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Pharmacy Benefit Managers

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Summary

The provision of prescription drug coverage to Medicare beneficiaries was a major issue in the 106th Congress, and is likely to continue to be a major issue in the 107th Congress. Much attention is being focused on this issue because of reports about the financial burden that prescription drug prices place on the elderly. Several legislative proposals introduced in the 106th Congress, which may be reintroduced in the 107th Congress, seek to create a prescription drug benefit for the Medicare population that is managed by private entities, including pharmacy benefit managers (PBMs).

All of the major bills introduced in the 106th Congress that would provide a prescription drug benefit for seniors would use private entities (including PBMs) to manage the benefit. Under S. 2342 (the President's bill), S. 2541 (the "MEND" bill), and S. 2758 (the "MOD" bill), the federal government would provide prescription drug coverage to Medicare beneficiaries, but the benefit would be managed by private entities, such as PBMs. H.R. 4680 and S. 2807 (the "Breaux-Frist" bill) would allow private entities contracted by the federal government (likely insurers, or other risk-bearing companies) to provide coverage; these private entities could use PBMs to manage the benefit.

A PBM manages a prescription drug benefit on behalf of the benefit sponsor, which may be a health plan, a health maintenance organization, or an employer. To control costs, PBMs help determine which drugs are used and negotiate prices for those drugs. PBMs control costs by employing mechanisms such as formularies, prior authorization, tiered co-payments, therapeutic substitution, generic substitution, mail order pharmacy services, disease state management, and drug utilization review. Additionally, PBMs negotiate rebates with manufacturers and discounts with retail pharmacies.

This report examines various options that are available to policymakers as they consider whether to make use of PBMs to deliver a prescription drug benefit to seniors under Medicare. With respect to a PBM benefit, the central (though not the only) issue is implementation of cost-control mechanisms. Various techniques are used in the private sector to control costs. As with private sector providers of benefits, policymakers face an array of options that will determine the extent to which the prescription drug benefit is restrictive. This report describes the operation of the PBM industry, its techniques for serving its benefit sponsors and clients, and various issues that are raised by the prospect of employing PBMs under Medicare. This report will be updated as necessary.

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Introduction

The price of prescription drugs receives much attention from both the press and policymakers. The cost of drugs can impose significant financial difficulties on those who do not have health insurance or whose health insurance does not cover prescription drugs. Although there are uninsured in most, if not all, segments of the population, particular emphasis has been placed on the elderly. Most elderly receive health insurance through the government's Medicare program, yet Medicare does not provide coverage for most outpatient prescription drugs. While approximately 65% of the elderly have prescription drug coverage through some sort of non-Medicare supplement, the remaining elderly must purchase their prescription drugs out-of-pocket.[1] Even for those who have some form of prescription drug benefit, coverage may not be sufficient given their medical needs.[2]

There are numerous legislative proposals that attempt to address the prices of prescription drugs for the elderly. One proposal would allow pharmacies to buy prescription drugs from manufacturers at the same prices that the federal government pays for its drugs and let the pharmacies pass the savings on to elderly consumers. Various other proposals would create a prescription drug benefit for the elderly.[3] The proposals to create a drug benefit would rely on private entities to manage the benefit on behalf of the federal government. The private entities allowed to administer the benefit include, but are not limited to, pharmacy benefit managers (PBMs).[4] Finally, some proposals would allow all Americans, including the elderly, to more easily

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[1] Michael M. Weinstein, "For Medicare, A Rocky Road To Competition," *New York Times*, February 21, 1999.

[2] A study performed for the Henry J. Kaiser Family Foundation found that supplemental benefits offered by Medicare HMOs (including a prescription drug benefit) varied greatly in the level of coverage, with some offering very generous coverage while others offered very limited coverage. See "Analysis of Benefits Offered By Medicare HMOs, 1999: Complexities and Implications," The Henry J. Kaiser Family Foundation, August 1999. Another study by the National Economic Council states that the only meaningful form of private prescription drug coverage is retiree drug coverage, and only 25% of the elderly have this type of coverage. See "Disturbing Truths and Dangerous Trends: The Facts About Medicare Beneficiaries and Prescription Drug Coverage," National Economic Council Domestic Policy Council, July 22, 1999.

[3] For a comparison of the various Medicare drug benefit proposals, see CRS Report RL30593 "Medicare: Side-by-Side Comparison of Selected Prescription Drug Bills" by Jennifer O'Sullivan and Heidi Yacker, Updated 20, 2000.

[4] Other entities that would be allowed to participate include private health plans, retail pharmacy chains, insurance companies, and combinations of these entities.

obtain prescription drugs from other countries, where prices may be significantly lower than U.S. prices.[5]

The use of PBMs to manage a senior prescription drug benefit could have many advantages and limitations. One advantage would be that, because PBMs would negotiate prices with manufacturers and pharmacies, the government would not need to take an active role in determining payments for drugs supplied to beneficiaries. Another advantage would be that PBMs could potentially improve the quality of pharmaceutical care that Medicare beneficiaries receive by tracking prescriptions and seeking to prevent adverse drug reactions. However, there could also be limitations to using PBMs for a senior drug benefit. One concern is that drugs may be added to formularies based more on manufacturer rebates than on safety and efficacy. There could also be a public backlash against PBM cost-control techniques if they were to limit access to certain drugs.

The government could restrict the use of certain cost-control techniques, which could reduce the level of savings for the government compared to those achieved in the private sector. These limitations could be minimized in the design of the prescription drug benefit. Formulary guidelines could be developed, the public could be educated about the benefits of PBM cost-control techniques, and costs could be controlled using less controversial techniques, such as tiered co-payments, mail order pharmacy services, and physician education.

This report discusses PBMs in the context of a prescription drug benefit for seniors. The report begins with background information on the structure of the PBM industry. Second, the report provides a description of some of the cost-saving mechanisms that PBMs employ. Third, the report discusses the benefits and limitations that are associated with PBMs' cost-saving techniques. Fourth, the report provides a detailed discussion of PBMs in the context of an outpatient prescription drug benefit for the Medicare population. Lastly, the report presents policy options.

PBM Industry Structure

Numerous companies provide pharmacy benefit management services. The 2000 *Drug Topics Red Book* lists 72 companies in its pharmacy benefit manager directory.[6] According to one source, the top 20 PBMs managed about 70% of all prescriptions covered by private third-party payers and about 47% of all prescriptions dispensed through retail pharmacies.[7] Furthermore, experts note that in 1998, the industry was

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[5] For a summary of these proposals, see CRS Report RL30678, "Prescription Drug Imports: Issues Raised by the Amendments to the FY2001 Agriculture Appropriations Bill" by Donna U. Vogt and Blanchard Randall IV, updated September 18, 2000.

[6] The *Drug Topics Red Book* is a reference guide for pharmacists and other professionals that purchase and supply prescription drugs. It is a companion publication of *Drug Topics*, a periodical about prescription drug issues.

[7] Anna Cook, Thomas Kornfield, and Marsha Gold, "The Role of PBMs in Managing Drug (continued...)

dominated by three firms: Merck-Medco Managed Care, PCS Health Systems, and Express Scripts, Inc.[8] In 1998, these three PBMs handled 64.2% of all prescriptions processed by PBMs and handled 27.1% of all prescriptions dispensed in the United States in that year.[9] The relative sizes of PBMs is continually changing, however. As recently as October 2000, Advance Paradigm, a major PBM, completed its acquisition of PCS Health Systems.

In the early 1990s, three PBMs were acquired by pharmaceutical manufacturers. Concerns were raised regarding the impact of these acquisitions on the competitiveness of the industry. Specifically, some believed that the parent pharmaceutical manufacturers would use their influence over the subsidiary PBMs to give their products preferential treatment on the formulary.[10] To address these concerns, the Federal Trade Commission (FTC) imposed restrictions on some of the manufacturers acquiring PBMs. One such restriction required the PBM subsidiaries to offer open formularies, which include a wide selection of drugs, even those that compete with the parent company's products. In recent years, two of the three pharmaceutical manufacturers that owned PBM subsidiaries have divested these operations because the subsidiaries were unable to significantly increase profitability for their parent companies.[11] Currently, Merck-Medco is the only manufacturer-owned PBM.[12]

However, some PBMs have been purchased by chain retail pharmacies, or chain pharmacies have started their own PBMs. According to the PBM directory published in the 2000 *Drug Topics Red Book,* Eckerd, Kmart, CVS, Walgreen, and Wal-Mart each operate a PBM. As with manufacturer ownership of PBMs, pharmacy ownership of PBMs may raise concerns about conflict of interest. This concern about conflict of interest arises from the fact that a PBM determines how much it will reimburse pharmacies for drugs dispensed to PBM patients. A PBM subsidiary owned by a retail pharmacy could set such low reimbursement rates that other pharmacies would lose money or refuse to do business with the PBM. The PBM's parent retail pharmacy company would accept such a low reimbursement rate because its PBM subsidiary shares in the savings achieved from a low reimbursement rate; in

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[7] (...continued)
Costs: Implications for a Medicare Drug Benefit," prepared for the Henry J. Kaiser Family Foundation, January 2000.

[8] "Prescription Drug Trends – A Chartbook," Henry J. Kaiser Family Foundation.

[9] Ibid.

[10] For more information on the concerns associated with mergers between PBMs and pharmaceutical manufacturers, see "Doubts Emerge About Drug Industry Mergers," *Business & Health*, November 1994. The U.S. General Accounting Office studied the impacts of such mergers. See "Pharmacy Benefit Managers: Early Results on Ventures with Drug Manufacturers," U.S. General Accounting Office, GAO/HEHS-96-45, November 1995.

[11] Elyse Tanouye, "Drug Makers' PBM Strategy Produces Uneven Results; Merck's Purchase of Medco Pays Off, but FDA Move Clouds Future Prospects," *Wall Street Journal*, February 11, 1998.

[12] "Merck-Medco Leads All PBMs in Processing Retail Rxs," *Drug Benefit Trends*, 11(5), 1999.

effect, the revenues from the PBM business would subsidize low reimbursement rates paid to the pharmacy business. The result of a PBM setting such a low reimbursement rate is that the PBM's parent retail company supplies all of the prescriptions for the PBM, to the exclusion of competing pharmacies. Allegations of setting excessively low reimbursement rates have been leveled against Rite Aid (which sold its PBM subsidiary in October 2000) and CVS (which owns PharmaCare Management).[13] Pharmacies that own PBMs argue that the reimbursement rates set by their subsidiaries are sufficient for their retail pharmacies to earn a profit. They suggest that other pharmacies cannot earn a profit on the set reimbursement rates because those pharmacies operate inefficiently.[14] In the case of CVS, independent pharmacies have filed a class action suit against the company. CVS counters that such claims are without merit.

How PBMs Operate: Cost-Saving Mechanisms

In the private sector, PBMs administer a prescription drug benefit on behalf of the benefit sponsor. Benefit sponsors include health plans, health maintenance organizations, unions, and employers. Some health plans contracted under the Federal Employees Health Benefits Program (FEHBP) also use PBMs to administer the prescription drug portion of the health plan. In administering the benefit (including a benefit operated through the FEHBP), PBMs utilize several techniques that lower the cost of the benefit for the benefit sponsor. The following is a description of some of the cost-saving mechanisms employed by PBMs.

Formulary Development

A key element of controlling the costs of a prescription drug benefit is determining which drugs are the most cost-effective. To accomplish this, PBMs develop formularies. A formulary is a list of drugs that the PBM deems to provide the highest benefit to the patient at a relatively low cost. Patients who use drugs included in the formulary will generally save their health plans more money than if the patients were to use non-formulary drugs.

Formularies can be implemented in one of three ways: closed, open, or managed. Under an open formulary, all drugs prescribed for a patient are covered regardless of whether those drugs are included in the formulary. Under a closed (restricted) formulary, the patient's drugs are covered only if those drugs are included in the formulary; if a patient chooses a non-formulary drug, he or she must pay the entire cost of the drug.[15] A third type of formulary is the managed formulary (also known

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[13] See Robert Berner, "Medicine Chess: Pharmacies Say Rates Paid by Rite Aid Unit are Doing Them In," *Wall Street Journal*, June 30, 1999. See also Robert McCarthy, "Mass Appeal...and Suit," *Drug Benefit Trends*, April 1999.

[14] See Robert Berner, cited above.

[15] Closed formularies tend to provide coverage for non-formulary drugs if, for medical reasons, a patient is not able to use a formulary drug. Of course, even if there is no medical

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as a partly closed formulary or an incentive-based formulary). Under a managed formulary, financial incentives are created to encourage the patient to choose formulary drugs over non-formulary drugs. The clients of the PBM (which include health plans, employers, unions, and health maintenance organizations) usually determine how a formulary will be implemented in a given drug benefit.

Generally, PBMs consult with an independent pharmacy and therapeutics (P&T) committee to assist in developing formularies. For a given ailment, there may be several brand-name drugs that are chemically different but can be used to treat that particular ailment. Such drugs are said to be *therapeutically equivalent* or belonging to the same *therapeutic category*.[16] Not every drug in a given therapeutic category may be included in a formulary. The P&T committee evaluates the safety, efficacy, substitutability, and cost of therapeutically equivalent drugs. If the P&T committee believes that one drug provides clear medical benefits over other therapeutically equivalent drugs, then the drug is usually added to the formulary. However, if there are drugs that have very similar characteristics, then, based on the net cost of each drug, the PBM may decide which drug to adopt for the formulary.[17] P&T committees usually consist of physicians, pharmacists, and medical directors; in some cases (about 38% of P&T committees) PBM personnel are committee members.[18] Because of the potential conflict of interest that might arise, many of the largest PBMs do not allow their employees to participate in P&T committees.

The formulary provides an overall guide to which drugs patients should use in order to achieve the greatest savings for the health plan. In general, the drug benefit sponsor determines how the formulary is used, and relies on the PBM to enforce the sponsor's provisions. The formulary is not usually a stand-alone cost-control technique. Rather, to lower costs, formularies tend to be used in conjunction with the following practices:

Manufacturer Rebates. PBMs tend to receive rebates from a pharmaceutical manufacturer if the PBM is able to increase the utilization of the manufacturer's drugs relative to competing manufacturers' drugs (a practice referred to as "moving market share").[19] PBMs move market share by establishing formularies, which encourage patients (or require them, if the formulary is closed) to use certain drugs over competing, therapeutically equivalent drugs. The rebates effectively lower the net

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[15] (...continued)
reason to use a non-formulary drug, a patient can still choose a non-formulary drug and cover the cost out-of-pocket.

[16] For example, antiulcer drugs, such as Zantac, Pepcid, and Axid, belong to one therapeutic category. Antidepressant drugs, such as Prozac, Zoloft, and Paxil, belong to another therapeutic category.

[17] Terry Troy, "Defining Your Firm's Formulary," *Managed Healthcare*, February 1999.

[18] Hoechst Marion Roussel's 1998 *HMO-PPO/Medicare/Medicaid Digest*, cited in "More HMOs Are Using Drug Formularies," *Drug Benefit Trends*, 11(2): 8-9, 1999.

[19] For more analysis on manufacturer rebates, see CRS Report RL30373, "The Cost of Prescription Drugs for the Uninsured Elderly and Legislative Approaches," November 24, 1999.

prices that the benefit sponsor must pay for the prescription drugs its members use. These rebates vary significantly across the industry, and there is no reliable data to suggest the size of such rebates.

Therapeutic Substitution. Within any therapeutic category of pharmaceuticals, there may be several different prescription drugs that perform the same function. A PBM may not include every drug in its formulary; rather, it may include only one or two drugs from each therapeutic category. If a physician prescribes a non-formulary drug, the PBM (or a pharmacist acting on behalf of the PBM) may contact the physician and request that the prescription be changed to a therapeutically equivalent drug that is included in the formulary. If the physician agrees, the patient will be prescribed a lower-cost, formulary drug in place of a higher-cost, non-formulary drug. If the physician refuses to change the prescription, then the lower-cost drug cannot be dispensed to the patient; the patient may or may not have to pay for the additional cost of using a non-formulary drug, depending on how the benefit is structured by the benefit sponsor.

Tiered Co-payments. Beneficiaries may be charged different co-payments, depending on whether a drug is included in the formulary. For drugs that are not included in the formulary, beneficiaries may be charged a higher co-payment than if the drug is included in the formulary. According to one survey released in June 1999, the average co-payment for a brand-name, formulary drug was $12.56 (ranging from $5 to $20) while the average co-payment was $26.53 (ranging from $10 to $50) for non-formulary drugs.[20] Tiered co-payments are also used to encourage patients to choose generic drug over brand-name drugs, which will be discussed later in the report.

Prior Authorization

In certain cases, a health plan will not cover certain drugs unless the member obtains prior authorization. Prior authorization is usually required for drugs that are high cost and/or are likely to be misused (e.g. appetite suppressants, growth hormones). For drugs that require prior authorization, the patient must meet some pre-determined guidelines in order for the drug to be covered. For example, a patient may be required to try an older, less expensive drug first; if this drug proves to be ineffective, then the health plan may cover a newer, more expensive therapeutically equivalent drug.

Retail Pharmacy Discounts

In addition to obtaining rebates from manufacturers, PBMs also obtain discounts from retail pharmacies. A PBM often arranges a network of retail pharmacies. In order to have their drugs covered, patients may be required to use only pharmacies belonging to the PBM's network. The retail pharmacies in the network agree to accept the PBM's reimbursement rate. This reimbursement rate is often lower than what retail pharmacies charge cash-paying customers not covered by a health plan.

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[20] "Class System: Multi-Tier Benefits Take Off; Managed Care Patients Pay More for Non-Formulary Drugs," *Business Wire*, July 30, 1999.

Pharmacies generally accept the lower PBM price because belonging to the PBM's network results in a larger volume of business.[21] The discounted pharmacy price results in additional cost savings for the PBM and its clients.

Generic Substitution

For many brand-name drugs whose patents have expired, generic versions of the drugs are available. Generic drugs have the same active ingredients as the brand-name drugs, although the inactive ingredients may be different. On average, generic drugs are 50% less expensive than their brand-name counterparts.[22] In many cases, a generic drug will be dispensed in place of a brand-name drug even if a brand-name drug was prescribed by the physician. Since 1984, laws facilitating the substitution of brand-name drugs with generic drugs have existed in all 50 states.[23] Generally, pharmacists are allowed to substitute a generic drug for a brand-name drug unless the prescribing physician specifically designates on the prescription that only the brand-name drug is to be used.

Although pharmacies can generally switch to generic drugs without a physician's permission, some consumers may still prefer brand-name products. Generally, the benefit sponsor develops incentives to encourage patients to choose generic drugs when available, and the PBM ensures that the incentives are implemented. Private sector benefit sponsors often choose a tiered co-payment system to encourage the use of generic drugs. The sponsor sets one co-payment for generic drugs, sets a higher one for brand-name drugs included in the formulary, and sets an even higher co-payment for brand-name drugs not included in the formulary. According to one survey released in June 1999, the average co-payment for a generic drug is $6.19 (ranging from $5 to $10) while the average co-payment is $12.56 (ranging from $5 to $20) for brand-name drugs and $26.53 (ranging from $10 to $50) for non-formulary drugs.[24]

Mail Order and Internet Pharmacy Services

Many PBMs operate mail-order (and, more recently, Internet) pharmacies. Benefit sponsors often encourage their beneficiaries to use mail-order services, generally by charging lower co-payments for prescription filled via mail-order and higher co-payments for prescriptions filled at traditional retail pharmacies. Mail-order and Internet pharmacies, because they operate at lower costs than traditional retail

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[21] For more analysis on pharmacy discounts, see CRS Report RL30373 (cited above).

[22] "The Benefit of Generic Drugs," National Association of Pharmaceutical Manufacturers (a trade group for generic drug manufacturers), available at http://www.napmnet.org/Docs/benefitcontent.html.

[23] Roy Levy, "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change," Bureau of Economics Staff Report, Federal Trade Commission, March 1999, p. 18.

[24] "Class System: Multi-Tier Benefits Take Off; Managed Care Patients Pay More for Non-Formulary Drugs," *Business Wire*, July 30, 1999.

pharmacies, tend to be less expensive for the benefit sponsor.[25] Furthermore, because the patient does not expect the prescription immediately, mail order/Internet pharmacies have more time to employ other cost-saving mechanisms, such as seeking physician approval for therapeutic substitution or checking for adverse drug interactions.

Disease State Management

Disease state management (DSM) is an approach to managing prescription drug use with the goal of lowering overall health care costs. DSM also seeks to improve the quality of care by identifying treatments that have been shown by medical literature to offer the best outcomes while at the same time avoiding treatments that have been shown to be ineffective. DSM follows a pre-specified protocol that begins with the first sign of illness. Based on the results of each diagnosis, test, or procedure, the protocol specifies the next step that should be taken to treat the patient.

Because DSM focuses on overall health costs, it may increase the amount that the benefit sponsor spends on prescription drugs. However, a successful DSM program would offset any increases in drug expenditures by lowering expenditures on physician services, hospital procedures, and other medical costs incurred by the PBM client. DSM generally requires an integrated, coordinated approach to medical care, an approach often taken in a managed care setting, such as a health maintenance organization (HMO).

Drug Utilization Review

PBMs perform drug utilization review (DUR) to ensure that drug use is consistent with the PBMs' cost-effectiveness guidelines. DUR evaluates both patient use and physician prescribing behavior. Among the practices examined by DUR are whether a patient was prescribed the proper dosage, whether the patient is refilling prescriptions too frequently (and thus overusing medication or letting medication go to waste), and whether physicians are prescribing more non-formulary drugs than medically necessary. DUR also screens prescriptions for drugs that may be inappropriate for the patient, for dangerous drug interactions, for duplicate prescriptions, for the overuse of controlled substances, and for fraud and abuse. Actions resulting from incidents uncovered through DUR can vary. PBMs may adjust payments or deny claims, send educational material to the physician and pharmacist, or send a letter discussing the patient's condition to the physician or pharmacist. In extreme cases, PBMs may limit a patient's coverage, drop coverage altogether, or remove a physician or pharmacy from its network.[26]

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[25] For example, mail-order and Internet pharmacies can operate from a few regionally located facilities, whereas traditional retail pharmacies must operate many stores located close to customers.

[26] For more description of DUR practices, see John Kralewski, Albert Wertheimer, and Edward Ratner, "Prescription Drug Utilization Review in the Private Sector," *Health Care Management Review*, Spring 1994.

Benefits and Limitations of Cost-Saving Mechanisms

Under normal operating conditions, there are benefits and limitations to the way PBMs employ their cost-saving mechanisms. Some or all of these benefits and limitations might also be expected to occur under a government-sponsored prescription drug plan for the elderly.

Benefits

The obvious benefit of each cost-saving technique is that it contributes to the savings that the PBM can achieve for the drug benefit sponsor. There are several costs associated with administering a prescription drug benefit. The benefit sponsor pays (either fully or partially) for the prescription drugs that the beneficiaries use. Techniques such as therapeutic substitution, manufacturer rebates, retail pharmacy discounts, generic substitution, and mail order pharmacies attempt to lower the net prices that benefit sponsors pay for the beneficiaries' drugs. The cost of a drug benefit is also affected by the quantity of prescription drugs used by beneficiaries. Techniques such as prior authorization attempt to curb the overuse of prescription drugs by beneficiaries, leading to greater savings. Furthermore, the benefit sponsor incurs costs when ineffective medication is prescribed to a beneficiary; in this case the benefit sponsor must pay for the ineffective drugs as well as subsequent treatments until the patient is effectively treated. The PBM program of disease state management (DSM) attempts to limit these costs by limiting the use of drugs that have been proven ineffective. Finally, the benefit sponsor incurs costs when beneficiaries suffer from adverse health effects caused by misuse of their prescription drugs or errors in the prescribing process. PBMs attempt to reduce these costs by engaging in drug utilization review.

Of course, benefit sponsors could implement the cost-saving mechanisms themselves. But PBMs offer the benefit sponsor administrative simplicity. The PBM administers the various cost-saving techniques, while the role of the benefit sponsor is relatively minor. Furthermore, depending on the contract arrangement, the PBM and the benefit sponsor may have a risk sharing arrangement. Under a risk sharing arrangement, the PBM and the benefit sponsor set a target cost per member per month (PMPM). Any differences between the target cost and the actual cost are divided between the client and the PBM. If the actual cost falls below the target cost, the PBM keeps some of the savings. If the actual cost rises above the target cost, then the PBM must bear some of the cost overruns. Under such an arrangement, the risk of unexpected costs is passed partly from the benefit sponsor to the PBM.

Arguably, patients also benefit from the implementation of drug utilization review by PBMs. Drug utilization review, which reviews which drugs a patient is utilizing, can alert health care professionals about potentially harmful drug interactions the patient may experience or patient allergies to certain medications. Such review helps to ensure that the patient is taking the proper medication and prevent future health problems. A PBM is not necessarily needed to ensure that a patient is receiving the proper medication; any physician, pharmacist, or health care practician could consult with the patient to determine what medications the patient is taking if any problems may arise. However, that approach is limited when patients cannot

remember all of their medical history or when patients change physicians and pharmacies. Some experts believe that PBMs are well suited to drug utilization review because they maintain centralized medical profiles of patients. Health care professionals, including those unfamiliar with the patient's history, can access the patient's profile and determine whether a given medication will have adverse effects on the patient.

Limitations

While PBMs provide substantial benefits in the private sector, some commentators are critical of PBM cost-saving mechanisms. These criticisms center around the use of formularies. In particular, commentators believe that the way formularies are developed and implemented reduces safety and quality of care for patients.[27]

A drug is included in formularies based on its characteristics, which include safety, effectiveness, price, and rebates offered by the drug's manufacturer. Some critics are concerned that P&T committees include drugs based more on rebates than on efficacy.[28] Furthermore, in the case where the PBM may be owned by a pharmaceutical manufacturer, critics argue that P&T committees may give preference to drugs manufactured by the parent company.[29] However, only one PBM, Merck-Medco, is owned by a pharmaceutical manufacturer. Merck-Medco does not allow any employee of the PBM or the parent pharmaceutical company to participate on the P&T committee. Other PBMs have adopted similar policies; in many cases, P&T committees do not include representatives of the PBM. This practice is to ensure that the primary decision on whether to include a drug is based on medical concerns rather than financial concerns. According to one survey, the most common members of P&T committees are physicians, pharmacists, and medical directors; only about 38% of P&T committees have PBM personnel as members.[30]

There has also been criticism about the use of therapeutic substitution to promote formulary compliance. As described above, therapeutic substitution involves switching one prescription drug for a drug which is chemically different but achieves the same result. Therapeutic substitution requires a physician's approval.[31] Several physicians have voiced opposition to this cost-control mechanism. These physicians resent the questioning of their medical decisions by a PBM representative, particularly

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[27] See Peter Keating, "The Right Prescription? A Hard Look at the Plan to Extend Medicare to Cover Medications," *Money*, October 1999. See also Robert Pear, "Tracking Just What the Doctor Ordered: Medicare Changes Would Bolster Prescription Management Services," *New York Times*, July 13, 1999.

[28] See Robert Pear, cited above.

[29] See Cook, et. al., p. 35.

[30] Hoechst Marion Roussel's 1998 *HMO-PPO/Medicare/Medicaid Digest*, cited in "More HMOs Are Using Drug Formularies," *Drug Benefit Trends*, 11(2): 8-9, 1999.

[31] Therapeutic substitution is different from generic substitution, which does not require a physician's approval because generic drugs are chemically equivalent to their brand-name counterparts.

since the PBM representative did not examine the patient.[32] It is also argued that patients can potentially suffer adverse reactions when their medications are switched from what was originally prescribed.[33] However, if a physician believes that serious harm would occur from therapeutic substitution, he or she could refuse to change the initial prescription, although this could result in a higher prescription cost for the patient.

PBMs Under a Prescription Drug Benefit for Seniors

Various legislative proposals have been introduced in the 106th Congress that would create a prescription drug benefit for senior citizens. All of these proposals would rely on private entities, including PBMs, to administer the benefit on behalf of the federal government.[34] While a senior prescription drug benefit failed to be enacted in the 106th Congress, some of these proposals may be reintroduced in similar form during the 107th Congress. This section outlines the major legislative proposals that would use PBMs to manage a federally administered senior prescription drug benefit, and discusses how PBMs would operate under these proposals vis-a-vis the private sector. This section also discusses the benefits and limitations associated with using PBMs to manage a prescription drug benefit for the Medicare population.

Major Legislative Proposals

One proposal to create a senior prescription drug benefit is the Medicare Rx 2000 Act (H.R. 4680, Representative Thomas), which was passed by the House of Representatives on June 28, 2000. H.R. 4680 would establish prescription drug coverage provided either by a prescription drug plan (PDP) offered by a plan sponsor or by a Medicare+Choice organization. Beneficiaries would choose among various plans, and the newly created Medicare Benefits Administrator would be required to ensure that beneficiaries have at least two plans (offered by different plan sponsors) from which to choose. PDP providers would have to be licensed by the state to bear risk (i.e., insurance companies) or meet certain solvency criteria established by the Medicare Benefits Administrator.

The Clinton Administration's bill, the Medicare Modernization Act of 2000 (S. 2342, Senator Moynihan, by request) would establish a Medicare prescription drug benefit that is administered by private entities (referred to as "benefit managers"). The Secretary of Health and Human Services (HHS) would have the responsibility of contracting with the entities. The bill does not specify which organizations may

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[32] See Robert Pear, cited above.

[33] Sheryl Gay Stolberg, "Drug Switching Saves Money, but There Is a Cost," *New York Times*, June 13, 1999.

[34] This report provides only a brief description of the proposals. For more detail, see CRS Report RL30584, "Medicare: Selected Prescription Drug Proposals" by Jennifer O'Sullivan, updated September 14, 2000. See also CRS Report RL30593, "Medicare: Side-by-Side Comparison of Selected Prescription Drug Bills" by Jennifer O'Sullivan and Heidi Yacker, updated September 20, 2000.

compete for the contract to administer the benefit, but eligible entities have been described to include PBMs, retail drug chains, and health plans. The government would group beneficiaries into at least fifteen geographic regions, and the government would contract with only one private entity per region. The Medicare Expansion for Needed Drugs (MEND) Act of 2000 (S. 2541, Senator Daschle, et al) would provide a Medicare prescription drug benefit very similar to the Administration's proposal. Eligible entities under MEND include prescription drug vendors, retail pharmacies, health care providers, or any other entity the Secretary may specify, which feasibly could include PBMs.

The Medicare Outpatient Drug (MOD) Act of 2000 (S. 2758, Senator Graham) is another legislative proposal that would use private entities to administer a Medicare prescription drug benefit. Under the bill, the Secretary would designate at least ten different geographic areas and award contracts to at least two entities in each area. Eligible entities include PBMs, health plans, insurers, retail pharmacies, or any other entities approved by the Secretary.

The Medicare Prescription Drug and Modernization Act of 2000 (S. 2807, Senators Breaux and Frist) would establish a new agency, the Medicare Competition Agency (MCA), that would operate outside of HHS. The MCA would contract with private entities to provide a prescription drug plan to beneficiaries. Eligible entities would need to be licensed in a state to bear financial risk, or meet solvency standards determined by the Commissioner of the MCA. An eligible entity could include a PBM, a retail pharmacy delivery system, an insurer, or any entity the Commissioner deems appropriate.

The role PBMs would play in a senior prescription drug benefit differs significantly among the different legislative proposals. Some plans would have the federal government bear the full financial risk of costs associated with coverage. That is, the government would be responsible for paying the costs not covered by the beneficiary cost-sharing provisions. The President's bill (S. 2342), the MEND bill, (S. 2541), and, to some extent, the MOD bill (S. 2758) take this approach. The role of the PBM, or whatever private entity is contracted by the government, is to manage the benefit in exchange for a fee. In the private sector, this approach is equivalent to the arrangement between a PBM and a health plan or an employer. The MOD bill would allow the private entity to take on some financial risk that is tied to its performance in managing the prescription drug benefit; such an arrangement is used in many private sector contracts between PBMs and their clients.

A second approach, which is taken by the Thomas bill (H.R. 4680) and the Breaux-Frist bill (S. 2807), is for a private entity, under contract with the government, to assume a significant portion of the financial risk associated with coverage. That is, the private entity would be responsible for costs not covered by beneficiary cost-sharing, though federal subsidies would offset some of these costs. In the private sector, such an arrangement is equivalent to the relationship between an employer and a health plan; it is also similar to the relationship between the federal government and health plans in the Federal Employees Health Benefits Program (FEHBP). Under this approach, it is not clear whether PBMs would bid directly for contracts with the government, or whether health plans and insurers would be the primary bidders. Some experts have stated that PBMs are reluctant to assume full financial risk

associated with prescription drug coverage.[35] When they do accept financial risk, it is usually tied to their performance in controlling costs on behalf of the benefit sponsor. For example, if the PBM is unable to negotiate manufacturer rebates to the degree promised to the benefit sponsor, then the PBM may have to cover the difference. Conversely, a PBM is generally not responsible for beneficiary costs incurred because, for example, the pool of beneficiaries is relatively unhealthy and needs to use more medications. However, it is possible that, under this approach to a prescription drug benefit for the Medicare population, the health plans contracted with the government would contract with PBMs to manage the benefit. A similar situation occurs with the FEHBP, where some of the health plans in the program use PBMs to administer the prescription drug portion of the benefit.[36]

Differences from the Private Sector

In some ways, the operation of PBMs under the above proposals would differ from how they operate in the private sector. In other ways, however, PBMs would function similarly to the private sector.

One significant difference between the private sector operation of PBMs and the operation of PBMs under a federally administered senior drug benefit would be beneficiary access to negotiated prices. Many of the bills require that the contracted entities allow beneficiaries to pay the prices which the entity negotiated with manufacturers and pharmacies, even when the beneficiary is paying the entire bill (for example, because the beneficiary has not met the deductible or because he or she has exceeded the coverage limits). This is significantly different from the private sector, where PBMs pass negotiated savings directly to the benefit sponsor. It may be feasible for PBMs to pass on savings negotiated with pharmacies directly to beneficiaries; pharmacy reimbursement is determined in a relatively straightforward manner.[37] At the point of sale, such discounts could be deducted from the price that beneficiaries would otherwise pay.

However, passing on rebates negotiated with manufacturers may be more difficult for PBMs. Unlike pharmacy discounts, rebates are determined in a relatively complex manner. Rebates from manufacturers are paid to PBMs quarterly or semiannually. A rebate for a given prescription drug is calculated retroactively based on, among other factors, the volume of that drug dispensed to the PBM's beneficiaries. At any given point of sale for the individual beneficiary, neither the PBM nor the manufacturer will know the size of the rebate that will ultimately be paid. Thus, it would be complicated (if not impossible) for manufacturer rebates to

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[35] Testimony of Carol J. McCall, Executive Vice President for Allscripts, Inc., before U.S. Senate Committee on Finance, March 29, 2000.

[36] For more information on PBMs under the FEHBP, see "Pharmacy Benefit Managers: FEHBP Plans Satisfied With Savings and Services, but Retail Pharmacies Have Concerns" by the U.S. General Accounting Office, GAO/HEHS-97-47, February 1997.

[37] Retail pharmacies are typically reimbursed on a per prescription basis, with the reimbursement expressed as the list price minus a negotiated percentage, plus a fixed dispensing fee.

be paid to the beneficiary at the point of sale; rather, such rebates might need to be paid to the beneficiary months after he or she purchases the medication. Furthermore, manufacturers and PBMs keep rebate information confidential. It has been suggested that if such information were revealed in the transaction price, manufacturers may be discouraged from offering steep discounts.[38] To be more consistent with common PBM practices, some experts have suggested that rebates be passed to the federal government, then passed on to beneficiaries in the form of lower premiums.[39] However, one drawback of this approach is that lower premiums would benefit all beneficiaries equally, and those with higher drug costs would not necessarily receive a greater share of the savings.

Other than requiring negotiated prices to be passed directly to the beneficiary, the above proposals would allow PBMs to operate similarly to how they operate in the private sector. All of the above legislative proposals allow for the private entities to use formularies, although the bills set certain guidelines. The Thomas bill, the Breaux-Frist bill, and the MOD bill require formularies to include all therapeutic categories; The Thomas bill and the Breaux-Frist bills require the formulary to include at least one drug for each therapeutic category, while MOD bill requires that at least two drugs from each category are included. Furthermore, the Thomas bill requires that the formulary be developed by a P&T committee, with at least one member a pharmacist and at least one member a physician. The MOD bill requires that formularies comply with standards developed by the Secretary and a newly created Medicare Pharmacy and Therapeutics Advisory Committee. The President's bill and the MEND bill allow the use of formularies subject to limitations and guidelines set in the contract with the government, but the bills prohibit the Secretary from authorizing a particular formulary or instituting a price structure.

In the private sector, the benefit sponsor typically determines a target level of savings it wants the PBM to achieve. However, in doing so, the benefit sponsor must consider that achieving a high level of savings requires that the PBM implement cost-control mechanisms that may limit beneficiary access to certain drugs, such as a closed formulary or prior authorization. The benefit sponsor may then determine which cost-control mechanisms the PBM will use, and how they will be implemented, to achieve the target level of savings. The benefit sponsor may decide whether a formulary is used, and, if so, whether the formulary should be closed, open, or managed. The benefit sponsor may also decide the size of the formulary. For example, Merck-Medco offers benefit sponsors a choice of three different formularies, each with a different number of drugs included, and each capable of achieving a different level of savings. Thus, the guidelines established in the legislative proposals described above do not differ significantly from guidelines that might be set by a private sector PBM client. However, in private-sector plans, such choices affect the savings that the PBM is able to achieve. Managed care organizations, such as health maintenance organizations, generally choose a closed formulary with a limited number of drugs available; this type of formulary is likely to achieve a relatively high level of savings.

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[38] See Anna Cook, Thomas Kornfield, and Marsha Gold, "The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit," prepared for the Henry J. Kaiser Family Foundation, January 2000.

[39] Ibid.

Conversely, fee-for-service health plans may choose open or managed formularies with a large number of drugs available; this type of formulary is likely to achieve a lower level of savings relative to a closed formulary. If the final prescription drug benefit for seniors includes provisions that require a larger formulary, then the government should expect that PBM will achieve lower savings than if a relatively limited formulary were permitted.

Each of the bills has a provision that allows beneficiaries access to off-formulary drugs when medically necessary and/or allows beneficiaries to appeal entities' denying access to off-formulary drugs. In the private sector, benefit sponsors that use PBMs usually adopt such provisions as well, though the appeals process may vary by client. The Thomas bill gives beneficiaries the right to appeal the denial of coverage of an off-formulary drug when a physician determines that the therapeutically equivalent formulary drug is less effective or has significant adverse effects. The Breaux-Frist bill requires the contracted entities to have a process whereby beneficiaries can appeal the denial of coverage for off-formulary drugs. The President's bill and the MEND bill guarantee beneficiaries access to off-formulary drugs when medically necessary and gives beneficiaries the right to appeal when coverage of off-formulary drugs is denied. The MOD bill requires entities to cover off-formulary drugs when medically necessary.

In general, the major legislative proposals do not restrict private entities from using the cost control mechanisms commonly used in the private sector; the proposals list what mechanisms could be used, but do not limit the private entities to those mechanisms. The Thomas bill requires contracted entities to have in place an effective cost and drug utilization management program, including incentives to use generic drugs. The President's bill and the MEND bill allow the contracted entities to employ various cost-control mechanisms subject to guidelines defined in the contract with the Secretary. Thus, any limitations placed on the use of certain cost-control techniques will depend on the finalized contract reached between the private entities and the government. However, the two bills state that the Secretary cannot "interfere with the competitive nature of providing a prescription drug benefit through private entities." The MOD bill allows private entities to use mechanisms to "provide the benefits economically" and to "encourage eligible beneficiaries to select cost-effective drugs or less costly means of receiving drugs." According to the bill, mechanisms that would achieve these goals include formularies, alternative methods of distribution, (e.g. mail order pharmacies), generic drug substitution, therapeutic substitution, and disease management programs. The Breaux-Frist bill allows private entities to use cost-control mechanisms "customarily" implemented by employer-sponsored health care plans that offer coverage for outpatient prescription drugs. According to the bill, such "customary" mechanisms include formularies, tiered co-payments, selective contracting with providers of outpatient prescription drugs, and mail order pharmacies.

Additionally, the Thomas bill and the MOD bill specifically require entities to have in place utilization review systems that would detect and prevent adverse drug interactions and prescribing errors. As described earlier, such utilization review programs are one of the mechanisms typically employed by PBMs in the private sector.

Although PBMs under the major legislative proposals would not operate differently from PBMs in the private sector, the savings achieved by PBMs on behalf of the federal government may be less than those achieved by PBMs on behalf of certain private sector benefit sponsors. Private sector benefits sponsors differ significantly from each other. Some benefit sponsors prefer to aggressively control costs, which means that utilization and access to prescription drugs must be tightly controlled; other benefit sponsors may prefer to allow greater access and utilization, in return for less cost control and higher expenses. How much the government saves by using PBMs vis-a-vis the savings achieved by private sector benefit sponsors depends on which approach the government takes. The legislative proposals described above provide a framework, but leave much discretion to the federal government as to how aggressively cost-control mechanisms would be implemented.

PBMs Under a Senior Drug Benefit: Benefits and Limitations

Some experts believe that using PBMs to manage a prescription drug benefit for the Medicare population can significantly benefit the federal government and Medicare beneficiaries. At the same time, however, there may be challenges to using PBM techniques, particularly formularies, to manage such a benefit.

In a recent study published by the Henry J. Kaiser Family Foundation, some experts have noted that there are many strengths to using PBMs to manage a senior prescription drug benefit.[40] One strength noted by the authors of the Kaiser study is the lower prices PBMs are able to negotiate with pharmacies and manufacturers. Because PBMs are able to negotiate lower prices, the government is distanced from direct involvement in pricing and does not need to take an active role in determining payments for drugs supplied to beneficiaries. Another benefit noted in the Kaiser study is the potential for PBMs to improve the quality of pharmaceutical care that Medicare beneficiaries receive. PBMs are able to track prescriptions, regardless of where they are dispensed (including different pharmacies and mail order). By tracking prescriptions, pharmacists can more easily conduct utilization review to prevent adverse drug interactions or contraindications. Furthermore, according to the Kaiser study, the pricing of PBM services is competitive in the private sector; allowing the government to pay a competitive reimbursement rate based on PBM services may be easier than having it determine an appropriate capitation rate for Medicare managed care plans.

The authors of the Kaiser study also note some potential limitations that may arise if PBMs are used to manage a senior prescription drug benefit. One such noted limitation is the conflict of interest that may arise because PBMs may develop formularies that are influenced by manufacturer rebates, rather than by what drugs are the most cost-effective. The authors of the study argue that, under a senior drug benefit, the government may need to play a role in setting formulary guidelines (much as benefit sponsors do in the private sector). As described above, each of the legislative proposals establish some formulary guidelines, or allow the government to establish formulary guidelines during the contracting process.

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[40] Cook, et. al., cited above.

Another limitation cited by the Kaiser study is the possibility that, under a prescription drug benefit for the Medicare population, PBMs would be vulnerable to public backlash over their cost-control mechanisms. Public backlash could arise if beneficiaries do not fully understand PBM techniques for controlling costs. According to the authors of the Kaiser study, the federal government would have a responsibility to help educate beneficiaries about their drug benefit and the impact of PBM cost-control mechanisms. In a separate report, the U.S. General Accounting Office (GAO) also stated that, under a senior prescription drug benefit managed by PBMs, beneficiaries would need to be informed about how cost-control mechanisms affect access to their medications and the prescribing practices of their physicians.[41] Each of the major legislative proposals described above has provisions requiring the government and/or the contracted entities to disseminate information to beneficiaries regarding the scope of their coverage.

There are other challenges related to the use of PBMs to manage a senior prescription drug benefit, according to the Kaiser study. It is unclear, the authors of the study state, the extent to which Congress and government agencies would allow PBMs to use their cost-control mechanisms. In the private sector, the benefit sponsor plays a role in determining how aggressively costs will be controlled, including which cost-control mechanisms are used and how the formulary is implemented. Managed care providers, such as health maintenance organizations, often employ aggressive cost-controls, including restricting access to certain prescription drugs in favor of therapeutically equivalent drugs that are more cost-effective. Under a prescription drug benefit for the Medicare population, it is argued that the government is likely to favor a less restrictive benefit than those usually employed by managed care providers. In the private sector, PBMs work with different types of benefit sponsors, including those that favor a restrictive benefit and those that favor a less restrictive benefit. For PBMs to succeed under a drug benefit for Medicare beneficiaries, it is argued that expectations on savings will need to be realistic given the choice of cost-control mechanisms that PBMs are allowed to employ. Furthermore, according to the Kaiser study, PBMs will need to be allowed flexibility to manage the senior benefit effectively. As described above, the legislative proposals do not explicitly restrict the implementation of cost-control mechanisms, though the contracting process allows the government some discretion regarding which mechanisms will be employed.

Because some PBMs exclude patient access to certain drugs, their formularies tend to generate controversy. Such controversy may intensify under a prescription drug benefit for the Medicare population. Most Medicare beneficiaries are accustomed to a fee-for-service system which allows patients to see any health care provider willing to accept Medicare payments. The Kaiser study suggests several ways this controversy could be minimized. First, a managed formulary (rather than a closed formulary) could be used; formulary compliance could be achieved using tiered co-payments, therapeutic substitution in certain drug categories, mail-order pharmacy services, prior authorization, and physician education.[42] Second, Congress

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[41] See William J. Scanlon, U.S. General Accounting Office. Testimony before the U.S. Senate Committee on Finance, March 22, 2000. GAO/T-HEHS

[42] According to the Kaiser study, physician education can be quite effective because a small (continued...)

and the federal government could set specific guidelines that PBMs would need to follow when developing a formulary. These guidelines could require a minimum number of drugs to be included from each therapeutic category and recommend which therapeutic categories are most appropriate for therapeutic substitution. The guidelines could be established by a national P&T committee. As described above, the legislative proposals to allow PBMs to manage a Medicare drug benefit already contain formulary guidelines similar to those recommended by the Kaiser study, such as a national P&T Advisory Committee (the MOD bill) and guidelines specifying that a minimum number of drugs be included (the Thomas bill, the MOD bill, and the Breaux-Frist bill)

GAO points to several other challenges to implementing a formulary under a prescription drug benefit for the Medicare population.[43] In the private sector, P&T committees develop formularies privately, something which, according to GAO, "would not be tolerable for Medicare, which must have transparent policies that are determined openly."[44] Because formularies would be developed openly and because of the stakes involved in a drug being preferred on a formulary for the Medicare population, GAO states that there may be intensive efforts to offer input and scrutinize the drug selection process. Furthermore, GAO states that, even if a formulary is in place, it may be difficult to steer utilization or prevent access to non-formulary drugs because of the fee-for-service environment to which most Medicare beneficiaries are accustomed. According to GAO, if utilization cannot be directed towards one drug and away from another, then manufacturers may not have any incentive to offer rebates. Without the effective operation of a formulary, GAO argues that the government may need to adopt an open formulary with administratively determined prices (much the way the government receives rebates from the Medicaid program).[45] However, administratively set prices counteracts what Kaiser sees as a potential strength of PBMs: relying on PBMs to negotiate prices and releasing the government from the complex process of determining appropriate prices and discounts.

Policy Options

There are various options for structuring a benefit for the Medicare population using PBMs. The controversy and complications cited by the Kaiser study and GAO center around the cost-control techniques used by PBMs. Therefore, when choosing if and how PBMs will be used to manage a senior prescription drug benefit, the major issue that would need to be addressed is the extent to which PBMs should be allowed to implement cost-control mechanisms similar to those used in the private sector. The

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[42] (...continued)
number of physicians are generally responsible for a large share of drug expenditures.

[43] See Testimony of William J. Scanlon, cited above.

[44] Ibid, p. 8.

[45] For more information on Medicaid rebates, see CRS Report RS20295, "Outpatient Prescription Drugs: Acquisition and Reimbursement Policies Under Selected Federal Programs" by Heidi G. Yacker, August 9, 1999.

options available to Congress lie along a continuum, ranging from (1) allowing aggressive cost-controls, to (2) allowing cost-controls, but setting guidelines to ensure a given level of access, to (3) not allowing any cost-controls that restrict access, to (4) not using PBMs altogether.

One option for Congress is to allow strict cost-control mechanisms to be employed. With this approach, PBMs would manage a drug benefit for the Medicare population similarly to how they would manage a benefit sponsored by a health maintenance organization, or any other client interested in aggressively controlling costs. The benefit of this approach is that the government could achieve the greatest amount of savings that PBMs can offer. PBMs would be able to easily steer drug utilization towards the most cost-effective drugs, and they would likely be able to negotiate relatively large rebates from manufacturers. The drawback to this approach is that patient access would need to be significantly limited. To achieve maximum savings, PBMs would need to implement closed formularies. According to the Kaiser study discussed above, such an approach may lead to public backlash against PBMs.

Another option is to enact a benefit similar to those in the legislative proposals introduced in the 106th Congress. Under these proposals, PBMs (if they are awarded contracts by the government, or if they are contracted by government-contracted insurers) would be able to implement many of the cost-control mechanisms employed in the private sector. However, guidelines would ensure beneficiaries more access to drugs than the first approach. Such guidelines could be established by the government, or by a national pharmacy and therapeutics (P&T) committee. The guidelines could specify a minimum number of drugs that must be available, require that any drug be covered when medically necessary, and establish an appeals process when beneficiaries are denied coverage. The government or the PBM could educate beneficiaries about what cost-control techniques are employed, and how the techniques affect access to medications. The benefit of such an approach is that PBMs could still manage to achieve savings for the government while providing beneficiaries access to a significant number of drugs. This approach is similar to many private sector fee-for-service plans that use open or managed formularies. The drawback to this approach is that the savings achieved would not likely be the same as those achieved using the first approach. In particular, manufacturer rebates may not be as large because the PBM would be less able to steer utilization. Furthermore, this approach still entails restricting coverage to certain drugs in certain circumstances, so there still may be some degree of public backlash against the use of PBM techniques.

A third option for the government is to not allow any cost-saving mechanisms that would restrict the ability of beneficiaries to obtain whatever drugs they choose. If a formulary is used under this approach, it would have to be an open formulary, with some incentives to encourage patients to use generic drugs, when available. PBMs would be very limited in their ability to steer utilization from one brand-name drug to a chemically different (but therapeutically equivalent) brand-name drug. Consequently, manufacturer rebates and pharmacy discounts would not be significant. The role of the PBM might be limited to processing claims, performing drug utilization review and disease state management, and providing mail order pharmacy services. The benefit of such an approach is that patients are guaranteed access to all prescription drugs, and the risk of public backlash against PBM cost-controls is

minimized. The drawback of this approach is that it is unlikely that the PBM would be able to achieve significant savings for the government. The government may be able to achieve some savings on its own because it would become a bulk purchaser of prescription drugs.

A last approach is to not use PBMs altogether. Under this approach, the drawbacks of PBM cost-control mechanisms are avoided. Prescription drugs and pharmacy services could be provided on a fee-for-service basis, much the way physician services are currently provided under the Medicare program. The benefit of such an approach is that patients would be assured access to all prescription drugs, unless the government decided to implement certain restrictions. The drawback of this approach is that beneficiaries might not use the most cost-effective medications. This might mean that the cost of the prescription drug benefit under this approach could be higher than under the other approaches. The government could attempt to control costs through mandatory rebates (similar to the Medicaid program) and setting low reimbursement rates. However, the pharmaceutical industry is strongly opposed to any proposal which would result in federal price controls. Low reimbursement rates to pharmacies might trigger a similar reaction if this approach is taken. Additionally, beneficiaries would not receive the benefits associated with PBMs, such as drug utilization review to prevent adverse drug interactions or contraindications, and the overall efficiency frequently associated with PBM programs.