table 4). This growth in prescrip-

tion drugs compares with just 4 percent or less overall growth of private insurance payments for each of those three years. In fact, the growth in prescription drug payments accounted for 55 percent of the growth in private health insurance payments and nearly 30 percent of the growth in all private fund payments in 1997 (table 4). Consequently, prescription drug expenditures are a significant factor in the increased payments from private sources, and they became the primary factor in the growth of private health insurance payments in 1997.

Table 4
**Private Health Care and Prescription Drug Expenditures
 Annual Growth Rate, by Source, 1991–1997**

	1991	1992	1993	1994	1995	1996	1997
All Private Funds	7.9%	7.7%	6.1%	2.3%	2.6%	4.2%	4.3%
Consumer payments	7.9	7.8	5.9	2.1	2.4	4.0	3.9
out-of-pocket payments	5.7	5.5	3.3	0.9	1.5	4.2	5.3
private health insurance	9.3	9.1	7.5	2.7	2.9	4.0	3.2
Prescription Drugs	11.9	10.6	8.7	9.0	10.6	13.2	14.1
Private funds	10.6	11.2	7.7	8.6	10.1	12.9	13.0
Consumer payments	10.6	11.2	7.7	8.6	10.1	12.9	13.0
out-of-pocket payments	6.1	5.7	3.8	0.9	-3.1	5.3	5.6
private health insurance	17.0	18.1	12.2	16.6	22.1	18.3	17.7
Percentage of Growth in Each Source Attributable to Prescription Drugs							
All private funds	10.1	11.1	10.0	30.2	33.3	28.0	29.9
Out-of-pocket payments	13.3	13.1	14.6	13.3	-26.8	15.4	12.9
Private health insurance	9.9	11.6	10.2	40.3	56.6	40.9	55.0

Source: Author's calculations based on data in table 3.

Table 5
Prescription Drug Expenditure Growth by Source and Inflation, 1993-1998

	1993	1994	1995	1996	1997	1998
Medical Care Inflation	5.9%	5.4%	4.4%	3.2%	2.9%	3.2%
Physicians	5.1	4.4	4.4	3.0	2.7	3.0
Hospitals	7.6	5.5	4.6	4.1	3.2	3.3
Prescription drugs	3.3	3.3	2.0	3.2	2.5	3.7
Total Expenditure Percentage Growth	8.2	8.1	9.7	10.1	14.2	n/a
Volume, mix, and new products	5.2	6.4	7.8	8.5	11.7	n/a
Price	3.0	1.7	1.9	1.6	2.5	n/a

Source: U.S. Department of Labor, Bureau of Labor Statistics, *CPI Detailed Reports* (Washington, DC: U.S. Department of Labor, April 1998); *Health News Daily*, "Prescription Drug Price Inflation Accelerated in 1998 to 3.7%," January 15, 1999; PhRMA, *Industry Profile* (Washington, DC: Pharmaceutical Research and Manufacturers of America, 1998).

Inflation Versus Increased Volume

When discussing expenditure growth, it is important to distinguish between inflation (the growth of prices of available products) and increased product volume (more of both previously available drugs and newly available drugs being purchased). The prescription drug inflation rate was nearly equivalent to the overall medical inflation rate of just over 3 percent from 1996 through 1998, according to the Labor Department (table 5). Consequently, from 1993 to 1997, the overwhelming majority of the cost growth in prescription drugs was attributable to increased volume, mix, and availability of pharmaceutical products. More than 80 percent of the growth in prescription drug expenditures in 1997 was due to these factors, although some of the new products are drugs that are substitutes for drugs already available.⁵

Discussion of Increasing Expenditures

As noted above, the overwhelming majority of the growth in prescription drug payments is due to the increased volume of drugs being consumed. The pharmaceutical industry is one of the most innovative industries in the United States, as reflected in the Food and Drug Administration's (FDA) approval of 53 new molecular entities (NMEs) in 1996 and another 39 in 1997. These NMEs led to new drugs that replaced ones previously available or established new drug treatments for diseases. The new drugs that replace old ones in most cases have fewer side effects, easier dosage regimens, or greater impact on the disease being treated.

Easier dosage regimens appear to be necessary improvements, since it is estimated that only about one-half of prescribed medicines for chronic care conditions

are taken properly (Pharmaceutical Research and Manufacturers of America (PhRMA), 1998). The cost associated with medication noncompliance is estimated at \$100 billion a year, according to a pharmaceutical industry representative, due to increased hospital admissions, nursing home admissions, lost productivity, and premature death (National Pharmaceutical Council, 1992).

Furthermore, other new drugs have led to more effective treatment of some conditions, such as depression and osteoporosis, and the ability to begin treating previously untreatable ailments, such as HIV/AIDS. Therefore, public policy changes aimed at curtailing prescription drug expenditures need to recognize the benefits associated with these increased expenditures.

Another factor affecting the increased volume of prescription drugs is the movement of individuals into managed care plans. These plans typically have had generous drug benefits with low out-of-pocket payments, as reflected by the previously noted surge in private health insurance expenditures, relative to individual out-of-pocket payments. Furthermore, the availability of a drug plan has been shown to lead to a higher level of drug utilization (Davis, et al., 1999). Thus, the transformation of the health insurance market has also contributed to the increased volume of prescription

⁵ Substitute drugs can have two opposing effects. Increased expenditures may result since more products are available, but with more drugs competing, price inflation will be reduced due to the competition among products. Substitute drugs appear to be getting marketed more quickly, causing the market exclusivity of innovative drugs to decline. For example, Tagamet, a H₂ antagonist for ulcers, was brought to market in 1977 and had six years of market exclusivity before Zantac was introduced in 1983. By comparison, Invirase, a protease inhibitor for HIV/AIDS introduced in late 1995, was on the market for approximately four months before Norvir came on the market in early 1996 (PhRMA, 1998).

Evidence suggests that drug companies face formidable costs and obstacles in successfully developing, testing, and marketing new pharmaceuticals.

drugs.⁶

A prominent explanation for the sharp growth in drug expenditures, compared with other health care services, is that prescription drugs are a substitute for other forms of health care services and help alleviate the need for other more costly forms of treatment. However, it is difficult to evaluate the extent to which prescription drug expenditures substitute for other types of health care expenditures. There are various studies that found cost savings due to pharmaceutical products in treating specific diseases. For example, in the Virginia Health Outcomes Partnership Program, an expansion of drug spending on Medicaid asthma patients led to, at most, an average 42 percent reduction in the rate of emergency room and urgent care visits among these asthma patients (Hawks, Levy, and Hass, 1985). Another study found that spending an additional \$1.7 million per 1,000 stroke patients to administer a clot-busting prescription drug not only reduced disability but also saved more than \$4 million in rehabilitation and nursing home costs (Fagan et al., 1998).

Other studies have projected the savings from more widespread use of certain prescription drugs. One study found that increased use of a blood-thinning drug could prevent 40,000 strokes a year, resulting in a \$600 million savings (Agency for Health Care Policy and Research, 1996). In addition, a study on the use of a “colony stimulating factor” drug for bone marrow transplant patients showed a savings of \$30,000 per patient in hospitalization costs (Peters, 1993). Each of these studies shows that the increased use of prescription drugs can lead to a lower level of expenditures elsewhere in the health care sector. (For a comprehensive list of studies showing cost savings through the use of pharmaceutical drugs, see PhRMA, 1998.)

Although there are significant benefits from the utilization of prescription drugs, serious problems also exist in their use. For example, in a study by the Wilkerson Group, nearly one-half of all prescribed medications for chronic care conditions were found to be

taken improperly (either the prescription was taken too often, too little, or the prescription went

unfilled for continued treatment) (PhRMA, 1998). In addition, 60 percent of people receiving medical care for the common cold are given unnecessary and useless prescriptions for antibiotics, which are ineffective against colds and may even be harmful by leading to increased antibiotic resistance (Gonzales, 1997). Furthermore, Willcox et al. (1994) found that nearly 25 percent of the noninstitutionalized elderly Americans receive an inappropriately prescribed drug.

Cromwell et al. (1999) found that a Florida Medicaid policy that restricted the coverage of anti-ulcer drugs led to a 33 percent decrease in the reimbursement of those drugs—without any significant associated increase in the rate of hospitalization for digestive-related conditions. Therefore, they suggest that some misuse of anti-ulcer drugs was prevalent among Florida Medicaid patients. Thus, while evidence does exist that increased appropriate use of prescription drugs has the potential to lower total health expenditures and increase the quality of care, the U.S. health care system still needs to make better use of the medications currently being prescribed.

Despite the potential that prescription drugs may have to offset or reduce total health expenditures, the prices of these drugs—especially newly marketed drugs—have received much attention. The fact that the average profitability of the pharmaceutical industry surpasses the average profitability of the 500 largest U.S. industrial corporations as listed by *Fortune* magazine contributes heavily to this debate.⁷ According to a recent

⁶ *Managed care plans now represent an overwhelming majority of the health plans in the health insurance market. Thus, any further changes in the make-up of the health insurance market are not expected to have additional effects on the level of drug expenditures. However, any design or benefit coverage changes of these managed care plans could have significant effects on the level of drug expenditures.*

⁷ *Some economists argue that standard accounting principles tend to overstate pharmaceutical companies' true rates of return on investment (Scherer, 1993).*

Table 6
**Percentage of Full-Time Employees Participating
 in a Medical Plan with a Prescription
 Drug Benefit, 1994, 1995**

Employer Size	Percentage with Prescription Drug Coverage
Small Private	91%
Medium and Large Private	96
State and Local Government	99

Source: Employee Benefit Research Institute, *EBRI Databook on Employee Benefits* (Washington, DC: Employee Benefit Research Institute, 1997).

PhRMA survey, research-based pharmaceutical

companies were expected to spend an estimated \$17.2 billion domestically on research and development (R&D) in 1998, or 20 percent of sales. In contrast, all other U.S. industries excluding drugs and medicine spent 3.4 percent of sales on R&D (PhRMA, 1998). Furthermore, only 3 out of 10 marketed drugs during the period 1980–1984 exceeded or matched average R&D expenditures (Grabowski and Vernon, 1994). Consequently, pharmaceutical firms have warned that without sufficient returns on their R&D investments, they will have difficulty attracting future investment capital to fund further R&D expenditures.

While many consumer advocates still assert that many of the new drug treatments becoming available are too expensive for the people who need them, pharmaceutical companies argue that the prices of their drugs must cover not only the costs of developing and marketing the successful drugs but also for all of the unsuccessful and experimental drugs as well. Evidence suggests that drug companies face formidable costs and obstacles in successfully developing, testing, and marketing new pharmaceuticals.

For instance, one study (DiMasi, 1995) determined that 18.3 percent of drugs that entered clinical trials from 1980 through 1984 are now on the market and a total of 23.5 percent are expected eventually to be on the market. The clinical and approval phases of drug development had a median length of approximately nine years in 1995, while the preclinical phase had a median

⁸ However, it should be noted that FDA's approval time for new drugs has been cut nearly in half over the past five years, due to new regulatory user fees paid by the industry under the 1992 Prescription Drug User Fee Act (PhRMA, 1998).

⁹ For a particular molecular entity, the period of patent protection has remained unchanged at 17 years, with an additional five years of patent exclusivity possible under the Patent Restoration Act of 1984. This does not mean that the drug will be on the market for the entire time of the patent protection. Time on the market with patent protection depends on when a drug receives FDA approval relative to its patent date.

length of approximately six years (National Wholesale

Druggists' Association, 1998; PhRMA, 1998).⁸ Furthermore, the number of clinical trials per new drug application, as well as the number of patients used to test a new drug, have grown steadily since the early 1980s (Peck, 1997).

In addition, increased competition in the pharmaceutical industry has led to shorter periods of exclusivity in a therapeutic class for some key new drugs that have reached the market, and managed care health plans tend to emphasize the use of less-expensive generic drugs once a pharmaceutical patent expires.⁹ These factors have made it more costly for drugs to be produced and more difficult for their investment to be recouped—which necessitates the higher price charged for new drugs, the industry argues.

As more new drugs become available and the costs of these new drugs continue to grow, consumer advocates continue to push for more affordability of life-saving drugs through such mechanisms as federal regulation of the rates of return on patented drugs. However, pharmaceutical companies respond that if they are not guaranteed a high return on successful drugs, far fewer resources will be invested in the costly and risky R&D of pharmaceuticals. Thus, future medical innovations as well as the understanding of human biological processes and the agents that threaten these processes could be lost. Regardless of any restrictions on patent rates of return, if pharmaceutical companies expect to gain the maximum return from a patent, they will be expected to prove the cost-effectiveness and quality of their new drugs. Otherwise, consumer advocates and health plans will seek out other less expensive medications that are worth the manufacturer's price.

*Private
Coverage*

Approximately 64 percent of the nonelderly population had health care

Table 7
Features of Prescription Drug Plans

	Plan Type			
	Indemnity	HMO ^a	PPO ^b	POS ^c
Percentage of Health Plans With Prescription Drug Carve-Out Plans, 1997–1998: Large Employer Health Plans (200 or More Employees)				
1997	28%	19%	37%	30%
1998	30	15	37	23
Percentage of Employers Offering Prescription Drug Card Plan Benefits, 1996–1997				
1990	24	n/a	n/a	n/a
1996	67	70	80	80
1997	66	72	81	77
Percentage of Employers Offering Prescription Drug Mail-Order Benefits, 1996–1997				
1990	20	n/a	n/a	n/a
1996	46	53	55	51
1997	47	49	64	60
Percentage of Prescription Drug Carve-Out Plans That Require Mandatory Use of Generic Drugs, 1997–1998: Large Employer Health Plans (200 or More Employees)				
1997	27	42	23	43
1998	25	41	26	37

Source: KPMG Peat Marwick, *Health Benefits in 1998* (KPMG Peat Marwick, 1998); William M. Mercer, *National Survey of Employer-Sponsored Plans, 1997* (New York: William M. Mercer, 1998); Foster Higgins, *National Survey of Employer-Sponsored Health Plans, 1996* (New York: Foster Higgins, 1997); Foster Higgins, *Health Care Benefits Survey, 1990: Report 1* (New York: Foster Higgins, 1991).

^aHealth maintenance organization.

^bPreferred provider organization.

^cPoint-of-service (plan).

coverage through an employment-based arrangement in 1997, a slight increase from 1995 (Fronstin, 1998a). Of those with employment-based coverage, nearly all have coverage for prescription drugs (table 6).

In providing this coverage, employers utilize various techniques to control costs and enhance the quality of a prescription drug benefit. Employers generally provide a prescription drug benefit through their health plan or by “carving-out” the benefit from the general health plan (see below). In addition, the health plan or the employer can implement a prescription benefit by using a prescription drug card plan or mail-order plan, and can also require the substitution of less expensive generic drugs or restrict the number of drugs approved for coverage through the use of formularies—lists of the preferred drugs of a prescription drug plan.

Carve-Out Plans

“Carve-outs” are plans in which the employer offers a prescription drug benefit separate from the rest of the health plan in order to control the costs and improve the quality of the benefit. In 1998, between 15 percent and 37 percent of plans offered by employers with 200 or more employees carved-out their drug benefit, depending upon the health plan type offered, with the remaining amount being provided directly through the health plan. This was a slight overall decline in the percentage of

plans with carve-outs from 1997 (table 7). Employers that offer carve-out plans often are those that self-insure medical benefits and contract with a pharmacy benefit manager (PBM) to provide all the services necessary for a high-quality, cost-effective drug benefit.

PBMs currently provide managed pharmacy benefits for approximately one-half the insured population in the

United States.¹⁰ There are approximately 40 PBMs in the United States today, although the top five companies account for more than 75 percent of the market. PBMs originally provided only prescription claims processing and mail-service pharmacies. However, in recent years PBMs have expanded their services into the development and management of formularies, the negotiation of drug rebates with manufacturers, the establishment of pharmacy networks, the proper substitution of generics, and the utilization review of drug use. Some PBMs have even instituted disease management programs that attempt to provide the most cost-effective treatments of specific diseases (U.S. General Accounting Office, 1995). Many managed care plans also contract with PBMs or provide the same services within their plan as those offered by PBMs. Under these arrangements, PBMs (or health plans) can monitor all the prescription drugs that

¹⁰ This is combined use by employers directly and by managed care plans that also use pharmacy benefit managers.

an individual receives. This allows the PBM to check for possible drug interactions that arise if the benefit was not coordinated through one entity.

In addition, the PBM can suggest more appropriate drug treatments for various ailments, since it focuses on utilizing the most cost-effective and quality-enhancing drugs. Thus, cost savings and quality can be achieved through the same process.¹¹ In fact, a study by the U.S. General Accounting Office (GAO) (1997) of the use of PBMs by three Federal Employees Health Benefits Program (FEHBP) health plans found that the pharmacy benefit costs were reduced by 20–27 percent for each of these plans, compared with what these plans believed they would have been without the PBMs. Furthermore, the plans met most of the performance standards established by the plans and also received a high degree of patient satisfaction.

However, PBMs have been criticized because of their ownership structure and access to patient data. Pharmaceutical companies own some PBMs, which raises a conflict-of-interest question: Are PBMs potentially influenced to use their owner's products over competing products, when other manufacturers' drugs may be better or comparable? A 1995 study by GAO was inconclusive on this issue. It found that one PBM company appeared to add the drugs of its partner firm to its preferred list when it was in the process of merging, but another PBM saw no change in its formulary in either number or cost of its new partner's drugs. This GAO report did recommend continued monitoring of these types of mergers by the Federal Trade Commission (FTC) in light of the one PBM's change in its preferred list, even though there is no unequivocal evidence that PBMs owned by pharmaceutical companies are favoring their owners' drugs. In addition, the FTC has established

guidelines on how these ownership arrangements must be structured to prevent conflicts of interest.

Yet another complication has resulted from the proposed purchase of a PBM by a retail pharmacy chain, which raises new questions about the potential ownership of a PBM by a retail pharmacy to affect the competitiveness of the retail pharmacy market. For example, will the pharmacy be able to leverage discounts from pharmaceutical manufacturers for the retail unit in exchange for including the manufacturer's drugs on the PBM's preferred list? Or will the PBM favor the retail pharmacy in any use of preferred providers, at the expense of other pharmacies?

PBMs' access to health care data has also been questioned. In particular, patient privacy concerns have been raised due to PBMs' suggesting additional treatments or influencing the medication choice for plan participants. A PBM's practice of enrolling individuals in (or suggesting individuals enroll in) group therapy or other types of treatment for those who are taking a pharmaceutical drug associated with a mental illness has provoked media attention. Despite the potential benefit of this type of treatment, patients may not want their employer or others to know or discover they have a mental condition requiring medical attention. Most employers choose not to receive this type of information, and PBMs say they have procedures in place to limit access to the information. However, there are no clear state or federal laws that govern the use of this kind of data.

In response to the lack of federal standards for privacy of health records, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) required that the Secretary of the U.S. Department of Health and Human Services (HHS) recommend privacy standards to ensure the protection of confidential medical information by August 1997. Those recommendations were released September 11, 1997, and are intended to advise Congress on writing medical privacy protections into law. If Congress does not act by August 21, 1999, HHS is authorized to promulgate final regulations containing

¹¹ *The potential exists for a PBM to switch to drugs that are more profitable for the PBM without affecting the cost to or the treatment of patients. However, there is no conclusive evidence currently available whether or to what extent this happens.*

Since it has been estimated that between 65 percent and 75 percent of prescription drugs are used to treat chronic conditions, mail-order plans have become a significant source of the distribution of prescription drugs by health plans and PBMs.

these standards six months later. Although some legislation with detailed privacy provisions has been introduced (i.e., S. 300 and H.R. 448), Congress has been slow to enact the HIPAA-required statutory privacy standards. Consequently, HHS may be forced to address this issue through regulatory action.

Another controversy is the fact that some PBMs discuss with physicians the medications their patients are receiving, and suggest alternative treatments or drugs that might be better suited or less costly with near-equal or equal efficacy for the patient. Many physicians are reluctant or refuse to discuss their prescribing patterns with PBMs because of ethical considerations and concern for their patients' privacy. In contrast, some physicians welcome the discussions and use them to learn about new or alternative treatment options.

While these PBM activities can irritate both patients and physicians and raise serious questions, they also can have beneficial effects. Patients may discover new or additional therapies that they may not know were possible. Because new medicines are always coming on the market, it is difficult for physicians to keep up on all drugs for treating all illnesses. Thus, PBMs can provide easily accessible education for physicians. Furthermore, close monitoring by PBMs can screen for allergies and potential interactions of the multiple prescriptions that patients may receive. Consequently, while there are potential benefits to enrollees for PBMs to undertake such activities, these benefits need to be weighed against individuals' rights to or desires for privacy.

Cost Containment and Quality-Enhancing Techniques

In providing prescription drug benefits, health plans and PBMs typically employ certain techniques that allow them to contain the costs and improve the quality of the

benefit. First, the use of a prescription drug card by an enrollee allows a participating pharmacy to verify enrollment and easily submit claims for payment. It also allows the pharmacist to charge the correct copayment or coinsurance, which reduces fraud and billing errors and thereby lowers reimbursement costs

for all parties. Between 66 percent and 81 percent of employers in 1997 offered a card plan, depending on the health plan type offered by the employer. This is a significant increase from the 24 percent of employers that offered a card plan in 1990 (table 7).

Second, mail-order drug plans are used because health plans and PBMs can negotiate lower prices from one mail-order pharmacy to provide prescriptions to the entire enrollment of the plan, due to volume discounts and efficiencies in having to make payments to only one company. In addition, these mail-order plans can also increase convenience for enrollees, particularly for the elderly and disabled who may lack the mobility to pick up their prescriptions at a pharmacy. This benefit is offered concurrently with a standard drug benefit, since it is only practical to use the mail-order feature for the delivery of drugs that are taken on a regular basis.

Sometimes the mail-order feature is required for enrollees, but generally there is only an incentive to use the mail-order feature either through a lower copayment or coinsurance. Since it has been estimated that between 65 percent and 75 percent of prescription drugs are used to treat chronic conditions (Kirking et al., 1990), mail-order plans have become a significant source of the distribution of prescription drugs by health plans and PBMs. The portion of employers who offer a prescription drug plan that has a mail-order feature ranged from 47 percent to 64 percent in 1997, depending on the type of health plan offered, up substantially from 20 percent for indemnity plans in 1990 (table 7).

Another feature that health plans and PBMs use to contain costs is the use of generic substitutions for

Prescription drug plans also frequently use formularies, which are lists of the preferred drugs in various dosages and forms that are considered most effective in the treatment of diseases. Formularies generally determine which drugs are covered by a particular health plan.

brand-name drugs, since generic drugs are often less expensive because they incur lower marketing and research costs. In one employer survey of carve-out plans, between 25–41 percent of these plans required generic substitution in 1998 (depending on the health plan type), a slight decline from 1997 for all health plan types except for preferred provider organizations (table 7). Health plans also may require a smaller copayment from enrollees for generic drugs, compared with brand-name drugs. The median copayment for each type of drug for those plans that require a copayment is \$10 for brand-name drugs and \$5 for generic drugs (William M. Mercer, 1998a). Consumers may also be encouraged to use less-costly generic drugs by the drug plan's use of deductibles or coinsurance.

In general, pharmacists are allowed to make a generic substitution unless the physician specifies that no substitution is allowed. Some states allow "therapeutic substitution," where a pharmacist can substitute an entirely different drug from the one prescribed by the physician, if it has the same therapeutic effect. These programs have helped to increase the generics' share¹² of the prescription drug market from 33 percent in 1990 to 44 percent in 1997 (PhRMA, 1998). Some pharmaceutical companies and physicians caution that certain drugs do not have suitable generic alternatives available, and have worked to prevent the generic substitution of particular pharmaceuticals in various states. In addition, FDA has been criticized by some for the less rigorous evaluation standards for generic drugs compared with those for brand-name drugs. However, the FDA's approval process for generic drugs includes tests to ensure the chemical equivalency and bioequivalency of generics, as well as its bioavailability (the rate at which the drug

is absorbed by the body). Specifically, this bioavailability must be within a relatively narrow specific range of the brand-name prescription's bioavailability.

Prescription drug plans also frequently use formularies, which are lists of the preferred drugs in various dosages and forms that are considered most effective in the treatment of diseases. Formularies generally

determine which drugs are covered by a particular health plan and are categorized as follows:

- **Open formularies** are formularies that include all FDA-approved drugs and drug products (with some rather limited exceptions).
- **Managed (incentive-based) formularies** are essentially open formularies that contain preferred drugs, the use of which is encouraged by financial incentives to physicians, pharmacists, and patients.
- **Closed (restricted) formularies** are formularies that contain a specific list of approved drugs for coverage. Many plans with closed formularies allow coverage for drugs outside the formulary on a limited basis through preauthorization by the plan, and the patient is likely to face an additional cost.

In 1995, one survey reported that 6 percent of employers' drug plans contained reduced benefits for nonformulary drugs, and 2 percent offered no benefits for nonformulary drugs (Foster Higgins, 1996). However, in a 1997 survey of employers with 200 or more employees, 50 percent of the employers said they were somewhat or very likely to more aggressively use formularies in the next two years (William M. Mercer, 1998b).

Some consumer advocates have reservations about the use of formularies, particularly those that require preauthorization and/or additional costs to the enrollees. In many cases, these advocates are skeptical of the methods that are used to compile the formulary. They suggest that drugs are chosen based upon their

¹² The generics' share is measured in countable units, such as tablets.

cost, not on their efficacy, and they point out that not all medications have the same effects on all individuals. Thus, a patient who does not respond to the formulary drug may be forced to pay out-of-pocket for a nonformulary drug. However, most health plans have exceptions to their formularies for such cases.

Health plans and PBMs counter that their formularies contain the best and most cost-effective drugs in the various therapeutic categories. However, more restrictive formularies apparently are becoming more popular in prescription drug plans, not just to control costs but also to promote the proper use of prescription drugs. Consequently, the selection of drugs for formularies is certain to remain an important and contentious issue in the next few years.

Since prescription drug expenditures are the fastest-growing component of private health insurance payments, both health plans and employers are likely to be changing their prescription drug plans to ensure that the benefit is providing only the most efficacious drugs.¹³ There is anecdotal evidence that copayments are increasing substantially from the present \$10 and \$5 levels. Some health plans are also including prescription drug costs in their capitated payments to physicians, a move that would provide financial incentives for physicians to identify the most cost-effective drugs for treating various ailments. Furthermore, prescription drug plans are expected to make more aggressive use of more restrictive formularies, which will mean a closer examination of new drugs for their efficacy before they are included in a formulary.

However, employers generally provide health benefits—including prescription drug coverage—in order to keep their employees healthy and productive, as well as to help hire and retain valued workers. Consequently, a formulary that is too restrictive could counter the goals of providing this coverage. In addition, in some cases, expenditures for medications may prove to be small if they achieve significant reductions in sick leave and lost

productivity. For example, a study by Legg et al. (1997) showed that a new migraine drug reduced losses in productivity and labor costs. While the cost of the migraine medication was valued at \$43.78 per employee per month, the savings attributable to reduced loss of productivity and labor costs was valued at \$435 per employee per month. Consequently, careful design of prescription drug plans will be critical if employers are to take advantage of the potential cost savings of prescription drugs, both on overall health care expenditures and on labor expenses, while limiting the use of noncost-effective or unnecessary drugs.

Finally, the insurance coverage of medications that may add exclusively to the quality of one's life has received a great deal of attention. Employers and health plans have also been questioned about the fairness of covering a drug that may solely help men while not covering a drug that affects only women. Consequently, employers and health plans increasingly are being confronted with social and equity issues when deciding to cover a medication, not just the cost-effectiveness or quality of the drug.

Public Coverage

Medicaid, the federal-state health insurance program for the poor, is the largest govern-

ment purchaser of prescription drugs in the United States. Medicaid provides prescription drug coverage for its beneficiaries in all 50 states. In 1997, combined federal-state Medicaid spending on prescription drugs amounted to \$13.2 billion (HCFA, 1998).

However, for a pharmaceutical company to have its drugs reimbursed by the Medicaid program, it must pay a rebate on these products, and in 1996, these Medicaid rebates amounted to nearly \$2 billion (PhRMA, 1998). The rebates are based on several factors, specifically the average manufacturer's price for a drug, the manufacturer's "best price," and price increases relative

¹³ See William M. Mercer (1998b).

to the consumer price index. Medicaid participation by a prescription drug manufacturer has also been conditioned on participation in three additional governmental discount programs under the 1992 Veterans Health Care Act, most notably the Federal Supply Schedule (FSS), a governmentwide list of discounted products approved for federal agency procurement. The price of FSS-listed products is negotiated by the government not to exceed the price offered to the manufacturer's most-favored customer.

Medicaid can charge copayments only in limited cases, and the program has traditionally had fairly open prescription drug plans. However, as state legislators have looked to limit sharply rising Medicaid expenditures, restrictions have been imposed on which drugs are covered and the number of prescriptions a beneficiary can receive. The result has been that state Medicaid programs have had to face the same cost-control and quality-enhancing decisions as private employers in deciding how to design the Medicaid drug benefit. For example, a study by Soumerai (1991) found that when New Hampshire restricted the number of prescriptions reimbursed by Medicaid, drug utilization fell 35 percent while nursing home admissions increased by 60 percent. The net result was an increase in overall Medicaid health-care expenditures.

Medicare, the federal health insurance program for the elderly and the disabled, does not have an outpatient prescription drug benefit as one of its guaranteed benefits.¹⁴ Consequently, despite the fact that the elderly and disabled are the most likely to use prescription drugs, 35 percent of the noninstitutionalized Medicare beneficiaries did not have a source of coverage that provides prescription drug benefits in 1995 (Davis, 1999). Therefore, these individuals must pay out-of-pocket for any prescriptions they may need.

"Medigap" insurance policies are a source of coverage that many Medicare beneficiaries obtain in order to pay for the benefits that Medicare does not cover. However, the cost and/or the lack of availability of these policies with prescription drug coverage, due to

prescription drugs not being a required benefit of a Medigap policy, has prevented many beneficiaries from obtaining a supplemental source of coverage for prescription drugs. In fact, only 29 percent of those beneficiaries with an individually purchased Medigap policy had prescription drug coverage (Davis, 1999).

DTC Advertising

One issue that has been linked to rising prescription drug costs is the increased use of

direct-to-consumer (DTC) advertising by pharmaceutical companies. However, proponents of DTC advertising argue that it provides a valuable method to educate consumers about health conditions and possible treatments, and that public health can be improved by this advertising (Holmer, 1999). Critics of DTC advertising counter that it has negligible public health value and simply creates consumer demand for the advertised product, undermining physicians' authority to determine the need for a prescription drug (Hollon, 1999). It is true that DTC advertising increased 46 percent from 1996 to 1997, when it totaled \$917 million,¹⁵ which correlates to the recent significant increases in prescription drug expenditures. Yet, whether DTC advertising is the culprit of this expenditure growth, and is bad or good for public health, remains an open question.

Proponents of DTC advertising argue that this education of consumers about health conditions and possible treatments will lead to more consumers seeking care from physicians, which is a real and important

¹⁴ Many health maintenance organizations (HMOs) that serve Medicare beneficiaries offer drug benefits. As of December 1998, 67 percent of Medicare+Choice plans offered some outpatient drug benefit. In addition, Medicare has an inpatient prescription drug benefit.

¹⁵ This increase also correlates with the August 1997 relaxation of FDA regulations governing these advertisements. Spending on DTC advertising is projected to surpass \$1 billion in 1998.

Table 8
**Annual Prescription
 Utilization by Age, 1996**

Age	Average Number of Prescriptions per Capita
Under 5	4.53
5-14	1.61
15-24	1.62
25-34	2.09
35-44	2.82
45-54	4.17
55-64	5.47
65-74	8.59
75 and Older	11.65

Source: NWDA, *1998 Industry Profile and Healthcare Factbook* (Reston, VA: National Wholesale Druggists' Association, 1998).

benefit to public health. Proponents of DTC point to a national survey conducted by *Prevention Magazine* (1998) that concluded a projected 21.2 million consumers were encouraged by DTC advertising to discuss with their physician a medical condition that they had not previously discussed before seeing the DTC advertisement. This study found that DTC advertising might improve consumer compliance with drug treatments by making them feel more comfortable with taking their prescribed medicine and reminding them to refill their prescription. One year after the beginning of a DTC advertising campaign for a new osteoporosis drug, physician visits for osteoporosis nearly doubled (IMS Health, 1996), the study found. Consequently, this apparent ability of DTC advertising to influence such a significant number of patients makes it a potentially powerful tool to affect public health.

Ultimately, the true value of DTC advertising depends upon physicians' willingness to prescribe a particular drug—which can range from only when a patient truly needs a drug to whenever a patient demands a drug. But the evidence available on physicians' prescribing patterns is extremely limited. Supporting the claim that physicians are influenced by patient demand is a study by Schwartz et al. (1989) that cited patient demand as the most common reason why a prescription was written by physicians identified as appearing to overprescribe three specific drugs. Furthermore, Hamm et al. (1996) reported that patients' expectations were an important factor in physicians' decisions to prescribe antibiotics. However, in a study cited by a proponent of DTC advertising (Holmer, 1999), 51 percent of the patients who called a toll-free number from a DTC advertisement and saw a physician within three months of seeing the advertisement did not receive a prescription for the advertised drug. This led the author to conclude that physicians in these instances determined the drug was not appropriate, even though the patient presumably asked for the medication.¹⁶

The above studies indicate that physicians' prescribing patterns are not well understood, that patient demand does appear to influence physicians' prescribing patterns, and that further study is necessary.

However, even if DTC advertising were eliminated, the influence of patient demand would not likely disappear. It may be that DTC advertising is changing patients' mindsets from needing a *prescription* to needing a *specific* prescription.

A potentially troubling additional aspect of DTC advertising is that consumers may not fully read or understand a DTC advertisement. This worry seems to be supported by a *Consumer Reports* study (1996) that concluded that less than one-half of the DTC advertisements the magazine reviewed were clear about the efficacy of the drug being promoted. While the "clearness" of an advertisement is open to interpretation, unambiguous information is necessary if patients are expected to be good consumers, and DTC advertising has potential to be a vehicle to provide that kind of information. Thus, there appears to be a need for continual evaluation of DTC advertising, since it has the potential to both supply necessary information to consumers about possible treatments of various health conditions and to simply create patient demand for a specific drug that is advertised.

Policy Issues

For policy-makers in Washington, prescription drugs have

¹⁶ The determination that a prescription was not necessary raises the question of whether the doctor's visit was even necessary. This suggests the possibility that DTC advertising may also create wasteful use of physician resources. However, these potentially unnecessary visits would need to be weighed against the increased visits that result in the successful diagnosis of the condition treated by an advertised product.

Table 9
Average Annual Drug Expenditures by Age and Income per Capita, 1994-1995

Age	Income									
	All	Less than \$5,000	\$5,000-\$9,999	\$10,000-\$14,999	\$15,000-\$19,999	\$20,000-\$29,999	\$30,000-\$39,999	\$40,000-\$49,999 ^a	\$50,000-\$69,999	\$70,000 and over
Under 25	\$ 71	\$ 26	\$ 32	\$ 45	\$ 72	\$129	\$111	\$149	n/a	n/a
25-34	145	59	58	89	128	149	146	208	\$200	\$159
35-44	221	217	128	128	173	186	216	240	238	313
45-54	284	190	186	206	171	234	263	266	342	371
55-64	355	153	319	410	359	319	322	376	415	429
65 and Older	558	380	453	516	610	709	581	635	666	617

Source: U.S. Department of Labor, Bureau of Statistics, *Consumer Expenditure Survey, 1994-95* (Washington, DC: U.S. Department of Labor, December 1997).
^aFor those under age 25, \$40,000-\$49,000 is actually \$40,000 and over.

received increased attention because of the debate over creating a prescription drug benefit for Medicare beneficiaries. In addition, regulation of managed care plans' prescription drug formularies was included in some of the patient protection bills that were introduced in Congress last year and will be revived this year. States also have been acting on drug formulary laws for health plans within their regulatory jurisdiction. These issues could have a significant effect on the pharmaceutical industry, on employers in general, and on consumers.

The National Bipartisan Commission on the Future of Medicare has struggled with the idea of adding prescription drugs as a guaranteed benefit under Medicare. The push for a Medicare prescription drug benefit results from the growing importance of prescription drugs in treating many chronic diseases prevalent among the elderly and disabled.

Not surprisingly, the elderly spend significantly more money on prescription drugs than do younger people. In 1996, an average 4.17 outpatient prescriptions were written for those 45-54 years old, compared with an average 5.47 for those ages 55-64; an average 8.59 for those ages 65-74; and an average 11.65 prescriptions for those over 75 (table 8). Inevitably, this translates to significantly more money being spent for prescription drugs by the elderly. In 1994-1995, on average, an elderly individual (age 65 or older) spent \$558 on prescription drugs, compared with the average \$355 spent on prescription drugs by those ages 55-64 (table 9). These higher numbers of prescriptions and out-of-pocket costs are proponents' main argument that a drug benefit is needed for Medicare beneficiaries.

However, many analysts question the wisdom of adding an expensive new drug benefit at a time when the Medicare program is already projected to have inadequate resources to pay for the currently promised benefits. In addition, pharmaceutical companies are

leery of a drug benefit for Medicare beneficiaries, since it could lead to federal regulation of drug prices. If prices are regulated, these companies argue that research and development would have to be reduced and the elderly ultimately would be hurt because future innovations in the treatments of diseases would be slowed. Others counter that the increased purchases that would result from the new benefit could offset any price restraints that the government may enact. These arguments are difficult to evaluate, because the number of people who are not currently getting prescriptions that would receive prescription drugs if the benefit became available is unknown. However, if price restraints were too restrictive, then any increased purchases probably would not offset the effects of the restraints.

Some proponents have suggested that pharmacy benefit managers (PBMs) could service the benefit for Medicare, but this still could lead to direct price regulation and would complicate the Medicare debate with the controversies previously described relating to PBMs. Consequently, there does not appear to be strong support for this concept.

The major reform proposal being discussed by the Medicare commission is the restructuring of Medicare by using a "premium support model." This model is based on the Federal Employees Health Benefits Program (FEHBP), in which the government pays a certain portion of the premium of a private plan to be purchased by beneficiaries, and the beneficiaries pay the remaining amount.¹⁷ This plan could allow competition among health plans on premiums and supplement benefits,¹⁸

¹⁷ Medicare beneficiaries would also have the option to remain in the traditional Medicare program instead of joining a private plan, but would still be required to pay an amount similar to that paid by those who join a private plan.

¹⁸ All health plans would have to provide some agreed-on minimum benefits before they would be allowed to participate in the program.

A prescription drug benefit for Medicare beneficiaries could have a significant impact on the cost of retiree health plans. If Medicare began covering prescription drugs, sponsors of retiree health plans for the elderly might drop or alter their coverage for that benefit.

which could result in cost savings and higher-quality benefits for Medicare beneficiaries.

Providing a Medicare prescription drug benefit through these private plans likely would face the least resistance from all concerned parties.¹⁹

However, the largest stumbling block to this benefit is how it will be paid for:

from individual payroll taxes, or from general federal tax revenues. The design of copayments, coinsurance, and deductibles also will be heavily debated, as Congress struggles to keep prescription drugs affordable while minimizing potential incentives to overuse the benefit.

Instead of adding a prescription drug benefit to Medicare, some members of Congress are proposing that pharmacies or beneficiaries be allowed to purchase drugs for Medicare beneficiaries at prices established by the Federal Supply Schedule (FSS).²⁰ Most of these legislative proposals would allow pharmacies to purchase prescription drugs at FSS prices but would not regulate the mark-up that pharmacies could place on the drugs. Therefore, this type of regulation of drug prices could lead to regulation of prices at the retail level, or might allow pharmacies to improve their profitability from selling at a higher mark-up to Medicare beneficiaries.²¹

Critics of this proposal also argue that pharmacies would have to maintain different inventories for Medicare patients and for all other patients, that FSS prices would likely increase to offset lower revenues from the reduced markup, and that any governmental reductions or price controls could reduce research and development by pharmaceutical companies. However, those who support using the FSS price schedule argue that Medicare beneficiaries are the only individuals left paying full retail prices for prescription drugs, since other government programs are already receiving rebates and negotiated prices, and most managed care plans have also negotiated price discounts either directly from the pharmaceutical companies or from the preferred pharmacies in their network.

Federal regulation of managed care plans' prescription drug formularies has also been widely discussed. Many of the proposed patient protection bills generally would require prescription drug plans to cover any medication that a physician deems necessary to best treat a patient's ailments. Proponents of this concept argue that managed care plans use price—not efficacy—to determine which prescription drugs are on the plans' formularies. In addition, they argue that physicians, not health plans, should determine which medications are best for patients. However, opponents of this type of legislation counter that drug formularies can be an effective cost-containment mechanism, and more importantly, a quality-enhancing feature of a drug benefit. When used correctly, formularies can enhance the quality of care by covering only drugs that have been proven to be cost-effective and efficacious. Lastly, no clear understanding exists of how physicians prescribe drugs or how health plans determine their formularies, so eliminating drug formularies would not necessarily improve the quality of care received by managed care patients. Furthermore, since apparently not all physicians know the best medications for all ailments, opponents of formulary regulation say that health plans, through their use of formularies, could provide further education and checks on physicians for more appropriate use of prescriptions.

State legislators have also been active in the

¹⁹ PhRMA has recently stated that it would support the addition of a Medicare drug benefit if the benefit was provided solely through private plans that would service Medicare beneficiaries, but not through the traditional portion of Medicare.

²⁰ Government regulation of prescription drugs is not a new idea, and various proposals have been debated in the past on this issue (Employee Benefit Research Institute, 1992).

²¹ Proponents of this type of legislation counter that the competition among pharmacies for Medicare patients would prevent excessive mark-ups on the medications sold to them.

regulation of drug formularies for health plans they have the authority to regulate.²² Some states have either required specific medications to be included on drug formularies or have mandated that any drug prescribed by a physician be reimbursed. These laws have raised the same issues as the proposed federal legislation.

Implication for Employers

A prescription drug benefit for Medicare beneficiaries could have a significant impact on the cost of retiree health plans. If Medicare began covering prescription drugs, sponsors of retiree health plans for the elderly might drop or alter their coverage for that benefit. This could lead to significant savings for these sponsors, particularly since the prescription drug benefit is becoming an ever-growing portion of their total health benefit expenditures. One study found that prescription drug costs may amount to as much as 40 percent of health plan costs for plans that cover Medicare-eligible retirees (McDevitt, 1990).

However, the percentage of employers offering retiree health plans for Medicare eligibles has been declining throughout the 1990s (Fronstin, 1998b), and this trend is likely to continue. Thus, more elderly will be without employment-based retiree coverage for prescription drugs, regardless of Medicare changes. Consequently, dropping such a costly benefit might limit the erosion of employment-based retiree health coverage for other forms of health care, if employers found the savings to be substantial enough. The effects on employers of regulating drug prices by using the FSS are unclear, because whether retiree health plan participants would be classified as Medicare beneficiaries or private plan participants has not been established.

The regulation of drug formularies could lead to increases in drug expenditures and/or less effective drug benefit plans. Employers and health plans most likely would not be able to construct their formularies to include only proven drugs, which would result in higher costs.²³ However, restrictions on formularies could also

prevent plans and employers from using only price as the main factor for determining whether a drug is covered. Consequently, the proper use of formularies may not only prevent regulation but could also be more effective in treating diseases and limiting the improper use of medications. If formularies accomplish these goals, prescription drug expenditures could achieve cost savings in other areas of health care.

Conclusion

Prescription drugs are the fastest-growing segment of national health care expendi-

tures. While amounting to only 7 percent of total national health expenditures, prescription drug payments have grown to account for nearly 12 percent of all private health insurance payments. Thus, prescription drug expenditures have become a significant and rapidly expanding portion of these payments, which has forced both employers and health plans to review how they cover prescription drugs.

In any discussions of restructuring prescription drug coverage, employers and health plans should be cognizant of the potential for prescription drugs to more effectively treat some diseases and to lower total costs by eliminating the need for other more expensive health care services. There is some evidence that prescription drugs can offset the costs of treating certain diseases, but whether these drugs have lowered overall health expenditures still appears uncertain. However, there also is evidence of overprescribing medications by physicians and significant misuse of prescription drugs

²² Under the Employee Retirement Income Security Act of 1974 (ERISA), states are not able to regulate the health plans of employers and unions that self-insure their health benefits. See Copeland and Pierron (1998) for more details on ERISA.

²³ This may also hamper effective disease management programs used by employers and health plans.

If regulations make pharmaceutical companies unable or unwilling to commit as much to research and development as is currently being invested, new innovations may be delayed or even lost.

through patients taking their medication too much or too little and not completing the full regimen of the prescription. Therefore, changes are to be expected in the coverage of prescription drugs to promote the proper use and choice of medications to increase the quality of care from this benefit.

The addition of a prescription drug benefit for Medicare beneficiaries and/or the regulation of drug prices using the FSS are likely to be heavily debated in the current Congress. The design and implementation of these pieces of Medicare reform legislation could have a far-reaching impact on pharmaceutical companies, employers, and health plans. In particular, if these regulations make pharmaceutical companies unable or unwilling to commit as much to research and development as is currently being invested, new innovations may be delayed or even lost. However, prescription drugs are becoming an important part of treating many diseases that affect the elderly and disabled—which creates a budgetary, political, and medical dilemma for lawmakers who must decide whether to create a Medicare drug benefit.

While prescription drug expenditures are rising sharply, they are also becoming more important in the treatment of many diseases. Consequently, both employers and policymakers must carefully balance the design and cost of a drug benefit so that continual innovation is preserved and the benefit can remain affordable and effective.

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