Prescription Drug Benefits: Cost Management Issues for Medicare

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Little attention has been devoted in policy circles as to how Medicare would manage an outpatient prescription drug benefit. This article, first, discusses the role of the pharmacy benefits manager (PBM), the entity that processes claims and otherwise helps administer the benefit. It then discusses the major decisions that will be necessary regarding such matters as: which drugs should be covered; how broad should the pharmacy network be; whether there should be incentives to obtain generic rather than brand-name drugs when available; for drugs with no generic equivalent, should there be incentives to obtain less expensive, medically appropriate brand-name drugs; and how should prescription drug utilization be managed.

INTRODUCTION

Two primary factors underlie the interest in a Medicare drug benefit. First, prescription drugs represent a major expense for Medicare beneficiaries. In 1998 an estimated 27 percent of beneficiaries had no prescription drug coverage (Poisal and Murray, 2001), and for those who did, the scope of that coverage was highly variable. However, this figure, which is based on the MCBS conducted by CMS, likely overstates the prevalence of coverage (Fox, Snyder, and Rice, 2003). The U. S. Congressional Budget Office (2002) estimates spending on prescription drugs by Medicare beneficiaries to average $2,440 in 2003, of which 40 percent, or $976, is out-of-pocket. Ten percent of beneficiaries in 2003 can be expected to incur prescription drug expenses, reimbursed and non-reimbursed, of $6,000 or more (Henry J. Kaiser Family Foundation, 2003). Further-more, prescription drug costs have been escalating at double-digit rates in recent years.[1]

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. Indeed, lack of coverage, particularly among beneficiaries with low or moderate incomes, can result in needed drugs not being purchased, in some cases resulting in higher hospital and other medical costs.

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 PBMs—companies that administer the drug benefits on behalf of these plans—are able to promote

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[1] Total drug spending, nationally, increased 12.6 percent in 1999 over the prior year, 16.4 percent in 2000, and 15.7 percent in 2001 (Levit et al., 2003).

low-cost alternatives and reduce 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.

This article identifies key questions related to the management of the cost and utilization of a Medicare prescription drug benefit in a fee-for-service system, drawing heavily on the techniques adopted by many private sector purchasers and various government entities, including in their employee health benefits programs.

The next section of this article presents an overview of how PBMs administer drug benefits. The article then addresses the following policy questions that the Medicare Program will confront:

- What drugs should be covered?
- How inclusive should the pharmacy network be, since broader networks generally entail paying the pharmacies somewhat higher dispensing fees?
- How can beneficiaries be encouraged to obtain generic drugs, when available, rather than more expensive brand-name drugs?
- For drugs for which generic equivalents are not available, how can beneficiaries be encouraged to obtain less-expensive brand-name drugs where they are presumed to be equally effective?
- How can drug utilization best be managed?

The next-to-last section discusses several other policy issues that Medicare faces. The article concludes with a discussion of broad issues associated with the administration of the Medicare Program.

The information in this article is derived from three sources. First, extensive interviews were conducted with individuals who have extensive clinical and administrative experience in pharmacy benefits administration. Second, a literature review was conducted. Third, the author has drawn from his experiences as a consultant assisting private sector health plans and other purchasers of drug benefits to evaluate and select PBMs. On several occasions, this article reports survey data from employers collected by the Pharmacy Benefit Management Institute (2002). Although as good as any of the employer surveys, all of these surveys raise questions of reliability and validity; thus, the data should be regarded as approximations only.

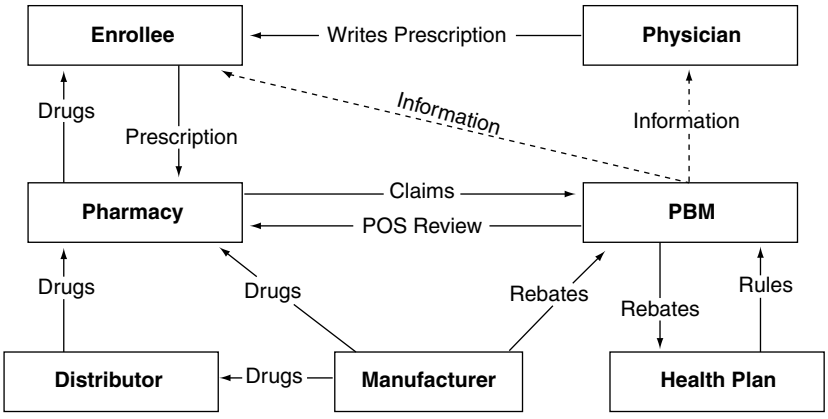
The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), extending prescription drug coverage to Medicare enrollees, was enacted in December 2003. It addressed some of the issues discussed in this article, including legislating that all drugs that can only be dispensed by prescription will be covered; that, in order to avoid excessive market power being concentrated in the federal government, PBMs and other private entities involved in the administration of the program will negotiate prices and establish formularies; and that these entities will absorb a significant share of the risk for the new benefit. In the interest of analytic completeness, the full array of options is presented in this article, including those that are addressed by this legislation.

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

Figure 1

Relationship Between the PBM and Various Parties to a Prescription Drug Benefit



SOURCE: PDF, LLC, Chevy Chase, Maryland (2003).

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.

For purposes of this article, the term "health plan" applies to whatever entity bears the financial risk for medical expenses. It can, for example, be an insurance company, a managed care organization such as a HMO, or a self-insured group. Thus, Medicare and State Medicaid agencies are considered to be health plans, except where they capitate private health plans, e.g., the Medicare+Choice (now referred to as Medicare Advantage) plans.

The MMA contemplates administration by PBMs, which pay claims and perform other administrative functions. Figure 1 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 article.
- The PBM that 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.
- 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 most cases, an intermediary between the manufacturer and the pharmacy, such as a wholesaler, distributor, or repackager.

Central to the administration of 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 has been made possible in large measure by the National Council of Prescription Drug Programs, a private non-profit organization that has established standards for submitting pharmacy claims electronically. For very large accounts, PBMs typically charge between

20 and 30 cents to process a claim electronically, although the fee can vary depending on the rebate arrangements. This amount is less than 1 percent of the cost of the average prescription, which is around $50.[2] 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.

Because claims processing costs have dropped dramatically as a result of electronic processing, other factors, both financial and non-financial, are likely to predominate in evaluating PBMs. For example, PBMs generally derive fewer revenues from claims processing than from drug manufacturer rebates. Furthermore, how well they perform in promoting use of less expensive products, promoting consumption of medications that can be life saving, and 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, formulary construction and enforcement, 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.

[2] AdvancePCS (2003), a large PBM reports an average ingredient cost per prescription, i.e., excluding the dispensing fee, of $44.41 in 2000. The average cost was $66.40 for a brand name, and $14.32, for a generic drug.

OPTIONS AND DECISIONS FACING MEDICARE

Designing and implementing a Medicare drug benefit requires resolving a number of issues relating to administering the benefit. Some of the more critical issues are addressed in this section.

Which Drugs Should Be Covered?

Quality-of-Life Drugs

Quality-of-life drugs are generally defined as those that improve patient satisfaction with the quality of life but do little to improve medical outcomes or reduce overall health care costs (Sevon and Mitrany, 1999). 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 are necessary. Viagra® is a case in point. Private health plans have, variously, covered it without restrictions, established monthly limits on the number of pills that care reimbursed, covered it only for patients with documented sexual dysfunction, 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 healthy individual but a significant medical risk in

someone with diabetes, warranting covering fungicides. As a final example, anti-obesity medications might be covered only for a morbidly obese person.

Whether certain drugs are considered quality-of-life drugs can be a matter of perspective. For example, non-sedating antihistamines such as Claritin® (now available over-the-counter [OTC]) and Allegra®, which have been heavily promoted through consumer advertising, are more expensive than other drugs that have been on the market for a long time but that commonly cause sleepiness. Some might view reducing sleepiness as medically necessary for someone who operates complex machinery but not for a non-worker. On the other hand, non-sedating anti-histamines may help keep Medicare beneficiaries active, allowing them to lead full lives.

Drugs That Are Expensive and Marginally Effective

An example of an expensive drug for which the benefits may not be worth the costs for many current users are the COX-2 inhibitor drugs (e.g., Celebrex™ and Vioxx®), which were launched in 1999, supported by heavy advertising campaigns. These medications reduce pain and inflammation. However, some argue that they are no more effective than OTC non-steroidal anti-inflammatory drugs (NSAIDs). Their major advantage is that they may have fewer gastrointestinal side effects in some people than considerably cheaper medications, such as ibuprofen, which are available OTC.

Another example is the angiotensin receptor blockers, which can substitute for angiotensin converting enzyme (ACE) inhibitors. Both products are used to treat hypertension and coronary artery disease. Medical experts consider these drugs to be equally effective, but the angiotensin receptor blockers are approximately twice the price. Interviewees report that between 5 and 15 percent of ACE inhibitor patients develop a cough, which is usually mild, albeit potentially annoying. Whether the difference in cost is worth the potential added benefit entails a value judgment.

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 6 months new brand-name drugs that are therapeutically similar to existing drugs, particularly if they are more expensive. However, they may also cover the drug sooner if there is favorable evidence from foreign countries, which may have authorized its earlier than in the U.S. health plans 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.

Coverage of OTC Drugs and Equivalents

Few private sector health plans cover 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. Increasingly, for drugs that have both prescription and OTC ver-

sions, private sector plans exclude the prescription version from the formulary. Many OTC drugs had, at one time, required prescriptions but 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, even though doing so may exceed the maximum dosing specified on the label.

Recently, Claritin®, a non-sedating antihistamine, became available without a prescription. Other drugs having roughly the same medical impact such as Allegra® and Clarinex® still require a prescription and are considerably more expensive. Should Claritin® be covered? If not, should the nonprescription alternatives be covered?

Ibuprofin, an NSAID 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 in slow-release form. Most plans cover prescription NSAIDs, although the enrollee's co-pay for the prescription drug may exceed the full cost of the OTC medication. Another example is naproxen, for which OTC equivalents, e.g., Aleve®, are available.

The major advantage of covering selected OTC drugs, when prescribed by a physician, 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.

How Broad Should the Pharmacy Network Be?

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 fewer contracting pharmacies. 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 (i.e., shift costs to) private sector purchasers.

The actual cost of the ingredient incurred by the pharmacy is generally not known to the PBM.[3] 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 that buyers rarely pay. Overall, the price at which retail pharmacies purchase brand-name products is believed to average about 18 percent below AWP.

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 90 percent of pharmacies, is for the pharmacist to receive AWP less 12 percent plus a nominal dispensing fee between $2.25 and $2.50.

A health plan that is willing to narrow the network to 75 to 80 percent of pharmacies in the areas where enrollees live can expect to receive an additional discount off of AWP of between 2 and 3 percent, and a reduction in the nominal dispensing fee to $2. For example, the payment to the pharmacy would be AWP less 14-15 percent plus $2.00. An additional couple of percentage points of savings may be achieved if the network has even fewer pharmacies (e.g., 40 to 60 percent). Some pharmacies are willing to offer these additional discounts in return for the increased volume that results from having fewer competitors

[3] The Federal Government receives information from manufacturers on the average price paid by wholesalers, known as the average manufacturer price, which is used to calculate legislatively mandated rebates for Medicaid.

in the network. Many health plans conclude that the potential for employee dissatisfaction 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 (1999) place the ratio at around one-half, i.e., the typical pharmacy acquisition cost for generics is AWP less 50 percent. CMS publishes a maximum allowable cost (MAC) list for most generics for which there are at least three suppliers. The CMS 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 CMS MAC in determining reimbursement, as do some PBMs. Most PBMs, however, develop their own because they find the CMS 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 varies between 12 and 45 percent.

Promoting Generics

A generic drug is the chemically equivalent compound of a brand-name drug. The medical and pharmacy professions generally regard generic drugs as equal in quality to their brand-name counterparts, as does the Food and Drug Administration (FDA). However, a small number of patients in individual circumstances seem to fare better on a brand-name drug, and conversely.[4]

[4] The FDA establishes a series of tests that a drug must meet to be considered generically equivalent; it allows some deviation in bio-equivalence, which may account for some patients faring better on one drug or another.

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 (Keating, 1998). PBMs report that a strong incentive to use generics can achieve a dispensing rate of 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 co-insurance (i.e., a percentage of the cost of the prescription), either of two approaches, which are not mutually exclusive, can be adopted. The first is to institute a co-pay 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, as discussed later. 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. Under either approach, some health plans elect to waive any penalty if the doctor requests that the prescription be dispensed as written, 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).

Beneficiary education can also serve to promote use of generics. Some consumers are skeptical of generic drugs, believing that brand-name drugs are inherently superior, a perspective that is not supported by clinical research literature.

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, which is 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 narrow therapeutic index 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.

Promoting Less Expensive Brand Name Drugs

For many drugs that do not have generic equivalents, there are alternatives that perform the same medical function, i.e., they are within the same therapeutic class, although they are not chemically equivalent. Examples of therapeutic classes include: anti-ulcer drugs, lipid-lowering drugs for treating cholesterol, ACE inhibitors for treating cardiac problems, and SSRIs for clinical depression.

Private sector plans generally have formularies, which serve to encourage the use of effective, less-expensive alternatives within a given therapeutic class. Health professionals generally hold that the formulary list should be broad enough to allow physician and patient choice among drugs because therapeutically similar drugs have different chemical compositions and may differ in their physiologic effects. The restrictiveness of the formulary within a therapeutic class generally depends on the extent of differences in physiological effects. For example, formulary choice can be relatively limited for anti-ulcer drugs, which generally have consistent effects. On the other hand, broader selection is viewed as desirable for anti-depressants, since patients vary greatly in how they react to different anti-depressives.

There are 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, through a process referred to as therapeutic substitution, the health plan or PBM may seek to influence the physician's choice of product through informational efforts such as newsletters, physician and patient profiling, or by telephoning the prescriber or patient to recommend a product switch. Some 52 percent of employers report that their PBM engages in efforts to promote therapeutic substitution (Pharmacy Benefit Management Institute, 2002).

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

The leading example of an incentive-based formulary is health plans' use of three-tier copay structures, which are coming into widespread use. The three-tier copay structure creates incentives to use generics where available and, if not, to use brand drugs that are on the formulary. Typically, 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 do not allow for such exceptions because they

view requests for exceptions as reflecting primarily the attitudes of individual physicians and patients rather than the patient's physiology.

An alternate approach is to select a reference price within a therapeutic class, e.g., based on the average of the three lowest cost drugs, and require that the beneficiary pay any excess over that price. 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.

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 Pharmacy Benefit Management Institute (2002) reports that 85 percent of employers use a formulary, and 36 percent use a three-tier incented formulary, a percent that is rapidly rising.

The matter of rebates is closely related to both formulary composition and the manner in which formulary compliance is promoted. Rebates from drug manufacturers serve 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 inappropriately described rebates as kickbacks. Rather, they should be regarded as discounts that, for reasons of administrative convenience, 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.

Policymakers face two critical decisions, i.e., whether a formulary should be adopted and, if so, who should decide on formulary composition. Federal law essentially precludes States from adopting formularies in their Medicaid Programs, although they may institute prior authorization requirements, and more than 35 States have done so (Gencarelli, 2003). These Federal 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.

Federal law also requires that manufacturers offer State Medicaid Programs the lowest price paid by any private purchaser (after factoring in rebates and other forms of discounts). Products sold to Federal agencies, such as the Department of Veterans Affairs, 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 (U.S. Congres-sional

Budget Office, 1996; Morton, 1997). This inflationary impact on private sector pricing would be considerably more pronounced were it to apply to Medicare, which represents approximately 36 percent of total outpatient drug expenditures, than it has been for Medicaid, which represents only 12 percent. Furthermore, as previously discussed, the manufacturers' best prices are generally granted to health plans that promote formulary compliance, such as by having a closed or incentive-based formulary, which Federal statute precludes State Medicaid Programs from doing.

Options for making ongoing formulary decisions include the following:

- *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 or 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 and, also, because it could induce a shift in physician prescribing patterns for non-Medicare patients as well. Also, having a Federal agency make formulary decisions runs the risk of being politicized.
- *Have decisions made by an independent, scientific body.* An independent, scientific body, appointed by the President and/or the Congress, could be created that would review the relevant clinical and cost literature. The findings of this body could be binding, or they could be advisory. Assuming that the deliberations were in the public domain, the recommendations would carry considerable weight and could reduce the potential for decisions being politicized.
- *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, given the large market share that Medicare represents. On the other hand, it is unclear that PBMs would have the incentive to achieve the right balance between the competing public policy objectives of cost containment and assuring beneficiary choice of drugs.
- *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.

How Should Prescription Drug Utilization Be Managed?

Utilization review of prescription drugs addresses both quality of care and cost. For Medicare, it will be important that the utilization review process 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 their being dispensed to be eligible for reimbursement. Among employment-based plans, prior authorization is generally restricted to a handful of expensive drugs. Some 77 percent of employers report requiring prior authorization for selected drugs (Pharmacy Benefit Management Institute, 2001). However, some State Medicaid Programs require prior authorization rather broadly as a substitute for having a formulary, which is precluded by Federal law. 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 drug requires medical monitoring, e.g., tests should be run before the patient receives the drug.

Step therapy encourages or requires that patients try lower cost drugs before consuming higher costs ones that might be in a different therapeutic class. Thus, it is conceptually similar to prior authorization. For example, in treating certain gastrointestinal problems, a 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.[5] The authorization process can often be automated by being incorporated into concurrent claims review. For example, in treating hypertension, the claims system can report at the time the prescription is presented to the pharmacist 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.[6] 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. Some 22 percent of employers report requiring step therapy for selected drugs (Pharmacy Benefit Management Institute, 2001).

Concurrent, or point-of-sale, review occurs at the time that the pharmacist fills a prescription and is an integral part of claims processing. 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 hard or soft edits. A hard edit means that the pharmacist is precluded from filling the prescription, e.g., because 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 the edits, including determining which should be hard versus soft.

[5] PPIs may be warranted for patients with gastro-esophageal reflux disease who do not respond to histamine (H2) blocking drugs, which are available OTC.

[6] 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.

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 take drugs inappropriately because they see multiple physicians, none of whom has a full picture of the drugs that the patient is consuming.
- Pharmacy outlets that may behave inappropriately; e.g., disproportionately dispensing in small amounts, raising suspicions 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. Some 69 percent of employers report conducting retrospective review (Pharmacy Benefit Management Institute, 2002).

OTHER COST MANAGEMENT AND ADMINISTRATIVE ISSUES

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 PBM, it can also be more proactive in promoting generics and formulary compliance. Savings are difficult to estimate but typically amount to between 5 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 3-month supply compared to a 1-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 some 12 percent of drug sales in 2001 (National Institute for Health Care Management Research and Education Foundation, 2002). However, this number has been growing in recent years, and for health plans that have strong incentives to use mail order, the percentage can be significantly higher. 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.

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 (Etheredge, 1999). To the extent that they do, they are likely to charge a risk premium, as would any insurer. Examples of private sector risk sharing 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 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.

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 Advantage plans) that are responsible for the full range of medical services. There could be either a single or multiple PBMs within a region. Proponents of having multiple PBMs argue that:

- Multiple PBMs would give the beneficiary choices, which would encourage high service levels. Also, 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 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.

However, multiple PBMs have disadvantages:

- Many beneficiaries lack the ability to make informed choices, potentially 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.
- Multiple PBMs would increase administrative complexity.
- 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.

CONCLUSION

Private health plans, periodically but with some regularity, change their formularies, make decisions regarding which new drugs are covered and which require prior authorization, and 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 instituting 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 article, 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; guidelines for formulary decisions; 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 assignment of responsibility to the National Association of Insurance Commissioners under the OBRA 1990 to determine the 10 standardized benefit packages for Medigap, which since 1992 have been the only Medigap policies that can be sold (Fox, Rice, and Alecxih). 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 National Association of Insurance Commissioners convened that had equal representation of consumers and industry.

Finally, 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 if it were to channel a very large volume of claims through a given PBM.

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REFERENCES

AdvancePCS: *Advisor: 2001 Drug Trends*. Advance PCS Advisor®, Irving, TX. Spring 2001. Internet address: www.advancepcsrx.com (Accessed October 2003.)

Gencarelli, D.M.: *Medicaid Prescription Drug Coverage: State Efforts to Control Costs*. National Health Policy Forum Issue Brief Number 790. Washington, DC. May 2003.

Etheredge, L.: Purchasing Medicare Prescription Drug Benefits: A New Proposal. *Health Affairs* 18(4):7-19, July/August 1999.

Fox, P.D.: *Prescription Drug Benefits: Cost Management Issues for Medicare*. AARP Public Policy Institute Report Number 2000-09. Washington, DC. August 2000.

Fox, P.D., Rice, T., and Alecxih, L.: Medigap Regulation: Lessons for Health Care Reform. *Journal of Health Politics, Policy, and Law* 20(1):31-48, Spring 1995.

Fox, P.D., Snyder, R., and Rice, T.: The Medigap Reform Legislation of 1990: A Ten-Year Review. *Health Care Financing Review* 24(3):121-137, Spring 2003.

Henry J. Kaiser Family Foundation: *Medicare and Prescription Drugs*. The Henry J. Kaiser Family Foundation. Menlo Park, CA. February 2003.

Keating, E.J.: Maximizing Generic Substitution in Managed Care. *Journal of Managed Care Pharmacy* 4(6):557-563, November/December 1998.

Levit, K., Smith, C., Cowan, C., et al.: Trends in U.S. Health Care Spending, 2001. *Health Affairs* 22(1):154-164, January/February 2003.

Morton, F.S.: The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored Customer Rules. *The RAND Journal of Economics* 28(2):269-290, Summer 1997.

National Institute for Health Care Management Research and Educational Foundation: *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs.* Washington, DC. May 2002.

Navarro, R.P., and Penna, P.M.: Measuring the Performance of Managed Pharmacy Benefits Programs. In Wertheimer, A.I., and Navarro R.P. (eds.): *Managed Care Pharmacy: Principles and Practice*. Haworth Press. New York, NY. 1999.

O'Sullivan, J.: *Medicare Prescription Drug Provisions of S.1, as Passed by the Senate, and H.R. 1, as Passed by the House*. Congressional Research Service. Washington, DC. July 2003.

Pharmacy Benefit Management Institute: *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*. Tempe, AZ. 2002.

Poisal, J., and Murray, L.: Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage. *Health Affairs* 20(2):74-85, March/April 2001.

Sevon, M.C., and Mitrany, D.: Quality-of-Life Drugs: Framing the Issues. *Journal of Managed Care Pharmacy* 5(3):185-190, May/June 1999.

U.S. Congressional Budget Office: *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*. U.S. Government Printing Office. Washington, DC. January 1996.

U.S. Congressional Budget Office: *Projections of Medicare and Prescription Drug Spending*. Statement of Director Daniel L Crippen, Before the Committee on Finance, U.S. Senate. March 7, 2002. Internet address: www.cbo.gov/health (Accessed November 2003.)

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