

PHARMACY BENEFIT MANAGERS AND MEDICARE BENEFICIARY ACCESS TO PRESCRIPTION DRUGS

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Despite the fact that prescription drugs are an increasingly important component of modern health care, especially for the elderly and disabled populations suffering from chronic conditions, 35% of Medicare beneficiaries lack any form of prescription drug insurance. Congress is currently debating six major proposals to extend insurance protection to outpatient prescription drugs under Medicare. Five of these proposals suggest the use of pharmacy benefit managers (PBMs) to improve the cost-effectiveness of the prescription drug benefit.

A Tufts Center for the Study of Drug Development (Tufts CSDD) survey of eight leading PBMs shows that during the last five years PBMs have increased their enrollment of Medicare beneficiaries considerably. PBMs currently facilitate moderate to full access to pharmaceuticals for approximately 20% of Medicare beneficiaries. Seven of the eight PBMs surveyed are also developing disease management programs targeted specifically at the Medicare population. However, regarding the feasibility of a universal prescription drug benefit, a number of issues concerning how to structure government contracts with PBMs and how to meet certain political challenges to PBM mediation remain unresolved.

Key Words: Medicare; Pharmacy benefit manager; Prescription drug benefit; Access to prescription drugs; Risk contract

BACKGROUND

PRESCRIPTION DRUGS PLAY an increasingly important role in the provision of health care. For example, ulcers that once required relatively expensive surgery and hospitalization are treatable using relatively inexpensive

outpatient drug therapies (1). Recent innovations in pharmaceuticals have led to improvements in health outcomes for persons living with chronic conditions such as heart disease, hypertension, diabetes, asthma, and arthritis—frequent ailments of the Medicare population.

The Medicare population, which includes the elderly, the disabled, and patients with end-stage renal disease, is particularly vulnerable to the high cost of prescription drugs, which are not a covered benefit under the current Medicare program. Not only do Medicare beneficiaries use more prescription drugs than the rest of the population (2,3), often as cash-paying individuals without pre-

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scription drug coverage, they pay considerably more for the drugs they use (4).

Approximately 35% of Medicare beneficiaries have no prescription drug coverage (1). Medicare beneficiaries without drug coverage tend to be both sicker and poorer than their counterparts with coverage (5). For the roughly 65% of beneficiaries with coverage, degrees of access vary widely. Eight percent have MediGap insurance, which provides coverage of pharmaceuticals (6). However, coverage through MediGap is limited and requires substantial cost sharing. Thirty percent of the beneficiaries have coverage through employer-sponsored retiree benefit plans (7). These plans tend to provide generous drug benefits. Nevertheless, employers' willingness to offer such benefits has recently been declining, due in part to rising prescription drug expenditures. Approximately 11% of the beneficiaries are covered through Medicaid for most of their pharmaceutical expenses (1). However, an even larger percentage (13%) of the total number of Medicare beneficiaries, while eligible for Medicaid, are currently not enrolled in the program (5,8).

Sixteen percent of Medicare beneficiaries are currently enrolled in Medicare+Choice plans (9); 80% of these plans offer prescription drug coverage (5,10). The inclusion of prescription drug benefits in Medicare+Choice plans has attracted many Medicare beneficiaries. However, diminished Medicare reimbursement rates subsequent to the enactment of the Balanced Budget Act of 1997, rising health care and pharmaceutical costs, and the problems of selection, have forced managed care plans to rethink their involvement in the Medicare market. (The problems of selection cut two ways.) On the one hand, adverse selection can arise given that drug coverage is offered on a voluntary basis, with premiums not reflecting varying health risks. Higher-cost beneficiaries are much more likely to want to enroll than lower-cost beneficiaries. On the other hand, without adequate Medicare payment adjustments to reflect the differential risk posed by beneficiaries, health plans have a financial

incentive to selectively enroll the healthy and avoid the sick.)

Many plans have raised the level of beneficiary premiums, increased copayments, and implemented restricted formularies. This has counteracted the degree of access to drugs initially achieved by Medicare+Choice enrollees. Moreover, an increasing number of Medicare+Choice plans have decided to abandon the Medicare market altogether. Ninety-five health maintenance organizations (HMOs) have withdrawn from or reduced services in the Medicare market as of January 1999, affecting 350000 Medicare beneficiaries. An additional 83 HMOs have withdrawn from or reduced services in the Medicare market as of January 2000, affecting an additional 400000 beneficiaries (11). Managed care plans are projected to disenroll more than 700000 Medicare beneficiaries in 2001 (12). Medicare beneficiaries who are involuntarily disenrolled often must fall back on traditional Medicare without prescription drug coverage.

COVERAGE AND ACCESS

Historically, definitions of access to pharmaceuticals have emphasized insurance coverage (13). Accordingly, measures of access to health care simply reflect numbers of insured beneficiaries. Based on this measure, 65% of Medicare beneficiaries have access to pharmaceuticals because they have drug coverage. This has led some policymakers and politicians to suggest that the problem of Medicare beneficiary access to pharmaceuticals is restricted to the 35% who are not covered. Nevertheless, a simple tallying of the number of covered beneficiaries tells only one part of the story of access to pharmaceuticals.

We can define degree of access to pharmaceuticals in terms of both availability of and ability to pay for prescription drugs. Availability of prescription drugs refers to whether the drugs beneficiaries need have been approved for marketing by the Food and Drug Administration (FDA) (14), and whether these drugs are on the beneficiaries' health

plan formulary. Ability to pay for prescription drugs indicates the degree to which those who need drugs can pay for them, or have a third party to defray a significant portion of the costs. Some wealthy Medicare beneficiaries with no coverage, for instance, still have full access to pharmaceuticals. Other beneficiaries with coverage have only moderate access, due to formulary restrictions and/or relatively high degrees of cost sharing.

The flowchart (Figure 1) illustrates the relationship between coverage and access. Y1 refers to the federal poverty level of income that constitutes the main eligibility requirement for Medicaid. Y2 denotes an income level, which under “normal” circumstances is sufficient to pay for prescription drugs out-of-pocket without having to make “hard choices” (ie, substituting drugs for necessity items). For instance, some analysts have used incomes above \$50,000 as a proxy (8).

For simplicity’s sake, we disregard certain other dimensions of access, including access to health care providers and pharmacies. We also ignore details surrounding what exact dollar amount would constitute a “high” pre-

mium burden and/or drug cap and/or copay percentage.

The flowchart begins with the question of whether a Medicare beneficiary is covered for prescription pharmaceuticals. If covered, beneficiaries’ access to pharmaceuticals may be moderate in varying degrees if formulary restrictions are imposed and/or relative levels of cost sharing are high. Or, access may be full, at least to those drugs approved for marketing by the FDA. If not covered, lack of coverage may be voluntary or involuntary. For those whose choice it was not to be covered, their level of income determines whether they can enjoy at least a moderate degree of access. Above or equal to y2, beneficiaries have full access. Below y2, beneficiaries’ degree of access is moderate to limited as their income declines. For those who are involuntarily uninsured, we can ask which beneficiaries have incomes above the federal poverty level (y1). Those whose income is equal to or below y1 are Medicaid eligible, but not enrolled (or enrolled as so-called Qualified Medicare Beneficiaries or as Special Low-Income Medicare Beneficiaries),

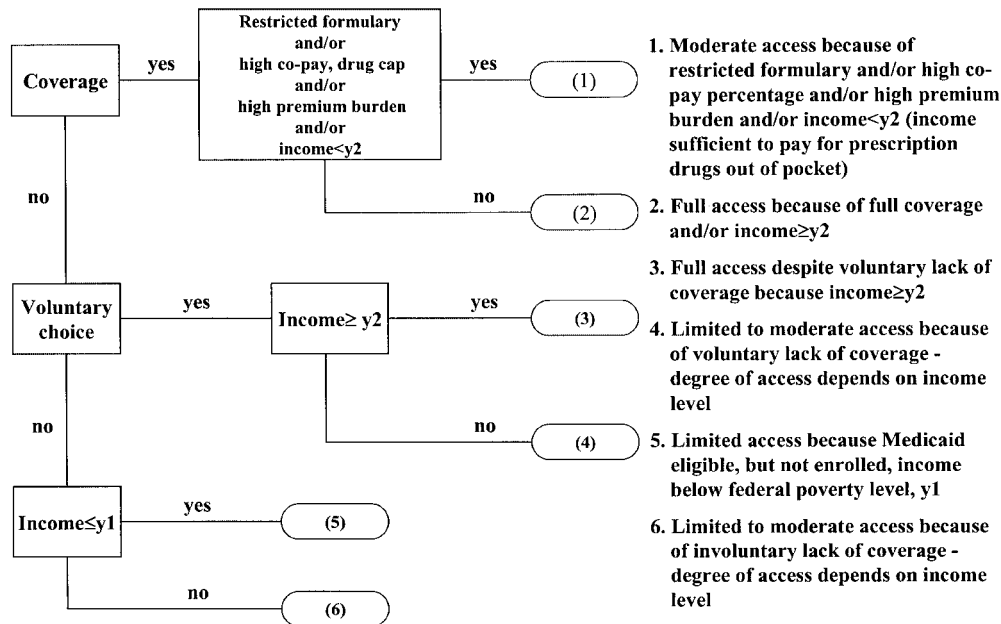


FIGURE 1. Prescription drugs: Coverage and access.

and hence have limited access. Those with incomes exceeding y_1 have limited to moderate access as their income rises.

We can attach numbers to the flowchart to give an impression of how coverage and access relate. Sixty-five percent of Medicare beneficiaries have prescription drug coverage. Out-of-pocket expenses for those who are covered average less than \$250 per beneficiary annually (1,8,15). Most of those covered have varying degrees of moderate access to prescription drugs. Of the Medicare+Choice beneficiaries, between 10% and 15% enjoy full access, that is, they either have incomes above \$50,000 and/or have no formulary restrictions or cost sharing (8,10). Out-of-pocket spending for those not covered averages around \$550 per beneficiary annually (1,8). Of those not covered, the percentage that chooses not to be covered is unknown. Of those not covered, a small percentage (around four percent) of relatively well off beneficiaries enjoys full access (5). Most uncovered beneficiaries have incomes between y_1 and y_2 . However, more than 30% of the uninsured have incomes below y_1 . Notably, close to 60% of beneficiaries with incomes equal to or below the federal poverty level are not enrolled in Medicaid, and, therefore, are not covered and are without access (5).

PUBLIC POLICY AND PHARMACY BENEFIT MANAGERS

Two kinds of public policy proposals are intended to address the current problem of inadequate access to pharmaceuticals for Medicare beneficiaries. The first is a stand-alone drug benefit proposal, for example, the Clinton Administration plan to add a Part D prescription drug benefit to Medicare (16). The second is a comprehensive Medicare reform proposal that incorporates a drug benefit as part of a restructuring of the entire Medicare program, for example, the Breaux-Thomas premium support plan (17).

As of August 2000, there are six major proposals for Medicare prescription drug coverage being debated in Congress (18). Some prescription drug benefit proposals,

such as the Breaux-Thomas plan, target a specific beneficiary subpopulation—those with incomes below 135% of the federal poverty level. Other proposals, such as the Clinton Administration plan, are designed to subsidize the drug costs of all Medicare beneficiaries, usually on a sliding income scale.

From a public policy perspective, each proposal needs to be evaluated in terms of societal costs and benefits: In other words, are the health outcomes and possible cost savings associated with an added drug benefit worth the cost of implementing the proposals? An added drug benefit's probable effect on health outcomes is positive, yet uncertain at this point. In addition, the drug benefit's effect on budget savings resulting from the substitution of inpatient for outpatient care is difficult to predict with any precision.

More precise figures are known about costs. For example, the Clinton Administration estimates its plan will incur net outlays (costs minus premium revenues) of 120 billion dollars for the period 2002 to 2009. A Congressional Budget Office cost estimate of the Clinton plan's net outlays is somewhat higher at 136 billion dollars (19).

In an effort to control costs, the federal government could contract with pharmacy benefit managers to manage a Medicare prescription drug benefit. During the 1990s, PBMs became an important player in the prescription drug market. In 1999, PBMs managed the prescription drug benefits of between 160 and 190 million insured individuals in the United States (20). Approximately five million Medicare beneficiaries are currently enrolled in Medicare+Choice plans that contract with PBMs. An estimated four million Medicare beneficiaries are enrolled in fee-for-service plans that contract with PBMs (6).

PBMs manage prescription drug benefits for plan sponsors, including HMOs, private employers, the federal government, indemnity insurance companies, and preferred provider organizations. Among other things, PBMs process pharmacy claims, develop drug formularies, design copay schedules, obtain rebates from drug manufacturers and

discounts from retail pharmacies, develop and implement disease management programs, and manage drug utilization in conjunction with health care providers and pharmacists. PBMs negotiate rebates from drug manufacturers in exchange for designating the manufacturers' drugs to health plan drug formularies. Likewise, PBMs negotiate discounts from retail pharmacies in exchange for guaranteeing a network of pharmacies a large pool of health plan enrollees. These discounts effectively lower the price employers, health plans, and government agencies pay pharmacies for drugs. An unknown portion of the rebates and discounts obtained by PBMs is passed on to the plan sponsors, while the remainder is kept as earnings.

Plan sponsors, including federal and state governments, want to minimize exposure to unnecessary prescription drug costs, while ensuring affordable coverage of quality pharmaceuticals (21). Increasingly, plan sponsors are turning to PBMs to reconcile these two goals. Together with plan sponsors, PBMs help to delineate degrees of access to pharmaceuticals at the following four levels:

1. Benefit plan design—which therapeutic categories are included in the prescription drug coverage package,
2. Formulary—within each therapeutic category, which drugs are covered and what kind of co-pay structure is in place (Typically, a three-tiered copayment structure is put in place in which generic drugs have the lowest copayment, followed by brand-name drugs on the formulary, followed by brand-name drugs off the formulary.),
3. Prior authorization—whether authorization from the plan sponsor has been obtained for certain covered drugs, prior to their being dispensed, and
4. Drug utilization review—which quantities of the authorized drug are considered appropriate and whether drug-drug interactions have been reviewed.

PBMs could assist the federal government in its efforts to contain the growth of Medicare prescription drug expenditures. In turn,

this may lead to lower retail pharmacy prices for Medicare beneficiaries, so long as a portion of the rebates and discounts obtained by PBMs is passed on to the beneficiaries. Here, PBMs face a tradeoff between open formularies and extended pharmacy networks (ie, increased beneficiary access), and the economic leverage restricted formularies and networks provide vis-à-vis drug manufacturers and pharmacies. The level of cost savings PBMs can achieve will depend on the extent to which PBMs are allowed by Congress to adopt incentive-based formularies and differential cost-sharing arrangements in the Medicare fee-for-service sector, similar to those they currently use in the private, managed care sector. PBMs are not as familiar with the fee-for-service sector as they are with managed care. The Tufts CSDD survey reveals that nearly 60% of the Medicare beneficiaries enrolled in PBMs are in managed care plans.

As profit-maximizing businesses, PBMs would agree to contracts with the Health Care Financing Administration (HCFA) to manage a prescription drug benefit if they anticipate making a profit, at least in the long term. Profits would depend in part on the ability of PBMs to facilitate cost-effective pharmaceutical care. A government contract with PBMs would most likely involve some degree of risk sharing between HCFA and PBMs (22,23). Full or even partial capitation would put PBMs at considerable financial risk. Managed care's recent Medicare+Choice pullout illustrates the inherent problem associated with capitation contracts. Before signing on to a risk-sharing arrangement that involves fixed (capitated) premiums, PBMs would need to calculate the expected (monetary) effects of adverse selection and cost management risks. Universal coverage of a prescription drug benefit may mitigate adverse selection. Nonetheless, PBMs still need to be able to maintain some degree of control over cost growth factors, such as physician prescribing patterns, in order to diminish cost management risk. The Tufts CSDD survey (see Appendix) shows that although PBMs are well suited to play a significant role in

TABLE 1
PBM Attitudes Toward the Medicare Prescription Drug Benefit

PBMs Can Play a Significant Role in Managing a Medicare Prescription Drug Benefit	Selection Risk is the Largest Risk Factor that a PBM Needs to Consider in Deciding Whether to Offer a Medicare Drug Benefit for a (partially) Capitated Premium
7 strongly agree, 1 agrees	4 strongly agree, 2 agree, 1 neutral, 1 disagrees

managing a Medicare prescription drug benefit, individuals (executives, etc.) within PBMs are concerned about risk factors associated with managing such a benefit (see Table 1).

Having PBMs solely bear financial risk for the provision of a drug benefit puts PBMs under pressure to limit drug expenditures, without regard for the cost-effectiveness of pharmaceutical care in terms of the overall health care budget. This may defeat the federal government's purpose of containing overall Medicare expenditures. It is economically prudent to include in government contracts incentives for PBMs to contain the pharmacy budget in conjunction with other health care budgets, as opposed to capping a "carved out" pharmacy budget without taking into account its effect on the other budgets.

An area where the promotion of cost-effective pharmaceutical care could be successfully integrated with other health care delivery components is chronic disease man-

agement. According to the Tufts CSDD survey, PBMs are becoming increasingly involved in implementing chronic disease management programs (see Table 2). At present, however, resources allocated to disease management are relatively limited when compared, for instance, to the resources appropriated to PBM pharmacy and therapeutics committees. With constrained resources at their disposal, the majority of PBMs report that disease management activities are limited to compliance and patient/physician education issues (6).

Results from the Tufts CSDD survey indicate that PBM-led disease management is still in the developing stages. The PBMs surveyed are divided on what disease management's primary objective should be—cost saving or health quality improvement (see Table 3). Nevertheless, the fact that seven of the eight PBMs surveyed reported to the firm's pharmacoeconomics function, and the same seven agree that disease management should incorporate a drug/nondrug tradeoff

TABLE 2
PBM Disease Management

Resources Allocated to Disease Management Annually	Chronic Conditions Designated for Disease Management	Disease Management Reporting Structure	Disease Management Instituted			
More than \$10 million:	0/8	Congestive Heart Failure:	8/8	Clinical Services Department:	7/8	In 1994: 1/8 In 1996: 3/8
Between \$5–10 million:	1/8	Diabetes:	8/8	Pharmacy & Therapeutics Committee:	1/8	In 1997: 1/8 In 1998: 3/8
Between \$1–5 million:	2/8	Asthma:	8/8	Pharmacoeconomics Function:	7/8	In 1999: 0/8
Less than \$1 million:	5/8	Hypertension:	7/8			
		Alzheimer's:	0/8			

TABLE 3
PBM Attitudes Toward Disease Management

Disease Management is Primarily a Cost Saving Tool/Cost Effectiveness Device	Disease Management is Primarily a Quality of Care Improvement Tool	Disease Management is a Pharmacy Budget Carve Out	Disease Management Should Incorporate a Drug/Nondrug Cost Tradeoff
4 agree, 4 disagree	5 strongly agree, 2 neutral, 1 disagrees	1 agrees, 3 neutral, 4 strongly disagree	1 strongly agrees, 6 somewhat agree, 1 neutral

suggests that disease management is used as a cost saving or a cost-effectiveness device.

Given that the chronically ill Medicare population accounts for close to 60% of the total costs of the Medicare program (24), the potential cost savings associated with improved management of chronic diseases are high. More than 20% of health care costs attributed to the chronically ill are prescription drug expenditures (22). The prescription drug share is likely to increase with future improvements in outpatient pharmacotherapy. To maximize the value of disease management, PBMs might want to link their pharmacy claims databases with HCFA's medical claims databases to better identify Medicare beneficiaries at risk per disease category. In turn, PBMs could recommend appropriate drug therapy, and inform patients and their physicians about compliance as well as best clinical practice methods based on both clinical and economic considerations.

APPENDIX

For the purpose of gaining additional insight regarding current PBM involvement in Medicare, a survey of 14 leading PBMs was carried out by the Tufts CSDD in February and March 2000. Eight PBMs completed the survey (Ten PBMs responded to the survey, of which eight completed the questionnaire. The survey participants are Advance Paradigm, Caremark, Inteq, MIM Health Plans, Pacificare, PCS Health Systems, ProVantage, and RESTAT. These PBMs serve roughly 60% of the total number of covered lives in the United States.). These eight PBMs cover a total of approximately 110 million lives, of which about seven million are Medicare

beneficiaries. The PBMs surveyed enrolled over 700000 Medicare beneficiaries in 1999.

The survey examined three topics:

- Current Medicare beneficiary enrollment in PBMs; number of beneficiaries added in 1999, proportion of Medicare beneficiaries enrolled in a managed care as opposed to a fee-for-service plan,
- PBM-led disease management programs; length of time that disease management has been an officially instituted function of the surveyed PBMs, resources allocated to disease management, disease management reporting structure, chronic diseases designated for disease management, and
- PBMs' role in managing a Medicare prescription drug benefit, the selection risk involved, and disease management as a pharmacy budget "carve out" (A pharmacy budget "carve out" implies that costs and benefits related to disease management are measured solely on the basis of the drug budget impact, and not measured across health care budgets.). Using a Likert-scale questionnaire, respondents were presented with statements to which they could either strongly agree, somewhat agree, neither agree or disagree, somewhat disagree, or strongly disagree.

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