Prescription Drug Benefits:
Cost Management Issues For Medicare

by
Peter D. Fox
PDF Incorporated

David Gross, Ph.D., PPI Project Manager

The Public Policy Institute, formed in 1985, is part of the Research Group at AARP. One of the missions of the Institute is to foster research and analysis on public policy issues of importance to older Americans. This paper represents part of that effort.

The views expressed herein are for information, debate, and discussion, and do not necessarily represent formal policies of AARP.

© 2000, AARP.
Reprinting with permission only.
AARP, 601 E Street, N.W., Washington, DC 20049
AUTHOR’S ACKNOWLEDGMENT

This paper could not have been written without considerable help. In particular, Judy Cahill, Executive Director, and Richard Fry, Senior Director of Pharmacy Affairs, with the Academy of Managed Care Pharmacy, offered guidance and suggestions throughout the project, including identifying leading figures in the field for me to contact. Also, the paper has benefited from their careful critique of an earlier draft as well as from the review of: John McGrath, Vice President, Client Programs, Advance Paradigm Clinical Services; Debi Reissman, President, Rxperts; and Jeff Sanders, Senior Vice President, PCS Health Systems. Although most of the interviewing was by telephone, Advanced Paradigm, Inc., in Hunt Valley, MD, hosted a full-day visit. Finally, I am most grateful to the people who were interviewed (listed in the Appendix) and to David Gross, Senior Policy Advisor with the AARP Public Policy Institute, for his guidance and thoughtful suggestions.
FOREWORD

Although prescription drugs have become an increasingly important part of medical treatment, Medicare—the federal health care program for older and disabled Americans—does not pay for prescription drugs bought in outpatient settings. While many beneficiaries have some form of prescription drug coverage, such coverage may be expensive and frequently provides inadequate protection against high out-of-pocket costs. As a result, many Medicare beneficiaries face financial barriers to obtaining their needed prescriptions. A growing awareness of these problems has led to a major public policy debate about whether and how Medicare should provide prescription drugs to Medicare beneficiaries.

One key element in the Medicare drug benefit debate is whether such a benefit should be administered by private contractors, such as pharmacy benefits managers (PBMs). PBMs currently administer drug benefits for many private insurers. This study, by Peter D. Fox, Ph.D. of PDF Incorporated, examines a number of issues that would have to be addressed if PBMs were to administer a Medicare prescription drug benefit. Among these issues are how to structure the benefit; which drugs should be covered by the benefit; how to encourage use of lower cost drugs of equal effectiveness to alternatives; and how to promote appropriate use of prescription drugs.

This paper does not present recommendations. Rather, it sets forth approaches and options, drawing heavily on the experiences of private sector health plans. In preparing the paper, Dr. Fox relies on a combination of: (1) the available literature; (2) extensive interviews with knowledgeable individuals in the field; and (3) his own experience as a managed care consultant in helping private sector health plans address such issues.

Dr. Fox’s analysis and presentation provides useful information to policymakers and policy analysts about the range of issues that must be assessed in developing a Medicare drug benefit.

David Gross, Ph.D.
Senior Policy Advisor
Public Policy Institute
# TABLE OF CONTENTS

**EXECUTIVE SUMMARY** ................................................................................................................. i

I. INTRODUCTION .................................................................................................................................. 1

II. PBM ADMINISTRATION OF DRUG BENEFITS ..................................................................................... 3

III. DRUG COVERAGE OPTIONS ........................................................................................................... 7  
    A. “QUALITY OF LIFE” DRUGS ........................................................................................................ 7  
    B. DRUGS THAT ARE EXPENSIVE AND MARGINALLY EFFECTIVE OR FOR WHICH INDICATIONS FOR USE ARE UNCLEAR ................................................................................................... 8  
    C. SELECTIVE COVERAGE OF NEW DRUGS .................................................................................... 9  
    D. COVERAGE OF OVER-THE-COUNTER DRUGS AND DRUGS WITH OVER-THE-COUNTER EQUIVALENTS .................................................................................................................. 9

IV. THE RELATIONSHIP BETWEEN THE DISPENSING FEE AND THE SIZE OF THE NETWORK ................................................................................................................................. 10

V. INFLUENCING PRODUCT CHOICE: GENERICS VS. BRAND NAME DRUGS .................................. 12

VI. INFLUENCING PRODUCT CHOICE: FORMULARY MANAGEMENT .............................................. 13 
    A. DEFINITIONS ................................................................................................................................. 14  
    B. ENCOURAGING FORMULARY COMPLIANCE ............................................................................. 15  
    C. PHARMACEUTICAL MANUFACTURER REBATES ....................................................................... 17  
    D. MEDICARE FORMULARY OPTIONS ............................................................................................ 17  
       1. Should there be a formulary? ........................................................................................................ 18  
       2. If there is a formulary, who should make formulary composition decisions? .................. 19  
       3. How should formulary compliance be promoted? ................................................................... 20

VII. UTILIZATION REVIEW .................................................................................................................... 20  
    A. PRIOR AUTHORIZATION ............................................................................................................... 20 
    B. STEP THERAPY ............................................................................................................................ 21  
    C. CONCURRENT, OR “POINT-OF-SALE,” REVIEW ..................................................................... 22  
    D. RETROSPECTIVE REVIEW ........................................................................................................... 23

VIII. OTHER COST MANAGEMENT AND ADMINISTRATIVE ISSUES .............................................. 24  
    A. MAIL ORDER PHARMACIES ......................................................................................................... 24  
    B. DISEASE MANAGEMENT ............................................................................................................. 25  
    C. PAYMENT TO PHARMACISTS FOR COGNITIVE SERVICES ..................................................... 25  
    D. PBM ASSUMPTION OF FINANCIAL RISK ................................................................................... 26  
    E. SINGLE OR MULTIPLE PBMS WITHIN A REGION ..................................................................... 26

IX. CONCLUSION ..................................................................................................................................... 27

BIBLIOGRAPHY ......................................................................................................................................... 30

LIST OF INTERVIEWEES .......................................................................................................................... 32
EXECUTIVE SUMMARY

Background

Medicare coverage of prescription drugs has moved to the forefront of the national health policy debate. Two considerations are driving this interest. First, prescription drugs represent a major expense for Medicare beneficiaries. An estimated 35 percent of beneficiaries had no coverage against the cost of prescription drugs in 1999, and for those who did the depth of that coverage was highly variable. Second, advances in pharmacology have led to the development of drugs that can be an integral part of medical practice. While Medicare covers physician office visits, it does not cover what is commonly the major outcome of that visit—a prescription.

Simultaneous with the growing therapeutic importance and cost of prescription drugs has been increasing private sector sophistication in managing drug benefits. As a result, private plans and pharmacy benefits managers (PBM)—companies that administer the drug benefits on behalf of these plans—offer ways to promote more cost-effective drug alternatives and also prevent the consumption of inappropriate drugs while encouraging consumption of needed ones.

Many observers believe that if Medicare were to provide a prescription drug benefit, it would likely be administered through private contractors such as PBMs. This paper identifies key issues related to the private management of the cost and use of a Medicare prescription drug benefit in a fee-for-service environment. It draws heavily on an analysis of techniques that private sector purchasers and state agencies employ to manage their drug benefits.

Methodology

The information in this paper comes from a combination of: (1) a review of the literature; (2) interviews with knowledgeable individuals with experience managing pharmacy benefits; and (3) the author’s experience as a consultant in assisting private sector health plans in evaluating and selecting PBMs.

PBM Administration of Drug Benefits

PBMs perform numerous functions on behalf of health plans with which they contract. These functions include: paying claims, contracting with pharmacy networks, screening pharmacies for evidence of fraud or abuse, establishing and encouraging the use of formularies (lists of drugs that are favored or approved for payment by the plan), negotiating price discounts in the form of rebates with drug manufacturers, performing utilization management, analyzing data, and in some cases performing or assisting with disease management. Although PBMs serve as the agent of the health plan, it is the health plan—not the PBM—that determines benefits and coverage policy and has considerable say on such matters as how to conduct utilization

---

1 In this paper, the term “health plan” refers to an insurance company; a managed care organization (such as a health maintenance organization [HMO]); a self-insured group; and Medicare and state Medicaid agencies, except where they capitate private health plans, such as under the Medicare+Choice program.
management and how to encourage formulary use. Furthermore, PBMs do not assume the financial risk associated with the drug benefit; rather, the health plan maintains this function.

Options and Decisions that Medicare Will Face

Designing and implementing a Medicare drug benefit will require resolving a number of issues relating to administering the benefit. Among the key issues are the following:

1. Which drugs should be covered?

Although Medicare could cover all drugs approved by the Food and Drug Administration (FDA), it could also limit which drugs would be covered in an attempt to reduce cost. One issue is whether to cover so-called “quality of life” drugs, which are drugs that improve patient satisfaction with the quality of their lives but do little to improve medical outcomes or reduce overall health care costs. Examples are: (1) drugs that combat male pattern baldness and (2) topical anti-aging preparations that make facial skin clearer. Many policymakers may not hesitate to exclude these particular drugs from Medicare coverage. However, deciding whether a product can be considered a “quality of life” drug is not always cut-and-dried and will require policy judgments. For example, there are differing views about the therapeutic importance of drugs as diverse as Viagra (for the treatment of male sexual dysfunction) and nonsedating antihistamines (since antihistamines that may be sedating are available at lower cost).

Additional issues to be addressed include:

- whether Medicare should automatically pay for costly drugs that are only marginally effective or which are more effective than existing products for a small proportion of the population;

- coverage of new drugs whose effects and safety when used by older people may not be well understood; and

- coverage for prescription drugs that have over-the-counter equivalents.

2. How broad should the pharmacy network be?

The size and composition of the pharmacy network have implications both for beneficiary access and for the dispensing fees that Medicare will face. There is a tradeoff between the breadth of the network and the dispensing fee that participating pharmacies charge, since pharmacies may be willing to offer discounts in return for having fewer competitors. Medicare can achieve savings by limiting network size, but doing so may reduce beneficiary access. Private sector purchasers generally find that savings of between 2 percent and 3 percent of total drug costs can be achieved by narrowing the network from
one that is extremely broad—with, perhaps, 98 percent of pharmacies—to one with 80 percent to 90 percent of pharmacies. An additional couple of percentage points of savings may be achieved if the network has even fewer pharmacies (e.g., 40 percent to 60 percent). Many health plans elect to have a broad network, concluding that the potential decline in enrollee satisfaction associated with a narrow network outweighs the savings.

3. To what extent, and how, should beneficiaries be encouraged to obtain generic rather than brand name drugs when they are available?

A generic drug is the chemically equivalent compound of a brand-name drug. Generic drugs cannot be produced until after the patent on the brand name drug has expired. The medical and pharmacy professions generally regard generic drugs as equal in quality to their brand name counterparts, as does the FDA. However, a small number of patients in individual circumstances, for reasons that may not be understood, seem to do better on a brand name drug. (Conversely, a small number of patients seem to do better on generics.)

Most health plans encourage the use of generic drugs by incorporating financial incentives into the benefit design, such as by: (1) having coinsurance (e.g., 20 percent or 50 percent), thereby requiring the enrollee to pay a higher amount when a higher cost drug is purchased; (2) instituting a higher copay for brand name than generic drugs (e.g., $10 for brand name vs. $5 for generic); or (3) requiring that the enrollee pay the difference in cost between a generic and a brand name drug. Some health plans elect to waive any financial penalty if the doctor requests that the prescription be “dispensed as written (DAW),” or the plan can require that the doctor justify the medical necessity of dispensing by brand name (for example, by noting that the patient has had a negative reaction to a generic version of the drug).

4. For drugs without a generic equivalent, to what extent, and how, should beneficiaries be encouraged to obtain less expensive brand name drugs that are determined to be equally effective?

Private sector plans generally have formularies, which serve to encourage the use of effective, less expensive alternatives within a given therapeutic category of drugs (for example, anti-ulcer drugs; lipid lowering drugs for treating cholesterol; ACE inhibitors for treating cardiac problems; and SSRIs for treating clinical depression). Health professionals hold that the formulary list should be broad enough to allow physician and patient choice among drugs within a therapeutic class, because therapeutically similar drugs have different chemical compositions and may differ in their physiologic effects on some people. The restrictiveness of the formulary within a therapeutic class generally depends on the extent of differences in physiological effects. For example, formulary choice may be relatively limited for anti-ulcer drugs, which generally have consistent effects. On the other hand, broader selection is viewed as desirable for antidepressants, since patients vary greatly in how they react to different anti-depressives.
A health plan can adopt several types of formularies, the definitions of which are not always used consistently.

- **An open formulary** is one in which prescribed products are reimbursable regardless of whether or not they are on the formulary. However, the health plan or PBM may seek to influence the physician’s choice of product through informational efforts, physician and patient profiling, or telephoning the prescriber to recommend a product switch.

- A **partially closed or incentive-based formulary** has financial incentives for patients to use formulary products or requires patients to obtain prior authorization for certain products.

- A **closed formulary** requires that the patient use only formulary products. However, virtually all so-called closed formularies have an exceptions process. Thus, in practice there is no such thing as a totally closed formulary.

The Medicare program will face choices regarding whether or not there should be a formulary; whether the formulary should be open, partially closed, or closed; what the role of the federal government will be vs. the PBM in making formulary decisions; and how to encourage formulary compliance.

The matter of rebates is closely related to formulary composition as well as to the manner in which formulary compliance is promoted. Rebates from drug manufacturers serve, in effect, to reduce drug prices paid by the health plan. However, since prescription drugs are dispensed primarily through retail pharmacies rather than by the health plan, it is not administratively feasible for the pharmacy’s pricing structure to reflect all of the various health plan or PBM arrangements. Instead, the PBMs (or, in some cases, the health plans, e.g., large HMOs) negotiate rebates with manufacturers. Some people have described rebates, inappropriately, as “kickbacks.” Rather, they should be regarded as discounts that manufacturers pay retroactively in return for the health plan increasing the market share of its products.

Depending on the level of restrictiveness of the formulary and the effort devoted to encouraging formulary compliance, the amount of the rebate can range from $1 to $3 for every prescription that the health plan covers (whether or not the prescription in question generates a rebate). When a PBM is involved, the health plan and the PBM typically share the rebate. For example, the health plan might receive 80 percent of the total amount rebated, with the PBM retaining the balance.
5. How should prescription drug utilization be managed?

Utilization review of prescription drugs focuses on quality of care as well as cost. For Medicare, it will be important that the utilization review process particularly reflect the needs of older beneficiaries, for whom certain drugs are inappropriate or are over-prescribed. Utilization review can occur at three points: (1) before a drug is dispensed, i.e., prior authorization; (2) at the time the prescription is filled, i.e., concurrent review; and (3) after it is filled, i.e., retrospective review.

**Prior authorization** requires that the PBM or health plan approve the use of selected drugs prior to being dispensed for them to be covered. Prior authorization is generally restricted to expensive drugs. The circumstances under which prior authorization might be appropriate include the following:

- The drug is covered only for certain medical conditions, e.g., dexedrine might be approved for attention deficit disorder and narcolepsy but not as a stimulant or appetite suppressor.

- The enrollee or beneficiary is expected to try another, less costly, drug first, e.g., a prescription nonsteroidal anti-inflammatory drug (NSAID) might be allowed only if there is medical justification, such as a failure with an over-the-counter NSAID such as Motrin or generic ibuprofen.

- The drug requires medical monitoring, e.g., before the patient receives the drug certain tests must be run.

**Concurrent, or “point-of-sale,” review** occurs at the time that the pharmacist fills a prescription. Using a computer, the pharmacist sends the prescription and customer identification number to the PBM or health plan electronically, which in a matter of seconds checks eligibility, provides information on whether the drug is approved for payment, and informs the pharmacist of any patient cost-sharing liability. The computer also generates what are known as either “hard” or “soft” edits. A hard edit means that the pharmacist is precluded from filling the prescription, e.g., the drug requires prior authorization or may be appropriate only for patients of certain ages. Soft edits are advisory to the pharmacist, who can act on them or ignore them. Examples of soft edits include: a possible drug-disease contraindication or the drug prescribed appears to duplicate another drug that serves the same purpose. Medicare, should it implement concurrent review, would be able to customize which edits should be applied and which should be hard vs. soft.

**Retrospective review** generally entails profiling physicians, patients, and pharmacists in order to identify inappropriate use (including underuse). Retrospective review can, for example, serve to identify:
• physicians or other prescribers who are outliers in formulary and/or generic usage or who reveal patterns of inappropriate prescribing;

• patients who are not refilling their prescriptions when they should (e.g., for blood pressure medication) or who see multiple physicians, none of whom has a full picture of the drugs that the patient is consuming; and

• pharmacy outlets that may behave inappropriately; e.g., disproportionately dispensing in small amounts, potentially indicating that they may be dividing a single prescription into multiple ones to maximize dispensing fees.

Retrospective review can result in targeted educational efforts with both patients and physicians in the form of letters, telephone calls, or group meetings as well as more intensive disease management or care management programs. It can also serve to identify patterns of particularly high drug usage within a population such as an employer group or geographic area. For example, high use within a geographic area of sedatives or tranquilizers might lead to community-wide efforts to educate physicians about therapeutic alternatives.

Other Cost Management Issues

Medicare would face other cost management issues, as well, in designing a privately-administered prescription drug benefit. These issues include:

• Relying on mail order pharmacies. Mail order pharmacies are able to purchase drugs in larger quantities and at deeper discounts than can most retail pharmacies. Since the mail order pharmacy typically is under the direct control of the health plan or PBM, it can also be more proactive in promoting generics and formulary compliance. Nationally, in 1996 mail order pharmacies accounted for 10 percent of prescriptions filled. Savings typically amount to between 5 percent and 10 percent for those prescriptions that are filled by mail.

• Disease management. The term “disease management” usually conveys programs to assist individuals who have a single or dominant condition, generally chronic in nature, and entails processes for identifying patients, educating them or their doctors about the management of the condition in question, and ongoing monitoring. The programs differ in terms of how co-morbidities are handled, whether there are face-to-face interactions with the patient, the relationship to the primary care provider, and the degree of emphasis on medication compliance.

A major focus of disease management is ensuring that patients follow their drug regimen, e.g., that someone with congestive heart failure (CHF) takes ACE
inhibitors or other medication as prescribed. Disease management programs of PBMs tend to be of the less intensive (as well as less expensive) variety, relying on general printed materials or customized mailings rather than direct contact with physicians or patients, such as through case management programs or classes for patients.

- **Paying pharmacists for cognitive services.** Many pharmacists would like to be reimbursed for counseling patients or coordinating care with a patient’s physician. The problem that arises for Medicare, in common with other insurers, is identifying when a service is beyond the usual functions performed by the pharmacist.

- **PBM assumption of financial risk.** Most PBMs are not interested in assuming financial risk, whether in the form of being capitated for prescription drug benefits or through a risk-sharing arrangement. Examples of private sector risk-sharing exist but are few and far between. PBMs, however, do commonly enter into performance guarantees, with penalties attached if the standards are not met. Standards to which PBMs are commonly held accountable include: amount of rebates generated, overall savings achieved, enrollee satisfaction as measured by surveys, claims processing accuracy, mail order turn-around time, and customer service telephone response time. Medicare may want to determine the relevancy of standards used by private plans to the administration of its prescription drug program.

- **Single or multiple PBMs within a region.** A Medicare prescription drug program is likely to be administered through PBMs, selected on a regional basis. Policymakers will face the question of whether a single PBM should be designated within each region or whether, instead, there should be multiple, competing PBMs.

**Conclusion**

If Medicare covers prescription drugs, a myriad of decisions will be needed on an ongoing and timely basis, e.g. which drugs should be included on any formulary and which should be subject to prior authorization. Furthermore, the rapid rate of product innovation and pricing changes calls for timely decisionmaking that may benefit from its insulation from the political process. These decisions might be best made by an independent body or commission. Two successful models of such bodies are: (1) the Defense Base Closure and Realignment Commission, which has been charged with recommending closing specific military facilities, and (2) the joint consumer-insurance industry committee that was convened by the National Association of Insurance Commissioners to determine the standardized benefit packages under the Medigap reform legislation that was enacted in 1990.
Finally, the federal government should recognize the impact on the private sector, such as the potential to shift costs to the private sector under certain circumstances and the potential to promote monopolistic behavior, such as by channeling a very large volume of claims through any one PBM.
I. INTRODUCTION

Medicare coverage of prescription drugs has moved to the forefront of the national health policy debate. A variety of bills have been introduced in Congress that differ in terms of who should be eligible, how broad the benefits should be, how the program should be financed, and how it should be administered. Whether or not a bill is passed in 2000, the issues will remain prominent.

Two primary factors underlie the interest in a Medicare drug benefit. First, prescription drugs represent a major expense for Medicare beneficiaries. An estimated 35 percent of beneficiaries had no coverage against the cost of prescription drugs in 1999, and for those who did, the scope of that coverage was highly variable. Beneficiaries without drug coverage are projected to have spent an average of $590 a year in 1999. An estimated 25 percent of all Medicare beneficiaries (including those with coverage) had out-of-pocket drug expenses of $500 or more. Furthermore, prescription drug costs have been escalating at double digit rates in recent years. Beneficiaries are considerably more at risk for high prescription drug expenses than for either hospital or physician expenses, given what is covered under both Medicare and the most commonly purchased private policies that supplement Medicare (“Medigap”).

Second, advances in pharmacology have led to the development of drugs that can be lifesaving and that are an integral part of medical practice. For example, new developments in lipid (cholesterol) lowering drugs and heart medication have undoubtedly resulted in improved

---


health status. Medicare covers physician office visits, but not what is commonly the major outcome of that visit: a prescription, which is often more costly than the visit itself.

Simultaneous with the rise in drug costs has been increasing private sector sophistication in managing drug benefits, facilitated by developments in computer technology. In particular, the electronic processing of drug claims has resulted in lower processing costs and far better information than was available a few years ago. As a result, private plans and pharmacy benefits managers (PBMs)—companies that administer the drug benefits on behalf of these plans—are able to promote low-cost alternatives and, to some extent, prevent the consumption of inappropriate drugs while encouraging consumption of needed ones. In many instances, cost management and the promotion of appropriate medication practices are intertwined. For example, one large PBM reported sending 5 million alerts to pharmacies of potentially harmful drug interactions in 1998.

This paper identifies key questions related to the management of the cost and utilization of a Medicare prescription drug benefit in a fee-for-service environment, drawing heavily on the techniques that many private sector purchasers and state Medicaid agencies employ to manage the drug benefit in a fee-for-service environment. Although benefit design is not the primary focus of this paper, it and the ongoing management of the drug benefit are at times intertwined.

The second section of this paper presents an overview of how PBMs generally administer drug benefits. The paper then discusses the following policy “levers” that would be options for Medicare if prescription drugs are covered:

- What drugs should be covered? (Section III)
- How inclusive should the pharmacy network be, since broader networks generally entail paying the pharmacies somewhat higher dispensing fees? (Section IV)
- How can beneficiaries be encouraged to obtain generic drugs, where they are available, rather than more expensive brand name drugs? (Section V)
- For drugs for which generic equivalents are not available, how can beneficiaries be encouraged to obtain less expensive brand name drugs that are believed to be equally effective? (Section VI)

---

6States purchase prescription drug benefits principally through their respective Medicaid programs and their benefit programs for state employees; the federal government does the same through the Federal Employees Health Benefits Program.
• What policy options are available to manage the utilization of drugs within the fee-for-service Medicare structure? (Section VII)

The next-to-last section discusses several other policy issues that Medicare will face if prescription drugs are covered. The paper concludes with a discussion of broad issues associated with the administration of the program.

The information in this paper is derived from three sources. First, extensive interviews were conducted with knowledgeable individuals in the field, including people with extensive clinical and administrative experience in pharmacy benefits administration. (See Appendix.) Statements of a clinical nature reflect these interviews. Second, a literature review was conducted. Third, the author has drawn from his experiences as a consultant assisting private sector health plans to evaluate and select PBMs.

II. PBM ADMINISTRATION OF DRUG BENEFITS

Many private health plans contract with PBMs to manage the drug benefit on their behalf, including paying claims, contracting with pharmacy networks, screening pharmacies for evidence of fraud or abuse, establishing and encouraging the use of formularies (lists of drugs that are favored or approved for payment by the plan), negotiating price discounts in the form of rebates with drug manufacturers, performing utilization management, analyzing data, and in some cases performing or assisting with disease management. PBMs serve as the agent of the health plan, which determines benefits and coverage policy and has considerable say on such matters as how to conduct utilization management and how to encourage formulary use.

Medicare would be such a “health plan” were it to cover prescription drugs under the standard fee-for-service program. It could administer the benefit directly. More likely, however, it would contract with a PBM, as reflected in many of the legislative proposals introduced in the U.S. Congress. This paper assumes that Medicare would contract out this function, whether to an established PBM or another company. Exhibit I shows how the PBM relates to the various parties with a prescription drug benefit:

• The enrollee, i.e., the beneficiary in the case of Medicare.

• The health plan, which determines the benefit package as well as the “rules of the road” that are the topic of this paper. The health plan is the risk-bearing entity. It can, for example, be an insurance company, a managed care organization such as a health maintenance organization (HMO), or a self-insured group. For purposes of this paper, Medicare and state Medicaid agencies are considered to be health
Exhibit I
Key Stakeholders
plans, except where they capitate private health plans, as does the Medicare+Choice program.

- The **pharmacy benefits manager** (PBM), which administers the benefit on behalf of the health plan. Some large health plans, including some state Medicaid programs, administer their drug benefits directly rather than contracting out the function. To date, the policy options discussed for Medicare have focused on a contractor or private health plan performing this function.

- The **physician or other prescriber** authorized under state law to write a prescription.

- The **pharmacy**, whether retail (independent or part of a chain) or mail order.

- The **drug manufacturer**.

- In some cases, an **intermediary** between the manufacturer and the pharmacy, such as a wholesaler, distributor, or repackager.

In some instances (not shown in Exhibit I), the health plan, rather than the PBM, negotiates rebates with the manufacturer and is paid the rebate directly. Also, within a few years, prescriptions are likely to be transmitted from the doctor to the pharmacy via the internet. Doing so will reduce paperwork and allow online edits, such as indications of potentially adverse drug reactions as discussed in Section VII, to be communicated directly and instantaneously to the physician rather than through the pharmacy.

The PBM industry has become large and established. The largest PBMs and the estimated number of lives for which they process claims is displayed in Exhibit II.\(^7\)

Central to administering the drug benefit is claims processing. The electronic filing of claims is more advanced with respect to prescription drugs than any other medical service, with more than 99 percent of PBM claims being processed electronically. This is made possible in large measure by the National Council of Prescription Drug Programs (NCPDP), a private nonprofit organization that has established standards for submitting pharmacy claims

\(^7\)Robert P. Navarro and Suzanne S. Blackburn, “Pharmacy Benefit Management Companies” in Robert P. Navarro (ed.), *Managed Care Pharmacy Practice* (Aspen Publishers, Gaithersburg, MD, 1999), pp. 221-241. Authors obtained data “from PBM reports and websites.” Thus, the data have apparently not been verified, and there could be some double counting if, for example, an individual were covered by one PBM for drugs dispensed through retail pharmacies and another for mail order.
electronically. For very large accounts, PBMs typically charge between 20 and 30 cents to process a claim electronically. This amount is less than one percent of the cost of the average prescription, which is around $35. Other services that the PBMs provide may either be included in the base fee or priced separately. For example, issuing or replacing enrollment cards, selected aspects of utilization review, data reporting beyond producing a standard set of tables, and preparing and distributing of consumer information may entail additional charges.

**Exhibit II**
Major PBMs and Numbers of Enrollees (1999)

<table>
<thead>
<tr>
<th>PBM</th>
<th>Enrollees</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCS Health Systems</td>
<td>60 million</td>
</tr>
<tr>
<td>Merck-Medco</td>
<td>51 million</td>
</tr>
<tr>
<td>Express Scripts</td>
<td>45 million</td>
</tr>
<tr>
<td>Advance Paradigm</td>
<td>27 million</td>
</tr>
<tr>
<td>WellPoint</td>
<td>16 million</td>
</tr>
<tr>
<td>Caremark</td>
<td>10 million</td>
</tr>
<tr>
<td>Medimpact</td>
<td>9 million</td>
</tr>
<tr>
<td>National Prescription Administrators</td>
<td>7 million</td>
</tr>
<tr>
<td>Others</td>
<td>10 million</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>235 million</strong></td>
</tr>
</tbody>
</table>

Because claims processing costs have dropped dramatically as a result of electronic processing, other factors, financial and non-financial, are likely to predominate in evaluating PBMs. Relative performance of these factors is often harder to assess. For example, PBMs generally derive fewer revenues from claims processing than from drug manufacturer rebates, a topic that is discussed in Section VI. Furthermore, how well they perform in promoting use of less expensive products, promoting consumption of medications that can be life saving, and

---

8 Advance Paradigm, a large PBM, reports an average cost per prescription (ingredient cost plus dispensing fee) of $34.35 in 1998. See Advance Paradigm, *Advance Analysis, 1998* (call 1-800-426-4488). As another benchmark, PCS reports (during a telephone interview) an average cost per prescription in 1999 of just under $36 overall. The average cost was $53 for brand name drugs and $9 for generics.

9 Includes Diversified Pharmaceutical Services and ValueRx, both PBMs that Express Scripts acquired.
preventing unnecessary or dangerous medication practices can easily outweigh claims processing cost considerations. Factors other than cost that health plans examine in contracting with PBMs include data analysis and reporting capabilities (including the ability to combine drug and medical claims data), accuracy of claims processing, timeliness in filling mail order prescriptions, the availability of disease management programs, and customer service, such as ease of telephone access and the skill levels of the enrollee service representatives.

An administrative issue that policymakers will face with respect to Medicare is whether to have multiple PBMs or a single PBM available to beneficiaries in a given region of the country. This matter is discussed later in this paper.

III. DRUG COVERAGE OPTIONS

One of the first questions that Medicare will confront is which drugs to cover. It could cover all prescription drugs that have been approved for sale by the Food and Drug Administration (FDA), as do some employers, especially those in highly competitive markets. However, other options are available that can constrain program costs.

A. “Quality of Life” Drugs

“Quality-of-life” drugs are generally defined as those that improve patient satisfaction with the quality of their lives but do little to improve medical outcomes or reduce overall health care costs. A classic example are drugs that combat male pattern baldness, the presumption being that preventing or reversing hair loss does not constitute a medical necessity. Another example is topical anti-aging preparations that mostly result in clearer skin. Many policymakers would have no hesitation about excluding such drugs from Medicare coverage. However, there are other drugs that fall in a gray zone and for which value judgments will be necessary.

An example of a recently released drug that has caused considerable controversy is Viagra. Private health plans have, variously, covered it without restrictions, established monthly limits on the number of pills that can be prescribed, covered it only for patients with documented sexual disfunction, and excluded it altogether.

Some drugs are considered quality-of-life drugs for coverage purposes under some circumstances but not others, e.g., Viagra may be approved only for patients with documented sexual dysfunction. Also, toenail fungus may be considered a cosmetic condition in an otherwise

---

10 For a good discussion on the issues relating to quality-of-life drugs, from which this discussion draws heavily, see: Mary C. Sevon and Devora Mitrany, “Quality-of-Life Drugs: Framing the Issues,” Journal of Managed Care Pharmacy, Vol. 5, No. 3 (May/June 1999), pp. 185-190.
healthy individual but a significant medical problem in someone with diabetes, warranting covering fungicides. As another example, anti-obesity medications might be covered only for a morbidly obese person. Some health plans cover such medication only if the enrollee presents evidence of participating in behavioral modification, wellness, or education programs, e.g., being in an organized exercise program and, also, receiving dietary instruction. However, Medicare would have difficulty administering such a restriction because participation in such programs would be difficult to verify.

Whether certain drugs are considered quality-of-life drugs can be a matter of perspective. For example, nonsedating antihistamines such as Claritin and Allegra, which have been heavily promoted through consumer advertising, are expensive substitutes for drugs that have been on the market for a long time. Some might view reducing sleepiness as medically necessary for someone who operates complex machinery, but not for a non-worker. If budgets are limited, one might assign a lower priority to a drug such as a nonsedating antihistamine than to one that reduces blood pressure. On the other hand, nonsedating antihistamines may help keep Medicare beneficiaries active, allowing them to lead full lives. These drugs could be covered only for beneficiaries who take other sedating drugs, such as a benzodiazepine, to avoid the combined effect of taking two such drugs.11

B.** Drugs that are Expensive and Marginally Effective or for which Indications for Use Are Unclear**

An example of an expensive drug for which the benefits may not be worth the costs are the COX-2 inhibitor drugs (e.g., Celebrex and Vioxx) which were launched in 1999, supported by a heavy advertising campaign. Estimated sales exceeded $1.5 billion the first year on the market.12 These medications reduce pain and inflammation. However, some argue that they are no more effective than over-the-counter nonsteroidal anti-inflammatory drugs (NSAIDs). Their major advantage is that they have fewer gastro-intestinal side effects in some people than considerably cheaper medications, such as ibuprofen, which are available over-the-counter. According to experts consulted for this project, some pharmacologists contend that the circumstances under which use of COX-2 inhibitors are justified remains unclear, particularly since the drug is too new for long-term studies to have been performed.

Another example are the new angiotensin receptor blockers (ARBs), which can substitute for ACE inhibitors. Both products are used to treat certain patients with hypertension or coronary artery disease. Medical experts consider these drugs to be equally effective, but the

---

11 Benzodiazepines are tranquilizers that many medical professionals regard as over-prescribed for older adults.

ARBs are approximately twice the price. Interviewees report that roughly 20 percent of ACE inhibitor patients develop a cough, usually mild but, for some, annoying. Whether the difference in cost is worth the potential added benefit entails a value judgment.

C. Selective Coverage of New Drugs

When a drug is first released for public sale, the information available on it is limited. For example, older people are commonly excluded from clinical trials, as are individuals who take multiple drugs, and rarely are long-term side effects known for drugs in a new class. Arguably, the decision on the appropriateness of new drugs should be between the doctor and the patient, and the fact that a drug is new should not by itself be a reason for exclusion. Some plans routinely exclude from coverage for up to six months new brand-name drugs that are therapeutically similar to existing drugs, particularly if they are more expensive. They may also exclude breakthrough drugs where there are safety concerns. One option would be for Medicare to exclude such drugs until the manufacturer can produce studies that are relevant to an older population.

D. Coverage of Over-the-Counter Drugs and Drugs with Over-the-Counter Equivalents

Few private sector health plans cover over-the-counter (OTC) drugs other than insulin for diabetics. In contrast, most state Medicaid programs cover a specified list of OTC medications and commonly require prior authorization for an equivalent drug that is available only by prescription. Many OTC drugs previously required prescriptions and were subsequently approved for sale in non-prescription strength. However, prescription strength can be achieved by taking a larger quantity of tablets of OTC drugs.

Ibuprofen, an NSAID, is a case in point. It is used to treat pain and inflammation, similar to aspirin, and is available both OTC and by prescription. The prescription version may be higher strength, or may be slow-release, although the chemical formulation to the OTC version is identical. Most plans cover prescription NSAIDs, which can induce the patient to obtain a prescription to obtain the coverage, although the enrollee’s copay for the prescription drug may exceed the full cost of the OTC medication.

Another class of drugs that is available in both prescription and non-prescription form are the histamine (H₂) blockers, such as Zantac, Pepcid, and Tagamet. They are used to treat ulcers and gastro-esophageal reflux disease (GERD), which manifests itself as severe acid indigestion.

The major advantage of covering selected OTC drugs for which the doctor writes a prescription is that they substitute for equivalent, more expensive prescription drugs. However,
doing so may generate added cost in terms of both increased use of the drug itself and physician billings for additional office visits.

IV. THE RELATIONSHIP BETWEEN THE DISPENSING FEE AND THE SIZE OF THE NETWORK

This section illustrates the tradeoff that private purchasers face between the dispensing fee and the size of the network, using representative data based on both my experience contracting with PBMs and interviewing them in preparing this paper. Individual PBMs typically offer their clients several choices in terms of network breadth and composition.

Network size and composition have implications for both beneficiary access and the dispensing fees that Medicare will face. For private sector purchasers, the dispensing fee is inversely related to the number of participating pharmacies, i.e., savings can be achieved up to a point by reducing the dispensing fee, but the tradeoff is lower pharmacy participation rates. Medicare may be able to pay lower amounts than private health plans because of the volume of prescriptions that it represents, although doing so could result in pharmacies having to raise prices for private sector purchasers, a process that is often referred to as “cost shifting.” Another concern is whether too low a dispensing fee runs the risk of endangering the financial viability of some retail, particularly nonchain, pharmacies.

The actual cost of the ingredient incurred by the pharmacy is generally not known to the PBM. Drug manufacturers do, however, publish the “average wholesale price (AWP),” a list price that is almost always above the actual transaction price. As such, the AWP is analogous to the sticker price on a new car, an amount buyers rarely pay. Pharmacies differ in what they pay for drugs. For example, a large chain might obtain a better price for certain drugs than an independent pharmacy because it buys in larger quantities. Overall, the price at which retail pharmacies purchase brand name products is believed to average about 18 percent below AWP. Generics are handled differently, as described below in this section.

For brand name drugs, the standard contract language entails the health plan reimbursing pharmacies the lesser of: (1) the usual and customary cost of the drug at retail and (2) AWP less some fixed percent plus a nominal dispensing fee. A typical arrangement for a broad network, encompassing approximately 98 percent of pharmacies, is for the pharmacist to receive AWP less

---

13 The federal government, on a confidential basis, receives information from manufacturers on the average price paid by wholesalers, known as the “average manufacturer price (AMP).” The AMPs are used to calculate legislatively mandated rebates for Medicaid.

14 Information obtained through interviews with representatives of PBMs.
12 percent plus a nominal dispensing fee of between $2.25 and $2.50. Thus, the true dispensing fee for a broad network is the nominal dispensing fee plus the difference between (1) AWP less 12 percent and (2) the pharmacy’s acquisition cost.

The difference between the nominal and the true dispensing fee can be illustrated as follows:

Assume that a particular drug has an AWP of $36.00 and that the health plan agrees to pay AWP less 12 percent plus a nominal dispensing fee of $2.50. The cost of the drug then will be $36.00 less $4.32 (= 12% of $36.00) plus $2.50, which equals $34.18. However, if the pharmacy obtains the drug for AWP minus 18 percent, the acquisition cost would be $29.52, and the true dispensing fee would be $4.66 (= $34.18 minus $29.52).

A health plan that is willing to narrow the network to 80 to 90 percent of pharmacies in the areas where enrollees live can expect to receive an additional discount off of AWP of between 2 percent and 3 percent, i.e., the payment to the pharmacy would be AWP less 14 percent to 15 percent plus the nominal dispensing fee. An additional couple of percentage points of savings may be achieved if the network has even fewer pharmacies (e.g., 40 percent to 60 percent). Some pharmacies are willing to offer these additional discounts in return for having fewer competitors. Many health plans conclude that the potential decline in enrollee satisfaction associated with having a narrow network outweighs the savings, and therefore elect to have a broad network.

Generics are priced differently from brand name drugs, in part because the ratio of the pharmacist’s acquisition cost to the AWP is lower. Navarro and Penna place the ratio at around half, i.e., the typical pharmacy acquisition cost for generics is AWP less 50 percent. The Health Care Financing Administration (HCFA) publishes a “maximum allowable cost” (MAC) list for most generics for which there are at least three suppliers. The HCFA MAC is generally set at 150 percent above the lowest price in publicly available compendia for a given quantity of a drug. State Medicaid agencies use the HCFA MAC in determining reimbursement, as do some PBMs. Most PBMs, however, develop their own because they find the HCFA MAC list to be slow in recognizing manufacturer pricing adjustments and, at times, not responsive to local market conditions. The pricing that PBMs make available to health plans is, typically, the lesser of (1) the MAC and (2) AWP minus some percentage (an amount that I have seen vary between 12 percent and 45 percent).

V. INFLUENCING PRODUCT CHOICE: GENERICS VS. BRAND NAME DRUGS

In addition to issues concerning the dispensing fees, Medicare will face issues associated with the price of the product and quantity consumed. This section addresses how generic drugs can be promoted where they are available. (Section VI addresses how to encourage consumption of lower cost products within a drug class in situations where generic drugs are not available. Section VII addresses utilization review, which influences the quantity of drugs prescribed.)

Coinsurance, by itself, promotes the use of less expensive products because beneficiaries pay a percentage of costs, as opposed to a copayment, which is a fixed amount that does not vary with the cost of the prescription. However, the cost-sharing structure for Medicare coverage will not be known until legislation is enacted and, in any event, additional cost containment measures besides coinsurance may be appropriate.

A generic drug is the chemically equivalent compound of a brand name drug. Drugs that have generic equivalents are also referred to as “multi-source” drugs. Generic drugs cannot be produced until after the patent on the brand name drug has expired. The medical and pharmacy professions generally regard generic drugs as equal in quality to their brand name counterparts, as does the FDA. However, a small number of patients in individual circumstances, for reasons that may not be understood, seem to do better on a brand name drug. (Conversely, a small number of patients seem to do better on generics.)

Drugs that are not available as generics are referred to as “single source” drugs. Single source drugs, even those within a given class, differ in their biological and chemical properties. As a result, they cannot be freely substituted like generics, creating a different set of issues regarding how to encourage the use of lower cost products when doing so is appropriate. (See the next section of this report, dealing with formulary management.)

Increasingly, health plans mandate or strongly encourage substituting generics for brand name drugs, which under state law can be generally done by the pharmacist without having to consult the physician. Also, all states allow doctors to prevent substitution, such as by checking a “dispense as written” box on a prescribing form or stating “medically necessary” or a similar phrase. Some states require generic substitution unless the patient requests otherwise. Nationally, around 42 percent of drugs are dispensed generically.

PBMs report that a strong incentive to


use generics can increase the rate to around 50 percent; in contrast, if no effort is made to promote generics, the rate is likely to be around 33 percent.

Most health plans encourage generic substitution through cost-sharing differentials. For plans in which enrollees pay copays (i.e., a fixed amount per prescription filled), rather than coinsurance (i.e., a percentage of the cost of the prescription), either of two approaches is adopted. The first is to institute a copay differential, e.g., $5 for a generic and $10 for a brand name drug. Increasingly common is a “three-tier” copay structure, which also creates an incentive to select formulary over non-formulary brand name drugs. (The three-tier copay structure is discussed in the next section of this report.)

The second approach is to hold the enrollee who purchases a brand name drug liable for the difference above the MAC amount if a generic is available. MAC pricing limits can be incorporated into plans that have coinsurance rather than copays.

Under either approach, some health plans elect to waive any penalty if the doctor requests that the prescription be “dispensed as written (DAW),” or the plan can require that the doctor justify the medical necessity of dispensing by brand name (for example, by noting that the patient has had a negative reaction to a generic version of the drug).

A subset of generic drugs is known as Narrow Therapeutic Index (NTI) drugs, i.e., drugs for which there is a small margin between the dose that is large enough to be therapeutic and one that is potentially toxic. Examples include warfarin, a blood thinner, and digoxin, a cardiac medication. The FDA asserts that such drugs can be substituted generically, but some medical professionals disagree. Health plans may, variously: (1) treat NTI drugs as if they did not have generic equivalents, (2) handle them in the same manner as they would any other drug with a generic equivalent, or (3) make a drug-by-drug decision.

VI. INFLUENCING PRODUCT CHOICE: FORMULARY MANAGEMENT

A formulary is a vehicle for encouraging the use of less expensive, appropriate drugs within a class. This section first describes how a formulary works and how private health plans encourage compliance. It then discusses whether Medicare should adopt a formulary and, if so: (1) who will make decisions regarding formulary composition and (2) how compliance might be promoted.

---

18In some instances, the cost of the brand name drug may be below that of the generic equivalent.
A. Definitions

A formulary is a list of drugs approved for use within a health plan or health care setting. Pharmacy benefits managers often emphasize having a **formulary system**, which is the process of continuously updating the formulary and also incorporating formularies into clinical guidelines or treatment protocols.\(^{19}\) Formulary decisions are generally made by a “pharmacy and therapeutics” (P&T) committee, which is comprised mainly of physicians and pharmacists. Sax describes formulary construction as follows: “If safety and efficacy are roughly equivalent and if the product is not particularly unique, then cost can be a determining factor. However, most pharmacy and therapeutics committees continue to base their decisions on safety and efficacy.”\(^{20}\) Dillon and others hold that “Formularies do not work in isolation. The effect on quality is most often noted when formularies are incorporated into clinical guidelines or treatment protocols.”\(^{21}\)

Major price differences often exist within such categories of drugs as anti-ulcer drugs, lipid lowering drugs, ACE inhibitors, and the newer antidepressants. However, the drugs have different properties and may differ in their physiologic effects. Therefore, health professionals generally hold that the formulary list should be broad enough to allow physician and patient choice. The restrictiveness of the formulary within a drug class generally depends on the extent of differences in physiological effects. For example, anti-ulcer drugs generally have consistent effects, and formulary choice might be limited; on the other hand, patients vary in how they react to different antidepressants, and thus broader selection is desirable.

A health plan can adopt several types of formularies, which can be characterized as follows:

1. An **open formulary** is one in which prescribed products are reimbursable regardless of whether or not they are on the formulary. However, as discussed below, the health plan or PBM may seek to influence the physician’s choice of product through informational efforts.

2. A **partially closed** or **incentive-based formulary** has financial incentives for patients to use formulary products or requires prior authorization to obtain certain products.

---

\(^{19}\)Dillon, 1999.


\(^{21}\)Dillon, 1999.
3. A **closed formulary** requires that the patient uses only formulary products, although virtually all so-called closed formularies have an exceptions process. Thus, in practice there is no such thing as a totally closed formulary.

The general trend is away from open formularies and toward listing fewer products within a therapeutic category.\(^{22}\)

**B. Encouraging Formulary Compliance**

Under an **open formulary**, physicians can be encouraged to prescribe formulary or “preferred” drugs in a variety of ways, having differing levels of effectiveness:

1. Printed information may be sent physicians and patients explaining the reasons for the formulary and providing the actual formulary. This information may be in the form of a booklet that ranks specific drugs within a drug class on relative cost, using “$” for inexpensive and “$$$$” for very expensive. Some health plans give patients wallet cards.

2. Physicians and other prescribers may be profiled in terms of their patients who are on formulary vs. non-formulary drugs. To encourage product switches, letters are mailed or faxed to physicians listing the names of patients on non-formulary drugs.

3. The pharmacist or the health plan (or PBM) may telephone the physicians of individual patients suggesting a product switch, a process sometimes referred to as “therapeutic interchange.”\(^{23}\) In most cases, this occurs for refills for chronic medications, although some PBMs will encourage pharmacists to make these calls selectively for new prescriptions. Some PBMs obtain patient permission before calling the patient. Also, some PBMs pay pharmacists incentives that reflect the proportion of drugs dispensed that are on the formulary or may pay for individual phone calls regardless of the resulting number of switches.

---


\(^{23}\)The term “therapeutic interchange” is not always used consistently. Spencer and Crouse define the term as follows: “In general, therapeutic interchange involves the dispensing of a chemically different drug, considered therapeutically equivalent, in place of a drug originally prescribed by a physician.” Unlike for generics, physician permission is required to make a change. See Natalie A. Spencer and M. Therese Crouse, “Drug Policy and Regulation in Managed Care,” in Navarro (ed.) 1999, pp. 525-556.
A partially closed or incentive-based formulary (also known as a “restricted formulary”) can be defined in different ways. The leading example of an incentive-based formulary is health plans’ use of three-tier copay structures. Such a plan design is being adopted at a rapid rate. The three-tier copay structure creates incentives to use generics where available and, if not, to use brand drugs that are on the formulary. The tier with the lowest copay, e.g., $5, applies to generics. An intermediate level of copay, e.g., $10, applies to brand name formulary single-source drugs (i.e., drugs with no generic equivalent). The highest level of copay, e.g., $25, applies to covered non-formulary drugs, including brand name drugs with generic equivalents. Some health plans allow payment at the lower or intermediate level if the doctor submits medical justification for non-formulary products. Other plans reason that the generation of requests to grant exceptions to plans’ copayment restrictions has more to do with physician and patient attitudes than with the patient’s physiology and do not allow for such exceptions. It should be noted that a cost-sharing structure with coinsurance rather than copays has a similar effect as three-tier copays in encouraging cost consciousness.

Huskamp et al., in a recent article, explore incentive pricing for brand name drugs, which would be similar in concept to MAC pricing for generics. Their proposal would entail setting a reference price within a category of therapeutically similar drugs and requiring the beneficiary to pay any excess over the reference price. They point out that a key issue would be how the drugs are grouped. For example, for antidepressants, the reference price would be dramatically different depending on whether the newer, and more expensive, selective serotonin reuptake inhibitors (SSRIs) are treated as a separate category or, instead, are included in the same grouping with the older tricyclic antidepressants.

Another example of a partially closed formulary is one that makes extensive use of prior authorization to obtain certain high cost drugs, as discussed in the next section of this paper.

In theory, a closed formulary means that non-formulary drugs are not reimbursed. However, in practice, virtually every formulary has an exceptions process. In some cases, if the doctor simply submits a statement that the non-formulary drug is medically necessary, coverage is

---

24 Some consider plans with three-tier copay structures to have open formularies, since patients can be reimbursed for any covered drug, although they face higher copays for certain products.

25 For example, United Health Group, one of the largest managed care organizations in the U.S., has announced that it expects to convert most of its enrollment to benefit plans with three-tier copays.

26 Haiden A. Huskamp et al., “The Medicare Prescription Drug Benefit: How Will the Game Be Played,” *Health Affairs*, Vol. 19, No. 3 (March-April 2000), pp. 8-23. Neither the author of this paper nor that of the *Health Affairs* article is aware of this approach having been tried in the U.S. [Based on conversation with Dr. Huskamp.]
authorized. In other cases, exceptions require prior authorization (see Section VII of this paper), with the physician indicating the reason for the non-formulary use.

C. Pharmaceutical Manufacturer Rebates

Rebates are related to the topic of formulary composition and the manner in which formulary compliance is promoted. Many drug manufacturers offer discounts to health plans that increase the manufacturer’s market share by favoring their products. However, prescription drugs are dispensed primarily through retail pharmacies rather than the health plan, and it is not administratively feasible for the pharmacy’s pricing to reflect all of the various health plan or PBM arrangements. Instead, the PBMs (or, in some cases, the health plans, such as large HMOs) negotiate rebates with manufacturers. Depending on the level of restrictiveness of the formulary and the effort devoted to encouraging formulary compliance, the amount of the rebate can range from $1.00 to $3.00 for every prescription that the health plan covers (whether or not the prescription in question generates a rebate). When a PBM is involved, the rebate typically is shared with the health plan and the PBM. For example, the health plan might receive 80 percent of the total amount rebated, with the PBM retaining the balance.

Rebates have been described inappropriately by some people as “kickbacks;” rather, they should be regarded as retroactive discounts that manufacturers pay in return for the health plan enhancing the market share of its products, particularly since a high proportion of the commercially insured population faces fixed copays that make them indifferent to the price of a drug.

Two points are noteworthy in considering the economic impact of rebates. The first is that the aggregate financial impact is significant when one considers that the average price of a prescription is around $35. Thus, rebates can amount to between 3 percent and 9 percent of benefit payments. However, not surprisingly, manufacturers often offer the largest rebates on products that are the more expensive ones within a drug class. Thus, in making formulary decisions, it is the price after taking any rebate into account that should be examined, not the rebate amount per se.

D. Medicare Formulary Options

Medicare has choices in how to approach formularies, each with cost consequences as well as potential consequences for patients and private markets.
1. Should there be a formulary?

Pharmacy manufacturers wishing to sell to Medicaid enrollees are required to give a 15.1 percent discount below the Average Manufacturers Price, which is the price at which they sell drugs distributed through retail pharmacies. However, state Medicaid programs are prohibited from having formularies, and an option for Medicare is to adopt a similar provision. How the savings level achieved by this approach compares with what might be realized through a formulary is not known since the answer would depend on how the formulary is constructed and enforced.

These Medicaid provisions assure savings and avoid politicizing the formulary process as a result of drug manufacturers’ lobbying to have their drugs included. However, this approach treats high and low cost drugs equally. If adopted for Medicare, rather than fostering price competition among manufacturers it is likely to induce drug companies to increase prices to all consumers for those drugs that are heavily used by Medicare beneficiaries. The federal government could preclude such price increases, or not recognize them in setting reimbursement levels. However, such a protection would be temporary since all brand name drugs ultimately lose their patent protection, and the prohibition would not be meaningful for drugs that are newly introduced.

Federal law also requires that manufacturers offer state Medicaid programs the lowest price paid by any private purchaser (after factoring in rebates or other forms of discounts). Products sold to federal agencies, such as the Veterans Administration, the Department of Defense, and the Indian Health Service are exempted from the lowest price calculation.

While this provision has saved money for the federal government, at least two studies have documented that it has also raised private sector prices. This inflationary impact on private sector pricing would be considerably more pronounced were it to apply to Medicare beneficiaries, which represent approximately 36 percent of total outpatient drug expenditures, than it has been

---

27Section 1927(h) of the Social Security Act.

28Legislation passed in 1990 precluded states from having formularies but did allow states to have programs to require prior authorization before a drug could be dispensed. Legislation enacted in 1993, in theory, allows states to have formularies, but it requires that all non-formulary drugs be available, subject to prior authorization. The latter requirement has had the effect of nullifying any change from what existed prior to 1993.

for Medicaid, which represents only 12 percent.\textsuperscript{30} Furthermore, as discussed above, the manufacturers’ best prices are generally granted to health plans that promote formulary compliance, such as by having a closed formulary, which federal statute precludes state Medicaid programs from doing.

2. \textbf{If there is a formulary, who should make formulary composition decisions?}

Health plans and PBMs make formulary decisions on an ongoing basis. Thus, if Medicare adopted a formulary, a mechanism would be needed to make these decisions. Options include the following:

\begin{itemize}
  \item \textbf{Have the decisions made by the federal government.} Doing so would ensure uniformity nationally and would also avoid decisionmaking by private organizations that might not have at heart the best interests of the beneficiaries and the federal government. On the other hand, a single national formulary could have a dramatic impact on private markets, because of the volume that Medicare represents in its own right and, also, because it could induce a shift in physician prescribing patterns for non-Medicare patients as well. Also, having a federal agency make all formulary decisions runs the risk of being politicized. Finally, a national formulary could not reflect local practice patterns.
  \item \textbf{Leave the decision to PBMs or other private agents.} Individual PBMs are accustomed to making formulary decisions for a multitude of clients and would be less subject to political pressure than would the federal government. Differences among PBMs in formulary composition across plans could be studied, thereby allowing the Medicare program to learn about the preferred approaches. Furthermore, these differences would minimize the market dislocations that might be caused by a single formulary and would also allow local practice patterns to be better reflected in formulary composition. On the other hand, it is unclear that PBMs would have the incentive to achieve the right balance between the competing federal objectives of cost containment and assuring beneficiary choice of drugs.
  \item \textbf{Allow PBMs to make decisions but subject to strong federal oversight.} Under this approach, one or more PBMs in a multi-state region would each establish formularies and negotiate rebates, subject to federal oversight. For example, the federal government might: (1) set standards for how formularies are developed and for the minimum number of distinct products that must be on the formulary by class of product and (2) regulate how the PBMs are allowed to promote formulary compliance.
\end{itemize}


-19-
3. How should formulary compliance be promoted?

If the Medicare prescription drug benefit has coinsurance (i.e., cost-sharing that is a percent of the price of the drug in question) rather than copays, the beneficiary would have more incentive to be cost conscious. Formulary compliance can also be promoted through information campaigns directed at doctors and beneficiaries, encouraging both appropriate medication practices and the desirability of prescribing lower cost drugs in situations where they are believed to be equally effective. In addition, a PBM could be given broad latitude in how it promotes compliance, subject to federal guidelines. In short, policymakers can select from among the full range of options used in the private sector.

VII. UTILIZATION REVIEW

This section discusses the following types of utilization review: (1) prior authorization; (2) step therapy; (3) concurrent, or point-of-sale, review; and (4) retrospective review. Importantly, the emphasis of utilization review is—or, at least, should be—on quality of care by promoting the appropriate use of drugs, including underuse, misuse, and overuse, rather than on cost per se. Although the interventions are presented in terms of private sector experiences, they illustrate options that would be available to Medicare. For Medicare, it would be particularly important that the utilization review process reflect the needs of older people, for whom certain drugs are inappropriate or over-prescribed.31

A. Prior Authorization

Prior authorization means the PBM or health plan must approve the use of a drug prior to its being dispensed for it to be covered. The following exemplify the circumstances under which prior authorization might be appropriate.32

- **The drug is covered for certain conditions only.** For example, dexedrine might be approved for attention deficit disorder and narcolepsy but not as a stimulant or appetite suppressor. Also, Viagra might be approved only where there is evidence of a sexual disfunction.


32The examples below mostly reflect the health benefits plan of the United Mine Workers of America Health and Retirement Funds, which has 74,000 participants, all mine worker retirees and dependents, 85 percent of whom are on Medicare.
• **Certain drugs must be tried first because they are less costly.** For example, unless there is medical justification, the health plan might require a failure with an over-the-counter NSAID such as Motrin or generic ibuprofen before covering a prescription NSAID. As another example, Ticlid, a blood clotting inhibitor, might be allowed only for patients who have a documented risk of stroke and have tried aspirin first.

• **Prior approval is required for selected drugs that are commonly misprescribed, unless they are prescribed by certain specialists who have specialized expertise.** For example, Neurontin, used for the treatment of epilepsy, might require prior authorization unless prescribed by a neurologist.

• **Prior authorization is required to ensure that appropriate medical monitoring is in place.** For example, Epogen and Procrit are used to enhance red blood cell production, such as for certain cancer, AIDS, and renal patients; the health plan might want to ensure that blood pressure is under control and that certain lab values are normal. As another example, if Rezulin is prescribed for someone with diabetes, the health plan may want to ensure that liver functions tests are being performed periodically.

Prior authorization usually entails the prescriber telephoning or submitting a form to the health plan or PBM.\(^\text{33}\) Also, the retail pharmacist may provide the information to the health plan if he/she has it available. The circumstances under which prior authorization is required should be clearly communicated to physicians so that the process can occur before the patient faces a possible denial of payment at the pharmacy. In developing a prior authorization process, an important consideration is the cost and burden confronted by the various parties: the patient, the physician, the retail pharmacist, and the pharmacist reviewer at the health plan or PBM. State Medicaid programs use prior approval more extensively than private health plans because federal law precludes them from having formularies. For example, Iowa requires prior authorization for brand name NSAIDs, whereas some plans would exclude these drugs from the formulary.

**B. Step Therapy**

**Step therapy** is an alternative to prior authorization for some drugs. It entails encouraging patients to try lower cost drugs before consuming higher cost ones that might be in a different drug class. This process can often be automated, thereby obviating the need for the physician to contact the health plan. For example, in treating certain gastro-intestinal problems, a

\(^\text{33}\)Within a few years, this process is likely to be handled over the Internet.
requirement might be instituted for the trial of a generic histamine blocking drug (which is also available in non-prescription form) before the more expensive proton pump inhibitors (PPI) will be covered, unless there is medical justification for taking the PPI initially.\textsuperscript{34} The authorization can be automated for most patients because it is granted based on a review of the claims file. For example, in treating hypertension the claims system can report whether the patient has tried the less expensive and generally effective combination of diuretics and beta blockers before approving more expensive medication such as ACE inhibitors.\textsuperscript{35}

Another approach to step therapy is through physician education, e.g., encouraging trials of first or second generation antibiotics prior to using more expensive later generation drugs.

C. Concurrent, or “Point-of-Sale,” Review

Concurrent, or “point-of-sale,” review occurs at the time the pharmacist fills a prescription. It represents a major advance that has been enabled by the electronic processing of claims. The function is generally included in the cost of claims processing rather than being separately priced. The pharmacist receives the prescription from the patient or the doctor and enters it into the computer along with the identification number of the patient. The information is sent electronically to the PBM or health plan, which, in a matter of seconds, checks eligibility, provides information on whether the drug is approved for payment, and informs the pharmacist of any patient cost-sharing liability.

The computer also generates what are known as either “hard” or “soft” edits, which the PBM can, to a significant extent, customize for its individual clients. A \textbf{hard edit} means that the pharmacist is precluded from filling the prescription. The following are examples of hard edits:

- Refill too early. For example, the health plan might require that 75 percent of the number of days supply have passed before a refill will be covered, although exceptions can be granted (e.g., the enrollee will be out-of-town).

- Drug requires prior authorization.

\textsuperscript{34}PPIs may be warranted for patients with gastro-esophageal reflux disease (GERD) who do not respond to histamine (H\textsubscript{2}) blocking drugs, which are available over-the-counter.

\textsuperscript{35}The reason for prescribing ACE inhibitors for hypertension is usually not that the beta blocker/diuretic combination is ineffective but that it causes sleepiness in some patients.
• Drug not appropriate for age, e.g., growth hormones for an adult (although they may be appropriate for someone with AIDS).

**Soft edits** are advisory to the pharmacist, who can act on them or ignore them. Examples include the following:

• Drug-drug interaction. The health plan may elect to treat particularly dangerous drug-drug interactions as hard edits.

• Drug appears to duplicate another drug that serves the same purpose, e.g., two benzodiazepines, such as Valium and Xanax, or two H₂ anti-ulcer medications such as Zantac and Pepcid. Therapeutic duplication can also be a hard edit.

• Possible drug-disease contraindication.

• Prescription refill late, a possible indicator of drug underuse. For example, if a hypertension medication is filled an apparently overly long time after the previous fill, it may indicate that the patient should be counseled regarding the need to follow the prescribed treatment regimen. This information can also serve to generate a call to the patient or the doctor.

The hard edits are clearly effective because they inform the pharmacist that if the prescription is filled contrary to instructions, it will not be reimbursed. On the other hand, the prevailing view among experts is that pharmacists generally ignore soft edits because of the time pressures under which they operate and the lack of incentive to counsel patients or call doctors.

One study of the effectiveness of point-of-sale review conducted in the Medicaid programs estimated savings to range from $500,000 for West Virginia to $22 million for New York.³⁶ Unfortunately, neither population nor utilization data necessary to calculate savings rates are provided.

### D. Retrospective Review

Retrospective review entails analyzing the pattern of care after the prescription is dispensed. This capability is important because multiple prescribers may not be informed of all of the medications that a patient is taking. Claims data can be analyzed to determine whether:

physicians or other prescribers are outliers in formulary and/or generic usage (such information may be also reveal patterns of inappropriate prescribing);

patients are taking medications inappropriately, e.g., not refilling their medications when they should; or

pharmacy outlets are behaving inappropriately, e.g., disproportionately dispensing in small amounts, potentially indicating that they may be dividing a single prescription into multiple ones to maximize their dispensing fees.

Retrospective review can result in targeted educational efforts with both patients and physicians in the form of letters, telephone calls, or group meetings as well as more intensive disease management or care management programs. Retrospective review can also serve to identify patterns of particularly high drug usage within a population, such as an employer group or geographic area. For example, high use of sedatives or tranquilizers within a population might lead to community-wide efforts to educate physicians regarding the appropriate use of these medications.

Retrospective review can be performed by either the PBM, if there is one involved, or the health plan, i.e., HCFA or its carrier/intermediary in the case of Medicare. Retrospective review is most powerful if drug and medical data are combined to obtain as complete a picture as possible of both patients and providers. One limitation, however, is that prescription drug claims do not include diagnostic information, although diagnosis may be inferred from the medication, and physician recording of diagnostic information in patient records is often inaccurate or incomplete.

VIII. OTHER COST MANAGEMENT AND ADMINISTRATIVE ISSUES

A. Mail Order Pharmacies

Mail order pharmacies are able to purchase drugs in larger quantities and at deeper discounts than can most retail pharmacies. Since the mail order pharmacy is under the direct control of the health plan or PBM, it can also be more proactive in promoting generics and formulary compliance. Estimating savings is difficult but savings typically amount to between 5 percent and 10 percent of costs for mail order prescriptions. However, there may be some waste because the prescriptions tend to be of larger size (for example, a three-month supply compared to a one-month supply that might be filled in a local pharmacy). Also, many health plans have lower copays for mail order drugs to encourage their use, resulting in some offset to savings.
Nationally, mail order pharmacies accounted for 10 percent of prescriptions filled in 1996.\textsuperscript{37} PBMs generally report this percent to be in the low teens where there are mild plan design incentives to use mail order, such as reduced copayments. Some view mail order pharmacy as more of a convenience for enrollees, particularly for older people with mobility problems, than as a way of achieving savings.

B. Disease Management

The term "disease management" generally refers to programs to assist individuals who have a single or dominant condition, generally chronic in nature, by identifying patients, educating them or their doctors about the management of the condition in question, and ongoing monitoring. The programs differ in how co-morbidities are handled, whether there are face-to-face interactions with the patient, the relationship to the PCP, and the degree of emphasis on medication compliance.

A major focus of disease management is ensuring that patients follow their drug regimen, e.g., that someone with congestive heart failure (CHF) takes ACE inhibitors or other medication as prescribed. Many PBMs offer disease management as separate modules that can be purchased. They tend to be at the "lighter" end, relying on general printed materials or customized mailings rather than more intensive approaches that entail direct contact with physicians or patients, such as case management programs or classes for patients. An illustration of a PBM-based disease management program is that of the United Mine Workers of America Health and Retirement Funds, which provides health benefits to some 74,000 retirees and their dependents, 85 percent of whom are on Medicare. The PBM periodically analyzes its claims to identify diabetics, who are sent mailings encouraging proper self-care. The mailings are based on the guidelines of the American Diabetes Association.

C. Payment to Pharmacists for Cognitive Services

Many pharmacists would like to be reimbursed for counseling patients on appropriate medical use, and pharmacists in some HMOs play roles in counseling patients. Another form of a cognitive service entails coordinating care with a patient’s physician. The problem that arises in Medicare fee-for-service is identifying when a service is additional to what a pharmacist normally does. An evaluation of a pilot that entailed paying pharmacists for cognitive services conducted by the State of Washington Medicaid program found that the number of such services did not increase in response to additional payment.\textsuperscript{38} However, this is only one study of a single pilot.

\textsuperscript{37}Cook, 2000.

PCS Health Systems has undertaken several small pilot studies in which pharmacists are paid for cognitive services and preliminary results, as yet unpublished, are encouraging.

D. PBM Assumption of Financial Risk

Most PBMs are not interested in assuming financial risk, whether in the form of being capitated for prescription drug benefits or through a risk-sharing arrangement. Examples of private sector risk-sharing exist but are rare. PBMs do, however, commonly enter into performance guarantees, with penalties attached if the standards are not met. Medicare would likely want to determine the relevance of these standards to the administration of a prescription drug program. Examples of standards to which PBMs are held accountable include: amount of rebates generated, overall savings achieved, enrollee satisfaction as measured by surveys, claims processing accuracy, mail order turn-around time, and customer service telephone response time.

E. Single or Multiple PBMs Within a Region

The presumption in public policy debates to date has been that regional PBMs would administer a Medicare drug program, except to the extent that it is administered by comprehensive health plans (such as Medicare+Choice plans) that are responsible for the full range of medical services. One controversial issue at hand is whether, within a region, there should be a single or multiple PBMs to provide coverage to the non-Medicare+Choice population.

Proponents of having multiple PBMs in a region argue that:

- They would give the beneficiary choices, which would encourage high service levels. If the PBMs have some discretion over formulary composition, subject to federal oversight to assure its adequacy, beneficiaries taking chronic medications would have greater opportunity to select a PBM that included a particular drug on its formulary.

- Multiple PBMs, each having some latitude subject to federal oversight, would be less likely to be subject to political interference, such as with respect to formulary decisions.

• The opportunity for a PBM becoming dominant in a region, including unilaterally establishing the norm of prescribing practice for physicians (e.g., in choice among brands) would be reduced.

• For those older people who have drug coverage under their Medigap policies, multiple PBMs would increase the likelihood that claims could be processed by a single carrier, since many PBMs also process claims for Medigap carriers.

However, multiple PBMs have disadvantages:

• Choosing a PBM can be technical, and many beneficiaries may not have the ability to make informed choices, creating consumer confusion and rendering meaningless the notion of competition. Indeed, there is little or no private sector experience with PBMs’ competing for individual enrollees rather than for clients.

• Multiple PBMs would likely result in higher marketing costs as each PBM vies for enrollment. To some extent, the ability of health plans to market could be constrained, such as by limiting marketing budgets or the manner in which PBMs advertise.

• Multiple PBMs would add complexity to the process of administering a prescription drug program.

• Attention would have to be paid to the basis of competition as well as the decisionmaking latitude afforded the PBMs. Depending on how the PBMs are compensated, issues of risk selection might arise, which would weigh in favor of restricted or tightly enforced formularies. On the other hand, the PBMs might compete to have lax formularies to attract enrollees. Little is known about how to design a payment system that achieves the proper balance.

IX. CONCLUSION

Private health plans, on a regular and timely basis, change their formularies, make decisions regarding which new drugs are covered and which require prior authorization, adjust the prices paid pharmacists for generic drugs, and so forth. This process contrasts with that of the current Medicaid program, which by law precludes states from having formularies or making decisions on which drugs may be excluded from coverage as medically unnecessary. Also, many
PBMs and private health plans do not rely on the federal MAC limits for generic drugs because they find that the pricing adjustments are often late and fail to reflect local market conditions.

Thus, in designing a Medicare prescription drug benefit, consideration should be given to whether to institute a degree of insulation from political pressures by appointing an independent body or commission. Such a body could be empowered to make operating decisions with respect to many of the topics addressed in this paper such as:

- the drugs that Medicare should cover, especially newly introduced ones;
- the drugs that should be subject to prior authorization as well as the criteria for approval;
- if there is a MAC pricing structure for generics, the pricing adjustments are made in response to changing market conditions;
- guidelines for formulary decisions;
- utilization management and quality assurance; and
- PBM selection and performance oversight.

There are two successful precedents. The first is the Defense Base Closure and Realignment Commission, which was charged with recommending closure of specific military facilities. The second is the process that was established under OBRA ‘90 through the National Association of Insurance Commissioners to determine the 10 standardized benefit packages for Medigap, which, since 1992, have been the only Medigap policies that can be sold. In both cases, Congress assigned to the two bodies a task that was technically complicated and politically contentious. In the case of prescription drugs, decisions would be necessary regarding the charge of the newly created independent body. For example, little or extensive guidance could be given regarding such matters as the latitude in making formulary decisions or deciding which drugs should require prior authorization. In the case of the development of the 10 standardized policies, broad latitude was accorded a committee that the NAIC convened that had equal representation of consumers and industry.

Finally, for a given budget level, a tradeoff exists between increasing beneficiary cost-sharing and the level of control the government exerts on program costs. Some of the choices are relatively noncontroversial. For example, most would agree on the desirability of promoting generic drugs where they are available. Other choices raise tougher issues, e.g.:

- what should be the composition of any formularies and what processes should be followed in making such decisions;
- what drugs, if any, should require prior authorization; and
- how much retrospective profiling should be performed and how should profiling data be used.

The federal government should also recognize private sector impacts, such as the potential to shift costs to the private sector under certain circumstances and the potential to promote monopolistic behavior, such as by channeling a very large volume of claims through a given PBM.
BIBLIOGRAPHY


LIST OF INTERVIEWEES

Jeff Abraham
Merck-Medco Managed Care

Donald Herman
Division of Medical Services
Department of Human Services
State of Iowa

Lee Bernhardt
Advance Paradigm, Inc.

Judith Cahill
Academy of Managed Care Pharmacy

Peter Collis, MD
United Mine Workers of America Health and Retirement Funds

Todd Edgar
Advance Paradigm, Inc.

Joseph Filipek
Advance Paradigm, Inc.

Fran Finnegan
Bureau of Medical Services
Department of Human Services
State of Maine

Richard Fry
Academy of Managed Care Pharmacy

Susan Gaston
Health Care Financing Administration

Diane Giaquinta
StrategiCare

Geoffrey Gibson
1199 National Benefit Fund

James Hook
BlueCross BlueShield Association

John D. Jones
Prescription Solutions

Terry S. Latanich
Merck-Medco Managed Care

Michele M. Lepore
Conseco

Joseph Mahrenholz
Division of Medical Services
Department of Human Services
State of Iowa

John McGrath
Advance Paradigm, Inc.

Terri Smith Moore
United Mine Workers of America Health and Retirement Funds

Susan Morisato
Conseco

Gary Persinger
National Pharmaceutical Council
Debi Reissman
Rxperts

Jeff Sanders
PCS Health Systems

Michael E. Thomas
ExpressScripts

Beth Tortolani
Division of Medical Assistance
Commonwealth of Massachusetts

Karen Williams
National Pharmaceutical Council

Alan Wright, MD
Advance Paradigm, Inc.