

PBMs and a Medicare Prescription Drug Benefit

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I. INTRODUCTION

In 1965, two large-scale government health programs, Medicare (for the elderly and disabled) and Medicaid (for the poor) were established to provide these subpopulations with a health insurance safety net. The Healthcare Financing Administration (HCFA) was set up to manage the federal Medicare program as well as the federal portion of the federal-state Medicaid program. Prior to the creation of Medicare and Medicaid, the elderly, disabled, and poor had little access to health insurance.¹ In terms of both healthcare access and health outcomes, Medicare and Medicaid have clearly improved the status of these vulnerable subpopulations. Close to thirty-five years after their establishment, however, both health programs are due for structural reform.²

Calls for structural reform have been driven by the evident need to contain costs or at least make healthcare delivery more cost-effective as both federal and state budgets increasingly have become constrained. A political consensus has yet to emerge as to the exact configuration of reform. Nevertheless, it is clear from recent policy initiatives that the shape reform will take will mold itself in one way or another after managed care. Across the entire healthcare system, managed care virtually has displaced the traditional fee-for-service system of healthcare delivery and finance. Typically, a managed care organization is reimbursed a fixed amount per time period and per enrollee, in return for which it agrees to provide a broad spectrum of healthcare services. Thus, unlike a fee-for-service system, in which the healthcare provider had an incentive to increase the numbers of services provided, the approximate marginal revenue from delivering additional services in a managed care setting is zero.³

The Balanced Budget Act of 1997⁴ took a number of major legislative steps towards facilitating the enrollment of Medicare and Medicaid beneficiaries into managed care health plans. Recent data indicate just how involved managed care is in Medicare and Medicaid. In 1997, almost half of Medicaid beneficiaries were enrolled in a managed care health plan, compared with less than ten percent in 1991.⁵ Medicare enrollment of beneficiaries in managed care health plans has not followed as dramatic a path. Currently, about six of the 39 million Medicare beneficiaries are enrolled in so-called Medicare+Choice plans.⁶

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¹ Gail Wilensky & Joseph Newhouse, *Medicare: What's Right? What's Wrong? What's Next?*, 18 HEALTH AFF. 92 (1999).

² This is not to say that the original Medicare and Medicaid bills as passed in 1965 have not been amended since their inception. For example, Medicare's approach to reimbursement was based on a retrospective fee-for-service system prior to a 1983 amendment that introduced a prospective fee-for-service system based on diagnosis-related group. HCFA pays the admitting hospital a set amount for each enrollee based upon the admission diagnosis. *Report to the Congress: Medicare Payment Policy (MEDPAC)*, Mar. 1999, at 6.

³ Willard Manning et al., *Health Insurance and the Demand for Medical Care: Evidence From a Randomized Experiment*, 77 AMER. ECON. REV. 251 (1987).

⁴ Pub. L. No. 105-33, 111 Stat. 251 (1997).

⁵ NATIONAL PHARMACEUTICAL COUNCIL, *PHARMACEUTICAL BENEFITS UNDER STATE MEDICAL ASSISTANCE PROGRAMS*, Reston, Va. (1998).

⁶ Although Medicare+Choice plan enrollment still is rising, growth in enrollment has slowed considerably. When a Medicare beneficiary enrolls in a Medicare+Choice plan, HCFA, acting as the beneficiary's sponsor, agrees to pay the plan a fixed amount per month per enrollee. Thomas Kornfield & Marsha Gold, *Monitoring Medicare+Choice*, Mathematica Policy Institute Research Brief (1999).

How has managed care influenced the pharmaceutical side of the healthcare delivery system? It is difficult to trace exact causal connections. Several observations, however, indicate the direction managed care is going with respect to pharmaceutical care. Over the last decade, concurrent with the huge growth in managed care enrollment, pharmaceutical coverage and spending have increased dramatically. The growth in pharmaceutical spending can be divided into two components: (1) drug volume and, (2) drug price increases. Most of the recent growth in pharmaceutical spending is accounted for by drug volume, with the volume having increased by at least fifty percent over the last decade.⁷ Presently, patients are being prescribed more drugs than ever in addition to there being increased numbers of breakthrough drugs on the market.⁸ There is speculation that the cost-effectiveness of outpatient drug care relative to hospital inpatient care (when it can be substituted) has been recognized by managed care, and that this in turn has contributed to growth in pharmaceutical spending.⁹ It is characteristic of managed care to promote preventive and ambulatory services that often include prescription medication. According to recent estimates, over eighty percent of Medicare+Choice plans cover prescription drugs.¹⁰ A decade ago, fewer than fifty percent of health plans covered prescription drugs, suggesting that managed care regards outpatient drug care as a cost-effective alternative to inpatient hospital care and physician services.

With respect to prescription drugs, there are countervailing forces at work in the managed care environment. On the one hand, managed care organizations encourage the use of prescription drugs by including them in their benefit plans. Data show prescription drug usage among managed care enrollees (for both generic and brand name drugs) is significantly higher than under traditional fee-for-service plans.¹¹ Including prescription drug coverage effectively shields the enrollee from the actual price of the drugs being purchased, whereas under fee-for-service the patient pays retail price for the drugs.¹² On the other hand, often through the mediation efforts of pharmacy benefit management companies (PBMs), managed care organizations attempt to contain drug costs while controlling drug usage by securing price rebates and discounts and by monitoring prescribing behavior. Hence, managed care has appeared to be willing to pay for the bulk of the prescription drugs prescribed to enrollees, as long as the prescribing behavior has been reviewed properly.¹³

Since the early 1990s, close to 5 million Medicare beneficiaries have enrolled in Medicare+Choice plans.¹⁴ For those enrolled, this has alleviated their burden

⁷ Alan Lyles & Francis Palumbo, *The Effect of Managed Care on Prescription Drug Costs and Benefits*, 15 PHARMACOECON. 129 (1999).

⁸ Robert Dubois et al., *Explaining Drug Spending Trends: Does Perception Match Reality?*, 19 HEALTH AFF. 234 (2000).

⁹ Of course, we cannot ignore the fact that growth in pharmaceutical spending has been driven in part by recent advances in technology or the possibility that the rise in direct-to-consumer advertising of prescription drugs also has contributed. Numerous breakthrough drugs targeted at large subpopulations have come onto the market during the last decade. Direct-to-consumer advertising of these drugs certainly has raised awareness of the fact that these drugs are currently available. *Id.*

¹⁰ Margaret Davis et al., *Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries*, 18 HEALTH AFF. 231 (1999).

¹¹ See *supra* note 7.

¹² Note that under fee-for-service plans, both physician and enrollee are shielded from the actual price of all healthcare services except for prescription drugs. The latter are paid out-of-pocket by the enrollee.

¹³ Sheila Shulman, *Pharmacy Benefit Management Companies (PBMs), Why Should We Be Interested?*, 14 PHARMACOECON. 49 (1998); see also BARBARA WALSER, PHARMACEUTICAL COST CONTAINMENT AND QUALITY ASSURANCE: TRENDS IN OUTPATIENT UTILIZATION REVIEW PROGRAMS AND PHARMACEUTICAL BENEFITS MANAGEMENT, Basel, Switzerland, Editions Roche (1994).

¹⁴ See *supra* note 6.

of high prescription drug costs.¹⁵ The Medicare/managed care movement, however, appears to be stalling. Currently, managed care plans are disenrolling almost as many Medicare beneficiaries as they are enrolling.¹⁶ If Medicare+Choice enrollment were to continue to stall, this would leave the bulk of beneficiaries in traditional fee-for-service Medicare without a prescription drug benefit. This also sets the stage for the current discussion in Congress about adding a Medicare prescription benefit for those in traditional Medicare. Foreseeing the possible danger of pharmaceutical costs going out of control as a result of increased coverage, most of the legislative proposals on adding a prescription drug benefit envision an active role for PBMs.¹⁷

Section II of this paper describes the structure of PBMs and their functions, paying close attention to the formulary decision-making process. Section III discusses possible ways for PBMs to facilitate the process of adding a Medicare prescription drug benefit. This paper concludes with several policy suggestions concerning how to make a PBM-mediated prescription drug benefit feasible.

II. PBMs

During the last two decades, much has changed from the perspective of all parties involved in a pharmaceutical transaction. To illustrate, let us review the simplified steps a typical patient would take to fill his prescription in an unmanaged versus a managed healthcare environment. Suppose that our typical patient in an unmanaged healthcare environment is insured with a fee-for-service indemnity plan. He goes to the physician of his choice without a gatekeeper. The physician makes her diagnosis and writes out a prescription for the brand-name drug, giving little attention to the retail price of the drug. The patient goes to the pharmacy and fills the prescription, paying the full retail price out-of-pocket for the drug, as his indemnity plan does not cover prescription drugs.

Now consider the managed care environment. Our patient goes to a physician in the managed care network, "a preferred provider." The physician makes her diagnosis, writes out a prescription, often for a generic drug, upon consultation with the online drug utilization review protocol established by the managed care contractor through PBM mediation. The patient goes to a "preferred pharmacy," one that is in the pharmacy network established by a PBM and, fills his prescription, paying a small co-pay for the drug. In brief, we can see from this hypothetical example how managed care organizations such as Health Maintenance Organizations (HMOs) and PBMs influence physicians prescribing patterns, which drug is purchased, how much is paid for the drug, and where it is purchased. The role of PBMs has become crucial in this monitor and control process.¹⁸ Notice in particular the third-party monitoring that goes on at each step in the process of filling a prescription.

PBMs come in different shapes and sizes. Originally, PBMs served as pharmacy claims processors. Now some are HMO subsidiaries, while others are in the business

¹⁵ Robin Strongin, *Providing Outpatient Prescription Drugs Through Medicare: Can We Afford To? Can We Not Afford To?*, NATIONAL HEALTH POLICY FORUM, Issue Brief 749 (1999).

¹⁶ Also, for some beneficiaries still enrolled in Medicare+Choice plans, prescription drug benefits are becoming less generous with added premiums and higher co-payments. *See supra* note 6.

¹⁷ Including a prescription drug benefit package would raise Medicare's expenditures considerably. With appropriate drug usage, however, possibly overseen by PBMs, increased accessibility to prescription drugs actually may decrease overall healthcare expenditures.

¹⁸ GAO, *Pharmacy Benefit Managers: Early Results on Ventures With Drug Manufacturers*, GAO/HEHS-96-45, (1995); *see also* Sheila Shulman & Louis Lasagna, *12 PBMS of the 1990s: Why They Deserve a Second Look*, J. PHARMACEUTICAL MARKETING. & MGMT. 1-6 (1998).

of directly providing healthcare. Most, however, subcontract with third-party payers, such as health plans and employers. At present, over 175 million people are served by PBMs—in PBM jargon these 175 million people represent “covered lives.” PBMs process over sixty percent of all retail drug prescriptions covered annually by third-party payers. Furthermore, the market for pharmacy benefit management is concentrated, with five PBMs having more than eighty percent of the market share, according to 1999 data.¹⁹

As with any other for-profit business, the PBM’s objective also is to maximize profits. PBMs do this by securing drug price rebates from drug makers and discounts from pharmacists in exchange for a contract fee from third-party payers.²⁰ The most common technique used by PBMs to put downward pressure on prescription drug prices is mediation between third-party payers and drug manufacturers with respect to large volume purchases of drugs. Drug makers agree to pay rebates in exchange for a place for the purchased drugs on the formularies PBMs design for third-party payers. PBMs also design generic substitution plans for third-party payers to lower their costs. These plans indicate when it is appropriate for prescribers to substitute a generic version of a drug for a brand name. A common feature of generic substitution is a three-tiered co-payment approach, with enrollees paying lower co-pays for generics than for brand name drugs on the formulary, and higher prices for brand name drugs off the formulary than on the formulary.

PBMs establish pharmacy networks, offering health plans and their enrollees a network of pharmacies that are geographically accessible. The pharmacies’ incentive to participate is based on the virtual guarantee of access to the enrollee base of health plans that transact with the PBMs. In exchange for this, pharmacies agree to a reimbursement formula established by the PBM—expressed as a discount off the average wholesale price and a dispensing fee per prescription.²¹ In return for channeling large enrollee bases to pharmacies, PBMs arrange for health plans and employers to pay lower transaction prices for drugs at those pharmacies.²²

¹⁹ Elizabeth Mitchell, *The Potential for Self-Interested Behavior by Pharmaceutical Manufacturers Through Vertical Integration With Pharmaceutical Benefit Managers: The Need for a New Regulatory Approach*, 54 FOOD & DRUG L.J. 151 (1999).

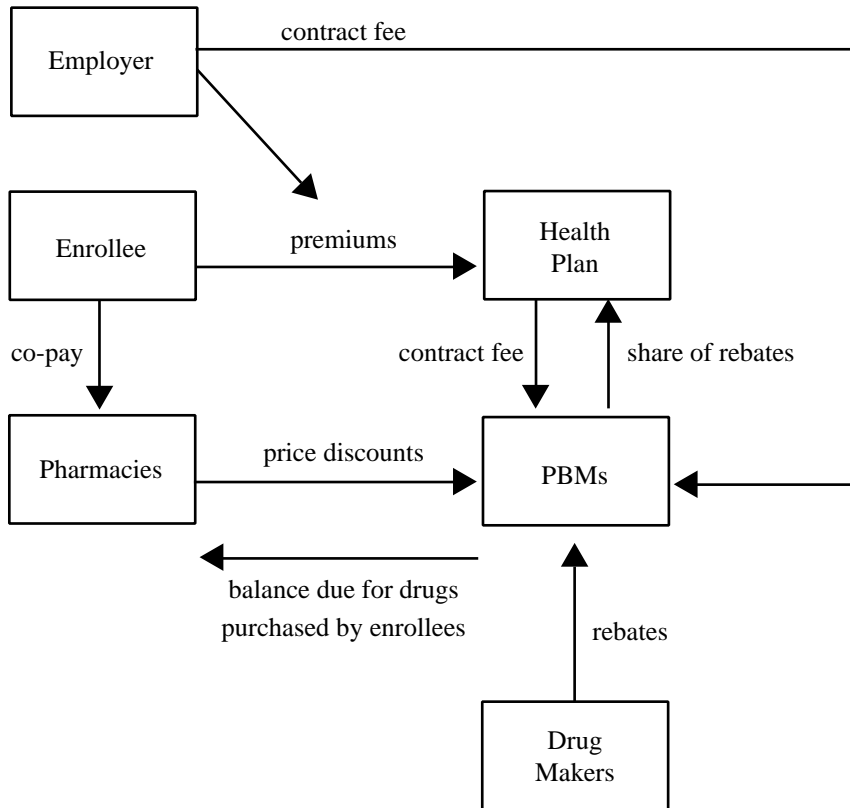
²⁰ The contract fee charged by the PBM can be a fixed, capitated payment covering the entire enrollee pool (all the “covered lives”) the PBM is managing, or a fee-for-service payment. Under fee-for-service, the health plan or employer pays the PBM the prescription cost of the drug being managed by the PBM, less the employee’s contribution, plus an administrative fee. The PBM passes on to health plans and employers a portion of the prescription savings gained through manufacturer rebates and pharmacy discounts. Under capitation, the third-party payer pays the PBM a fixed amount regardless of a number of prescriptions used. This puts both the PBM and third-party payer at financial risk. In addition to the contract fee, the PBM retains a portion of the negotiated rebates and discounts. See WALSER, *supra* note 13.

²¹ GAO Report, *Pharmacy Benefit Managers: FEHBP Plans Satisfied With Saving and Services, but Recall Pharmacies Have Concerns*, GAO/HEHS-97-47 (1997).

²² PBMs also operate mail order pharmacies that allow enrollees to obtain prescriptions by mail. Congressional Budget Office (CBO) data confirm that PBMs can have a downward effect on drug. CBO was able to obtain limited data on prices paid by different types of purchasers for prescription drugs. The prices that pharmacies pay can be seen as a proxy for the final price paid by customers who do not have a managed drug benefit or PBM to negotiate rebates and discounts from manufacturers and pharmacies respectively. Based on the average invoice prices for top-selling drugs sold primarily to retail pharmacies, hospitals and clinics pay nine percent less than retail pharmacies, on average, while HMOs pay on average eighteen percent less. See also *Impact of the Balanced Budget Act on the Medicare Fee-For-Service Program: Hearings Before the Comm. on Commerce*, 105th Cong., at xii (1999) (testimony of Dan Crippen, Director, CBO).

The diagram below summarizes the cash flow transactions associated with prescription drug benefit management.

Figure 1
Cash Flow and Pharmacy Benefit Management



Note that employers and/or health plans may negotiate contract fees and rebate shares directly with PBMs. Note further that employers often contribute to the enrollee premiums paid to health plans.

A. P&T Committees

A particularly important PBM sub-entity is the Pharmacy and Therapeutics Committee (P&T Committee). Like traditional hospital P&T Committees, PBM P&T Committees are comprised of physicians and clinical pharmacists. The P&T Committee's most important task is to make recommendations to plan sponsors on formulary drug selection, laying the basis for coverage decisions. A formulary is a list of "preferred" drugs in each therapeutic class, selected on the basis of enrollee care and cost consid-

erations.²³ The formulary decision-making process captures relevant information about drugs' availability, safety, and cost-effectiveness.

On a PBM's formulary, drugs are grouped by indication (the type of illness they treat) and mechanism of action (what the drug actually does). For example, ulcers may be an indication and some of the drugs that treat ulcers coat the stomach, whereas others block acid secretion. In other therapeutic classes, such as cardiovascular therapies, each drug may have the same mechanism of action. P&T Committees first decide whether a drug should be included on the formulary, for instance, they decide whether to include a new drug offering significant therapeutic advantages over existing drugs. Next, once it has been established which subset of drugs is on the formulary, this subset is prioritized using methods such as generic substitution. A generic drug which is approved based on bio-equivalence is usually given preference over more expensive brand name drugs.

In addition to generic substitution, P&T Committees perform drug utilization review. A P&T Committee drug utilization review panel analyzes patterns of drug use among enrollees, using pharmacy claims data information gathered by PBMs on dosage, duration of medication usage, indications, and interactions with other drugs.²⁴ Unlike the formulary, which is not targeted at specific enrollees (patients) or specific physicians, drug utilization review analyzes in detail specific instances of prescribing behavior on the part of physicians. Often, this leads to the P&T Committee instituting rules that require physicians, whose historical prescribing patterns appear to be less cost-effective than the "norm," to obtain prior approval before making further prescription decisions for their patients.²⁵ Finally, P&T Committees carry out therapeutic interchange. This appears to be the most controversial technique included in a PBM's monitoring activities, as it directly intrudes on the patient-physician relationship. With therapeutic interchange, PBMs attempt to obtain a physician's permission to substitute one brand-name drug for another drug with a different chemical composition that is in the same therapeutic class and is included on the formulary.²⁶ Usually, therapeutic interchange is done for cost containment purposes only.²⁷

B. Disease Management's Potential

PBMs started out as companies whose sole focus was cost containment. Recently, some PBMs have expanded into the area of disease management as a corollary to their drug utilization review activities.²⁸ No longer content with having PBMs merely stem the rise in prescription drug prices, third-party payers are beginning to ask PBMs to use their expertise and extensive pharmacy claims data resources to improve the cost-effectiveness of pharmaceutical care delivery per disease category.²⁹ Until now, PBMs'

²³ There are open, incentive-based, and closed formularies. Open formularies are merely lists of preferred drugs, suggested by the P&T Committee. Incentive-based formularies are linked to co-payment schedules, with enrollees paying higher co-pays for nonformulary drugs. Closed formularies restrict physicians from prescribing nonformulary drugs at all. Most current formularies are either open or incentive-based. Closed and incentive-based formularies give the PBM the greatest leverage with manufacturers in negotiating price rebates because the PBM is able to shift enrollee volume to the manufacturer offering the lowest prices. See Grabowski & Mullins, *infra* note 28, at 534.

²⁴ Anna Cook et al., *The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit*, Mathematical Policy Research, Inc. 13 (2000) (as prepared for the Henry J. Kaiser Family Foundation).

²⁵ *Id.* at 15.

²⁶ *Id.* at 17.

²⁷ *Id.* at 18.

²⁸ Henry Grabowski & Daniel Mullins, *Pharmacy Benefits Management, Cost-Effectiveness Analysis and Drug Formulary Decisions*, 45 Soc. Sci. & Med. 535 (1997).

²⁹ *Id.* at 536.

disease management programs have concentrated on patient compliance and physician treatment guideline protocols. Potentially, PBMs could work together with plan sponsors to assemble comprehensive databases that contain data on current prescribing practice patterns, health outcomes, and resource utilization. The kinds of questions that could be addressed by such population-wide databases include, for example, which anti-hypertensive drugs are the most appropriate for diabetic patients, and what method of preventing retinopathy is most cost-effective.

Diabetes is a prime candidate for PBM-led disease management, as it is a chronic, high-cost illness with multiple symptoms covering a wide range of therapeutic classes, and whose treatment relies heavily on the extended delivery of pharmacotherapy.³⁰ With the current claims databases at their disposal, PBMs already can identify a number of factors leading to above-average treatment costs and lower-than-average quality of care (for example, inappropriate drug treatment and/or poor patient compliance).

Based on the cost control and drug management techniques employed by PBMs, including disease management, PBMs ought to be able to select drug therapies that are cost-effective; that is, therapies that are relatively inexpensive and provide more benefit than the next best alternative. PBMs currently, however, manage pharmacy benefits as a “carve out”—a cost item managed separately from other healthcare items. Carving the drug component out of the healthcare budget, to be tackled piecemeal, may lead to cost control failure as the impact of the drug component on the rest of the healthcare budget is not taken sufficiently into consideration. Plan sponsors that make use of PBMs ought therefore to employ an incentive structure that rewards PBMs not strictly on the basis of pharmacy cost containment, but instead on the basis of the cost-effectiveness of drug therapies in terms of the entire healthcare budget. Disease management, for instance, may suggest raising the level of drug spending for a certain disease because this reduces the overall level of healthcare spending on the disease. This suggested integration of the pharmacy budget with other healthcare budgets fits in with the general trend of the healthcare system as a whole, as managed care is developing a less compartmentalized system of care delivery.

III. MEDICARE AND PRESCRIPTION DRUG BENEFIT MANAGEMENT

A. *The Need for Medicare Coverage of Prescription Pharmaceuticals*

Since President Lyndon Johnson set up a Presidential Task Force³¹ devoted to the issue of possible inclusion of a Medicare prescription drug benefit, there appears to have been a cyclical pattern of interest and enthusiasm in such a benefit followed by indifference and pessimism. For instance, the 1988 Catastrophic Healthcare Act³² mandated outpatient prescription benefits for Medicare beneficiaries. This Act was repealed in 1989 prior to its implementation. Another illustration of this cyclical pattern is President Clinton’s ill-fated 1993 plan to overhaul the healthcare system.³³ Part of that plan included providing limited, prescription drug coverage to the elderly and the disabled. In 1994, the Clinton plan lost momentum and eventually lost support.³⁴

³⁰ Richard Epstein & Gorbach Sherwood, *From Outcomes Research to Disease Management: A Guide for the Perplexed*, 124 ANNALS OF INTERNAL MED. 832 (1996).

³¹ Daniel Waldo, *Estimating the Cost of a Medicare Outpatient Prescription Drug Benefit*, 15 HEALTH CARE FIN. REV. 104 (1994).

³² *Id.* at 105.

³³ *Id.*

³⁴ Theda Skocpol, *Boomerang: Clinton’s Health Security Effort and the Turn Against Government in U.S. Politics* (W.W. Norton ed., 1996).

Currently, there is renewed interest in extending insurance coverage to outpatient prescription drugs under Medicare. In part because the elderly and disabled beneficiaries especially seem vulnerable to the high cost of prescription drugs. In 1995, the average Medicare beneficiary paid fifty percent of the cost of prescription drugs out-of-pocket, while filling on average eighteen prescriptions annually.³⁵ By contrast, for the U.S. population as a whole, the national average share of out-of-pocket expenditures was much lower at thirty-four percent.³⁶ Because price sensitivity with respect to prescription drugs is known to be high, relatively small increases in out-of-pocket payments can lead to reductions in the consumption of drugs.³⁷ This in turn can result in adverse health outcomes, particularly for the elderly and disabled who depend on prescription drugs to remedy or at least stabilize their chronic conditions.

Historically, outpatient prescription drugs have not been a covered benefit under Medicare. Currently, however, sixty-five percent of Medicare beneficiaries have at least some level of drug coverage. Therefore, the fact that outpatient prescription drugs are not a covered benefit³⁸ does not imply that Medicare beneficiaries have no recourse to drug coverage. Medicare beneficiaries have a number of options for obtaining outpatient drug coverage: 1) several MediGap insurance plans; 2) some employer-sponsored plans; 3) Medicaid coverage, available to low-income beneficiaries; 4) Veterans Administration hospital coverage, available to veterans, and; 5) most Medicare+Choice plans.³⁹ Despite the presence of these coverage options, barriers to access remain. MediGap plans tend to have relatively high levels of premiums and cost-sharing. Increasingly, employers also are becoming reluctant to provide retiree prescription drug benefits.⁴⁰ Furthermore, many beneficiaries who are eligible for Medicaid do not enroll.⁴¹ Finally, a number of Medicare+Choice plans are reducing their benefits or withdrawing from Medicare altogether, owing to a combination of reduced HCFA reimbursement rates, rising drug costs and adverse selection.

To redress the problem of inadequate prescription drug coverage, a number of legislative proposals have been put forward. Several proposals suggest targeting insurance protection strictly at low-income elderly and disabled individuals. Other initiatives would provide coverage for at least low levels of drug spending under a universal benefit.

Table 1 (below) provides an overview of four of the most widely discussed stand-alone drug benefit proposals. With the exception of the Bilirakis/Peterson plan, the proposals noted in Table 1 suggest providing PBMs with a pivotal role in the management of drug benefits.

³⁵ See Davis, *supra* note 10.

³⁶ GAO, *Medicare: Considerations for Adding a Prescription Drug Benefit*, statement of Laura J. Dummit, Associate Director, Health Financing and Public Health Issues, Health, Education, and Human Services Division, GAO/HEHS-99-153 (1999).

³⁷ Brian Stuart & James Grana, *Ability to Pay and the Decision to Medicate*, 36 MED. CARE 202 (1998).

³⁸ Important exceptions: immunosuppressant medications for transplant patients for a period of thirty-six months, blood-clotting factors for hemophilia, erythropoietin, osteoporosis drugs used to treat bone fracture, certain oral anticancer drugs, oral and parenteral anti-nausea medications when used for treatment of side effects of chemotherapy, and a "reasonable" supply of antigens. See Waldo, *supra* note 31.

³⁹ See Davis, *supra* note 10, at 232.

⁴⁰ John Rother, *A Drug Benefit: The Necessary Prescription for Medicare*, 18 HEALTH AFF. 20 (1999).

⁴¹ Stephen Soumerai & Dennis Ross-Degnan, *Inadequate Prescription Drug Coverage for Medicare Enrollees—A Call to Action*, 340 NEW ENG. J. MED. 723 (1999).

Table 1
A Sample of Medicare Drug Benefit Proposals

Sponsor/Title	Coverage Proposal	Program Administration
Clinton Administration plan	Reimburse drug costs up to \$2,000 per year for beneficiaries below 135% of poverty. No premiums for those below 150% of poverty. Fifty percent cost-sharing. Monthly premiums, initially set at twenty-four dollars per month.	HCFA contracts out to PBMs, with PBMs competitively bidding for regions. Requires PBMs to provide ten to fifteen percent discounts on drugs for Medicare beneficiaries.
Bilirakis and Peterson/The Medicare Beneficiary Prescription Drug Assistance & Stop-Loss Protection Act (HR 2529)	Assist states in establishing and expanding state drug assistance programs to cover up to 200% of federal poverty.	Expansion of state pharmaceutical assistance programs.
Deutch and Wexler/Medicare Prescription Drug Benefit Act (HR 2012)	Raise Medicaid assistance level to 135% of poverty. Incorporate a \$200 deductible, along with a twenty percent co-payment up to \$5,200 per year.	PBMs contracted by Department of Health and Human Services (DHHS). Minimum standard set by government agency, including formulary mandates.
Kennedy, Rockefeller, and Wellstone/Access to Rx Medications in Medicare Act of 1999 (HR 1495)	Expand Medicaid to cover up to 135% of poverty. Beneficiaries pay twenty percent of drug costs after \$200 deductible, with stop-loss protection after \$3,000.	PBMs enter competitive bidding process for contracts with HHS. Agency pays PBMs for services.

B. Approaches to the Design of a Medicare Prescription Drug Benefit

There are two possible broad approaches⁴² to take with respect to the design of a stand-alone Medicare prescription drug benefit. The first is modeled after the Medicaid drug rebate program, and the second is modeled after a more market-oriented PBM-administered plan. The first relies on federal authority to lower drug prices by fiat through rebates paid by drug manufacturers.⁴³ For example, the Omnibus Budget Reconciliation Act of 1990⁴⁴ requires drug makers to give state Medicaid programs rebates on the wholesale price of brand-name drugs that Medicaid beneficiaries purchase as outpatients. As part of the Medicaid rebate program, under the so-called best-price provision, state Medicaid agencies obtain access to the lowest prices paid for prescription drugs by any private purchaser in the United States. Evidence suggests that success of this measure is somewhat limited as drug makers react by raising the lowest prices they charge other purchasers.⁴⁵

⁴² There are of course numerous ways of implementing each of these two broad approaches, some more market-oriented than others.

⁴³ See Cook, *infra* 49, at 30.

⁴⁴ Pub. L. No. 101-508, 104 Stat. 1388 (1990).

⁴⁵ See Cook, *infra* 49, at 30.

The second approach relies on PBMs to control costs and manage a prescription drug benefit using techniques such as incentive-based formularies, drug utilization review, volume rebates, and pharmacy discounts.⁴⁶ This approach is favored by the three legislative proposals above that give PBMs a central role in prescription drug management.⁴⁷ This is comparatively new territory for PBMs, which typically operate in a predominantly managed care environment, which traditional fee-for-service Medicare is not. The second approach would be superior to the first only if PBMs could employ the drug utilization techniques that come from having an incentive-based formulary coupled with differential beneficiary cost sharing.⁴⁸ Obtaining volume rebates from drug manufacturers and discounts from pharmacies depends crucially on the ability to use such incentive-based formularies.⁴⁹

Politically, the hurdles to implementing a PBM-mediated stand-alone drug benefit include the requirements of transparency and equity. A government agency such as HCFA would want drug price negotiations between PBMs and the drug makers to be transparent. PBMs, however, would not want to reveal secrets of the rebate and discount trade. Moreover, HCFA would want to distribute benefits among beneficiaries equitably, applying the principle that any distribution rule that affects one beneficiary should affect all beneficiaries equally. By contrast, PBMs, when recommending plan designs, tend to distinguish among beneficiaries through differential benefit and co-pay arrangements.

Although the problems of transparency and equity are real, they can be handled. As long as the rebates and discounts obtained by PBMs approximate the levels reached in the Medicaid drug rebate program, the federal government would probably be content to drop its demand for transparency. Furthermore, during the past decade, the federal and state governments have gradually allowed, and even encouraged, both Medicare and Medicaid to adopt managed care style practices that differentiate among beneficiaries through the use of incentive-based formularies.

The larger problem, however, is deciding on whether to add a stand-alone benefit or incorporate a drug benefit into a comprehensive restructuring of Medicare as proposed by Senators John Breaux (D-LA) and John Frist (R-TN).⁵⁰ A stand-alone drug benefit carries with it the pitfalls of carving-out the pharmacy budget from the rest of the healthcare budget. As managers of a carved-out drug benefit, PBMs are inclined to cut pharmacy costs, but do not have an incentive to be cost-effective in terms of the overall healthcare budget. It would therefore seem prudent for PBMs to adopt a cost containment strategy based on integration of pharmacy and healthcare budgets. In order for this to occur, however, the incentive structure of plan sponsor (employer, HMO, government) contracts with PBMs would need to reward PBMs for their performance with respect to healthcare cost savings, and not merely pharmacy cost saving.

⁴⁶ See *supra* note 6.

⁴⁷ *Id.*

⁴⁸ See *supra* note 34.

⁴⁹ Anna Cook, *Strategies for Containing Drug Costs: Implications for a Medicare Benefit*, 20 HEALTHCARE FINAN. REV. 29 (1999)

⁵⁰ Medicare Preservation and Improvement Act of 1999, S.1895, 106th Cong., 1st Sess. (1999) (still in committee).