CHAPTER 1

Medicare beneficiaries and prescription drug coverage

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A debate is evolving about how to address the growing prescription drug costs faced by Medicare beneficiaries, many of whom lack insurance coverage for prescription drugs. In assessing the need for a public policy response, policymakers should consider beneficiaries' abilities to access needed drugs, growth in prescription drug spending, and the adequacy of existing sources of coverage. If policymakers believe that a public policy response is warranted, they have several options. They may decide that adding a prescription drug benefit to Medicare coverage is the appropriate solution. Alternatively, policymakers may opt for policies that either serve as interim solutions before enactment of an enhanced Medicare benefit or serve as alternatives to adding a Medicare benefit. Some of these options would target assistance to low-income beneficiaries through a Medicaid expansion, a new program similar to the State Children's Health Insurance Program, or tax credits. Other options would aim to improve the drug coverage available through Medigap plans. This chapter seeks to assist policymakers in evaluating the need for a federal policy response and identifying potential policy approaches and the technical challenges inherent to each.

At the inception of Medicare, outpatient prescription drugs represented a relatively small portion of beneficiary health care spending and were excluded from the Medicare benefit package. Over time, prescription drugs have become an increasingly important part of treatment and have grown as a percent of beneficiaries' health care spending. Medicare has expanded coverage to a few outpatient drugs under specific and limited circumstances, and supplementary coverage has evolved to the point that most beneficiaries have some coverage for prescription drugs.[1] However, growing drug costs are increasing out-of-pocket costs for beneficiaries, and the future of supplementary coverage is uncertain. Consequently, there have been calls for federal policy solutions to assist beneficiaries in affording and accessing drug coverage.

This chapter begins by describing the current pressures for new public policy to expand coverage. It presents data on current and projected beneficiary spending on prescription drugs, sources of drug coverage and trends in availability, the importance of coverage to patient compliance, and the potential for prescription drugs to substitute for other health care services and improve quality of life. The second part of the chapter identifies key design decisions for policymakers to consider if they opt to add prescription drug coverage to the Medicare benefit package. These decisions concern benefit design, management and administration, and how Medicare payment should be determined. Lastly, the chapter identifies other policy options that could provide either interim solutions before an enhanced Medicare benefit is enacted or alternatives to adding a benefit. These options include expanding coverage through state insurance programs, reforming the Medigap market, and tax credits.

Pressures for new public policy to encourage coverage

Are beneficiaries' current spending patterns and trends sustainable or acceptable? Are the growing expenditures for drugs the primary problem, or is the problem one of inadequate sources of insurance coverage? Are all beneficiaries experiencing problems, or is a subset of beneficiaries most in need? To answer these questions, it is important to understand prescription drug spending growth and patterns, the availability and adequacy of insurance coverage for drugs, the relationship of coverage and beneficiary access to drugs, and substitutions between drugs and other health care services. In addition, a review of previous legislative experience with adding a Medicare drug benefit may provide some lessons for the future.

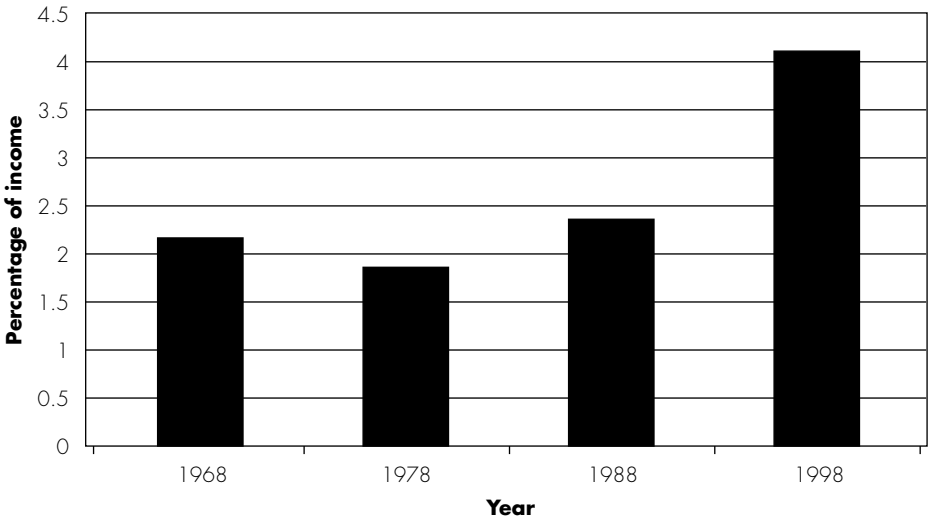
Prescription drug spending

Since the inception of the Medicare program, prescription drugs have come to play an increasingly important role in the treatment of conditions for all people. However, the strides in pharmaceutical technology have had particularly significant implications for the elderly. Seniors are far more likely to suffer from chronic conditions for which drug treatments are an important part of care, such as arthritis, diabetes, high blood pressure, heart disease, Parkinson's disease, and depression. Seniors spend more than three times as much on prescription drugs than do those under 65; seniors make up 13 percent of the U.S. population, but account for more than one-third of drug spending (HHS 2000).

Expenditures on prescription drugs for the Medicare population have grown dramatically. In 1968, seniors spent an average of $64 on prescription drugs.

FIGURE 1-1

Prescription drug expenses not paid by Medicare as percentage of income for beneficiaries ages 65 and older



Source: Estimates by Watson Wyatt Worldwide.

1 Medicare covers the following outpatient drugs: immunosuppressive drugs following a covered organ transplant, oral anticancer drugs identical to drugs that would be covered if not self-administered, erythropoietin for the treatment of anemia in persons on dialysis suffering from chronic renal failure, hemophilia clotting factors, and vaccines for pneumococcal pneumonia, hepatitis B, and influenza.

Previous legislative experience with a Medicare drug benefit

Policymakers previously approached the issue of adding Medicare prescription drug coverage: in 1988, with the Medicare Catastrophic Coverage Act (MCCA) of 1988, and in 1994, with the Health Security Act. Both efforts failed, but for different reasons and under different circumstances.

Medicare Catastrophic Coverage Act of 1988

In 1988, Congress added a catastrophic benefit to Medicare that would have provided comprehensive coverage for outpatient drug expenses greater than $600 in 1991 with a 50 percent coinsurance, and those greater than $652 in 1992 with a 40 percent coinsurance.[2] The coinsurance was to be lowered to 20 percent in 1993. The intent was to revise the deductible annually, providing 16.8 percent of beneficiaries with benefits each year. The new coverage was to be entirely financed by Medicare beneficiaries through an increase in the Part B premium and a supplementary surcharge. The surcharge was to cost higher-income beneficiaries—those with incomes greater than about $40,000—as much as $800 in 1989 and $1,050 in 1993 (Congressional Quarterly 1988, Coster 1990).

Opposition to the new benefit was fueled by confusion about the specifics of the financing (many lower-income beneficiaries thought they had to pay the full surcharge), as well as other concerns. First, enrollment in the program was mandatory, but many beneficiaries would never receive any benefits because their drug costs would never exceed the cap. Second, beneficiaries who already had drug coverage, from either Medigap or an employer-sponsored retiree plan, would be required to pay twice for the same benefit; these people also were the ones most likely to pay the maximum premium surcharge (although it is likely that retiree insurance premiums would either decline due to Medicare coverage or be a wrap-around benefit). Third, beneficiaries were required to start paying the supplemental premium in 1989, two years before the full benefit began. The law was ultimately repealed in 1989; few benefits had taken effect by this time.

Health Security Act of 1994

The Health Security Act, which was never enacted, proposed a new Medicare prescription drug benefit that would have included a $250 deductible, 20 percent coinsurance and an annual limit of $1,000 on out-of-pocket expenses. The deductible and out-of-pocket limit were to be indexed to ensure that the same proportion of beneficiaries received the benefit each year. It was estimated that 58 percent of beneficiaries would use the proposed drug benefit. The new coverage was to be added to Medicare Part B; approximately 75 percent of the benefit would be financed through general revenue and 25 percent through beneficiary premiums.

Opposition to this benefit focused on its complex cost-containment mechanisms and potential for price controls that some believed would stifle future pharmaceutical research and development.

For example, the Health Security Act would have limited Medicare drug spending by requiring manufacturers to provide a rebate in order for their drugs to be covered under the Medicare program. (No rebates would be required for generic drugs or for drugs used by beneficiaries enrolled in managed care.) The rebate was equal to the greater of the difference between average wholesale and retail prices or 17 percent of retail. An additional rebate would have been required for drugs with prices that increased faster than the rate of inflation. Because new drugs often initially have very high prices, the Secretary was to have the authority to negotiate special prices for breakthrough drugs considered overpriced and could exclude these new drugs from coverage if a rebate agreement could not be reached. The Act also would have created an Advisory Council on Breakthrough Drugs, which would advise the Secretary on the reasonableness of launch prices of new drugs representing significant advances over existing therapies. Although the findings of the council would not be binding, they would influence the Secretary and the drug payments of other entities with purchasing power. Most of the controversy over the Health Security Act focused on its means of achieving universal health insurance, but its prescription drug provisions and other cost-containment mechanisms contributed to the failure of this bill to become law. ■

2 The MCCA specifically prohibited the establishment of a national drug formulary.

Expenditures rose slower than general inflation during 1968–1978, but have accelerated since then. Drug expenditures per beneficiary nearly doubled from 1988–1998, even after adjusting for inflation. Expenditures per beneficiary were $848 in 1998. As a percent of income, beneficiary spending on drugs has increased from 2.4 percent to 4.1 percent from 1968–1998[3] (Figure 1-1).

Several factors have driven this increase in spending. Inflation for prescription drugs has averaged about 3.5 percent over the past five years. Although significant, this is only a small part of the overall growth.[4] The primary drivers have been the introduction of new products and the growth in prescription drug use. One study found that 36 percent of all drug spending in 1998 was on products introduced in the previous six years (Express Scripts 1999).

The introduction of new drugs to the marketplace is the result of substantial research and development (R&D) and a streamlined Food and Drug Administration (FDA) approval process. There has been a 14 percent annual rate of increase in R&D spending for pharmaceuticals over the past 19 years, with U.S. research-based companies spending $24 billion in 1999—equal to about 24 percent of U.S. outpatient spending for prescription drugs that year (HCFA 2000). Part of this increase is due to technological advances that have greatly increased testing capacity. Today, some 7,500 products are now under development—a 50 percent increase over five years ago. There are indications that more significant breakthroughs will occur in the future. Although the Human Genome Project has not yet influenced the products in the FDA pipeline, there is every indication that the mapping of the human genome will allow pharmaceutical scientists to develop more sophisticated drugs that will target not only individual diseases, but also individual patient variations (Maesner 2000).

The significant investment in R&D has been accompanied by an expedited FDA review process for new drugs. In 1992, the FDA implemented a program of user fees for companies that sponsor new drug applications, and by 1997 the new fees had allowed the agency to add 300 reviewers. Under the Food and Drug Administration Modernization Act of 1997, the FDA was also charged with expediting the review of priority drugs that offer patients significant therapeutic gains (PhRMA 1999). The result of expedited review has been dramatic; the average FDA approval time for new drugs has decreased from 23 months in 1993 to 12 months in 1998. As a result, the number of new drugs approved each year by the FDA has increased from 21.7 in the 1980s to 37.5 between 1995 and 1998 (Figure 1-2). Assuming that the addition of new FDA resources was responsible for breaking the approval bottleneck, the approval rate should now stabilize unless further resources are added.

Increased use has been spurred in part by the higher therapeutic value of many newer drugs. For example, peptic ulcers were frequently treated with surgery, but today, they are usually treated with drug therapy. Other examples of chronic conditions that can now be treated with improved drug therapies include migraine headaches, arthritis, depression, and allergies.

Definitions of insurance terms

Adverse selection—Any situation which results in a health plan, or group of health plans, having higher expected health costs as a result of risk selection (see risk selection).

Coinsurance—A type of cost sharing in which beneficiaries pay a fixed percentage of the cost or charge for a covered service.

Copayment—A type of cost sharing in which beneficiaries pay a fixed dollar amount for a covered service.

Cost sharing—Payments that health insurance enrollees make for covered services. Examples of cost sharing include coinsurance, copayments, deductibles, and premiums.

Deductible—A type of cost sharing in which beneficiaries must pay a specified amount for covered medical services before their insurer assumes liability for all or part of the cost of subsequent covered services.

Formulary—A list of drugs maintained by a provider or an insurer, containing drugs deemed appropriate for the treatment of designated conditions for both therapeutic and cost reasons.

Medical underwriting—The process of using information about a beneficiary's health status or prior use of medical services to determine the price of a health insurance policy or whether to sell a policy to a beneficiary.

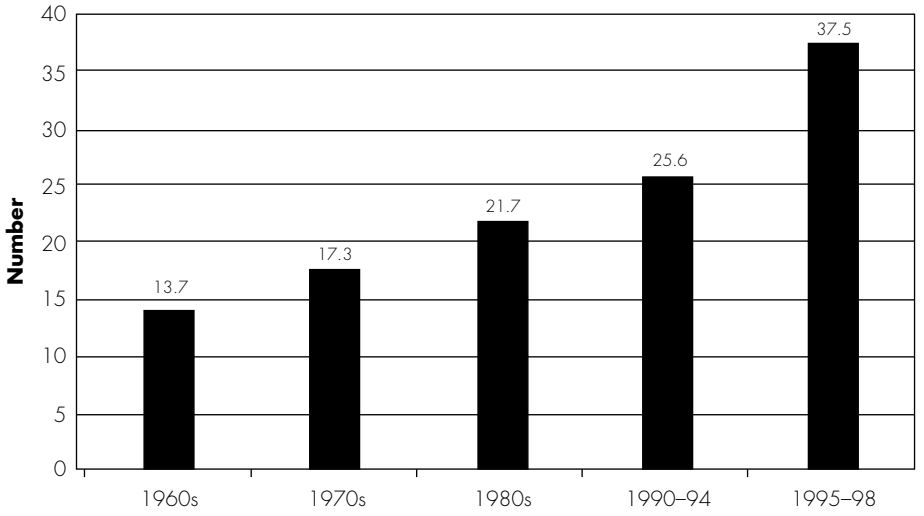
Risk selection—Any situation in which health plans differ from one another in the health risks associated with their enrollees because of enrollment choices made by the plans or the enrollees. Health plans' expected costs vary because of underlying differences in health of and use of services by their enrolled populations. ■

3 This calculation of spending as a percent of income was calculated with Watson Wyatt Worldwide's PreView Medical Benefits Modeling System.

4 The higher prices for new products are not reflected in the Consumer Price Index for prescription drugs, because the Consumer Price Index is based on the price of a fixed market basket of drug products.

FIGURE 1-2

Average annual number of new molecular entity approvals by the Food and Drug Administration: 1960–1998



Source: Lumpkin 1997, Lumpkin 1998, Lumpkin 1999.

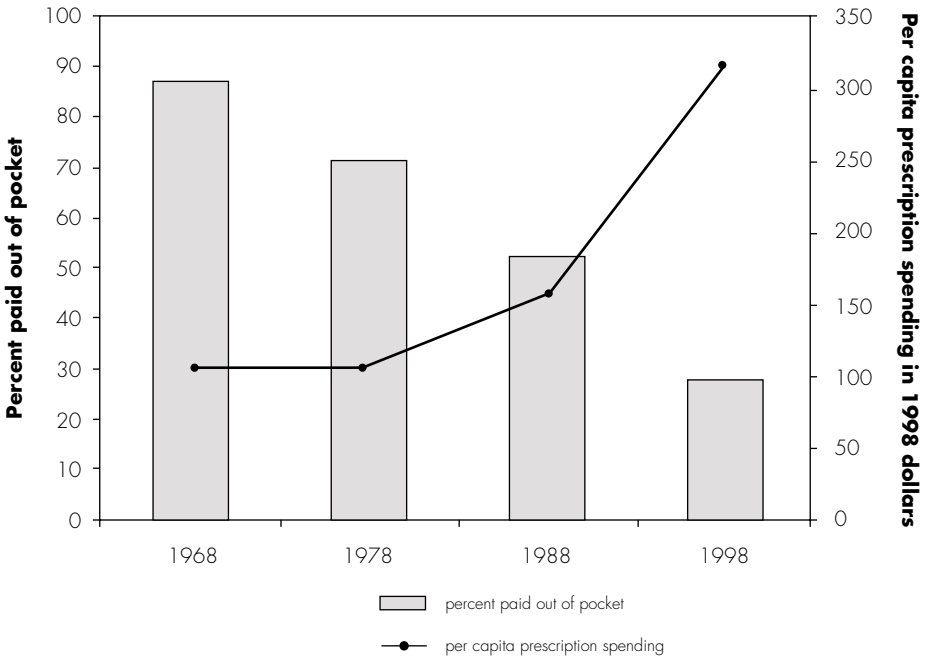
increases in both the dissemination of valuable information and unnecessary office visits.

Finally, substantial changes in the scope of third-party coverage for prescription drugs have reduced financial barriers for many people, allowing greater use. Research by the RAND Corporation in the 1970s found that people were very sensitive to price changes for prescription drugs (Liebowitz et al. 1985). For the entire U.S. population, 87 percent of outpatient prescription drug expenditures was paid out of pocket in 1968, falling to 28 percent in 1998. The percentage of prescription drug expenses paid out of pocket is considerably higher for the Medicare population, averaging 50 percent in 1996 (Davis et al. 1999). This decline in patient liability for prescription drug costs has been one of several factors that have contributed to a 200 percent increase in total real drug spending per person in the same period (Figure 1-3).

Another factor influencing use is the increased investment in marketing by pharmaceutical manufacturers. In 1997, the FDA loosened the advertising rules for prescription drugs. Manufacturers are now allowed to mention a product's name and the condition it could treat without disclosing all of the product's risks. Previously, full disclosure was required and advertisements could not fit all the required information into the short-time formats of television and radio commercials. In 1998, pharmaceutical manufacturers spent $8.3 billion promoting their products in the United States. Of that amount, $1.3 billion was spent on direct-to-consumer advertising, 55 percent more than in 1997 (Barents Group LLC 1999). However, it is unclear whether this advertising investment reinforces sound prescribing choices by alerting physicians and patients to the introduction of drugs offering real therapeutic value or whether it has encouraged inappropriate prescribing practices. Many physicians claim that the advertising has encouraged patients to make unnecessary appointments and request inappropriate prescriptions. It is likely that increased advertising has led to

FIGURE 1-3

Percent paid out of pocket for prescription drugs and U.S. per capita prescription spending in 1998 dollars, 1968–1998



Source: Watson Wyatt calculations based on National Health Accounts, HCFA and population estimates from HCFA.

Medigap insurance analysis: data and methods

Some studies based on beneficiary surveys, including the one by Poisal and Chulis (2000) presented in this chapter, have found 30 percent to 40 percent of Medigap purchasers have coverage for prescription drugs. MedPAC obtained insurance company filings to state insurance commissioners for an analysis of drug coverage. These data were from 1998 and had been compiled by the National Association of Insurance Commissioners (NAIC). MedPAC found that of all standard Medigap policies sold in 1998, only 7.4 percent included prescription drug coverage.

However, standardized policies make up only about 60 percent of the total Medigap market; another 35 percent are pre-standardized plans, and 5 percent are from the waiver states of Massachusetts, Minnesota, and Wisconsin. MedPAC communications with the waiver states suggest that up to a third of policies in those states are purchased with drug coverage. Calls to insurers that sell a substantial number of pre-standardized policies suggest that up to a fourth of those policies may include coverage for prescription drugs.

Analysis of the NAIC data suggests that not more than 15 percent of people with Medigap policies have any prescription drug coverage from those policies. This finding suggests that only 4 percent of Medicare beneficiaries in 1998 had prescription drug coverage through Medigap plans. It is unclear if this difference from other studies is a result of changes in the last few years or of methodological issues.

Data

In compliance with federal and state statutes, insurers annually file Medicare Supplement Experience Exhibits with state insurance commissioners. NAIC then collects this information from the states. The filings help determine whether insurers are meeting their loss-ratio requirements stipulated by law. However, these data also include information about covered lives, earned premiums, and certain plan characteristics. Data on the Medigap insurance market presented in this chapter stem from an analysis of the NAIC dataset containing filings reported as of December 31, 1998.

These data represent the best information on Medigap insurance currently available. They cover all polices in force during 1998, including pre-standardized policies, standardized policies, and policies for individuals living in the waiver states. The data are reported by insurers and required by law. Accuracy should, therefore, be fairly high. In addition, the data are not subject to recall bias, as consumer surveys might be.

Neverthless, several caveats apply. First, approximately 5 percent of the policies in the original dataset were missing information identifying the type of Medigap plan (pre-standardized, waiver state, or one of 10 standardized plan types). During the data cleaning process, we verified as many plan types as possible with insurers. In the final dataset, less than 1 percent of covered lives (57,000) were in plans still missing the Medigap plan type.

Second, the raw dataset included about 10.7 million covered lives. To increase the reliability of the results, we chose to limit our analysis to plans that included at least 50 covered lives. About 1.7 percent of covered lives (180,000) were lost when this criterion was applied. This approach is likely to result in a slight underestimate of pre-standardized policies, as the covered lives excluded from the analysis were more likely than those retained to be in pre-standardized policies.

Third, a number of policies in the dataset are identified as waiver state policies, although the state in which the policy is in force is not one of the waiver states. Some of these discrepancies may represent movements of beneficiaries from the waiver states to other states. During the data cleaning process, we reclassified some of these policies as pre-standardized because they had a date of issuance that preceded the standardization regulations. Nevertheless, the covered lives in waiver states may be overestimated. ■

To appreciate beneficiaries' financial risks for prescription drug expenses, it is important to look not only at the average drug expenditures of Medicare beneficiaries, but also at the distribution of the expenses. About 86 percent of Medicare beneficiaries have some drug expenditures, paid either out of pocket or through insurance coverage; average beneficiary expenditures were close to $1,000 in 1999. Because data are based on the Medicare Current Beneficiary Survey, which may somewhat under-report these numbers, the actual expenses may be even higher. About 32 percent of beneficiaries have expenses of more than $1,000, and 6 percent more than $3,000. Only about 14 percent of beneficiaries report no prescription drug spending (Gluck 1999) (Table 1-1).

Insurance coverage for prescription drugs

In 1996, about 70 percent of beneficiaries had supplementary prescription drug coverage, leaving 11.6 million without

TABLE 1-1

Distribution of Medicare enrollees by total prescription drug expenditures, 1999

No drug expenditures	14%
$1–$500	36
$500–$999	19
$1,000–$1,499	12
$1,500–$2,999	14
$3,000 or more	6

Note: Total does not add to 100% due to rounding.
Source: Gluck 1999.

coverage (Poisal and Chulis 2000). Thirty-one percent of beneficiaries had coverage through employer-sponsored health benefit plans, 11 percent had Medigap drug coverage, and 8 percent had coverage through Medicare+Choice plans. Medicaid covered about 11 percent of all those with coverage, while other public programs such as state drug assistance programs and the Department of Veterans Affairs covered about 2 percent of all beneficiaries. About 7 percent of beneficiaries switched coverage sources during the year, making the source classification unclear (Figure 1-4). Although these data represent the most recent comprehensive examination of prescription drug coverage for Medicare beneficiaries, MedPAC has examined the Medigap market and found differences between the comprehensive data reported here and specific Medigap data (see text box, page 8).

The prevalence of coverage varies by certain characteristics, such as age, income, and health status. Data sources are not entirely consistent on this point. However, an analysis by HCFA suggests that wealthier beneficiaries are more likely to have coverage, while those just above Medicaid eligibility are least likely. Older beneficiaries are less likely to have coverage than those younger than 85. This study also found that those with and without insurance tend to have about the same self-reported health status.

In assessing the need for a policy change, policymakers should consider existing sources of coverage, including the cost and scope of that coverage, and the adequacy of coverage in meeting beneficiary needs (Table 1-2). They should also examine indications of the future availability of coverage and how that availability might be affected by a new government-sponsored program.

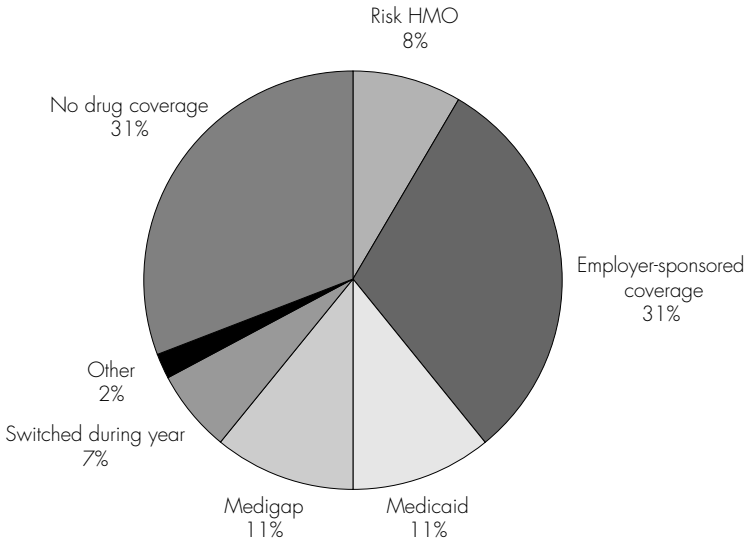
Employer-sponsored coverage

Employer-sponsored coverage is typically the most comprehensive supplemental drug coverage available for Medicare beneficiaries. The great majority of employer-sponsored medical plans for Medicare-eligible retirees include prescription drug benefits with low beneficiary cost sharing and no annual limits on the amount the plan will pay for prescription drug benefits.

Generally, the provisions of retiree medical plans closely parallel those of active employee plans. Based on active employee plans, most beneficiaries are not subject to a deductible and coinsurance for drugs, but they are typically subject to copayments in the $5–$15 range.[5] Beneficiaries pay an annual premium for their overall health insurance coverage (which includes prescription drugs) that averages $500–$600. Employer plans often include a $1 million lifetime cap, applicable to both medical and prescription drug costs, but this cap seldom comes into play because Medicare is the primary payer for costly medical services.

FIGURE 1-4

Coverage among noninstitutionalized Medicare beneficiaries by supplemental insurance status, 1996



Note: HMO (health maintenance organization). Total does not add to 100% due to rounding.

Source: Poisal and Chulis 2000.

5 The escalating costs of prescription drugs have induced employers to raise copayment levels substantially and move to implement newer plan designs, such as the three-tiered copayment structure.

TABLE 1-2

Typical benefit and cost sharing by source of coverage

	Prescription drug benefits			
Source of coverage	**Premiums paid by enrollee for entire insurance package**	**Deductible**	**Coinsurance/copay**	**Benefit maximum**
M+C HMO	$180	None	$5 generic $15 brand	Usually $500–$1500 per year, often unlimited
Medigap plans H, I and J	$2,000–$4,500 (varies by area)	$250 or $500	50%	$1,250 or $3,000
Employer	$500–$600	None	$5 generic $10 brand $20 off-formulary brand	$1,000,000* lifetime
Medicaid	None	None	less than $5	Some states limit fills per month

Note: M+C (Medicare+Choice), HMO (health maintenance organization).
* Applies to both medical and prescription drug costs.

Source: Watson Wyatt Worldwide survey of employer plans, HCFA's Medicare+Choice database, and beneficiary publications.

Retiree supplement plans were originally viewed by sponsoring employers as a low-cost benefit that filled some gaps of the Medicare program. Escalating costs have now made this benefit a substantial liability for many employers, and outpatient prescription drugs typically represent 50 percent or more of this liability.

Because of financial community concerns that employers had promised employees and retirees substantial future medical benefits that were not funded, in 1991 the Financial Accounting Standards Board[6] (FASB) required companies to begin reporting accrued post-retirement benefit obligations on their financial statements. This requirement has caused many employers to reassess their retiree medical commitments. Although the pay-as-you-go costs previously reported on their financial statements were substantial, reporting accrued obligations had a major negative effect on financial statements.

Over the past 10 years, many employers have been limiting future retiree medical commitments. One of the most common approaches has been to cap the level of future premium contributions. Today, 40 percent of large employers have instituted caps on future contributions (Health Policy Alternatives 1999), and some employers have already hit these caps. For example, under this approach an employer may cap its annual premium contribution at $2,000 for a benefit that currently costs $1,600 ($800 for drugs and $800 for medical expenses). If prescription drug spending grows 15 percent and medical spending grows 5.5 percent annually, in 10 years the benefit would be about $4,500, meaning that retirees would be paying about $2,500 in premiums on top of the $2,000 employer contribution.

The potentially large increases in the retiree portion of the premium are creating a sense of urgency to restrain plan spending. To control costs, employers have sought the help of pharmacy benefit managers (PBMs) to encourage generic substitution, negotiate discounts from pharmacies, promote the use of formulary drugs, and obtain manufacturer rebates. Employers are also experimenting with higher copayments and three-tier copayments that discourage the use of higher-cost brand drugs.

Finally, a substantial but unknown number of employers have dropped their retiree medical benefits for future Medicare-eligible retirees. Many took this action when the 1991 FASB requirement was implemented, but employers continue to drop coverage today. Recent analysis of the Current Population Survey indicates a decline in employer-sponsored coverage for seniors up to age 79. Prevalence of coverage in the youngest group of seniors fell about 3 percentage points from the 1994 level of 43 percent. Coverage for the other senior groups under age 80 fell by about 1 percentage point (Table 1-3).

While the prevalence of coverage in seniors ages 65-80 fell, the prevalence of coverage for those older than 80 actually rose. However, all members of these age cohorts had reached age 65 when the FASB standard was implemented in 1991,

6 The Financial Accounting Standards Board is recognized by the Securities and Exchange Commission as the designated organization in the private sector for establishing standards of financial accounting and reporting.

TABLE 1-3

Percentage of Medicare beneficiaries with employer-sponsored coverage, by age, 1994 and 1998

Age group	1994	1998
Total	35%	34%
65–69	43	40
70–74	37	36
75–79	33	32
80–84	24	28
85 and older	20	21

Note: Calculations based on Current Population Surveys for March 1995 and March 1999.

Source: Adapted from Copeland 2000.

and it is less likely that employers would have been able to drop coverage for those already eligible.

Medigap

Of the various forms of supplemental insurance, Medigap provides the least comprehensive coverage of prescription drugs. Most Medigap policies do not cover prescription drugs; those that do generally have high premiums and require significant out-of-pocket spending. In addition, Medicare beneficiaries with Medigap insurance, rather than other types of supplemental coverage, usually pay the entire premium out of pocket.

The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) led to the standardization of the Medigap insurance market. All Medigap policies sold since July 1992 must conform to one of 10 standard policies, labeled A through J. Each plan provides a specific set of benefits. Only three (H, I, and J) cover prescription drugs, and coverage is limited: H and I are subject to a $250 annual deductible, 50 percent coinsurance, and a maximum annual benefit of $1,250. Plan J has the same deductible and coinsurance structure, but a higher maximum benefit of $3,000.[7] When the plans were standardized, beneficiaries were allowed to maintain their existing policies. These pre-standardized plans make up a large portion of the policies held today.

Three states (Massachusetts, Minnesota, and Wisconsin) had Medigap standardization policies that superseded the OBRA-90 legislation. In Minnesota and Wisconsin, coverage for outpatient pharmaceuticals is offered as an optional rider to a core plan. In Massachusetts, one of three plan options includes prescription drugs. Wisconsin is unique in that the core benefit package includes coverage for catastrophic outpatient pharmaceutical costs (20 percent coinsurance after a deductible of up to $6,250). Table 1-4 provides a summary of outpatient pharmaceutical benefits in Medigap plans.

Premiums Premiums for Medigap insurance are high and increasing. Insurance experts estimate that the average premium in 1998–1999 was $1,500, with annual rate increases of 8–10 percent in 1999–2000 (Weller 1999). Total increases of 35 percent, on average, were experienced from 1994–1998 (Consumer Reports 1998). Premiums for Medigap policies that cover pharmaceuticals are considerably higher than those for plans without drug coverage.

Given the design of the Medigap drug coverage and the large differences in premiums for Medigap plans with drug coverage, some consumer advocates recommend that seniors with low drug costs not purchase these products (Morrow 1996). For example, a beneficiary with average annual drug costs of $750 will pay $500 out of pocket under plan H, I, or J ($250 deductible plus 50 percent coinsurance on the remainder) while the plan pays $250. On the other hand, individuals who decide not to purchase a policy with drug coverage when they are younger may not be able to do so at a later date.

Beneficiaries with Medigap prescription drug coverage According to 1998 insurance company filings with the National Association of Insurance Commissioners (NAIC), fewer than 500,000 beneficiaries hold plans H, I, or J. The NAIC data do not allow measurement

TABLE 1-4

Structure of outpatient pharmaceutical benefits under Medigap plans

	Characteristics			
Plan type	Deductible	Coinsurance	Benefit limit	Catastrophic coverage
Standardized plans H and I	$250	50%	$1,250	No
Standardized plan J	250	50	3,000	No
Massachusetts supplement 2	35/quarter	0 generic, 80 brand-name	None	No
Minnesota prescription drugs rider	None	≤50	None	No
Wisconsin prescription drugs rider	250	50	3,000	Yes (in core benefit plan)

Source: MedPAC summary of public information.

7 The 1997 Balanced Budget Act (BBA) authorized high-deductible options for plans F and J, but few, if any, high-deductible plans have been marketed to date.

of the number of people with pre-standardized plans or the number of people in waiver-state plans that have prescription drug coverage. However, calls to insurers and state insurance commissioners lead MedPAC to believe that fewer than 2 million beneficiaries have drug coverage from Medigap plans (see text box; p. 8). Premiums vary widely within and across markets. One study found that quotes for a 65-year-old male in Billings, Montana to purchase plan J ranged from $1,500 to almost $3,500 (Weiss Ratings 1999). That study also showed that the same company selling Plan H in four sample markets had premiums that differed as much as 36 percent among those markets.

Beneficiary Access to Medigap plans H, I, and, J Federal law mandates certain periods during which beneficiaries can enroll in any Medigap plan offered in their state, regardless of health status. These periods include the first six months when beneficiaries are both 65 or older and enrolled in Part B, and in certain cases when beneficiaries return to fee-for-service Medicare after enrolling in a Medicare+Choice plan. Otherwise, insurers can deny policies or charge more based on health status.[8]

States determine which standardized plans may be offered to consumers; federal law requires only that the basic package (plan A) be offered. Given the potential for adverse selection into plans H, I, and J, many carriers do not offer them. For example, in New York, 14 carriers are offering Plan A in 2000, while only 1 insurer is offering Plan J (Medicare Rights Center 2000). Among those carriers that offer plans with drug coverage, many use medical underwriting (surveying a beneficiary's health status to determine whether to sell a policy to the beneficiary) outside the open enrollment period. Although virtually all carriers use medical underwriting for plans with drug coverage, some do not underwrite for non-drug plans.

Medicare+Choice

Medicare+Choice (M+C) plans make decisions about their participation in the Medicare program and the structure of their benefit packages on an annual basis. Until 1998, an increasing number of beneficiaries were able to access drug coverage through M+C plans. Since then, payment changes and market dynamics have led many M+C plans to scale back benefits or withdraw from the program, raising questions about the future availability and generosity of drug coverage through M+C plans.

Although the percentage of beneficiaries with drug coverage available through M+C plans has declined between 1999 and 2000, most beneficiaries still have access to M+C plans with some prescription drug coverage. In 1999, 65 percent of beneficiaries had access to a plan with drug coverage; in 2000, 64 percent had access. About 54 percent of beneficiaries had access to a zero-premium plan with drug coverage in 1999; 45 percent did in 2000.[9] Medicare+Choice plans are more available in urban areas—which also tend to be higher payment areas—than in rural areas. In 2000, 79 percent of urban beneficiaries and 16 percent of rural beneficiaries have a plan with drug coverage available. Further, 57 percent of urban beneficiaries and 6 percent of rural beneficiaries have a zero-premium plan with drug coverage available.

Although the design of the M+C prescription drug benefit varies, there are some common characteristics. In 2000, about 60 percent of Medicare beneficiaries have access to a M+C plan that includes drug coverage with an annual cap of at least $500, generic copayments of no more than $15, and brand copayments of no more than $20. Of these beneficiaries, 60 percent would have to pay no premium to join the plan and 75 percent would have to pay no more than $35 per month.

Medicaid

Medicaid programs are administered by the states, and the federal government provides matching funds for qualified expenditures. Coverage of outpatient prescription drugs is optional under Medicaid, but all states have chosen to provide this benefit. Medicaid coverage is comprehensive, with nominal copayments. There is no benefit cap, although some states impose a limit on the number of prescriptions filled each month.

States choosing to cover outpatient prescription drugs under Medicaid must cover, for their medically accepted indications, all FDA–approved prescription drugs made by manufacturers who have entered into drug rebate agreements with the Secretary of Health and Human Services. There are some exceptions, including vitamins, and drugs for anorexia, weight gain, fertility, hair growth, cosmetic effects, cough and cold relief, and smoking cessation.

8 Before the BBA, beneficiaries had no guaranteed access to Medigap policies after the open enrollment period. The BBA extended guaranteed issue rights to certain individuals leaving Medicare managed care plans, losing employer-sponsored coverage, or switching between Medigap plans. However, most of these guaranteed issue rights were limited to plans A, B, C, and F, which do not cover prescription drugs. There are two situations in which these beneficiaries may purchase drug plans:

1. Enrollees who enrolled with a Medicare+Choice plan when they first became eligible for the Medicare program at age 65 and who choose to return to FFS Medicare within the first 12 months of their initial enrollment in a Medicare+Choice plan may purchase any Medigap plan, including one that covers prescription drugs.
2. Beneficiaries who terminated a Medigap policy to enroll in a Medicare+Choice plan or other Medicare managed care plan for the first time, and subsequently disenroll within the first 12 months, may return to their previous Medigap policy (including H, I, and J) if it is still offered. Beneficiaries who terminated a pre-standardized plan may not return to that plan, as insurers are not allowed to sell them.

9 There is some evidence that the percentage of M+C enrollees with drug coverage is declining. A research team led by Dana Gelb Safran at the New England Medical Center found that the percentage of M+C enrollees whose M+C plan included drug coverage dropped by about 12 percentage points between 1998 and 1999 (Wall Street Journal 2000). MedPAC staff analysis suggests that there may have also been a drop between 1999 and 2000.

Most states use one or more tools to manage the benefit:

- Thirty-three states impose some form of prescription drug cost sharing (typically $0.50 to $3 per prescription).
- Forty-two states have some form of prior authorization process.
- Forty-six states place some limits on prescriptions, including a 30- to 34-day limit per prescription, a 100-unit dose limit per prescription, and a limit on the number of refills over a given time.

The Medicaid drug benefit is only available to individuals eligible for full Medicaid benefits. People in special groups—such as Qualified Medicare Beneficiaries, Specified Low Income Medicare Beneficiaries, and Qualifying Individuals, which have eligibility criteria that can include people with incomes up to 175 percent of poverty level—are not covered. Eleven percent of Medicare beneficiaries receive Medicaid drug coverage.

State drug assistance programs

Sixteen states operate pharmacy assistance programs. Several other states enacted programs in 1999 that are not yet operational, and several more states are actively exploring legislation to establish programs. For the most part, these programs are targeted at people 65 and older, and to a lesser extent, the disabled. Some programs cast broader coverage nets and make persons eligible based solely on level of income, rather than on age or disability status.

Collectively, these programs provide assistance to approximately 800,000 people. Three states (New Jersey, New York, and Pennsylvania) account for more than two-thirds of all state drug assistance program enrollees, and most states with operating programs are in the Mid-Atlantic and New England.

Most programs offer comprehensive prescription drug coverage, but some limit coverage through criteria such as disease-specific requirements, income limits, and formulary restrictions. All programs institute some form of cost sharing—typically a copayment of a few dollars per prescription, although in some programs the copayment can be substantially higher—and a few require deductibles. Funding sources are varied and include general revenues, state lottery proceeds, casino revenues, and tobacco settlement funds.

Department of Veterans Affairs

In fiscal year 1999, the Department of Veterans Affairs (VA) spent more than $1.8 billion (11 percent of its health care budget) to provide prescription drugs to approximately 3.65 million veterans, of which approximately 1 million are Medicare beneficiaries. Under this pharmaceutical benefit, veterans pay nothing for prescription drugs if they are being treated for service-connected conditions or have service-connected disabilities rated at 50 percent or greater. Veterans with service-connected disability ratings of less than 50 percent, those treated for non-service-connected conditions, and those who do not qualify as low income have $2 copayments for each 30-day drug supply. Covered drugs are distributed through a VA system of medical facilities and a mail service program for outpatient drugs.

The VA manages this drug benefit through a national formulary system administered by its Pharmacy Benefits Management Strategic Healthcare Group. This group can add and delete FDA-approved drugs from the formulary on the basis of its interpretation of cost, safety, and efficacy data. It also determines which drugs are therapeutically interchangeable and develops clinical guidelines to protect veterans from the inappropriate use of certain drugs. Final decisions are made by a Medical Advisory Panel, a group of 12 physicians responsible for managing the pharmaceutical benefit. From 1997 through 1999, this panel added 26 drugs and deleted 6 from the national formulary. Generic drugs are used whenever possible.

Prescription drugs not on the national formulary may be available to veterans if listed on the formularies of their local medical centers or Veterans Integrated Service Network (VISN), a regional organization responsible for basic decision-making and budgetary duties of the VA program.[10] These formularies include all drugs listed on the VA national formulary as well as drugs a VISN or medical center designates as necessary to address the special needs of the population it treats. As a result, local formularies provide some flexibility in the VA system by allowing physicians access to additional drugs.[11] Physicians may also prescribe drugs not listed on the national, VISN or medical center formularies if granted a nonformulary drug waiver.[12] New drugs may be added to VISN and medical center formularies immediately upon FDA approval. In contrast, such drugs may not be added to the national formulary until they have been on the U.S. market for at least one year, unless the FDA designates the product as a unique therapeutic entity. The VA believes this delay helps protect veterans from potential side effects not identified during the FDA drug review and approval process. They note that clinical trials are conducted with relatively small numbers of people and in environments that may not accurately reflect the drug usage and side-effect rates found in the VA population. This

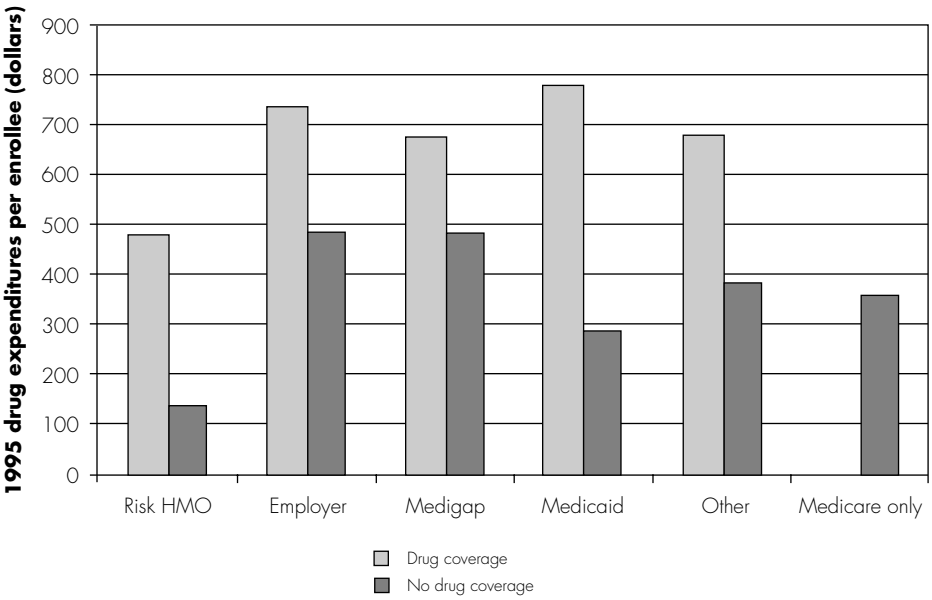
10 There are 22 VISNs, all of which have individual formularies. Only some medical centers have formularies.

11 Officials in charge of VISN and medical center formularies may not delete drugs listed on the national formulary or add drugs to classes for which there are national committed-use contracts, agreements which require the VA to primarily use specific products in a therapeutic category in exchange for reduced prices.

12 In a report to the Congress in February 1999, the VA stated that VISNs received an average of 109 requests to use nonformulary drugs each month in 1998. Eighty-eight percent of these requests were approved. Nationally, nonformulary drugs account for approximately 3 percent of all VA prescriptions (GAO 1999).

FIGURE 1-5

Drug coverage and drug expeditures per beneficiary, 1995



Note: HMO (health maintenance organization). About 3 million enrollees are excluded from this chart because they switched their source of coverage during 1995. Excludes institutionalized beneficiaries.

Source: Adapted from Davis et al. 1999.

treatment of new drugs creates discrepancies across VA's health care system, allowing veterans treated in some facilities to benefit from new drugs before veterans treated at others. It can also be argued that veterans receiving new drugs sooner may be exposed to side effects that could be identified within the first year of general use.[13]

Coverage and beneficiary access to prescription drugs

The type, or lack, of supplemental drug coverage appears to have a large effect on beneficiaries' prescription drug spending. Figure 1-5 shows average prescription drug spending by beneficiaries with different types of supplemental coverage, including whether that coverage includes a prescription drug benefit. Beneficiaries with employer-sponsored insurance or Medicaid have the highest total drug expenditures. These coverage sources tend to offer the most comprehensive benefits. Whether beneficiaries have any coverage at all seems to be more related to total expenditures than is the type of coverage: Those beneficiaries without supplemental drug coverage spent considerably less than those with coverage did in 1995.

The difference in drug expenditures between beneficiaries with and without drug coverage is also illustrated by a study of 1996 data that found beneficiaries with coverage purchased an average of $769 of prescription drugs and filled 21.1 prescriptions annually, compared with $463 and 16.0 prescriptions for those without coverage (Poisal and Chulis 2000).[14] However, beneficiaries who seek coverage are more likely to have significant drug costs. Also, the presence of coverage may induce beneficiaries to seek more prescriptions for drugs to help their conditions because they do not bear the full costs.

As a result of the costs borne by insurance, beneficiaries with drug coverage tend to spend considerably less out of pocket than do those without coverage. In 1996, those with coverage spent an average of $253 out of pocket, compared with $463 spent by those without drug coverage. On a per-prescription basis, covered beneficiaries paid $12 and non-covered enrollees paid $29 (Poisal and Chulis 2000).

Two studies illustrate the direct relationship between coverage and drug use. When the New Hampshire Medicaid program limited coverage to three prescriptions per month, chronically ill elderly and disabled enrollees significantly reduced the use of such medications as insulin, lithium, cardiovascular agents, and bronchodilators (Soumerai 1999). A more recent study found that those with drug coverage were more likely to purchase needed hypertensive medications (Blustein 2000).

Even nominal cost sharing appears to significantly reduce treatment compliance for low-income groups. One study of elderly and disabled Medicaid participants found that beneficiaries with even nominal copayments ($3 or less per fill) had significantly lower levels of drug utilization, compared with similar beneficiaries with no copayments (Stuart and Zacker 1999).

Substitution between drugs and other health care services

The lack of prescription drug coverage can lead to reduced compliance with drug treatment regimens, which may in turn lead to a greater need for other medical

13 The Institute of Medicine is currently evaluating the restrictiveness of the VA's formulary system, its impact on cost and quality, and how it compares with other formularies in the private and public sector. The report is to be released in June 2000.

14 The "number of prescriptions" figure per person should be used with caution and may be misleading because the total amount of the drug per prescription varies, particularly by whether it was received from a pharmacy or through mail order.

care covered by Medicare. This relationship is of particular budgetary concern because an increased need for other health care services will increase costs. One study found that 11 percent of Medicare hospital admissions were the result of non-compliance with drug regimens, with a lack of insurance coverage cited as one of the contributing factors (Col et al. 1990).

The ability of drug treatments to substitute for other types of health care services and the potential of expanded drug coverage to produce overall health care savings has drawn interest from policymakers. However, empirical evidence has not shown a consistent quantitative expression of this relationship. In some situations, new drugs have been found to reduce an individual's total health care costs—for example, anti-hypertensive drugs prevent strokes and the need for attendant health care services. In other cases, the new drugs have increased costs as people begin to treat conditions that previously went untreated (or were treated by less expensive and sometimes less effective drugs), such as arthritis. Lastly, because drugs may extend lifespans, overall health care spending may increase. To the extent that the increase in costs resulted in improved treatment outcomes and quality of life, many would argue that a drug's therapeutic value was worth the additional cost. The relative cost savings or cost effectiveness of expanding Medicare coverage is further complicated because as beneficiaries take more drugs, the chances of adverse drug reactions increase. These reactions can lead to costly hospital stays and other medical services.

Existing research studies on cost effectiveness and savings also make it difficult to generalize about the relationship between improved coverage and total health care costs, but it is safe to say that adding a prescription drug benefit to Medicare would increase total Medicare spending. Congressional Budget Office (CBO) analysts have expressed their reluctance to attribute savings based on studies of the Medicaid population (Christensen and Wagner 2000). Another group of analysts notes that evaluating cost effectiveness depends on what the analysis deems the relevant comparative treatment (or baseline treatment), and there may not always be consensus on the appropriate comparison (Neumann et al. 2000). Both teams concluded that a Medicare drug benefit would increase Medicare's overall costs.

Adding prescription drugs as an integrated Medicare benefit

Improving prescription drug coverage for the elderly and disabled could be addressed by adding a drug benefit to fee-for-service Medicare and requiring all M+C plans to provide the benefit. Advocates of this approach note that prescription drugs have become an essential component of the acute-care arsenal to combat disease and improve quality of life, and as such are an appropriate addition to the Medicare benefit package.

In considering the specifics of a Medicare prescription drug benefit, policymakers need to weigh various possible objectives, including targeting beneficiaries most in need of assistance versus helping all beneficiaries without adequate coverage, maximizing efficiency, safeguarding investments in research and development, minimizing government regulation, and achieving fundamental program reform, among others. This chapter does not evaluate the possible objectives that motivate policy choices, nor does it address questions about who should finance the benefit or how to avoid displacement of current resources. Instead, it identifies key design questions that define the terms and scope of coverage and the ability to control costs for beneficiaries and the Medicare program.

Policy decisions for an integrated Medicare benefit policy include:

- whether the drug benefit would be voluntary or mandatory for beneficiaries,
- whether to provide federal subsidies,
- how the benefit will be designed or specified,
- how the benefit would be managed,
- which drugs will be covered and how appeals would be handled,
- which entity or entities should administer the benefit, and
- how Medicare payment would be determined.

Voluntary or mandatory benefit

Under a voluntary benefit, beneficiaries could decide whether they wanted to enroll in the prescription drug portion of the expanded Medicare benefit. A voluntary benefit avoids requiring beneficiaries to receive and (depending upon the premium structure) pay for a benefit they do not want or already receive from another source. However, a voluntary benefit invites concern about adverse selection, a situation in which only those beneficiaries who believe they will experience high costs tend to opt for the coverage. This phenomenon would raise the average premium for all enrollees. Ways to minimize adverse selection—including subsidies, benefit design features, and enrollment restrictions—are discussed throughout this chapter.

A mandatory benefit requires that all people receiving all or certain Medicare benefits must also receive and (depending on premium requirements) pay a portion of the premium for the benefit. A mandatory benefit eliminates concerns about adverse selection because the cost of the benefit will be spread across high- and low-use beneficiaries. However,

because some beneficiaries may not want to purchase this coverage—particularly if it is not as comprehensive, or as good a value, as their current coverage—this approach may be controversial.

Subsidies

Policymakers may consider subsidizing a portion of the premium for prescription drug benefits. Subsidies could be tailored to certain low-income beneficiaries or extended to all beneficiaries. In addition, the subsidies could be considered taxable income for higher-income beneficiaries. Subsidies serve two functions. First, they relieve some of the burden of the cost of prescription drug coverage, which may result in more coverage and possibly better health care. Second, sufficiently generous subsidies encourage more beneficiaries to enroll in a voluntary prescription drug benefit product, which addresses the problem of adverse selection. If the benefit were voluntary, it is unlikely that crippling adverse selection effects could be avoided without substantial subsidies. However, in addition to federal budget concerns, providing federal subsidies for a drug benefit would raise concerns about the effects on employer-sponsored retiree drug coverage. Subsidies would almost certainly affect employer policies and actions, and would replace private-sector resources currently spent on prescription drug coverage for Medicare beneficiaries. Employers may drop coverage altogether, and either reduce retirement compensation packages or make up for the lost benefits by increasing pensions. To the extent that the new Medicare coverage is less comprehensive than previous employer-sponsored coverage, some beneficiaries will have reduced coverage under this scenario. Employers could also change the design of their health coverage to "wrap around" the new Medicare benefit, which may include paying the premium for the Medicare coverage as well as providing additional coverage. Finally, given incentives, employers could reduce prescription drug coverage but expand other benefits.

Benefit design

Plan sponsors—entities offering a drug benefit—have at their disposals many techniques for influencing the behavior of beneficiaries, physicians, and pharmacists. When deciding how to structure a drug benefit, plan sponsors must carefully define the goals of the plan. For example, is the goal to target certain beneficiary segments (such as high users), or is the goal to provide a broad-based benefit to all?

Once goals have been established, the most efficient techniques to meet those goals need to be considered. Plan sponsors must ensure that the drug benefit features do not conflict with their goals or with other plan features. For example, cost-sharing differentials that are too small to effectively steer beneficiaries to the desired drugs may not be worth the administrative costs of setting up a complicated, multi-tier copayment system. Similarly, a benefit that appeals only to a subset of beneficiaries may undermine the plan's ability to spread insurance risk or provide meaningful insurance coverage. Some cost-sharing features, such as deductibles, out-of-pocket maximums, and benefit limits, can be triggered when a fixed amount of spending has been exceeded. Others, such as copayments and coinsurance, can be triggered each time a service is delivered.

Deductibles, out-of-pocket maximums, and benefit limits

A deductible is the amount of money that beneficiaries must spend in a year before the plan begins to pay for expenses. An out-of-pocket maximum caps beneficiaries' annual cost sharing at a certain amount, after which the plan pays all expenses for the remainder of the plan year. An annual benefit limit is the amount above which beneficiaries must pay the full amount for additional services. A plan might include both an out-of-pocket maximum and a benefit limit. In this case, beneficiaries would have no further cost-sharing obligations after the out-of-pocket maximum (for example, $1,500) was met, but still would be responsible for all expenses above the benefit limit (for example, $1 million lifetime).

Many employer-sponsored plans include overall deductibles of $250 or more. Less common are deductibles specific to the drug benefit, typically $25 or $50 per year. To steer beneficiaries to cost-effective providers and drugs, drug-specific deductibles can apply only to non-network pharmacies or non-formulary claims. In contrast, out-of-pocket maximums and benefit limits are typically imposed not to encourage particular behaviors, but to limit the exposure of the beneficiary or the insurer.

A deductible can also finance other plan provisions. Annual prescription drug expenditures are typically distributed with many low users at one end of the scale and few high users at the other. With such a distribution of spending, in which nearly everyone has some drug expenditures, a plan could lower its drug costs considerably by imposing a deductible. If nearly everyone met the deductible, the plan could lower the premium cost by almost as much as the deductible amount, or use the savings to raise the benefit maximum or lower the out-of-pocket maximum.

There are administrative costs, however, to including a deductible in the benefit design. Plans would have to track where beneficiaries stood relative to the deductible. Each plan would have to communicate clearly to beneficiaries about which expenditures count toward fulfilling the deductible. For example, beneficiaries might believe that all drug expenditures count, but the plan might measure expenditures as the amount it would have paid for approved products. If the plan included a deductible, the beneficiary might not think to get approval or discover the amount that the plan would allow for a particular purchase.

If enrollment in the drug benefit is voluntary, then the plan sponsor faces other considerations in structuring the

benefit. If the benefit encourages sicker beneficiaries to enroll, then risk will not be evenly spread and the cost of the benefit will increase. A plan with a high deductible and an out-of-pocket maximum might increase the likelihood of attracting sicker enrollees. Beneficiaries who anticipate that they will meet the deductible and may need the out-of-pocket maximum are most likely to enroll. On the other hand, a benefit with a low deductible and no out-of-pocket maximum will be more appealing to healthier beneficiaries, whose inclusion in the purchasing pool will keep the average cost per beneficiary of the benefit lower. This is important if beneficiaries are paying all or part of the premium. To the extent that a low deductible is financed by higher copayments or coinsurance, beneficiaries who use many services will pay more.

Alternatively, a Medicare benefit could be designed to have only an out-of-pocket maximum and provide no coverage before reaching the maximum. This benefit would offer protection from high drug costs, but has several disadvantages. First, if enrollment is voluntary, it may be attractive only to beneficiaries who anticipate high drug costs, driving up the cost of the coverage to enrolling beneficiaries. Second, it may limit beneficiaries' incentives to control costs, especially as the out-of-pocket maximum amount is approached.[15] Third, this design requires that beneficiary spending be calculated under a standard methodology so that it would be clear when the out-of-pocket maximum is met, triggering coverage (Moran 2000).

Coinsurance and copayments

Copayments and coinsurance define the amount of each prescription paid by the beneficiary once the plan deductible has been satisfied. A copayment is a fixed dollar amount per prescription; a coinsurance is a fixed percentage of the cost per prescription (typically 20 percent).

These cost-sharing features influence beneficiary behavior. For example, copayments may vary depending on whether the drug is generic, brand on-formulary, or brand off-formulary. In specifying a lower copayment for preferred brand drugs and generics, patients are steered toward these preferred or less expensive alternatives. Currently, a common copayment structure is a "three-tier" system, under which the copayments might be $5 for a generic drug, $10 for an on-formulary or preferred name-brand drug, and $25 for other branded drugs.

A variation on the three-tiered approach would make cost-sharing dependent on the price of designated "reference" drugs—those drugs deemed most cost efficient in each class. Although more complicated to administer and not widely used in the private sector, this copayment arrangement is designed to encourage the use of those drugs deemed the most cost efficient; therefore, a beneficiary selecting a drug priced higher than the reference drug in a given class would pay the difference in price, in addition to the copayment.

Reference pricing would make drug manufacturers more likely to price their products competitively than would a three-tier copayment model. Under a three-tier copayment, manufacturers that believe their drugs will not be on the formulary have little incentive to price their products competitively, because beneficiaries pay a flat copayment for all off-formulary brand drugs regardless of price. In contrast, under a reference price approach, beneficiaries pay all of the additional cost above the reference drug price, which can be quite substantial. This difference in price sensitivity may induce manufacturers to bid more competitively, even for off-formulary drugs.

Perhaps the greatest challenge in implementing a reference-pricing approach is determining how to define clinically meaningful drug classes. If classes are narrowly defined, cost savings will be more difficult to achieve, because many drugs will be designated as reference drugs and the pool of other drugs in the classes will be small. The breadth of the classes also has important implications for the comparability of drugs within a class and for beneficiaries' access to prescribed drugs that will meet their clinical needs.

In employer-sponsored plans, copayments are far more common than coinsurance arrangements because they are simpler to administer and limit beneficiary liability in a predictable fashion. There are disadvantages of fixed copayment arrangements: beneficiaries are desensitized to rising drug costs, and the plan must absorb all price increases unless copayments are adjusted over time. Coinsurance arrangements, in contrast, preserve the cost-sharing balance between the plan sponsor and the beneficiary as costs increase. Some plans will impose "corridors" around the coinsurance rates to ensure that beneficiary payments are not less than a minimum amount or more than a maximum amount.

Benefit management

To control the use and cost of prescription drugs, plan sponsors have techniques, other than benefit parameters, that address provider and pharmacy behavior. Many of these tools have been developed and used by PBMs or other organizations that handle large volumes of claims and have relationships with pharmacy networks. Therefore, private third-party payers often contract with PBMs to manage their drug benefits. In addition to processing claims for prescription drugs, PBMs use many of the management tools, discussed in detail below, to reduce costs and improve quality of services and care. PBMs are not licensed to bear insurance risk. (Certain managed care plans have internal divisions that function like PBMs.) One reason that PBMs have not chosen to

15 Beneficiaries may drop their existing coverage, and insurers providing front-end coverage have a reduced incentive to manage costs because their liability will end once the out-of-pocket maximum is triggered. If the out-of-pocket maximum is high (for example, $1,000), beneficiaries with a significant copayment (or no other coverage) will minimize out-of-pocket expenses to some degree.

become insurers is that they have limited influence over the prescribing patterns of physicians, and are therefore restricted in their abilities to control costs. However, contracts between plan sponsors and PBMs may include payment incentives for improved service or other features within a PBM's control.[16]

For years, PBMs have negotiated discounts with pharmacies and rebates from pharmaceutical manufacturers. More recently, PBMs have taken more active roles in encouraging the substitution of lower-cost or more appropriate medications. This may involve communication with plan enrollees, phone calls to prescribing physicians, and dispensing through mail service vendors who supply maintenance medications for patients with chronic conditions.

Tools for benefit management

The next section discusses the tools used in the private sector and their potential applicability as part of an integrated Medicare drug benefit. Employer-sponsored plans most commonly encourage generic substitution through beneficiary cost sharing. Next in popularity are formularies (typically open) and concurrent drug utilization review. Less popular tools include retrospective drug utilization review, prior authorization, therapeutic substitution, disease management, and pharmacy incentives to dispense generic drugs.

Generic substitution Generic drugs contain the same active ingredients as their counterparts and are judged by the FDA to be bioequivalent. Generic drugs cost less than their brand-name counterparts and have played a significant role in constraining total prescription drug spending. The CBO estimates that by substituting generic drugs for brand-name drugs, purchasers saved $8 billion to $10 billion in 1994 (CBO 1998). In 1998, generic drugs accounted for 46.5 percent of all outpatient prescriptions dispensed—up from 18.4 percent in 1984 (Cook et al. 2000). As a percent of expenditures, however, generics comprised only 17 percent of the total prescription drug market (Watson Wyatt Worldwide 2000).

The most direct way to encourage use of generic drugs is to require higher beneficiary cost sharing for brand drugs. Typical employer-sponsored plans charge $5 for generics and $10 or higher for brand drugs. Some HMOs impose even stronger financial incentives for generic substitution by limiting payments for brand drugs to $500 while providing unlimited coverage for generics. A few M+C plans offer drug coverage for generics only.

Through their pharmacy networks, PBMs can also encourage pharmacies to dispense generics when available by paying a higher dispensing fee for generics. The dispensing fee is the amount that PBMs pay pharmacies, in addition to the amount that the PBMs believe the drugs cost the pharmacies to obtain. For example, assume a brand drug has a wholesale price of $20 from the manufacturer, and its generic equivalent has a wholesale price of $10. If a PBM would usually pay a dispensing fee of $2, the pharmacy would receive $22 for the brand prescription, and $12 for the generic prescription. If the PBM wanted to encourage the pharmacy to switch the brand prescription to generic, it could pay the pharmacy a dispensing fee of $4 for the generic. Reimbursements would then be $22 for the brand and $14 for the generic.

Formularies and rebates A formulary is a list of drugs promoted for therapeutic and cost reasons. Within a group of therapeutically equivalent drugs, a subset of the group might be placed on the formulary because it is priced favorably by the manufacturer. Negotiations between PBMs (or provider groups) and manufacturers are common for the placement of drugs on formularies. Because pharmaceutical companies rarely sell their products directly to the PBMs—sales usually go through wholesalers—rebates based on sales to the PBMs are often the mechanism the manufacturers use to lower the effective price paid by the PBMs.

Under a formulary, physicians are notified of the preferred drugs and encouraged to prescribe them. "Step therapy" is also often used, in which a less costly treatment is tried as a first step and the more expensive non-formulary drugs are available only after the less expensive alternative has been deemed inadequate. Formularies differ in their degree of rigor. Open formularies, the most common type, are structured such that doctors are merely encouraged to prescribe from the formulary. Managed formularies provide coverage for a broad range of drugs, but typically involve more intervention with physicians and higher copayments when a non-formulary prescription is filled. Closed formularies often require beneficiaries to pay the full cost of drugs not on the formulary.

Discount arrangements with pharmacies Almost all pharmacies accept discounted payment arrangements. The dispensing fee may also be negotiated. Under certain circumstances, "restricted" networks of preferred providers—sometimes "high-performance" pharmacies that are effective in promoting formulary compliance—accept deeper discounts than average in return for the promise of greater market share.

Therapeutic interchange Therapeutic interchange occurs when doctors permit one drug to be substituted for a different one (not generically equivalent) in the same therapeutic class. PBMs and beneficiaries may be motivated to contact the physician for permission to make the switch if the drug originally prescribed is not on the formulary. PBMs tend to target up to 15 therapeutic classes for such switching, usually those that account for a large proportion of drug expenditures (Cook et al. 2000).

16 PBMs have contracted mostly with employer-sponsored insurers. The top 20 PBMs currently manage an estimated 71 percent of the volume of prescription drugs dispensed through retail pharmacies covered by private third-party payers. The industry is relatively consolidated, with the top three PBMs—Merck-Medco Managed Care, PCS Health Systems, and Express Scripts—managing approximately 45 percent of all such prescriptions (Cook et al. 2000).

Drug utilization review Retrospective reviews are conducted to identify patients and/or prescribers with usage patterns outside an established standard. For example, patients may be taking a medication longer than recommended or taking too high or too low a dose. Drug utilization review is effective in identifying physicians whose prescribing patterns vary from the norm. One study suggests that a small percentage of physicians are responsible for 50 percent of the savings that can be realized from this type of review. (Cook et al. 2000).

Concurrent drug utilization review is used to identify potential adverse drug interactions. Insurers (or PBMs under contract) and pharmacies can both perform concurrent review, but insurers have the advantage of being able to review drug usage across pharmacies.

Mail service Mail service is particularly useful for dispensing drugs that treat chronic conditions, because often those drugs can be purchased in larger quantities and do not require special handling or a high degree of physician monitoring. Mail-order prescriptions are typically filled with a 90-day supply, compared with a 30-day supply in the retail environment. Mail-order prescriptions promote efficiency, higher rates of generic substitution, and therapeutic interchanges. Mail service copayments are lower to encourage the use of this service. However, the service will not save money for the plan sponsor if the patient does not use the full prescription or if the copayment is too low.

Prior authorization Prior authorization requires patients to obtain special permission from the plan when seeking coverage for certain types of prescription drugs, typically those with high costs or potential for misuse. Drugs in this category include fertility drugs, growth hormones, cosmetic drugs, and appetite suppressants. Clear clinical criteria for coverage must be established for this technique to be effective.

Disease management Disease management programs are designed to identify patients with specific medical conditions, in order to manage their use of drugs and related health care. Common disease management programs target diabetes, asthma, and hypertension. Interventions range from mailing educational materials to monitoring compliance with the therapeutic regimen. In some cases, these programs may include individual patient and case management. Disease management programs under PBMs usually focus on providing information about a specific disease and following up to ensure that the patient complies with the drug regimen. PBM programs are limited in that they are not usually integrated with the rest of the patient's care (Cook et al. 2000).

Applicability to Medicare

Policymakers need to decide whether tools acceptable in private-sector plans and in current M+C plans that offer drug coverage would be acceptable as part of the Medicare fee-for-service (FFS) benefit.[17] Medicare beneficiaries in the FFS program are accustomed to wide choice in the marketplace; they can see virtually any doctor and go to any hospital, and are subject to minimal utilization review. Limiting beneficiaries' choices or requiring them to pay higher cost sharing depending on their drug choice raises issues not previously considered in the context of Medicare's FFS benefit.

The implications of using formularies illustrate the potential conflict between PBM-style management techniques and Medicare's traditional approach. Formularies are frequently central to plan sponsors' abilities to negotiate discounts and offer lower-cost drug coverage. However, if a formulary is used in which beneficiaries have no or restricted coverage for a particular drug, some may forgo needed medication or use a less desirable substitute. For current Medicare benefits, Congress has been reluctant to restrict beneficiary access to most providers. However, Medicare physicians may bill beneficiaries above the Medicare amount by a set percentage. Thus, although a closed formulary would appear to run counter to current Medicare payment policies, an open formulary or a multi-tiered approach appears to be consistent with other Medicare payment policies.

The process for exceptions to formulary restrictions or higher copayment requirements under a three-tier or reference drug approach raises another issue. Most plan sponsors allow beneficiaries to appeal plan administrators' decisions. Following this model, it would be necessary for beneficiaries to be able to appeal, and at the highest level of appeal, to Medicare directly.

Policymakers also need to decide whether it is appropriate for the federal government to pay PBMs to encourage physicians to switch prescriptions. The practice of therapeutic interchange is more risky for elderly people, because they do not tolerate medication variation as well as younger people do.

Similarly, policymakers would need to consider whether limitations on pharmacy networks are appropriate. To the extent that insurers or PBMs negotiate lower prices with pharmacies by restricting the number of participating pharmacies, beneficiary access to drugs may be viewed as inadequate. Requirements governing the geographic distance between beneficiaries and network pharmacies are an option. Similar requirements now apply to M+C plan provider networks. Policymakers will also need to consider how Medicare policy should relate to state "any-willing-provider" laws. Twenty-one states have such laws for pharmacies (Laudicina 2000).

17 Although beneficiaries in M+C plans are frequently subject to utilization management and tailored restrictions on non-Medicare benefits, they have the option to remain in fee-for-service, which imposes few benefit management restrictions.

Implications for improved quality of care for beneficiaries

Drug utilization review and disease management offer the potential for improved quality of care, particularly in their abilities to reduce medication errors. The incidence of prescribing errors is high for the general population, but Medicare beneficiaries are particularly at risk, given the number of prescriptions they take simultaneously, their greater frequency of coexisting illness, and their diminished physiological function. One study found that 23.5 percent of people aged 65 years or older received at least one contraindicated drug in 1987, and 20.4 percent received two or more such drugs (Wilcox et al. 1994).

If drug benefit management tools prevent adverse drug interactions, the quality of care for beneficiaries would improve. Drug benefit management tools include increased automation—providing fewer opportunities for human error, such as transcription problems—and prompts to ensure that the prescribing doctor and pharmacist have prescribed an appropriate dosage and considered potential side-effects, interactions, and confusion with look-alike or sound-alike drugs.[18] Some pharmacies have these systems in place now; some do not.

Types of drugs covered

Policymakers will also need to determine which drugs Medicare should cover and what entity should make such decisions. Several options exist. First, all FDA-approved drugs could be covered, which would include drugs ranging from so-called lifestyle drugs, such as Rogaine for hair replacement and Claritin for non-drowsy allergy relief, to every drug in all therapeutic classes, regardless of relative therapeutic value, time on the market, or cost. This standard would preclude coverage for experimental drugs.

Another consideration is whether coverage for FDA-approved drugs would be limited to on-label use (uses specified by the FDA). Once a drug is on the market, it can be prescribed for other non-FDA approved uses. Presumably, monitoring coverage for unapproved uses would be difficult. Current Medicare coverage of outpatient oral anticancer drugs includes all FDA-approved uses, as well as uses listed in certain prescription drug compendia.

Policymakers can cover prescription drugs only for some treatments, which could help contain costs. Alternatively, policymakers could choose to exclude certain classes of drugs. As mentioned earlier, Medicaid excludes coverage for certain lifestyle drugs: drugs for weight loss, hair restoration, and fertility, among others. Determining these exceptions can be difficult, as the distinction between what is medical treatment and what simply improves quality of life is not always clear. (For example, coverage policies for Viagra have attracted a great deal of policy debate.)

The VA has adopted another approach in limiting coverage: its national formulary excludes coverage for drugs in the first year after their approval by the FDA. This exclusion is intended to ensure greater safety of covered drugs, as some drugs are taken off the market after experience reveals unforeseen complications.

Cost-effectiveness analysis could serve as a basis to limit coverage. Some foreign countries have begun to use cost effectiveness as a coverage criterion. A framework for such analysis, as well as analyses focusing on quality-of-life improvements and the clinical needs of beneficiaries, would need to be developed and would likely be a difficult undertaking for each drug.

There are other possibilities. A wide range of drugs could be covered, but benefit administrators would be permitted to impose cost sharing and other benefit restrictions. For example, non-formulary drugs are often assigned a higher copayment. Alternatively, drugs could be covered, but in limited amounts. For example, some employer-sponsored plans cover a limited number of Viagra pills per month. Finally, prior authorization and compliance with clinical guidelines could be required to obtain the drug. Growth hormones are often handled in this fashion in the private sector. Depending on the degree of discretion afforded to plan administrators, however, this approach could present opportunities for abuse: for example, a plan could offer full coverage for Viagra but impose high copayments for drugs treating diabetes, in the hope of attracting a healthier subgroup of enrollees.

The decision-making process for a publicly funded program will likely differ from that for private-sector plans. Currently, M+C plans make these decisions individually, because drugs are not a covered benefit. In the Federal Employees Health Benefits program, individual plans determine which drugs they will cover (there are a few specific minimum requirements). In the Medicare FFS environment, however, variation may be less acceptable, as evidenced by the continuing controversy over variation among fiscal intermediaries' and carriers' coverage decisions regarding other Medicare services.

Uniformity could be achieved by a standard—such as all FDA-approved drugs—or the standard could allow for exceptions, similar to those in Medicaid. However, such criteria may be too inclusive, given the need to contain costs. To narrow coverage to a smaller subset, another public process—through a federal board or agency—may be necessary. Similarly, if the benefit design links coinsurance amounts to a reference drug in a given class, a public body would need to make class determinations.

18 According to the FDA, roughly half of the 6,000 medication errors reported to the agency between 1992 and 1997 were due to labeling and packaging issues. Of that half, some 27 percent were caused by generic or trade-name confusion. For example, FDA has received numerous reports of dispensing errors involving Celebrex, Cerbyx, and Celexa, three sound-alike drugs that treat very different conditions (National Coalition on Health Care and The Institute for Healthcare Improvement

Benefit administrator and pricing issues

Policymakers must decide how a new drug benefit should be administered, who should bear the insurance risk, and how the prices for drugs would be determined. There is a continuum of approaches on these issues that ranges from a centralized, regulatory approach to a decentralized approach that delegates authority to multiple private-sector entities. The list of approaches that follows is illustrative, rather than exhaustive.

- *HCFA administers the benefit*. Under this model, HCFA would bear the insurance risk and might set a fee schedule, as it does currently with physicians. Alternatively, HCFA could adopt approaches similar to those used by Medicaid or other public purchasers, including the VA.
- *Federal agency contracts with PBMs* to administer a defined drug benefit to FFS beneficiaries. The PBMs would be responsible for negotiating prices with drug manufacturers, managing the benefit, contracting with pharmacies, and processing claims for beneficiaries. Because HCFA would pay the PBMs on primarily a FFS basis, HCFA would bear the risk of the cost of the benefit.
- *Beneficiaries contract with drugs-only insurance plans*. These plans would offer a defined drug benefit. This proposal would allow beneficiaries to receive drug coverage from other currently available sources as well. The insurance plans would bear the risk.[19]
- *Federal agency contracts with private insurance plans* to offer a comprehensive array of Medicare benefits, including prescription drugs, as proposed under a premium support model. Although this approach is similar to Medicare +Choice, beneficiaries would likely have an increased financial incentive to join these plans. Beneficiaries who choose to remain in the traditional FFS program could also purchase a prescription drug benefit. The drug benefit available to all beneficiaries would be equivalent to a certain actuarial value. Insurance plans would bear the risk associated with their enrollees; the government would bear the risk for beneficiaries in the FFS benefit.

Medicaid, the Department of Veterans Affairs, and other federally funded programs

Definitions of terms

The following terms are important in determining the price paid for prescription drugs in both the Medicaid and Veterans Affairs programs.

Average manufacturer's price (AMP)—The average price paid to manufacturers for products distributed to the retail class of trade.

Average wholesale price—The suggested wholesale price of a drug published in various national compendia. It is often used by pharmacies as a cost basis for pricing prescriptions.

Federal supply schedule (FSS)—The FSS for pharmaceuticals is a price catalog containing about 23,000 pharmaceutical products available to federal agencies and institutions and several other purchasers, such as the District of Columbia, U.S. territorial governments, and many Native American tribal governments.

Reimbursement policies

Medicaid directly reimburses pharmacists for drugs purchased by Medicaid beneficiaries and collects rebates from manufacturers. Prices paid to pharmacies may be subject to upper limits established by HCFA, depending on the drug, plus a dispensing fee established by the state. Upper payment limits apply only to drugs that have at least two other generic competitors. The limit for these drugs is 150 percent of the published price for the least-costly therapeutic equivalent, plus a reasonable dispensing fee.

Total Medicaid rebates are based on the quantity of drugs purchased by Medicaid beneficiaries. The basic rebate on brand drugs is the greater of 15.1 percent of the AMP or the difference between the AMP and the lowest price the manufacturer charges any private purchaser in the United States. If a brand drug's price rises faster than the inflation rate, an additional rebate is imposed. For generic drugs, a rebate of 11 percent of each product's AMP is required.

The VA, the Department of Defense, the Public Health Service, and the Coast Guard pay the lesser of:

- The Federal Ceiling Price (FCP), a discount of at least 24 percent off the non-federal average manufacturers price, minus cash discounts, rebates, or similar reductions. The FCP applies to new drugs, including certain single-source and innovator multiple-source drugs, biologic products, and insulin.
- The price listed on the FSS. The prices must be equal to or lesser than the best price charged to the manufacturer's most favorable comparable customer. ■

19 Requiring that a drugs-only plan be offered to beneficiaries could also be pursued as part of Medigap restructuring, which is discussed later in the chapter. Depending on how this is structured, it may not be considered a Medicare benefit.

A more centralized approach would take advantage of Medicare's market power in purchasing drugs on behalf of beneficiaries. This approach may also be considered inevitable, if not initially desirable, to restrain costs if private-sector entities are not permitted the same flexibility they have in the private sector to manage a cost-effective benefit. This centralized approach is used in Medicaid, the VA, and other public programs.

In contrast, the intended advantages of delegating management to private entities or insurance plans are to achieve cost savings similar to that achieved in the private sector and retain a more pluralistic marketplace for prescription drugs, rather than creating a monolithic purchaser that could distort the marketplace.

Whether there is centralized or decentralized purchasing power has significant policy implications for the ability to negotiate prices, the impact on pharmaceutical research and development, adverse selection in the marketplace, achievement of private sector efficiencies, the willingness of plans to participate, and the flexibility of the benefits package. In making such a decision, policymakers will need to consider the following issues.

Achieving a balance between reduced prices for Medicare beneficiaries and adverse effects on pharmaceutical research and development

Ideally, policymakers should balance achieving fair prices for drugs for beneficiaries with retaining investment incentives for drug research and development. However, many controversial issues would need to be addressed. How much profit do manufacturers need to continue to invest in R&D? How should that be determined? Is it possible for government to judge and direct where manufacturers should spend money (for example, on marketing versus R&D)?

The impact on R&D could be adverse if prices were set such that manufacturers did not perceive sufficient returns on future investments. However, several factors may limit the threat to R&D for the foreseeable future. First, price reductions may be, at least in part, offset by a potentially higher volume of sales resulting from greater access of Medicare beneficiaries to prescription drugs.

Second, discounts for Medicare beneficiaries will likely encourage manufacturers to increase private-sector prices. This has been the previous experience with the Medicaid program. In 1991, when the best-price provision was enacted, nearly one-third of all brand drugs still under patent had a best-price discount as high as 50 percent. By 1994, when there was no longer a cap on the basic rebate, only 9 percent of brand-name drugs still under patent had a best-price discount in that range. A similar experience occurred when in 1991 and early 1992, the Federal Supply Schedule (FSS) was counted as best price, meaning that Medicaid had access to most FSS prices. As a result, FSS prices rose, the VA and other federal purchasers complained, and the Congress exempted FSS prices from the best-price provision in 1992 (Cook 1999).

Third, administered pricing often creates unintended incentives, allowing the regulated entity to "game the system." For example, because the additional rebate provision in the Medicaid program prevents manufacturers from raising prices to Medicaid faster than the rate of inflation after the drug is launched, manufacturers have an incentive to charge a somewhat higher launch price to offset the rebate. Similarly, to the extent that discounts are mandated as a percent of average wholesale price, manufacturers could increase their average wholesale prices, limiting the discount's effect.

Nevertheless, although administered pricing may create opportunities for gaming, it also could encourage inappropriate patterns of investment, which might irreversibly affect the market. For example, a pricing structure that is more relaxed for innovator drugs could divert resources from research on drugs in existing therapeutic classes to drugs in new classes. To the extent that this redirection led to the abandonment of needed research in existing classes, the policy would have failed. Further, if Medicare were perceived as a poor payer, R&D efforts might be redirected away from products that would be expected to be used mostly by the elderly.

If multiple purchasers were to negotiate with drug manufacturers on behalf of a subset of beneficiaries, there may be less pressure on R&D investments. However, to the extent that multiple purchasers lacked market power to negotiate reasonable discounts or were restricted from managing the benefit effectively, beneficiaries and taxpayers (depending on how the benefit was financed) would pay a higher price for this benefit.

Reducing adverse selection

Any proposal that requires beneficiaries to pay a portion of premiums and choose between insurers or PBMs for drug coverage creates a concern about adverse selection. To avoid adverse selection, there first must be enrollment rules that limit beneficiaries' abilities to opt for coverage only when high drug costs are expected. Otherwise, beneficiaries have no incentive to participate when they expect low costs, limiting the program's ability to spread risk across high and low users.

One way to help avoid adverse selection in a voluntary benefit is to subsidize the cost of the benefit. Subsidies can help attract a more even distribution of beneficiaries because they may make it cost effective for the vast majority of beneficiaries to participate, regardless of health status. The effect of the subsidy is illustrated in Medicare program experience. Part A is subsidized at 100 percent, requiring no beneficiary contribution. Part B is subsidized at 75 percent, and 97 percent of eligible elderly participate.

Second, policymakers could require that beneficiaries enroll within the first six months of Medicare eligibility (the current open enrollment period for Medigap purchase). After that time, beneficiaries could either be subject to

medical underwriting or not be permitted to enroll. Alternatively, beneficiaries could be allowed to enroll annually (or at some other longer interval). If more than a one-time enrollment period is permitted, policymakers may consider subjecting those beneficiaries to a premium surcharge (as is done for Part B enrollment) as an incentive for earlier enrollment. This design feature is particularly important because prescription drug expenditures are highly predictable for seniors with chronic medical conditions, many of whom are treated with costly maintenance medications.

Third, the enrollment process could be uniform for all plans. Uniformity can help reduce selection. Policies that help enforce this uniformity include guaranteed issue, guaranteed renewal, open-enrollment periods, waiting periods, "lock-in" rules, prohibition of medical underwriting, uniform basis of premium (community or age rating), and report cards for consumers (Etheredge 1999). Not all of these policies would be necessary, but policymakers could choose a logical combination of them.

Fourth, the benefit package for plans could be similar. This enables consumers to select plans based on price and quality, rather than on benefits. If plans are allowed wide variation in benefits, some plans may be more likely to attract healthier (low-cost) beneficiaries. In fact, it is possible that no plan will design a benefit that offers needed coverage to less healthy beneficiaries. For example, if plans are given a choice, they may avoid offering catastrophic drug coverage and instead opt to provide a low-deductible, capped plan.

Fifth, a risk-adjustment system could be developed; plans that experience adverse selection would be paid at higher rates, and those experiencing positive selection would be paid at lower rates. Such a system would remove some incentives to design a benefit package that would attract better risks. Currently, Medicare+Choice plans are paid on a risk-adjusted basis.

Another way to avoid some of the market segmentation problems is to mandate enrollment. This approach was pursued in the Medicare Coverage Catastrophic Act of 1988 and led, in part, to its repeal. Consequently, this design feature tends to have little political appeal, and has not been widely suggested in current proposals.

Structuring administration contracts

Although HCFA administers the Medicare program, it is not a benefit administrator. HCFA contracts with claims administrators to process, adjudicate, and pay claims. If a drug benefit were added to Medicare, HCFA would have to either expand its current administrative contracts or develop new ones specific to drug issues. If HCFA were simply to expand current administrative contracts, the agency probably could not make much use of PBM cost containment and other management techniques. Also, because current contractors do not make pricing decisions, the use of current contractors would probably occur only under an administered-pricing system. Thus, the rest of this section will pose issues for consideration only under a PBM-like, drug-only administrative model.

Selection of contractors How should drug administrators be selected to contract with Medicare? Should they receive the sole contract in a region or compete with other regional drug administrators for beneficiaries in the region?

Selecting one administrator per region through a competitive contracting process mitigates the adverse selection that can occur when plans compete for beneficiaries. Renewing its contract, rather than competing for market share, provides an administrator with incentive to improve the quality of service. Further, a single administrator per area has an enhanced ability to negotiate discounts because it has a guaranteed market share. Presumably, the contracting criteria would value cost and service.

On the other hand, if more than one administrator were selected per region, competition would be present for both contract awards and market share, which might further improve the quality of service. Multiple administrators may also reduce barriers to market entry, as new administrators would not have to prove they could serve the whole market overnight or be at a competitive disadvantage due to transition confusion that beneficiaries might experience with wholesale change.

Having multiple administrators in a region could also reduce the need for federal regulation on formularies or other management tools related to beneficiary satisfaction, because beneficiaries could "vote with their feet" by selecting the administrator that best met their needs. Also, a single administrator might not have sufficient capacity to meet the needs of all the beneficiaries in a given geographic area.

However, allowing multiple administrators per region raises questions as to whether beneficiaries will value having a choice among administrators and whether competition among administrators would lead to adverse selection. Selection concerns may be minimal if administrators are paid on a fee-for-service basis, but if capitated payment is pursued, it may be necessary to consider ways to risk-adjust payments.

Length of contract Several PBM executives have expressed preferences for longer-term contracts, in part because they would encourage investment in better management techniques, such as promoting formulary compliance by educating doctors and beneficiaries (Cook et al. 2000). In addition, short-term contracts that lead to turnover in administrators might confuse beneficiaries, who would have to become familiar with new formulary rules. However, a short-term contract allows for a check on poor-performing administrators and for new entrants, which would likely promote competition.

Definition of the market area Most proposals suggest that administrators would compete on a regional basis, allowing for differences in local practice patterns and promoting more purchasers in the marketplace. In determining the size of local markets, the desire for more purchasers needs to be balanced with purchasers' abilities to achieve economies of scale and scope. If divided into too-small regions, administrators will find it difficult to negotiate effectively. Also, because there are important returns on scale in processing claims, administrators would have lower average costs in larger markets.

Payments for the administrators PBMs do not appear to be eager to become risk-bearing entities, largely because they have no direct control over physician prescribing practices. Nevertheless, pharmacy administrators can influence some costs and have negotiated performance guarantees in the private sector. They typically keep about 20 percent of the negotiated rebates and often have contractual incentives to meet certain service or generic substitution targets. For example, administrators that exceed performance targets for generic substitution or therapeutic substitution might receive a bonus payment; if they fail to meet such targets, they might face a financial penalty.

This model could be adopted and expanded by Medicare. Administrators could be placed at limited financial risk within a "corridor" around a claims target. For example, administrators might assume 50 percent of the risk for savings or losses within 10 percent of the target, making the total risk for a pharmacy administrator 5 percent of the target (Huskamp et al. 2000). Another approach would be to establish bonus payments for meeting performance standards, including enrollee satisfaction, speed in processing and paying claims, and access to pharmacies. To the extent that such arrangements were possible, administrators would add value and efficiency to the system and function less like claims processors.

Creating incentives to encourage private insurers to participate

The policy approach to encourage enrollment in privately offered drugs-only insurance plans faces the challenge of inducing plans to offer the product. Currently, no insurer offers a drugs-only plan to Medicare beneficiaries because of concerns about adverse selection and the difficulty of pricing this product.[20]

However, if the ground rules created an environment with sufficiently limited risk, insurers might be more inclined to participate. First, the potential for adverse selection would need to be minimized, either by establishing enrollment restrictions or by allowing underwriting if beneficiaries wanted to enroll outside of designated open enrollment periods.

Second, policies would need to address the difficulty insurers face in pricing a drugs-only product. The large volume of new and costly prescription drugs coming to the market, together with the demand generated by direct-to-consumer advertising, makes private insurers reluctant to bear the risk of future cost increases. To encourage participation, policies could provide plans with the flexibility to increase premiums and index their benefit characteristics—such as deductibles and copayments—to drug cost growth, to require a standardized benefit package, and to mandate a deductible high enough such that plans would insure for risk, rather than "dollar-trading." Plans might also be more likely to participate if they could withdraw their product from the market, which is often illegal under state guaranteed renewability laws.

To reduce plans' concerns about adverse selection and encourage their participation, some have also proposed creating a voluntary drug benefit with a federal subsidy for beneficiaries with high drug costs. The subsidy would be paid from a "high-risk pool" to plans that have higher-cost (the top 5 percent) beneficiaries (Health News Daily 2000). This approach would theoretically limit the financial hardship for plans that enrolled higher-cost beneficiaries but it raises serious practical questions. Would the pool be national or regional? People in some areas of the country tend to use more drugs than do people in other areas. How would beneficiaries' relative drug costs be measured and policed to ensure that all plans were counting costs similarly? Would plans that are more effective in managing costs be penalized because they are less likely to meet the threshold for accessing the high-risk pool? Who would police the program? Would plans be willing to share beneficiary cost information that would likely reveal negotiated discounts and rebates often considered proprietary?

Defining the benefit package

Any legislation will have to determine how much influence the federal government has on benefit design and management techniques. Standardizing the benefit package can reduce market segmentation and facilitate comparison of plans, but it would limit the ability of plans to innovate in their benefit designs and respond in ways that might ultimately benefit consumers, such as reducing premiums or minimizing increases. These trade-offs have been demonstrated in the Medigap market. Standardization required in OBRA-90 eased beneficiaries' abilities to compare plans but prohibited plans from experimenting with alternative benefit designs that might have limited premium increases (and been popular with beneficiaries).[21]

Deciding how specific to be in prescribing benefits may depend on whether the benefit is through the traditional FFS program or through contracting private

20 Medigap standardization does not preclude insurers from offering a drugs-only product; it only precludes insurers from marketing such a product as a Medicare supplemental plan.

21 OBRA-90 allowed for plans to implement "innovative benefits," but regulators have been reluctant to define or approve acceptable variation from the standardized plans.

plans, similar to the Federal Employees Health Benefits (FEHB) model or M+C model. In the traditional FFS program, available benefits are uniform across geographic areas (although not used uniformly) and beneficiaries have a great deal of choice among providers. Accordingly, a highly specified benefit would be consistent, but not necessary. There could be some flexibility around an established core set of benefits.

If the benefit were added in a reformed Medicare program—similar to premium support—or outside the FFS benefit, the policy questions would be somewhat different. It might not be necessary to detail the design of the benefit as specifically. Policymakers could allow more variation than under the traditional program by setting an actuarial value or range for the benefit.

Even with the more flexible approach based on actuarial value, policymakers may want to define some benefit guidelines. The guidelines or limits within the actuarial values could, for example, include an out-of-pocket maximum for drug expenses, limiting the ability of plans to target only the healthiest beneficiaries. If these restrictions are not specified in law, it could be expected that a Medicare board would negotiate with plans on these points, as currently occurs under the FEHB program model. However, it is unclear whether beneficiaries and policymakers would be comfortable delegating this level of authority to an appointed board.

Determining actuarial equivalence raises a variety of questions. How would the program ensure that the calculation of actuarial equivalence captures the selection effects of plans that impose higher copayments on services normally needed by the less healthy (or have a low deductible and no out-of-pocket maximum)? Would plans be required to submit cost reports to verify their expected costs? Should actuarial value take into consideration strict utilization management policies, or is that information provided separately to beneficiaries? How are plan profits calculated as part of actuarial equivalence?

Alternative policies to expand access to drug coverage

In addition to considering adding drug coverage as a Medicare benefit, policymakers are exploring other policy approaches. Some intend for their proposals to substitute for an enhanced Medicare benefit; others intend their proposals to serve as interim steps toward an enhanced benefit. Some proposals target assistance to low-income or high-cost beneficiaries by helping states provide coverage or subsidizing private coverage. Other proposals try to improve the private market structure such that more insurers and beneficiaries would be willing to participate in a private prescription drug insurance market.

The preferred policy levers will depend on many factors, including the desired target population, concern for government regulation, speed of implementation, and cost implications for beneficiaries, as well as other parties who might finance the policy. Naturally, each approach has its advantages and disadvantages, and trade-offs need to be considered. It is also possible that a few of the approaches below could be pursued concurrently or consecutively. Also, there are many proposals in the Congress that may not fit neatly into any of the following categories. Proposals may combine parts of several approaches. The following discussion is not intended to be an exhaustive identification of policy options, but an attempt to identify some of the key issues. Once the Congress sets priorities among its goals for prescription drug coverage for Medicare beneficiaries, the Commission will analyze proposals as measured against those policy goals.

Expanding Medicaid eligibility

Expanding Medicaid prescription drug coverage for Medicare beneficiaries would be one approach to help low-income beneficiaries. There are already predefined low-income Medicare groups that could serve as the target population, such as Qualified Medicare Beneficiaries (QMBs) and Specified Low Income Medicare Beneficiaries, and possibly Qualifying Individuals. If these groups were used, states could continue to use their current administrative structures. This approach could produce a system that could be implemented quickly; however, there would be a lack of flexibility in benefit design, and the price-setting issues surrounding the current Medicaid system would be perpetuated. While about a third of Medicare beneficiaries might be eligible to join one of the qualifying groups, many eligibles have not signed up for the programs. A 1996 study found that in that year, 63 percent of those eligible for the QMB program participated (Moon et al. 1996). Critics claim that lack of knowledge and the stigma associated with Medicaid programs have kept participation rates low. It could be argued that the addition of a valuable drug benefit to these programs might increase participation, but also increase costs.

The current Medicaid prescription drug benefit payment policies have been controversial. One of the primary cost-control policies is the rebate program, in which drug manufacturers provide mandatory rebates to the state Medicaid programs based on the sales of their drugs to Medicaid recipients. A key feature of this program is that the state programs are entitled to the best price that the manufacturer offers to any purchaser in the United States. This type of pricing structure has had large effects in the private markets (CBO 1996). If the Medicaid market were expanded, manufacturers would be even more reluctant to grant price discounts to any purchaser because they would have to

pass the discount along to the expanded Medicaid market. Therefore, supporters of private market flexibility are unlikely to want to use the highly inflexible Medicaid approach to expand prescription drug coverage among Medicare beneficiaries.

Federal grants to states (State Children's Insurance Program-like program)

Under this general approach, the federal government would make grants to states to expand drug coverage for Medicare population. Programs like the State Children's Insurance Program (SCHIP) might provide federal matching funds to states to contract directly with providers, or provide coverage through private health insurers that meets specific standards for benefits and cost sharing, through state Medicaid programs, or through a combination of arrangements. This approach would give states more flexibility to design their own programs than does Medicaid.

Although states would have more flexibility in designing benefit packages than under Medicaid, the federal government is still likely to require a minimum level of coverage in order to qualify for federal funds. Policymakers would therefore have to decide how to set standards for qualified benefits. Under SCHIP, for example, the standards for the minimum level of benefits are partially determined by factors within the state, including the state's Medicaid package, the benefit packages and actuarial values of some private plans commonly available in the state, and the package of a nationally available plan.[22] Also, the standards limit cost sharing for certain recipients.

It is also likely that the federal government would limit its financial liability by setting standards for beneficiary eligibility. In the absence of standards, or requirements for state matching funds, states might allow everyone to participate at the federal government's expense. The existing SCHIP program limits family income for participants and requires states to match some of the federal funds.

State drug assistance programs

Currently, 16 states have pharmaceutical assistance programs targeted to Medicare beneficiaries. Perhaps some of these programs could serve as models for state grant program options. The programs vary in terms of eligibility, coverage, cost controls, and program approach. A brief examination of programs in Pennsylvania, Minnesota, and Rhode Island reveals some of the variations in these programs.

In Pennsylvania the program has two tiers, the Pharmaceutical Assistance for the Elderly (PACE) program and the PACE Needs Enhancement Tier (PACENET). PACE and PACENET covered nearly 250,000 people ages 65 and older in 1999. They cover most prescriptions for persons with low incomes, as well as insulin and syringes. The program uses a prospective drug utilization review system to identify drug interactions, duplicative therapies, underutilization and overutilization (PACE 1999). Cost sharing for PACE enrollees consists of a flat copayment for each prescription. Enrollees in PACENET may have higher incomes than those in PACE. PACENET coverage has an annual deductible and a two-tiered copayment slightly higher than the PACE copayment.

Minnesota's Senior Drug Program has a single tier. It covered about 5,000 people ages 65 and older in 1999. Eligibility is based on income and assets. Coverage includes almost all drugs on the Medicaid formulary, as well as insulin and syringes. Drugs are not covered if the manufacturer does not participate in a rebate program. Cost sharing consists of a monthly deductible.

Rhode Island also has a single-tier program, which covered nearly 30,000 people ages 65 and older in 1999. Eligibility is based on income. The program covers drugs by medical condition (for example, asthma, diabetes, heart disease, and others). Participants pay coinsurance of 40 percent of the price of the prescription.

Other states' programs include some persons with disabilities and may also use income-based sliding scales to determine cost-sharing amounts or enrollment fees or benefit caps. These 16 states are acting as laboratories for many different drug assistance program designs.

Because most states would have to establish new programs, this approach would take longer to implement than would a Medicaid expansion. Although SCHIP was established in the Balanced Budget Act of 1997, 10 states had not spent any funds as of January 1, 2000. This slow start-up would be especially problematic if this approach were used as an interim step.

Tax credits, deductions, and vouchers

Under this approach, the tax code would be used to subsidize insurance coverage for prescription drugs or to subsidize prescription drugs themselves. Proponents argue that a tax credit system could be implemented quickly, would limit government budget liability to a set amount per beneficiary, and would make use of the private insurance market. The specific policy could be structured so that lower-income beneficiaries receive a greater share, or even all, of the subsidies.

Although this general approach may be simple in concept, there are many design issues to consider. Tax credits, in their most basic structure, are sums of money that taxpayers can use to reduce their tax bills. Because they work through the tax code, they can be targeted to lower-income groups. However, there are complications when targeting tax credits to low-income people. For example, if a taxpayer has less tax liability than the amount of the credit, some of the value of the credit is lost unless the credit is refundable, meaning that the taxpayer

22 The benefit standards are complex in that there are many variations that depend on how the state provides the coverage, what the plans in the state's private sector cover, and what the state's Medicaid package covers. For a more detailed discussion, see Herz and Baumrucker 2000.

could receive a cash payment from the government. If tax credits are used to help poorer taxpayers, then it would be important to design the credit as refundable. Many poorer individuals may not even file tax returns; for example, the Treasury Department estimates that in 1995, only about one-third of elderly potential tax-filers with income between $15,000 and $20,000 filed a return (Office of Tax Analysis 2000). Thus, many of the poor would miss out on the credits unless there were a mechanism to educate and help these people file returns. Finally, it is questionable whether the poor would have sufficient cash available to purchase the insurance or drugs they need and then wait for the tax refund to come.

Many of these difficulties could be addressed if vouchers for insurance coverage were issued in advance, based on income from a prior year. This approach would introduce a new set of issues. Who would administer the program? Would there be provisions to provide vouchers for beneficiaries whose income drops from the previous year?

Alternatively, a tax deduction approach could be targeted to those in need as a result of high expenditures. Currently, health expenditures can be deducted from taxable income if total health spending exceeds 7.5 percent of total income. This percentage threshold could be lowered for Medicare beneficiaries or it could be redefined as a dollar amount instead of a percentage of income.

Medigap market reform

Under this approach, an attempt would be made to restructure the private Medigap market in hopes of improving the availability of prescription drug coverage. It is widely acknowledged that Medigap plans, as currently structured, do not meet many of the needs of beneficiaries wishing to purchase prescription drug coverage. The design of plan options provides only limited protection and promotes self-selection, resulting in prohibitively high premiums for many. Although this approach is most likely to help those who can afford to seek private drug coverage, it could be combined with one of the subsidy approaches to target low-income beneficiaries.

As discussed earlier in this chapter, there are 10 standard Medigap packages, only 3 of which have any prescription drug coverage. Those three plans are also expensive because they experience unfavorable selection. Only 7.4 percent of beneficiaries enrolled in a standard Medigap plan were in the plans that offer some drug coverage (plans H, I, and J).

Numerous reasons have been cited for the high cost of plans covering prescription drugs. First, there is evidence of adverse selection. Also, individuals with drug coverage may be more likely to purchase drugs than if they did not have coverage. However, the high coinsurance and deductibles of the Medigap plans should mitigate this factor. Finally, insurers who offer prescription drug coverage are limited in their ability to manage drug costs through variable copayments and are limited by state "any-willing-pharmacy" laws. The plans also do not have much incentive to manage the benefit, given consumer incentives of high cost-sharing requirements for beneficiaries and the plans' limited liability due to benefit caps. Therefore, carriers and beneficiaries do not generally benefit from the discounts commonly obtained by managed care plans and pharmaceutical benefit managers.[23]

Perhaps the biggest obstacle to this approach is avoiding adverse selection and thus attracting insurer participation. This might be handled by giving each package the same drug benefit as part of the core package. Selection across plans would then not be affected by beneficiaries' knowledge of their expected prescription drug use. Because prescription drug coverage is expensive relative to the other benefits covered by Medigap plans, the price of Medigap policies would rise substantially under this approach. To keep packages affordable while covering prescription drugs, other benefits would have to be adjusted. Some critics of the current Medigap packages believe this would be a good opportunity to trade some first-dollar coverage for better catastrophic and drug coverage. The NAIC is exploring this approach.

If standard packages were configured to include an improved drug benefit, policymakers would have to decide whether to "grandfather" current plans. When standard plans were introduced in 1992, previous insurers were allowed to continue the policies they had in effect for the beneficiaries currently enrolled. More than one-third of beneficiaries with Medigap coverage are still in their pre-standardized plans. If grandfathering were allowed, the proposed standard plans, all with drug coverage, would probably experience adverse selection for a few years, but it might be unpopular to force beneficiaries out of the plans they have into new plans that could be more expensive.

The nature of the Medigap market also produces other potential concerns for using this approach. Medigap coverage is marketed and sold to individuals, rather than groups, and therefore higher administrative costs are involved (Fox et al. 1995). Also, Medigap plans tend to manage the prescription drug benefit differently than do PBMs. Given the coinsurance and benefit caps in the Medigap plans, the plans do not have much liability for high drug costs. Thus, management tends to be minimal and the hefty 50 percent coinsurance rate is relied on to control consumer incentives.

Finally, there may be concerns about insurer participation. The Health Insurance Association of America has formally opposed the use of this approach, although some of its members are in favor. One concern is that relatively few

23 In addition, the standardization of the Medigap plans prevents the industry from allowing other forms of prescription drug coverage, or other combinations of supplemental coverage, that might be more attractive to consumers, or less susceptible to adverse selection.

TABLE 1-5

Selected characteristics of approaches to expanding prescription drug coverage for Medicare beneficiaries

	Existing infrastructure	Target population	Administration
Medicare	Current contractors, might need to contract with pharmacy specialists	All beneficiaries (could be voluntary)	HCFA or contractors (could be PBMs)
Medicaid	Current eligibility and pharmacy benefit structures	Low-income	States
State grants	Most states would need new program structures	Probably low-income	States, contractors or private insurers
Tax subsidies	Current tax system	Current or potential purchasers—difficult to target low-income beneficiaries	IRS and private insurers
Medigap market	Current structure may require modifications	Current or potential purchasers—subsidies needed to target low-income beneficiaries	Private insurers

Note: PBMs (pharmacy benefit managers), IRS (Internal Revenue Service).

current insurers offer Medigap plans with drug coverage. Our analysis of Medigap data found that United Health Group, under the AARP name, writes about 20 percent of the total Medigap policies, but writes about 35 percent of the policies with prescription drug coverage. Covering prescription drugs is more challenging than covering other benefits for Medigap plans, because with other benefits, insurers simply write checks to cover coinsurance for services for which Medicare has already verified eligibility and coverage. Because Medicare does not cover prescription drugs, the Medigap plan would have to determine beneficiary eligibility and coverage. Thus, many Medigap insurers would not be prepared to offer policies that included prescription drug coverage. However, they probably could quickly contract with a PBM to administer the prescription drug coverage for them.

Table 1-5 briefly summarizes some of the characteristics of the potential approaches discussed. ■

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