

Public Policy Monograph

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Medicare Reform:
Providing Prescription
Drug Coverage For
Medicare Beneficiaries



AMERICAN ACADEMY *of* ACTUARIES

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Medicare Beneficiaries

Executive Summary

One of the key issues being debated by Congress and in the presidential election campaign is whether and how prescription drug coverage could be provided to older Americans. This monograph discusses only one of the options available to provide prescription drug coverage to seniors – adding prescription drug coverage to Medicare. Many other options are available.

Currently, seniors may receive prescription drug benefits from a variety of sources – Medicare+Choice health plans, Medicaid, employer health plans, Medicare Supplement insurance policies, or other government sponsored health coverage. The integration of a Medicare prescription drug program with all other sources of health insurance in the current market will be difficult to plan out and administer.

Most of the Task Force's analysis is based on lessons learned from private sector health plans that offer similar coverage. Many of the drug benefit design features in those plans, including patient cost sharing, drug formularies and the use of fiscal intermediaries to administer the program, could be used if coverage is provided under Medicare. When fashioning a Medicare prescription drug benefit program, policy-makers will need to deal with the following issues:

- Should a prescription drug benefit be provided under Medicare in the absence of an overall reform of the program? Even if the prescription drug benefit is partially funded through participant premiums, paying the government share will have a substantial impact on the federal budget, especially during the retirement years of the “baby-boomers.” Further, a prescription drug benefit may have features that will lead to its cost rising faster than that for the other acute care services covered by Medicare. Adding another expensive benefit to Medicare is not prudent when the source of funding for the current benefit structure is uncertain. Assuring adequate financing for the program needs to be addressed in a comprehensive way.
- If a prescription drug benefit is offered through the Medicare program, how would the coverage be coordinated with those plans that currently provide prescription drug benefits to Medicare beneficiaries?
- Should the program be administered by a single fiscal intermediary or by one intermediary in specific geographical areas, or should there be competing drug plans providing the benefits?
- Whether, and to what extent, should the fiscal intermediaries be at financial risk for their role in controlling costs?
- There are a number of complex issues involving the design of the benefits to be provided, including the scope of drugs covered, the form and extent of beneficiary cost sharing, benefit maximums, and incentives to beneficiaries to use drug benefits efficiently.
- Another issue that needs careful study is the use of risk adjusted payment mechanisms that take into account the health status of the beneficiaries who participate in the program. Risk adjustment helps to make payments to competing payers more equitable and is especially important to discourage competing PBMs from avoiding beneficiaries with higher than average needs for prescription drugs.

Providing Prescription Drug Coverage for Medicare Beneficiaries

- There are questions concerning the network of pharmacies that would be used to provide prescription drugs to beneficiaries, such as beneficiaries' access to networks, whether networks are open to all pharmacies, and pharmacy incentive programs.
- Private sector drug programs manage prescription drug benefit costs in a variety of ways, including formularies (and associated rebates), generic substitution, mail order, and drug utilization management programs. Whether and to what extent such techniques would be used need to be determined.

These issues lie at the heart of any prescription drug benefit program and must be resolved if such coverage is offered under Medicare.

Introduction

Medicare provides a significant amount of support to older and disabled Americans in meeting their health care needs. Almost 98 percent of the population age 65 years or older in this country are covered by the Medicare program.¹ There has been a great deal of discussion over the past few years about whether, and how, Medicare should be modified in response to the changing health care environment in this country, both to assure adequate financing of future benefits and to extend coverage to prescriptions, which constitute an integral component of acute health care. A number of Medicare “reform” proposals and initiatives to cover prescriptions through Medicare have been introduced in Congress, discussed by various advisory commissions, and debated by candidates for public office.

To further the discussion about the Medicare program, and to help public policy makers understand the consequences of some of the recently proposed reform initiatives, the American Academy of Actuaries is publishing a three-part series of monographs on Medicare reform. The first monograph, *Using Private-Sector Competition Strategies*, examines ways in which competitive pricing techniques used in the private insurance market could be applied to Medicare. The second paper, *Evaluating the Fiscal Soundness of Medicare*, looks at how Medicare solvency is measured and discusses several proposals to strengthen the financial basis of the program. This monograph, *Providing Prescription Drug Coverage for Medicare Beneficiaries*, discusses the potential impact of a Medicare prescription drug benefit.

Currently, individuals who are eligible for coverage under the Medicare program may receive assistance in paying for prescription drugs from an employer health benefit or insurance plan, a government program or other source of assistance. Most of these individuals have their prescriptions filled in return for a fixed copayment (with or without additional payments such as premiums). In addition, some individuals purchase prescriptions and then apply for partial reimbursement from an insurer. Others may benefit from discounted prices charged by government facilities, health maintenance organization (HMO) clinics, mail order outlets or other private facilities.

There have been a number of significant changes in the health insurance market over the past 15 years, including prescription drug benefits. An understanding of the current operation of the prescription drug market and how those benefits are covered in private sector health plans is essential if the program design is to take advantage of the existing market structure. The first two chapters of this Monograph outline how the prescription drug market works and the general issues involved in providing drug coverage under an insurance program. This background should be kept in mind when looking at the design of a prescription drug benefit under Medicare.

The objective of this monograph is to assist policy-makers in understanding the primary features that could determine the cost of a federal initiative for prescription drug coverage for Medicare beneficiaries. The Monograph includes a discussion the following issues:

- Chapter I - How Prescription Drug Coverage Works, discusses the features of prescription drug markets and how such benefits are typically covered by health insurance.
- Chapter II - Prescription Drug Benefit Design, analyzes certain features that can affect the cost of a prescription drug benefit program.
- Chapter III – Providing Prescription Drug Coverage Under Medicare, analyzes some of the critical choices that must be made in developing a new federal program to provide prescription drug coverage to Medicare beneficiaries.

¹ Medicare Payment Advisory Commission, *Report to the Congress – Selected Medicare Issues*, June 1999.

Section I - How Prescription Drug Coverage Works

Prescription Drug Pricing

Brand and Generic Prescriptions

There are three general categories of prescription drugs for purposes of insurance coverage. These categories reflect broad underlying competitive and pricing dynamics in the manufacturer market, as well as different payment methods and levels of payment by insurers and pharmacy benefit managers (PBMs):

- *Single source brand name drugs:* The manufacturer (and any co-licensee) holds a patent on the primary ingredient of the prescription. Single source drugs do not have generic equivalents, although some have therapeutic equivalents.²
- *Multiple source brand name drugs:* This is the originator's version of a drug that has generic equivalents. In these instances, the manufacturer that discovered the drug and obtained the original patent continues to sell a drug after the patent has expired. Some physicians will continue to prescribe the drug by the brand name, but others will switch to prescribing it by its scientific or "generic" name.
- *Generic drugs:* Generic drugs are bioequivalent to their brand-name counterparts and are the generic versions of multiple source brand drugs.³ After a drug loses patent protection, a manufacturer that did not hold the original patent may develop a generically equivalent version.⁴

At the retail level, the highest prices are paid for single source drugs, especially those with unique therapeutic properties. The lowest prices are paid for generics. Table 1 shows the breakdown of payments between drug categories, as reported by a PBM during 1998.

Drug Type or Category	Percentage of Prescriptions	Percent of Expenditures
Single source brand	51%	82%
Multiple source brand	7%	6%
Generic	42%	12%

²Therapeutic equivalents are products that are considered to have the same clinical effects and safety profile when given to patients but do not have identical active ingredients. For example aspirin and ibuprofen are considered therapeutic equivalents.

³Bioequivalent drugs contain the same amount of active ingredient in the same dosage form, but may differ in characteristics such as shape and color. They have the same drug, dosage, and form with similar bioavailability (i.e., the same amount of medication is delivered to the body over the same time period).

⁴When the patent or exclusivity protection on a brand name drug expires, drug manufacturers may gain approval to market a generic version. Generic products are commonly substituted for brand name drugs as allowed by state law. The practice of dispensing generic drugs results in a substantial cost-savings for patients and payers while producing the same clinical effects as the branded product. The generic version of a brand name product must contain the same active ingredient(s) as the brand name product. Using a rigorous review process, the Food and Drug Administration (FDA) reviews generic drug applications to assess whether the proposed drugs are bioequivalent, (i.e., produce the same level of active ingredient in a patient's body as the patented drug). Products determined to be bioequivalent are included in the FDA's "Orange Book," so that third party payers can treat the products as therapeutic equivalents.

Notwithstanding the distinctions discussed in Table 1, prescription drugs are typically referred to as either “brand” or “generic.” A term often used when talking about either brand or generic drugs is *substitution*. There are two types of substitution:

- *Generic substitution* occurs when a physician or pharmacist substitutes a generically equivalent version for a multi-source brand drug. In most instances, this can be done without the prescribing physician’s approval.⁵
- *Therapeutic substitution* is the practice of replacing, with the prescribing physician’s approval, a prescription drug originally prescribed for a patient with a drug that is a therapeutic equivalent.

Transaction Prices

To understand how prescription drugs are priced, it is important to recognize the market structure that determines those prices. This structure includes:

- Manufacturer sales (direct or through wholesalers) to retail, mail order and internet pharmacies.
- Pharmacy prices charged to cash paying patients (including those that may be subsequently reimbursed by an insurer).
- Pharmacy prices charged to insurers that negotiate reimbursement rates, either directly or through intermediaries such as PBMs.
- Manufacturer rebates to PBMs or health plans.

Irrespective of the particular structure, all markets are characterized by constantly changing prices paid by the different purchasers. Other factors also affect the transaction price, including the purchasing power of the buyer and marketing strategies of prescription drug sellers (e.g., sales, promotional discounts, etc.). The price paid for prescription drugs by some federal agencies reflect legal mandates and the purchasing power of the federal government.

In addition, some purchasers (such as a managed care plan or PBM) can require that only certain types of drugs are dispensed, enabling these payers to obtain large rebates from the manufacturers of those drugs. As will be discussed in more detail below, the primary method used to limit the coverage for prescription drugs is through the use of a formulary.

Measuring Transactions Prices Using AWP

Although not itself a transaction price (despite its name), the average wholesale price (AWP) is widely used to set prescription drug transaction prices and in the analysis of prices. The AWP is generally taken as the highest among the manufacturer-listed or catalog wholesale prices that vary by the form, strength, and volume of drugs. In view of the variety of discounts offered by manufacturers and drug wholesalers, few transactions actually take place at the AWP, and many are substantially below the average wholesale price. However, the AWP does provide a base from which the prices of many transactions are determined, and it is a convenient benchmark for analysis of average prices charged in various markets.

⁵ Some states have “positive formularies.” This is a list of medications where generic substitution is permitted by law. Many of these laws refer to drugs listed in the FDA’s “Orange Book.” Sixteen states have positive formularies. Other states may have “negative formularies.” This is a list of medications where generic substitution is not permitted by state law even if a generic drug is available. Six states have negative formularies.

Net Prices Paid for Prescriptions

The net prices paid for prescriptions vary with the payer. In general, different prices are paid by:

- Patients paying cash (or credit), including those who are reimbursed in whole or in part by their employer or health plan.
- Health plans or employers paying directly or through PBMs, for whom the net price includes the effect of both pharmacy discounts and manufacturer rebates.
- Government agencies that can combine *de facto* formularies and very large purchasing power.
- Federal government agencies and state Medicaid programs that benefit from legislated maximum prices or minimum rebates.

The highest prices for prescription drugs are generally paid by individuals who pay cash and by the few health insurers that still reimburse patients for part of the cost of their expenditures based on cash receipts or other documentation.⁶ Prescription drug prices charged to cash customers vary significantly by pharmacy and region and can be several percentage points above the AWP. Insurers, managed care plans, and employer plans that utilize PBMs can obtain substantially lower prices.

Some government programs obtain substantially lower prices or large rebates from manufacturers by using the purchasing power of the Veterans Administration, the Defense Department and the Public Health Service.⁷ Other federally funded programs, notably the state-federal Medicaid programs, benefit from legislated rebates. Federal law requires manufacturers to pay a rebate for each prescription purchased through a state Medicaid program (other than drugs paid for through Medicaid managed care plans).⁸ The federal government also sets prices for certain inoculations provided to children in low-income families.

Variation in Utilization and Expenditures for Prescriptions

Prescription drug claims have a higher frequency and a lower average cost per unit than other types of health care spending. Spending on prescription drugs does not follow the traditional “80/20 rule,” where 20 percent of the population incurs 80 percent of the health care costs. For prescription drug expenditures, the rule is more like “55/20,” where 20 percent of the people incur approximately 55 percent of the cost. This pattern is shown in Table 2. Thus, pharmacy costs are more evenly spread

6 A number of insurers that market individual Medicare Supplement insurance policies and some third-party administrators of employer plans still reimburse patients for their out-of-pocket expenditures on prescription drugs. However, the share of expenditures handled in this manner has been rapidly declining. Generally, these plans benefit from the failure of patients to submit all prescription claims for reimbursement. The costs of administering these types of claims are significantly higher than administrative expenses for plans that directly reimburse the pharmacy for the cost of prescriptions.

7 The Veterans Health Care Act of 1992 sets maximum prices that manufacturers may charge certain federal agencies. The Federal Supply Schedule prices are set at the lower of negotiated amounts or 76 percent of the average actual wholesale prices for the products. These prices apply to purchases by the Veteran’s Administration, Department of Defense, Public Health Service, Coast Guard and the Indian Health Service.

8 State Medicaid agencies generally pay prices for prescription drugs based on federal law. Participating manufacturers must offer rebates of at least 15.1 percent on brand drugs, but in return, the states must cover the drugs in their Medicaid programs (i.e. they can not be excluded from coverage by failure to include them in a formulary). There is a mandatory rebate on generic drugs of 11 percent.

throughout a given population than, for example, hospital claims. This is because most seniors have at least one prescription drug claim within a year, and many of these expenditures are for the treatment of chronic conditions.⁹

Table 2 – Distribution of Prescription Expenditures for Seniors

Scripts per Year	Percent of			Relative to Population Average		Generic Drugs	
	Members	Scripts	Cost	Scripts	Cost	% of Scripts	% of Cost
0 to 12	21.9%	4.4%	2.1%	0.20	0.10	69%	41%
12 to 24	20.0%	11.0%	7.1%	0.55	0.36	58%	30%
24 to 36	18.2%	16.2%	12.6%	0.89	0.69	54%	27%
36 to 54	20.3%	26.4%	24.5%	1.30	1.21	50%	24%
54 or more	19.5%	42.0%	53.6%	2.15	2.74	47%	21%

Source: Data provided by a national Medicare+Choice Health Plan

The unit cost (i.e., the cost for an individual prescription) for these claims is also different from other types of health care claims. Many pharmacy claims have relatively low costs for a single prescription. For PBMs, approximately two-thirds of brand prescriptions cost less than \$50 per prescription, net of discounts.¹⁰ More than 75 percent of generic prescriptions cost less than \$20.

Another important difference underlying this pattern of prescription expenditures from those for other health care services relates to the persistency of expenditures over time. A primary reason for large annual expenditures for medicines is that many patients continue to use an expensive drug for a long period of time. Further, the use of many of the more expensive drugs can be predicted from their medical conditions.

All of the differences described above, taken together, mean that seniors (many of whom are on drug therapies for chronic medical conditions) can more easily predict the level of their out-of-pocket drug costs than is the case with their other health care costs. They also frequently know the specific drugs they will need. Accordingly, adverse selection presents a greater technical obstacle for programs with voluntary elements; for example, when there are different choices in the levels of coverage (e.g., different deductibles or annual maximums) or in the particular drugs covered (e.g., formularies). Similarly, the overall level of both prescription and other expenditures required by beneficiaries who use a specific drug is more predictable than the case with other acute health care services, and competing plan managers will be aware of their vulnerability to the financial consequences of adverse selection from covering that drug.

⁹ In a 1999 analysis of senior population drug utilization, which divided beneficiaries into low, medium, and high cost groups, PCS Health Systems found that hypertension, gastrointestinal and cholesterol drugs were commonly prescribed in each of the clusters they analyzed. Each of these medications is typically taken for longer duration than other drugs.

¹⁰ This estimate assumes average discounts and dispensing fees consistent with PBM-level discounts.

Pharmacy Benefit Managers

Pharmacy benefit managers are fiscal intermediaries that administer pharmacy benefits for employers, health maintenance organizations (HMOs) and other insurers. PBMs rely on a complex network of relationships with pharmacies, manufacturers, health plans, medical providers and patients. They use a variety of mechanisms to manage prescription benefit costs and encourage cost-effective utilization of prescription drugs. Some PBMs are independent, while others are owned by health insurers, managed care companies, pharmacy retail chains or pharmaceutical manufacturers. In addition, a number of HMOs administer prescription coverage in a manner similar to PBMs for their employer clients.

According to a recent Kaiser Family Foundation report, PBMs administer 71 percent of the retail and internet prescription drug purchases covered by a private third-party payer.¹¹ The current market is fairly concentrated, with three PBMs managing 45 percent of the market, and no other PBM with more than 4 percent. The degree of concentration, however, is less in many areas of the country than might appear from these figures. A number of smaller PBMs have very high market share in some local markets.

To help encourage more appropriate utilization of medications, PBMs manage drug costs through a variety of mechanisms, including:

- Establishing retail relationships and discounted pharmacy pricing.
- Designing and implementing prescription drug formularies.
- Encouraging generic and therapeutic substitution where appropriate.
- Establishing manufacturer relationships and negotiating rebates.
- Providing mail order capabilities.
- Conducting drug utilization review.
- Using different drug management mechanisms for certain medications.

These mechanisms can have a substantial impact on the overall cost of providing pharmacy coverage and each is discussed in more detail below. There are, however, a number of other factors that can affect the cost of a prescription program:

- Overall health plan benefit levels, including applicable deductibles, copayments, coinsurance and patient cost sharing maximums.
- The inclusion or exclusion of certain drugs or drug classes, such as “lifestyle” drugs or prescriptions that are administered by injection.¹²
- Age and sex distribution of the individuals enrolled in the health plan.

¹¹ The Kaiser Family Foundation, *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit*, January 2000.

¹² There are certain drugs today which, depending on how the definition of coverage has been written and classified, may either be covered under the pharmacy benefit or the medical benefit. These drugs were historically administered by a physician, but are now available for self-administration on an outpatient basis when purchased with a physician's prescription. Many of these medications are among the more expensive drugs available for outpatient use. The coverage and classification of such drugs is important for two reasons. First, in analyzing pharmacy claims experience, you need to know whether these types of claims are included since cost estimates can differ materially depending on whether they are included or excluded. Second, these types of drugs will become more prevalent in the future. For example, many biotech drugs and those based on genetic research will be administered by injection, at least initially and estimates of future costs will be higher and more difficult to predict if they are to be covered

- Disease management programs, which can prove very successful in improving health and lowering overall costs, but can also increase the amount of spending on medications.
- Other benefits offered by the health plan or their competitors, which may attract either healthier or less healthy individuals to enroll in the plan.
- Other sources of prescription coverage.

These factors are not typically controlled by the pharmacy benefit manager. Because of this lack of control, PBMs have been generally reluctant to assume full financial risk for prescription drug coverage. However, some PBMs may assume partial risk through risk corridors or performance guarantees.

Pharmacy Networks

One of the fundamental advantages that pharmacy benefit managers provide is their wide network of relationships with pharmacies throughout the United States. PBMs typically negotiate reimbursement rates for drugs that can be substantially below the pharmacy's usual and customary charges. The reimbursement rates may be structured in one of two ways. The first is calculated as a percentage discount off the AWP, plus a fee for dispensing the drug. The second method, typically used for generic drugs, calculates the pharmacy payment as a dispensing fee plus a preset amount from a fee schedule derived from net wholesale prices paid by pharmacies (sometimes referred to as the maximum allowable cost or "MAC").

For brand drugs, the average price paid by PBMs is approximately 87 percent of the AWP for the lowest volume, plus a dispensing fee of \$2.50.¹³ The final net prices, however, are lower when rebates are taken into account. For generic drugs, the average price paid by PBMs may be as low as 45 to 55 percent of the AWP.

Pharmacy benefit managers may also establish performance-based pharmacy networks. These are a smaller network of pharmacies with which they have negotiated a lower level of reimbursement which could take the form of greater percentage discounts from the AWP, lower fee schedules or lower dispensing fees. In these types of arrangements, in addition to the lower reimbursements, PBMs may negotiate incentive-based arrangements with pharmacies where the payment to the pharmacy varies based on the performance of certain activities or the level of certain metrics (such as increasing formulary compliance or generic substitution).

The pharmacy's interest in increasing the number of customers may be sufficient incentive to assure substantial discounts in pricing. Larger pharmacy discounts may be feasible if the size of the pharmacy networks is limited. Some PBMs have established "super-discount" networks. However, one limitation on PBMs establishing networks are state "any-willing-provider laws" which require those negotiating with pharmacies to accept any pharmacy that agrees to the terms of the network contract. These provisions undercut the incentives for pharmacies to enter into contracts that require large discounts in exchange for the possibility of a larger volume of customers since too many other pharmacies may also accept the terms for increased volume to materialize.

Drug Formularies

Formularies are lists of a health plan's or PBM's preferred medications, and they are a mechanism to encourage the use of less costly drugs. Typically, the PBM or health plan creates a list of preferred drugs

¹³ Wyeth-Ayerst Laboratories, *The Wyeth-Ayerst Prescription Drug Benefit Cost and Plan Design Survey Report*. 1999

within a drug class, for which they have negotiated lower pricing with manufacturers. The amount of the available discount or rebate depends on the particular nature of the mechanism used to provide incentives for formulary compliance and on how many different drugs are preferred within each of the therapeutic classes.

Formularies can be classified and administered as either “open”, “closed” or “incentive.” In an *open formulary*, drugs that are not on the list are still covered. These formularies have little impact on the prescriptions dispensed and hence on the rebates manufacturers are willing to pay. Rebates from manufacturers are typically the lowest in these types of arrangements. In these instances, PBMs will often create programs designed to work with pharmacies and physicians to encourage the use of preferred medications.

In *closed formularies*, non-preferred medications are not covered by the insurance company or employer health plan unless the physician provides information to the PBM establishing that criteria of medical necessity are met.¹⁴ Such arrangements can generate the highest levels of formulary compliance and rebates but can be difficult to administer. There are also access-to-care issues with such mechanisms if the prescription is not written for the preferred medication the first time and the process to obtain a medical exception certification is cumbersome or time consuming.

Under *incentive formularies*, it is generally not required to demonstrate medical necessity to access a non-preferred drug. Instead, there are price differentials for preferred and non-preferred drugs (e.g., \$5 copayments for generic drugs, \$10 for preferred branded drugs, and \$25 for non-preferred drugs). In these cases, patients have a financial incentive to request preferred medications. It can, however, leave the beneficiary paying more for a non-preferred drug, which may be the only drug that is fully effective or that minimizes side effects for that person.¹⁵

Merck-Medco (a PBM) has estimated that an open formulary with compliance interventions can decrease costs 2 to 3 percent over a plan without a formulary and that a three tier copayment incentive formulary can save anywhere from 5 to 9 percent over a plan without a formulary.

Managed care plans and PBMs normally rely on pharmacy and therapeutics (P&T) committees of medical experts to determine which drugs will be included on the formulary. The committees use clinical evidence to determine therapeutic equivalency. At that point, the net price after rebates available from the manufacturer can play an important role in determining the preferred drugs included on the formulary.

Formularies require frequent modification to reflect new drugs being introduced on the market, updated clinical information and changes in the competitive landscape within the drug industry. Such changes include:

- The introduction of landmark drugs for which there is no clinical equivalent. Sometimes this can equate to the creation of an entire new class of drugs.
- The emergence of new indications for an existing medication, which can make it clinically preferable to its competitors (at least until or unless the competition can secure approval for the same indications).
- The introduction of therapeutic (although not generic) equivalents within a class. In drug classes that represent growth opportunities, companies will launch a therapeutically equivalent

¹⁴ The level of the criteria and evidence that they are met varies by health plan. At the lowest level of review, a simple certification by the prescribing physician is adequate.

¹⁵ It is possible that people with the same disease who are taking the same drug can have different side effect and efficacy reactions because of their particular genetic make-up.

drug into an already existing class. At a certain point, the number of drugs within the class can become quite large, sometimes with few clinical differences between agents.

- After a drug patent expires, generic manufacturers can create generic alternatives for a drug that can be priced significantly below the cost of the original brand. This creates different competitive pressures for manufacturers, since a large portion of the market share will shift to use the generics.

Manufacturer Relationships and Rebates

Pharmacy benefit managers may negotiate rebates with manufacturers, lowering the net price paid for a drug when it is on the formulary. The level of rebates will vary by manufacturer and drug. In general, the level of rebates increases if the PBM achieves a greater market share for a drug within a defined class of drugs with similar therapeutic effects.

Significant rebates are not available on all drugs. For example, rebates are usually not provided (or tend to be minimal) for landmark or breakthrough drugs, since they generally have to be included in most formularies because no other comparable drug is available. Generic versions of multiple source drugs also have minimal (if any) rebates. Rebates may be paid for brand-name equivalents after they first lose patent protection, but the dollar volume of rebates tends to decrease as the market share of the generic version increases.

The availability of rebates is greatest in pharmaceutical classes with many therapeutically equivalent drugs. Manufacturers use rebates as an incentive to increase their market share while they still have patent protection. Drug patents last for 17 years, but the average time from the point a drug is first available on the market to the expiration of the patent is much shorter, generally around 7 years.¹⁶ Drug manufacturers typically want to have as large a market share as possible during the period a drug is under patent protection.

Because rebates can represent a material reduction in overall costs, PBMs and health plans use a variety of mechanisms to increase formulary compliance. In the end, it is the combination of formulary design, benefit design features and other incentive mechanisms that drive formulary compliance. Because these factors affect rebate levels, they can have a significant impact on overall prescription drug program costs.

Generally, PBMs retain a portion of the rebates and return most of the rebated amount to the risk-taking entity (i.e., the managed care plan or health insurer for which they are managing the prescription drug benefit). There are a number of issues concerning rebates, including:

- Rebates vary by actual market share and are calculated long after drugs are dispensed. Consequently, patient cost sharing amounts that depend on pharmacy prices will not reflect rebates.
- Since pharmacy benefit managers typically keep a portion of the rebate, there is a potential conflict of interest as PBMs have some incentive to pursue drugs with higher rebate levels (as opposed to drugs with the lowest net cost). There are situations where lower rebated drugs are less expensive than drugs that have substantial rebates. In addition, substituting a generic version may achieve significant savings but reduce rebates.

¹⁶ *The Economist*, The Alchemists, February 1998.

- Ownership of the PBM by a manufacturer may result in increased utilization of the owner's prescription drug products, rather than what may be the most cost-effective alternative.

Manufacturers use different pricing strategies to set both the average wholesale prices and the rebates for a particular drug. Some manufacturers set lower AWP prices and give lower rebates, while others set higher AWP prices and give larger rebates. It follows that PBMs should not be judged solely on their ability to get rebates. Additional performance metrics need to be included that hold the PBM accountable for the lowest overall cost, as opposed to achieving the highest level of rebates.

Generic Substitution

One of the keys to containing costs is to encourage, where appropriate, the substitution of generic drugs for the brand name equivalent. Increasing the use of generics can have a dramatic impact on costs. The cost of generic drugs, before taking any cost sharing differences into account, is approximately one-fourth that of single-source brand drugs and 40 percent of their multi-source equivalents, after PBM discounts. Using this simple relationship (assuming that 40 percent of prescriptions are for generic drugs), a 1 percent increase in generic drug usage could decrease total costs by between one-half to one percent.

There are many ways to promote the use of generic drugs. In many instances, PBMs offer pharmacies an incentive to increase generic dispensing. Other methods involve benefit design and use higher copayments or coinsurance for brand drugs to provide incentives for beneficiaries to use generics. Some plans will only pay for generic versions of a drug.¹⁷

Mail Order Drugs

Many PBMs provide mail order capabilities to their clients and use mail order as another means for containing costs. Mail order is most often used for medications for chronic illnesses requiring a number of refills.¹⁸ In these instances, the first prescription is usually filled at a retail pharmacy, and the refills are sent to a mail order facility. Most mail order prescriptions are for 60 to 90 day supplies of prescription drugs.

The cost of providing medications through mail order is usually lower than providing the same medications in a retail setting, because:

- Mail order pharmacies buy their drugs at a lower cost.¹⁹
- Mail order facilities may have greater operational efficiencies because of where the facilities can be located and how the prescriptions are filled. Many mail order houses are fully automated and some make extensive use of robotics to fill prescriptions.
- There are instances in which mail order can be used to increase generic and formulary compliance. Since there is no customer waiting, the pharmacy may take more time to contact the physician and try to persuade them to switch the medication from a brand name drug to a generic or from a non-formulary to a formulary drug.

¹⁷ It is customary for health plans to make some payment when the brand version of a multiple source drug is dispensed, charging the patient the sum of the normal copayment and the difference in cost between the brand and generic version.

¹⁸ Mail order can be used for medications for acute medical conditions, but because of the time required to fill the prescription and get it to the beneficiary, it rarely is.

¹⁹ Mail order pharmacies actually buy their drugs in a different class of trade with lower costs than retail stores.

Many PBMs operate their own mail order facilities. Others may contract with third-party vendors to provide mail order services. In addition, some of the larger retail pharmacy chains have mail order facilities.

Drug Management Mechanisms

Other mechanisms PBMs use to help contain costs are summarized below. There are differences in how and why one mechanism is used over another. However, all of them use clinical criteria to determine whether a particular prescription drug is appropriate for the specific medical condition.²⁰ If the clinical criteria are not met, the drug is usually not covered.

Mechanism	Used For	Issues
Prior Authorization (PA)	Used to check if the drug is appropriate for the medical condition. Used when drugs: <ul style="list-style-type: none"> ■ Are inherently dangerous ■ May have severe drug interactions ■ Are frequently prescribed when they should only be used for "niche therapy"²¹ ■ Are extremely expensive 	The emerging use of PA may conflict with: <ul style="list-style-type: none"> ■ The success of "direct to consumer" advertising ■ Consumer demand ■ Legislative mandates
Maximum Dispensing Limit (MDL)	Used to manage the quantity of pills that are dispensed. MDLs used to: <ul style="list-style-type: none"> ■ Check appropriateness of prescriptions for ages and quantities outside FDA indications ■ Prevent stockpiling of "as needed" drugs ■ Find outliers for quantity 	As drugs become more sophisticated for "as needed use," expect greater use of MDLs
Step Therapies	Used to check the medical appropriateness of using a "second-line" versus a "first-line" drug. ²² Used when: <ul style="list-style-type: none"> ■ Alternative therapies are readily available ■ System can check whether alternatives have been tried before requiring review ■ System allows a drug for a certain duration before needing review (duration corresponds to FDA indications) 	Requires sophisticated adjudication systems to work well. Works better with: <ul style="list-style-type: none"> ■ Physician-targeted edits ■ "Gold card" capability for certain providers, such as specialists

²⁰ The pharmacy benefit manager's P&T committee set the clinical criteria for these evaluations.

²¹ Drugs that are meant for a fairly small population of people with particular conditions are marketed and prescribed to a much broader population. This happens as a direct result of direct-to-consumer advertising and other manufacturer promotion campaigns.

²² As much as 7 to 8 percent of prescription drug cost increases are attributed to the use of newer, more intense and expensive therapies ("second line" drugs) rather than using older therapies ("first line" drugs) for the same condition as in the past.

These mechanisms can be very important in containing costs, especially when new, high-demand drugs are introduced, or when such drugs clinically intended for a small population are being prescribed to a much larger one. One possible problem is that these mechanisms involve interrupting the claims adjudication process to assess the criteria. While such mechanisms can help contain costs, they can be disruptive for physicians and beneficiaries. There is also less consistency *among* PBMs in terms of the list of drugs being reviewed and the clinical criteria they use to evaluate them.

The drug management mechanisms PBMs use can also enhance the quality of care for beneficiaries. They can make a significant contribution to quality by identifying potentially harmful drug interactions, duplicate therapies, and possible adverse reactions associated with taking certain medications.

Scope of Drugs Covered

The cost of a prescription drug program will vary depending on the scope of coverage. Variations in the types of coverage for prescription drugs found in private sector health plans include:

- Covering only “life saving” drugs. These are non-legend drugs sold “over the counter” that are required to maintain life for certain patients (e.g., insulin).
- Excluding certain “life style” drugs and drugs for which the medical need is difficult to establish (e.g., tranquilizers).
- Limiting conditions for which drugs are covered to diagnoses for which the drug was approved by the FDA (i.e., exclude prescriptions for “off label” uses).
- Covering a limited number of therapeutic categories.
- “Carve outs” of therapeutic classes, usually because they are covered under a separate program (e.g., drugs prescribed for mental and nervous conditions or substance abuse that may be covered under a separate health plan).

In the absence of carve outs, which usually simply transfer the cost to another program financed by the same payer, these coverage limitations will have a relatively minor impact on program costs. Limiting insurance coverage may cause medical providers to prescribe drugs that are covered rather than uncovered drugs that may be equally or more appropriate. In addition, the more difficult it is to implement limits on coverage, the more substitution will take place. For example, limiting a prescription drug program so only “maintenance drugs” are covered is difficult to implement in practice. Many drugs normally prescribed for chronic illness can be used to treat other medical conditions. Unless the administrators of the prescription drug program track the underlying medical condition, they will not be aware of how the maintenance drugs are ultimately used by patients

Patient Cost Sharing Design Issues

There are a number of different types of cost sharing arrangements in both public and private prescription drug programs. The cost of a prescription program will vary depending on the cost sharing imposed on patients at the time they obtain prescriptions. In general, patient cost sharing has two very important effects:

- *Direct effect:* patient cost sharing reduces the sponsor’s cost of the program directly in proportion to the amount patients are required to pay.
- *Indirect effect:* patient cost sharing may make patients more sensitive to the cost of the prescriptions they use, which can change utilization in ways that can have a large impact on the cost of the program. In particular:
 - *Induced utilization changes:* Patients will react to the level of payment they must make to purchase prescribed medicines (including requesting generic prescriptions or formulary drugs, and failing to fill prescriptions).
 - *Conservation:* Selective patterns of patient cost sharing (e.g., maximum benefit for brand prescriptions) can lead to patients saving the benefit for the possibility of future needs with the effect that some potential benefits are not used

Providing Prescription Drug Coverage For Medicare Beneficiaries

Calculating the direct effect of patient cost sharing is usually a relatively straightforward process, but there is no consensus as to how large induced utilization or conservation effects are. In addition, there may be important interactions to consider in program design, such as the impact of copayments on average prescription size, or of coinsurance on utilization of the most expensive drugs in a therapeutic category.

Coinsurance

With coinsurance the patient is responsible for a percentage of the pharmacy reimbursement for a prescription. Coinsurance provides each patient with: (a) a direct financial incentive to use the lowest cost drug that will satisfy their needs, and (b) a direct measure of their share of such cost. It also directly reduces the cost to the insurance program in proportion to the percentage amount.

Coinsurance may be expressed as a percentage of the price paid to the pharmacy, but it may also be a percentage of some reference price, such as the AWP, if it is desired to keep the pharmacy payment level confidential. Any additional rebate or other incentive payments to the pharmacy and any rebates to the PBM or health insurer are not usually reflected in the base price to which the coinsurance is applied. A similar problem arises with other cost sharing features expressed as a percentage of the actual expenditure for a patient's prescriptions (e.g., deductibles and benefit maximums).

Copayments

Copayments are a fixed amount per prescription that may vary by the size of the prescription, the type of drug (brand name drugs vs. generic) and whether the drugs are sold through a retail pharmacy or mail order. Copayments may also be different for some therapeutic categories of drugs (e.g., tranquilizers) or even for particular drugs (e.g., certain very high cost drugs or "lifestyle" drugs). Since a large copayment may exceed the price paid to the pharmacy for the drug, some programs limit the copayment to the lower of the normal copayment and the pharmacy base for payment. There is also the possibility that the copayment amount may exceed the pharmacy base for reimbursement and the normal retail price. Many pharmacies will simply charge the retail price when this is the case. The appropriate program design would specify the price paid to the pharmacy by the PBM or other insurer.

Fixed, predictable copayments are more acceptable to patients than unpredictable amounts of coinsurance, but have two major disadvantages for financing the programs. First, a copayment does not make the patient as sensitive to the cost of the drugs prescribed as does coinsurance. This is a particular problem for multiple-source drugs and for therapeutic categories in which there are a number of drugs with similar effects but substantially different net prices. Consequently, the decrease in utilization from a given amount of cost sharing will be less than if there is a direct impact on what patients must pay. This problem has caused many health plans to adopt multiple levels of copayments, with lower copayments for generically dispensed products. In addition to the copayment amount, the plan may charge patients for the difference in cost between the brand and generic versions of multiple source drugs.

Some health plans have also adopted a third level of copayment applicable to brand-name drugs not included on a formulary, to very expensive drugs that provide highly specialized therapy for a relatively small number of patients, or to the growing number of "lifestyle" drugs.

The other major disadvantage of copayments is that copayment amounts may need to be raised as overall drug costs increase. If the copayment amounts are not raised, overall program costs will increase at a higher rate than the increase in the cost of drugs.

Deductibles

A deductible is typically an amount that must be paid out-of-pocket before coverage for health care expenses is provided. The deductible may be limited to a specific medical procedure or coverage (e.g., prescription drugs or in-patient hospital costs) or may apply to all expenditures under a health insurance policy or health plan. Deductibles can limit program expenditures to patients who have the highest expenses (who presumably need the benefits the most). However, as with fixed-dollar copayments, fixed-dollar deductibles produce rates of increase in program expenditures that are “leveraged.” Since the deductible represents a decreasing proportion of the covered services used by the insured, the program cost will increase at a higher rate than the increase in the cost of drugs. In addition, more people will meet the deductible amount as costs increase. Further, the higher the deductible, the greater the leverage.

Catastrophic Coverage

A very high deductible can be used to make the coverage “catastrophic,” (i.e., designed only to assist those with very high expenditures for drugs, usually for patients who need an expensive drug over a long period of time). The primary cost implication of a very large deductible is to provide coverage for those most in financial need of assistance at a relatively low cost. There is also a potential long-run impact on the direction of pharmaceutical research and development efforts. Even a large deductible may represent a relatively small proportion of the annual cost of some potential drug therapies. This may occur either because the drug is very expensive to develop or because very few patients need it.²³

Overall Cost Sharing Limits

Theoretically, cost sharing limits can be set so as to limit the total out-of-pocket expenditures of patients to a level affordable to most beneficiaries. These limits are generally stated as a fixed dollar amount per individual (or per family) per year. As with deductibles, they introduce the problem of leverage, although with much lower impact since a smaller proportion of expenditures will be affected. A limit on cost sharing may also increase the financial incentives for manufacturers to develop expensive medicines.

Benefit maximums

Benefit maximums are a limit on the total dollar amount of coverage, usually expressed either as an annual or a lifetime cap. From a financial perspective, the primary purpose of insurance is to reduce the financial impact of the hazard insured against to a manageable level. With benefit maximums in place, expenditures by the insurance program are concentrated on those whose financial needs are least, rather than those whose financial burdens are greatest. Further, with per capita prescription drug

²³ The effect of a catastrophic level deductible is similar to that of annual deductibles on the cost of transplant operations. For example, a \$5,000 deductible is less than 5 percent of the cost for some organ transplants. Under current economic incentives, the research-oriented drug manufacturers have little incentive to develop such drugs. But with a catastrophic program that pays the full cost over a high deductible, the incentives will change. It may take a decade for such effects to begin to appear, but the potential markets presented by such programs could eventually have a significant impact on what drugs are discovered, developed and brought to market in the U.S.

expenditures expected to rise at double-digit rates, the proportion of patients who reach the maximum will grow exponentially.

Nevertheless, some drugs are so expensive that many prescription drug programs include maximum limits, especially programs that cover Medicare beneficiaries. Individuals subject to using these rare drugs are most likely to select a benefit plan with the highest limits available.

Benefit maximums, however, do offer several advantages. First, a fixed benefit maximum, or a benefit maximum indexed to the CPI, will reduce the rate of increase in program cost to below the rate of increase in drug costs (i.e., reverse leverage). Another advantage of benefit maximums is to provide an incentive for patients to save the maximum benefits by using lower cost drugs and seeking generic versions where available. Generic utilization can be encouraged further by applying the benefit maximum only to expenditures for brand drugs or by adopting a separate maximum for generically dispensed drugs. In the longer run, benefit maximums avoid providing an incentive for the development of extraordinarily expensive drug therapies.

Benefit maximums can have an important effect on adverse selection. Because prescription drug expenses of individuals are usually predictable, individuals with higher expenditures tend to choose health plans with higher maximums or with no maximums. This tendency is one of the reasons most Medicare+Choice (M+C) health plans and Medicare Supplement insurance plans offering prescription drug coverage have benefit maximums.

If health plan enrollees can change plans whenever they choose, however, enrollees who have reached their maximum will shift to another plan in order to have a new benefit maximum, which may negate its effects.

Interactive Effects of Inflation and Patient Cost Sharing

The per capita prescription expenditures of the elderly have been rising at a rate in excess of 15 percent annually, and many experts forecast such costs to continue to rise at this pace for the immediate future. It is important to understand the cause of these increases.

- *Price impact due to inflation*: the increases in the cost of currently available prescription drugs, usually measured by the consumer price index (CPI) component for prescription drugs.
- *Price impact due to mix of drugs*: the effect of introducing new drugs on the market, usually at much higher prices than existing drugs.
- *Volume of drugs consumed*: usually measured by the number of prescriptions per capita, although the number of doses would be a better measure.

Historically, over long periods, the volume and price factors have been relatively minor components of the increase in prescription drug costs. However, over the last few years both components have risen at sharply higher rates than their historic averages. The primary reason for higher prescription expenditures, however, has been the introduction of new drugs. The impact is seen in both the volume of drugs being prescribed and in the impact on the average price due to the mix of drugs dispensed.

Patient cost-sharing amounts that are fixed or adjusted at a rate other than the change in per capita prescription drug expenditures will have a leverage impact, which may augment its effect or reduce it. Table 3 illustrates the interaction of several forms of patient cost sharing features if: (a) if they are fixed in dollar terms and (b) the amounts are adjusted by the CPI (for all items).

As can be seen from the table, deductibles and copayments augment the effects of cost increases, whereas benefit maximums have the opposite effect. Leverage effects can be an especially significant

problem for a publicly financed program, since outlays that increase much more rapidly than tax revenues present a particularly difficult funding problem in the context of Congressional budgeting procedures (as is the case with the present Medicare program).

Table 3 – Annual Rates of Increases in Prescription Drug Insurance Plan Costs Per Capita Assuming 15 Percent Per Year Increases in the Cost of Drugs

Annual Rate of Increases		
Cost Sharing Feature	Through CY 2005	Through CY 2020
A. Fixed Dollar Amounts		
Copayments (\$10 Generic/\$20 Brand)	18.5%	15.5%
50% Coinsurance with annual deductibles of:		
\$100	15.7%	15.0%
\$500	18.8%	15.4%
\$2,000	29.2%	16.9%
50% Coinsurance with benefit maximums of:		
\$2,500	10.9%	2.4%
\$5,000	13.6%	4.3%
B. Amounts Adjusted for 2.5% annual increases in CPI		
Copayments (\$10 Generic/\$20 Brand)	17.9%	15.6%
50% Coinsurance with annual deductibles of:		
\$100	15.6%	15.0%
\$500	18.2%	15.5%
\$2,000	27.1%	17.3%
50% Coinsurance with benefit maximums of:		
\$2,500	11.9%	5.4%
\$5,000	14.0%	7.6%

Note: Trend in per capita spending assumed to be 15 percent per year. Per capita expenditures trend comprised of: prices (3 percent), mix of drugs (8 percent) and volume (3.5%)

Multiple Patient Cost Sharing Features

Most of the patient cost-sharing features described above are used in employer sponsored health insurance plans and M+C health plan options that include prescription coverage. Nearly all such plans have copayments, usually with a higher copayment for brand drugs than for generic drugs and, in some plans, the patient is responsible for the additional cost if the originator's brand is dispensed for a multiple source drug. Most plans also have benefit maximums. In addition, many have a modest deductible, sometimes applied quarterly. One problem with having multiple cost sharing design features is that patients may find it difficult to understand what the health plan covers and what they pay, and their incentive to use lower cost drugs may be obscured.

Price Guarantees for Prescriptions Not Reimbursed

Both public and private prescription drug programs may negotiate arrangements with pharmacies in which the price that will be paid by those insured will be the same whether or not there is any reimbursement for the particular prescription. Theoretically, the prices that the insurer obtains from pharmacies will be somewhat higher if all purchases by those insured will be affected. As a practical matter, it is likely that the average prices obtained will not be significantly increased. Thus this feature could constitute a valuable benefit to the insured for a relatively small, if any, increase in cost.

Encouraging Use of Mail Orders

In order to provide incentives to patients to order their prescriptions by mail, insurers and health plans have sometimes agreed to forego some copayments if the prescription is delivered by a mail order facility. For example, under some plans, if the prescription drug is purchased from a retail pharmacy, the patient would have to pay a copayment for each 30-day supply of drugs. With a mail order, these plans may permit the patient to purchase a 90-day supply of the same drug with only one copayment.²⁴

²⁴ Some state laws prohibit health insurers from offering better coverage if the prescription is purchased through a mail order facility rather than a retail pharmacy.

Under Medicare

There has been a significant amount of interest recently in proposals to provide coverage for prescription drugs to seniors. The issue has gained popularity in Congress and in the presidential election campaigns. This section examines issues that would have to be considered in designing a drug benefit program that would be covered by Medicare.

It is important to distinguish whether a government program would require offering drug coverage to all Medicare beneficiaries as opposed to using Medicare itself as a vehicle for a universal prescription drug benefit. As discussed below, some individuals who are eligible for Medicare, but are still employed, may be covered by an employer-sponsored health plan. If the intent is to provide prescription drug coverage for all individuals eligible for Medicare, such coverage could be provided directly through Medicare, private health insurance, or state-run prescription drug plans. Some legislative proposals have provided tax credits to seniors who purchase prescription drugs, or high deductible catastrophic coverage options designed to assist those individuals with significant prescription drug costs.

The discussion in this section deals with the Medicare program as the primary vehicle for offering a drug benefit. Other approaches – for example, providing seniors with tax credits to encourage the purchase of private health insurance – are not discussed.

Medicare Solvency and Prescription Drug Benefits

The 2000 Report of the Medicare Trustees states that the Hospital Insurance Program (Medicare Part A) will exhaust its trust fund in 2025. Further, under current budgetary procedures, federal transfers to the program to pay the interest on the Trust Funds and to fund the redeeming of the special Treasury bonds in which the Trust Funds are invested will require a major increase in federal budgetary expenditures that are likely to prove to be a burden on the economy. While the Supplementary Medical Insurance (Medicare Part B) trust fund is “self-funded” from tax revenues and participant premiums, it is expected to face increasing financial pressure due to higher health care costs and the number of “baby boom” workers who will be eligible for Medicare in the coming years.

One of the central questions that must be considered is whether a prescription drug benefit should be provided under Medicare in the absence of an overall reform of the program. Even if the prescription drug benefit is partially funded through participant premiums, the government share of the cost will be a substantial additional burden, especially during the retirement years of the “baby-boomers”. Adding another expensive benefit to Medicare is not prudent when the source of adequate funding for the present program is uncertain. Assuring sufficient funding of the entire Medicare program through the retirement years of the “baby boomer” population needs to be addressed in a comprehensive manner.

How Medicare Beneficiaries Are Covered Now

The Medicare program is available to nearly everyone age 65 years and older, certain disabled individuals and people with end-stage renal disease. Individuals who enroll in Medicare are automatically entitled to Part A, which covers hospital stays and skilled nursing home care. Individuals must choose to enroll in Part B of Medicare, which pays for doctor’s services and certain outpatient medical and surgical services. Medicare currently pays for a limited number of prescription drugs under Part B.²⁵ Medicare beneficiaries receive their care either from the “traditional” fee-for-service pro-

²⁵ A complete description of the Medicare program is available from the Health Care Financing Administration or through the HCFA web site (www.medicare.gov).

gram or through a “Medicare+Choice” managed care health plan.

Currently, seniors (including Medicare beneficiaries) may receive assistance in paying for prescriptions from a number of public and private programs, including:

- Medicare+Choice plans that choose to offer such coverage
- Federal-state Medicaid programs
- Employer-sponsored health insurance plans for employees and retirees
- Individually purchased Medicare supplemental policies
- TriCare for military retirees and dependents
- Veterans Administration programs
- Prescription benefits in individual or employer sponsored franchise insurance policies.
- Miscellaneous federal and state pharmaceutical assistance programs (e.g., state programs for low income aged)²⁶
- Various discount programs (e.g., AARP)

In 1995, approximately 9.5 percent of non-institutionalized persons eligible for Medicare received prescription benefits through an HMO (either under a Medicare+Choice plan or individual Medicare supplement insurance policy), 10.2 percent received prescription drug coverage through Medicaid, 32.4 percent participated in employer sponsored programs (including both group Medicare supplement and coverage of the working aged), 8.3 percent purchased Medicare supplemental policies with prescription benefits and 5.8 percent had other forms of coverage. This left approximately 33.8 percent without any coverage from any source. Some individuals have more than one source of coverage for prescription drug costs.²⁷

If a prescription drug benefit is offered through the Medicare program, one of the key issues is how the coverage would be coordinated with those plans that currently provide prescription drug benefits to Medicare beneficiaries. For example, would the Medicare Supplement plans that currently offer prescription drug benefits be discontinued? How would individuals who have those policies be treated? Would Medicare+Choice health plans and employer sponsored health plans that cover older workers or retirees be encouraged to continue prescription drug benefits? Should all of these options become supplemental to a basic Medicare prescription drug benefit, instead of replacing it?

Single-Payer and Competitive Models

Many of the most important design issues depend on whether the program of prescription drug coverage through Medicare is:

- A “national single-payer” model that is centrally administered either by the Health Care Financing Administration (HCFA) or by a third-party fiscal intermediary, so everyone is entitled to exactly the same benefits

²⁶According to the National Council of State Legislatures, there were 18 states with some type of prescription drug assistance program as of March, 2000, although not all of these plans may be available to seniors. For a description of the state programs see the NCSL web site (www.ncsl.org).

²⁷*Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries*, Margaret Davis, John Poisal, et. al., Health Affairs, January/February 1999.

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- A “regional single-payer” model, under which the residents of each designated service area would have the coverage offered by the winner among competing third-party fiscal intermediaries for the Medicare franchise in that area.
 - A competitive model under which beneficiaries have a choice of coverage options, each administered by a different entity (normally a PBM or insurer at least partially at risk for some component of the coverage offered).²⁸

A *national single-payer model* would provide uniform benefits throughout the United States in a manner similar to Part A and Part B of Medicare. This program could be run either by HCFA or under contract to a third-party. All aspects of coverage and administration would be set by regulations promulgated by HCFA, including the specific drugs offered in any formulary and the cost to beneficiaries for access to any non-formulary prescriptions.

A *regional single-payer model* would allow different third-party fiscal intermediaries to administer the program in separate geographic regions of the country, that are permitted to vary key aspects of the coverage (e.g. formulary) and are chosen according to a competitive process in which the projected cost to the program is a significant criterion. These fiscal intermediaries could be PBMs, HMOs or other types of insurance entity or third party administrators. The scope of coverage (including minimum formulary requirements), patient payments and all other aspects of operation would be contractual conditions set by HCFA.

Under the *competitive model*, the federal government would establish more general specifications for the minimum coverage to be provided. Bids would be solicited from insurers (including PBMs willing to accept the specified degree of risk, which could be limited by risk corridors) who would contract to provide coverage to Medicare beneficiaries in a particular geographic region. The health plans in that region would compete for beneficiaries and would be allowed to vary coverage and administration of the program. Depending on the design of the program, competition could be focused on lower cost sharing, additional coverage or lower enrollee premiums. The current M+C program has many of the characteristics of a competitive model.

A Medicare prescription drug program (whether it is single-payer or competitive bid) would likely establish national benefit design standards to assure a basic level of coverage for all beneficiaries. These standards could include a basic benefit package and requirements for access to pharmacy networks (usually expressed in terms of how close a pharmacy is to where beneficiaries reside), formulary coverage, and patient cost-sharing features. The potential for cost savings will vary by both the approach and how it is executed, especially as relates to how therapeutic categories are defined, the minimum coverage and access procedures required for non-formulary drugs, and the rules for participation in pharmacy networks. In addition, competition between fiscal intermediaries (whether for the regional franchise or with competitors for enrollees) may produce additional cost savings.

Comparison of Approaches

Assuming that the program will utilize third-party fiscal intermediaries to administer the prescription drug coverage, there are a number of factors to consider in deciding between the single-payer and competitive approaches. Although the following discussion is structured in terms of PBMs serving as

²⁸ Many PBM executives believe their existing infrastructure and technologies are directly applicable to providing pharmacy coverage to the Medicare population. See Henry J. Kaiser Family Foundation, *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit*, January 2000.

the fiscal intermediary, the same issues could apply to other intermediaries, such as health insurers or HMOs.

National Single-Payer Approach

A uniform national program would have several major advantages, including:

- Beneficiaries are assured the same coverage wherever they live, including when they change address.
- Implementing such a program could happen more quickly because of administrative simplicity.
- Mass purchasing power for HCFA would be very large. Exercising the purchasing power to obtain lower prices and/or larger rebates would depend on the degree to which HCFA was willing and able to limit coverage to a formulary, set “reference prices” within broad therapeutic categories or other financial incentives for use of formulary drugs and the procedures for paying for medically required non-formulary drugs.
- The issues surrounding competitive bidding and providing benefits through multiple entities are eliminated.²⁹
- A single payer model, whether national or regional, would eliminate adverse selection among enrollees.
- The prescription drug program would be similar to the present Part B of Medicare and easy for beneficiaries to understand.

There would also be disadvantages to a uniform national program.

- Under a uniform program, it will be difficult for the federal government to operate a formulary, reference price system or other variation in coverage and/or cost sharing designed to extract competitive prices from manufacturers, since individual beneficiaries with different medical conditions would not be treated equally by the program.
- Using a single, national PBM gives an advantage to bigger PBMs, which could reduce the field of bidders. It could also make it more difficult to introduce a competitive drug plan model in the future.
- Because the national PBM would have a monopoly, they would have little incentive to compete for beneficiaries based on service. These incentives become more important as the program increases the use of cost containment. To the extent that cost saving mechanisms are extensively used, additional monitoring of services would be needed.
- Changing to a new PBM (either at the time the contract is over or if there are performance or service issues) can be extremely disruptive and cause beneficiary dissatisfaction. Pharmacy coverage has distinct characteristics that make changing its administration to another inter-

²⁹ The issues associated with conducting competitive bids are beyond the scope of this monograph. See American Academy of Actuaries, *Using Private Sector Competition Strategies*, March 2000. Many of the issues outlined in that paper would be the same for competing PBMs such as bidding criteria, calculating reference premiums, risk adjustment, etc.

mediary quite challenging. A poorly handled transition of such a large beneficiary population to another PBM creates the potential for adverse health impacts.

- In the absence of price reductions and/or rebates obtained through competition, uniform national coverage is likely to ultimately lead to direct negotiations with prescription drug manufacturers over the prices paid for prescriptions (as has been the case with the other large federal programs paying directly for prescriptions, e.g., Medicaid, the VA, and the Defense Department).
- It will be difficult for the federal government to exclude any pharmacy from its network, since exclusion may constitute such a substantial competitive disadvantage with network pharmacies as to threaten commercial viability. Accordingly, it will be difficult to obtain substantial pharmacy discounts.
- As has been the case with the present Medicare program, the program would tend to codify present practices and fail to evolve with changes in private prescription markets and insurance programs.

Regional Single-Payer (PBM) Approach

Advantages of a regional single-payer model include:

- Purchasing power for the PBMs would be very large. Obtaining lower prices from manufacturers, however, would depend on the PBM's flexibility to determine the drugs offered within any formulary.
- If regional PBMs were permitted to offer different closed or incentive formularies, program costs would be decreased by the manufacturer rebates that would become available.
- Using a single regional PBM would eliminate adverse selection *among* PBMs and the need for a pricing mechanism to adjust for adverse selection.
- Administrative costs may be reduced through competitive bidding.

Disadvantages of a regional single-payer model include:

- Considerations of fairness to beneficiaries with different prescription needs who live in different areas are likely to restrict the flexibility of the regional PBMs to select the drugs offered in any formulary. Manufacturers are unlikely to agree to substantial rebates if the regional PBMs can not treat their products more favorably.
- In the absence of price reductions and/or rebates obtained through competition, uniform national coverage is likely to ultimately lead to direct negotiations with prescription drug manufacturers over the prices paid for prescriptions (as has been the case with the other large federal programs paying directly for prescriptions, e.g. Medicaid, the VA, and the Defense Department).
- It will be difficult for the federal government to exclude pharmacies from its network, since exclusion may constitute such a substantial competitive disadvantage as to threaten commercial viability. Accordingly, it will be difficult for regional PBMs to obtain substantial pharmacy discounts.
- A regional PBM model gives an advantage to bigger PBMs, which could reduce the field of bid-

- Because a single PBM would have a monopoly within a region, it would have fewer incentives to compete on the basis of service provided to beneficiaries. These incentives become more important as the program increases use of cost containment. To the extent cost saving mechanisms are extensively used in a single-PBM model, additional monitoring of services would need to be implemented.
- Changing PBMs (either at the time the contract is over or if there are performance or service issues) can be extremely disruptive and cause beneficiary dissatisfaction. Pharmacy coverage has distinct characteristics that make changing its administration to another intermediary quite challenging. A poorly handled transition of such a large beneficiary population to another PBM creates the potential for adverse health impacts.
- If formularies are permitted, it will be even more difficult to change PBMs. Arrangements will have to be made to continue the drug treatment programs for individuals changing administrators. Exceptions will have to be made for phasing in the new formulary.
- Selection of the regional PBMs requires development of procedures and criteria for selection and is thus more administratively complex than a national single payer approach.

Competitive Approach

A competitive approach would have some additional advantages:

- A competitive model may allow more flexibility in overall program design. To the extent it allows more use of traditional PBM mechanisms for controlling costs, it will provide more cost effective coverage. This would be especially true if competing PBMs were permitted to offer different formularies and pharmacy networks.
- By allowing competing PBMs, Medicare beneficiaries could be allowed to choose from different approaches to pharmacy cost containment. If a PBM proved to be too restrictive, beneficiaries could switch to another PBM at the annual open enrollment period. (Over time, however, the pressures described above relating to adverse selection are likely to force all competitors to offer very similar features, especially the drugs offered in each therapeutic category.)
- A benefit of a competitive PBM approach is that the knowledge gained from implementation would be applicable to introducing competitive bidding for other elements of Medicare. The problems with competitive bidding for pharmacy coverage would be similar to those encountered for Parts A and B of Medicare, but the order of magnitude for a pharmacy program is much smaller, because:
 - Many PBMs have (or can create) regional or national pharmacy networks, which reduces the complexity of having to administer bids in a large number of small regions.
 - PBMs, by definition, operate in a consolidated and competitive market, using similar or identical operating standards and many of the same techniques for managing costs. This makes it easier to create the evaluation criteria for qualifying bidders and measure results against those criteria.

Disadvantages of competitive options include:

- Competing drug plans will be subject to potential adverse selection, which could discourage offering more than the least expensive drug in each therapeutic category.

Manufacturers may perceive that commercial success depends more on assuring narrow therapeutic categories (especially if limited to their products) than on developing drugs that offer major therapeutic advantages.

- Administrative costs may be increased because each PBM would have overhead expenses and there would be reduced economies of scale. There would also be added costs to explain coverage choices to beneficiaries.

Additional policy questions that would need to be addressed include:

- How PBMs would be allowed to compete for beneficiaries; (i.e., which program elements should be the same across all PBMs and which can be used as the basis for competition)
- How communication with beneficiaries will occur. Communicating complex pharmacy coverage issues to beneficiaries can be difficult.

It should be noted that the cost effectiveness of any program design depends primarily on the resulting competitive price pressures on manufacturers and pharmacies. The most cost effective design will be that which results in (i) the greatest degree of flexibility to determine the drugs that will be preferred by inclusion in formularies and the maximum requirements allowable to restrict access to non-formulary drugs and (ii) the greatest degree of discretion to include or exclude pharmacies from networks.

Adverse Selection in A Competitive or Voluntary Program

A general aspect of voluntary insurance is that people with poor health tend to pick insurance plans that provide the most coverage. Those plans will then have the highest overall cost and higher than average premiums, and they will not be able to compete effectively in a competitive model. A competitive model in which beneficiaries choose between different options with different levels of coverage or different formularies raises issues of adverse selection. As noted earlier, prescription utilization is much more subject to adverse selection than most other types of health care services.

For example, if beneficiaries with medical conditions requiring expensive medicines have a choice between two plans with different formularies in an open enrollment period, it is an easy matter to determine which will cover more of their projected expenses and enroll in that plan. This fact will push competing drug plans to offer coverage in each therapeutic category that are preferred by beneficiaries with the lowest overall prescription expenses after considering not only the net cost to the PBM of the drugs (after discounts, patient cost sharing and rebates) but also the other prescriptions the beneficiaries are likely to be using if that drug is being prescribed. For this reason, over time the formularies offered by all competitors are likely to become very similar. There would still be pressure on the manufacturers to set prices in a manner that made their products competitive, which would reduce the cost of the program.

Similar problems are encountered by programs that are open to all applicants without restriction but financed entirely by premiums charged to participants. Insurer experience demonstrates that the average cost for those who enroll will be well above the average of all potential applicants, and that no premium may be high enough to cover the costs of those enrolled. The reason is that the higher the premium, the fewer potential applicants are willing to pay it.

The traditional approach of the insurance business is to carefully screen applicants to remove those who have a substantially higher than average expectation of suffering the hazard insured against, a process referred to as "underwriting." Other approaches that are less successful in reducing the average expected cost are to require long waiting periods for coverage, to exclude coverage of pre-existing conditions (i.e., medical conditions that arose before the insurance becomes effective) for some period of time, and to offer enrollment only during limited periods.

An approach that has proved successful in some kinds of insurance is to offer the coverage in a single initial enrollment period, and to underwrite subsequent applicants. If the insurance offers substantial advantages not available subsequently, many applicants with average expectations of need will enroll, and the cost of those with substantially higher than average need (most of whom will always enroll) will be spread over a larger base of average risks. Another approach is to raise the premium that must be paid for enrollment after an initial period or when first eligible. Another possible solution is to provide some type of adjustment for the plans with higher than average costs due to the health status of the people enrolled in the plan.

The approach used in Part B of Medicare and in most employer sponsored plans is to have a government agency or employer pay a large proportion of the cost, making participation a good actuarial value even for healthy enrollees. An insurer can be confident that with a substantial government or employer contribution, the enrollment in a voluntary program will have a stable and predictable average cost, and that the contract can be managed without risk of an adverse selection cost spiral.

Government programs can be directed toward the low income aged, but offered at the average cost to higher income groups. But when operated in this fashion, enrollment will be much higher among the subsidized income groups. There is, however, a strong subsidy to the upper income groups, based on the difference between their average cost to the program and the average cost of all enrollees. This subsidy to all income groups stabilizes the average cost of the program. Some state programs follow this general design.

Risk Adjustment Mechanisms

One issue that needs careful study is the use of risk adjusted payment mechanisms that take into account the health status of the beneficiaries who participate in the program. Risk adjustment helps to make payments to competing payers more equitable and is especially important to discourage competing PBMs from avoiding beneficiaries with higher than average needs for prescription drugs.

It must be recognized, however, that despite a number of years of development and experimentation, the science of risk adjustment for acute care services is still relatively experimental and that no current system is designed to compensate each competitor for the full financial effects of adverse selection. Further, there is no comparable development of risk adjustment systems for prescription utilization and development could require substantial time and effort.

In addition, risk adjustment calculations depend on having access to accurate information on the health status of beneficiaries. Keeping track of information for a large number of beneficiaries will be difficult (as it has proved for Medicare+Choice plans). Deciding how this information will be used to adjust payments to prescription drug plans will also be a challenge.

Pharmacy Networks

There are a number of issues to consider concerning the network of pharmacies that would be used to provide prescription drugs for beneficiaries. Most of these issues involve network size, pharmacy participation rights and restrictions, and pharmacy incentive programs.

- What would be the appropriate network size and pharmacy access requirements? How would compliance with these requirements be monitored?
- Can performance-based networks and incentive programs with pharmacies for the use of lower cost drugs be used? How would such programs be evaluated and monitored? Would the federal government or the prescription drug plan set the criteria for such programs?
- Can pharmacies be excluded from a network or will all pharmacies willing to accept the terms offered be allowed to participate (i.e., on an "any willing provider" basis)? If all pharmacies are allowed to participate, what sort of requirements or guidelines can fiscal intermediaries use regarding reimbursement levels and/or program participation?

Mail Order Programs

Using mail order capabilities can reduce the cost of drugs because of the lower reimbursement rates to mail order pharmacies. Considerations regarding mail order programs include the following:

- Would mail order benefits be allowed, and, if so, could benefit enhancements be an acceptable means of providing incentives for beneficiaries to use that option? If not, an alternative is to offer a mail order option as a convenience to beneficiaries.
- In a competitive model, would mail order be a standard benefit or something on which prescription drug plans would be allowed to differentiate themselves? If some plans do not have these capabilities, making it an option can increase the number of possible bidders.

Generic Substitution

Maximizing generic substitution can have a dramatic impact on costs. The considerations for generic substitution include the following:

- Will mandatory generic substitution be required? One alternative is to require the beneficiary to pay for the cost difference between the generic and brand drugs.
- In instances where the additional costs are borne by the beneficiary, PBMs use a fee schedule of generic drug costs to calculate the additional cost for the brand drug. Today, PBMs use many different fee schedules, which they either develop internally or obtain from an outside source. Would all of the participating plans be required to use the same national price list, or could they be different?
- Would there be a medical exception process? What criteria and procedures would be used to determine medical exceptions? If a beneficiary satisfies criteria of medical necessity for using a brand name version, would they still pay the difference in cost? Would appeals from this process be allowed?

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- Will fiscal intermediaries be allowed to use their current pharmacy incentive mechanisms to promote generics, such as differentiating pharmacy reimbursement rates based on certain performance metrics?

Drug Utilization Management

The main considerations here are whether to allow utilization management mechanisms and if so, how to measure and monitor them. In particular:

- Would some mechanisms be mandatory and others voluntary? If they are mandatory and it is intended that all beneficiaries are treated similarly, a national P&T committee would need to assure the consistency of criteria and approach across all prescription drug plans.
- Drug utilization mechanisms may be administered differently by fiscal intermediaries because of differences in their operational processes. In addition, some plans may not have the infrastructure to conduct a particular program. How would those prescription drug plans with less sophisticated operational capabilities be treated for the purposes of bidding?
- Criteria to measure payer performance would have to be carefully designed so that they do not provide incentives to maximize or minimize the number of medical exceptions that are made for formulary compliance.
- New programs may be developed because of changes in the drug marketplace, such as a drug losing patent protection. Such changes are usually therapeutic class-specific and can be unpredictable in terms of timing. Performance measurements would need to be program-specific and determined based on the type of drug, the prevalence of the disease it treats, and the appropriateness of the alternatives for certain subsets of the population.

Formularies and Rebates

Perhaps the most important issues relating to the cost effectiveness of any program revolve around the use of formularies. The net prices paid for the products of any manufacturer will vary inversely with the discretion that HCFA or PBMs have to restrict access or increase patient cost sharing for that manufacturer's products. Formularies may be used in any of the basic approaches described, but their effectiveness may vary to the extent that more discretion is permitted and competitive pressure is generated with competition. Purchasing power by itself does not necessarily mean lower prices.

The critical elements of formularies, regardless of the approach, are:

- How broadly therapeutic categories are defined for the purpose of determining minimum coverage that can be offered.
- The minimum number of drugs that must be offered in each category (which could be a single drug).
- The criteria of medical necessity for obtaining coverage of non-formulary drugs, and the procedures must be followed to obtain approval.

- The level of payment, if any, for non-approved non-formulary drugs.

The feasibility of cost savings from formulary selection and from consequent pricing leverage with manufacturers depends on the degree to which there is both the flexibility to limit the selection of expensive medicines for inclusion in the formulary, the difficulty of obtaining coverage of non-formulary drugs and the cost consequences to patients for using non-approved, non-formulary drugs. Accordingly, the primary differences in the cost savings that are feasible under the three basic approaches described above depends on how it impacts these features.

Congress could set very narrow therapeutic categories under any of the approaches (some perhaps including single drugs) which would preclude significant savings. Similarly, the criteria for medical necessity and procedures for obtaining approval for coverage of non-formulary drugs could be set in a manner that undermined the effectiveness of any formulary. (The extreme would be approval of any prescription in which a physician had checked a box on pre-printed prescription forms.)

One of the most important issues with a regional or national single-payer model is whether any formulary would be permitted.

- There would be pressure to have a single national formulary so that all beneficiaries had the same coverage and benefits regardless of where they lived.
- If there were a national formulary, there would need to be an extensive operational capability to decide on exceptions in cases where the formulary drugs were not clinically appropriate.
- A national P&T committee would likely decide which drugs would be on the formulary, and the process of selecting the drugs would be subject to severe political pressures.
- The inability to use a formulary may increase costs above what they would otherwise be. Even if the fiscal intermediary has greater purchasing power, without a formulary, it is unlikely be sufficient to make up for the loss of rebates. Price controls may be the only method for regaining the cost advantage.

With regional PBMs that are permitted to bid with a formulary for the regional franchise, issues that would need to be addressed include:

- Should there be a national or different regional formularies? It would be difficult for regional prescription drug plans to agree on a national formulary. For example, PBMs currently have different pharmaceutical manufacturer relationships. Deciding on a different manufacturer and formulary would either be extremely disruptive to existing clients or would not leverage existing relationships. This could provide less savings that might be expected from a formulary.

For a competitive bid approach, it may be more feasible to have formularies. Issues that would need to be addressed include:

- The definitions of therapeutic categories and the minimum number of products that must be offered in each.
- The degree of difficulty for patients (and their physicians) to obtain approval for dispensing non-formulary drugs.

- Whether drug plans would be allowed to enhance benefits in order to differentiate formulary from non-formulary drugs.

Another issue is how rebates would be handled. Because rebates are not available until well after the prescription is filled, there would need to be a mechanism for getting the value of the rebates back to the payer. Further, if there is coinsurance, deductibles or benefit maximums, how would rebates be taken into account? In addition, if there are performance guarantees to measure rebate performance, they need to be designed to take into account the final net cost of the medications, rather than just the size of the rebates.

The Role of a National P&T Committee

A national pharmacy and therapeutics committee would be needed to determine the formulary and medical criteria required for coverage of non-formulary drugs. If there is a competitive bid program, the P&T committee could be responsible to develop minimum standards. The extent to which the program is cost effective would depend on decisions reached by the committee. This raises many sensitive issues:

- How would the selection and operation of the P&T committee be insulated from direct political pressures.
- When and how a formulary could be changed.
- What to do for people currently on a specific drug therapy that is being removed from the formulary.
- How formulary information should be presented and communicated to beneficiaries and physicians.

Risk Sharing

In designing the overall program, it will be important to decide whether, and to what extent, the payers will be at financial risk for their role in controlling costs. One option is the use of performance guarantees. These measure the payer against specific metrics (e.g., generic index or formulary compliance) and require them to put a certain amount of money at risk for their performance. Another way is making the payer responsible for a portion of the actual drug costs.

In general, a payer such as a PBM would be extremely unlikely to take the risk for all prescription drug costs for reasons indicated in Section I. This is due to the fact that there are a number of factors influencing the overall cost of the Medicare program that are beyond the control of a PBM. Performance guarantees may be the best way, in a single-payer approach, to hold the payer accountable for its performance

The more risk a prescription drug plan takes on, the more program flexibility it would need in order to manage that risk and protection against selection effects. A model under which the payer took partial risk for pharmacy costs could create the need for a risk adjustment mechanism that recognizes the health status of the Medicare beneficiaries for which the payer is responsible.

Cost Sharing Features

All of the benefit design features discussed in Section II would have to be determined as part of the overall program. Under a competitive model the fiscal intermediaries could be allowed to offer variations in cost sharing within permitted boundaries. Under a regional PBM model, or if the only competition is how a uniform plan is administered (including perhaps such features as formularies), there will by definition be no variation in cost sharing among options.

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