



**The Value of Pharmacy Benefit Management
And the National Cost Impact of Proposed PBM Legislation**

Prepared for

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I. Introduction and Summary

The Pharmaceutical Care Management Association (PCMA) retained PricewaterhouseCoopers (PwC) to estimate the value of pharmacy benefit management as well as the potential impact, including higher health insurance premiums and loss of health insurance coverage, from enactment of proposed legislation that would restrict pharmacy benefit management (PBM) activities for consumers, private employers, health plans, unions, and state and federal governments.

- PricewaterhouseCoopers estimates that, on average, pharmacy benefit management reduces prescription drug costs by 25 percent compared to retail purchases with no pharmacy benefit management support.
- Pharmacy benefit management activities in 2005 will reduce costs by \$268 per enrollee in private plans, or about \$53 billion in total.
- PwC estimates that total savings from pharmacy management over the next 10 years, 2005-2014, will amount to about \$1.3 trillion.

The practices of pharmacy benefit managers are the subject of numerous legislative proposals under consideration in the various state legislatures. Each of these restrictions on PBM operations has the potential of reducing the savings from pharmacy benefit management. PricewaterhouseCoopers estimated the national impact of five legislative proposals that are representative of the bills under consideration in various states. As shown in Table 1, each of these illustrative legislative options, if enacted at the national level, would increase private drug costs managed by PBMs by a wide range, from as little as 3.0 percent to as much as 10.2 percent. These increases translate into a range of \$97 to \$328 billion over the 2005 to 2014 period. Higher drug costs would increase insurance premiums. Higher premiums, in turn, cause a reduction in the number of employers and consumers purchasing health insurance because of the added costs. As a result of each of these legislative proposals, the number of uninsured individuals would increase by between 100,700 and 321,000 in 2005 alone.

Table 1. National Impact of Legislative Proposals on PBM-Managed Drug Costs And Number of Uninsured

Legislative Proposal	Change in Managed Drug Spending (2005-2014)		Change in Uninsured Population, in thousands 2005
	Billions of Dollars	Percent Change	
Option 1: Limit Therapeutic Interchange	\$167	5.2%	172.8
Option 2: Limit Drug Management Techniques	\$158	4.9%	158.6
Assuming Therapeutic Interchange included	\$309	9.6%	321.0
Option 3: Limit Mail-Service Incentives	\$97	3.0%	100.7
Option 4: Require PBM Disclosure	\$225	7.0%	204.8
Option 5: Require Fiduciary Responsibility	\$99	3.1%	103.0
Assuming Disclosure required	\$328	10.2%	313.7

Source: PricewaterhouseCoopers calculations.

II. Background

Beginning in the mid-1980s, spending on prescription drugs began increasing faster than spending on healthcare overall. Even though prescription drug therapy may have substituted in some cases for other, more expensive medical treatments, the sheer increase in this cost category prompted employers and health plans to seek solutions on how to better manage their drug benefits. Employee benefit managers, who are responsible for ensuring that their members or employees have access to affordable healthcare coverage, began to shift administration of their pharmaceutical benefits to companies that have the expertise to handle this complex area.

These companies have evolved and today are known as pharmacy benefit managers or PBMs. Beginning around 1990, these PBMs provided real-time electronic claims adjudication. Many also provided and managed networks of pharmacies willing to accept negotiated discounts on drug prices and dispensing fees. PBMs' services have expanded to include clinical services, such as preventing dangerous drug interactions through drug utilization review. Mail-service pharmacy also has become a prominent part of PBMs' techniques for cost reduction. In addition, other organizations—such as health plans or employers—have moved to adopt PBM-like techniques to control spending. For the purposes of this report, we include the impact of all organizations involved in managing pharmacy care through these techniques.

A. The Role of PBMs

PricewaterhouseCoopers estimates that 200 million people, or about 68 percent of the U.S. population, are in private plans with pharmacy benefit management. Some public programs, such as Medicaid, also contract with PBMs to manage the prescription drug benefit. Government health programs, which have the power to set prices, do not usually use many of the key pharmacy benefit management services as described below. For that reason, this study omitted public insurance programs from all of the analyses reported below.¹

The percentage of seniors in PBMs is much lower than the non-elderly population. Only about 50 percent of the elderly population are estimated to be in plans in which the pharmacy benefit is managed, while about 74 percent of the non-elderly are in PBM-managed plans. On average, approximately 68 percent of all prescription drug spending is done through privately managed plans. In our calculations, we estimate that the share of elderly individuals with managed private pharmacy benefits will increase as a result of the Medicare Prescription Drug Coverage, Improvement, and Modernization Act of 2003 (MMA). The Act calls for prescription drug coverage to be provided and/or administered through PBMs and managed care organizations. Because most Medicare beneficiaries will have private health insurance plans, the number of people in plans managed by PBMs or similar organizations, is expected to jump to 217 million, or about 76 percent of the U.S. population.

Competing PBMs contract with union-sponsored plans, small and large businesses, health plans, state and federal-employee benefit plans, and state Medicaid plans. PBMs may be independent entities, subsidiaries of health plans, or operated by large retail chain drug stores. Since 2000, the PBM industry is estimated to have grown 30 percent as measured by membership.²

PBMs provide purchasers a variety of tools and techniques that promote quality, improve outcomes, and help drive down the cost of prescription drugs. PBMs typically offer clients a set of core services designed to contain and improve the value of drug expenditures. PBMs also provide clients with clinically based services designed to improve the appropriateness, safety, and quality of pharmacy benefits. Taken together, these tools can help improve the cost-effectiveness of the drug benefit and include such activities as:

- Electronic claims processing;
- Formulary development and management;
- Networks of pharmacies;
- Generic substitution;
- Rebates and discounts;
- Therapeutic interchange;

- Mail-service pharmacy option;
- Drug utilization review (DUR);
- Disease management;
- Consumer information; and
- Consumer compliance programs.

PBMs use different approaches to optimize their ability to deliver on those practices. For example, one such approach is cost sharing with the patient. Optimally, cost sharing, in the form of copays or coinsurance, is used to encourage the use of certain “preferred” drugs. Low levels of cost sharing may encourage overutilization while higher levels of cost sharing may discourage patients from filling necessary prescriptions. Organizations that contract with PBMs strive to establish cost-sharing structures that are “just right,” accomplishing their specific cost, quality and efficiency goals regarding prescription drug benefits. Other approaches offered to health plan sponsors by PBMs help promote cost-effective drug therapies. For example, a recent report from the U.S. Department of Health and Human Services cited methods such as generic incentive programs, prior authorization and drug utilization review as moderating drug spending starting in the late 1990s.³

Generally, the higher the level of management in the pharmacy benefit, the higher the savings. For example, health plans that limit coverage to drug on a “closed” formulary would be expected to produce more savings than health plans that allow patients to have access to all prescriptions drugs. However, “tighter” management may encroach on some patients’ choices, and some plan-sponsor PBM clients choose arrangements, such as “tiered” copayments, that allow patients to have access to a wider range of prescription drugs, with a corresponding higher costs for the plan sponsor and/or consumers. Just as managed care networks have moved to less restrictive networks and more consumer choice, so are many pharmacy benefit plans offering clients a broader choice of a variety of drug benefit options as well.

PBMs take on the complex tasks of evaluating thousands of competing drugs – both in terms of cost and efficacy. The sheer complexity of this role requires an intermediary that can focus on the thousands of drugs available. Spending on pharmaceuticals is determined by more than price of individual drugs. The volume and selection of drugs also bear considerable weight in how much is spent on drugs. Selecting the right drug for the right diagnosis is the essence of efficient healthcare spending. While physicians prescribe drugs, they are not in a position to negotiate prices or calculate the price differentials between competing drug therapies.

B. Purpose and Outline for This Report

While drug spending has been tempered in part by PBMs, health plans and employers continue to refine and seek innovation regarding how drug spending is managed to ensure appropriate use of the health benefit dollar.

This report provides an objective analysis of the savings achieved by PBMs and organizations that provide PBM functions. These savings could be at risk, depending on the outcome of various legislative proposals. Knowing the savings achieved through various pharmacy benefit methods, policymakers can make better decisions about the outcomes of such legislative proposals.

Some of these legislative proposals would intervene in benefit design issues, the scope of which private and public purchasers determine for PBMs. Dictating certain benefit design through legislation could limit an employer's ability to offer health insurance if it makes the benefit more expensive. As health insurance premiums have increased in recent years for a variety of reasons, more employers are opting not to offer insurance, or to raise the employees' contribution to health insurance premiums. Both cases contribute to rising levels of uninsured.

The following section of the report will provide estimates of the savings currently provided through pharmacy benefit management activities like those carried out by PBMs. Next, we will present our estimates of five illustrative legislative proposals to limit pharmacy benefit management.

III. Savings from Pharmacy Benefit Management

PBMs, as discussed in the previous section, reduce the cost of prescription drugs through a variety of techniques including formularies, disease management, retail pharmacy networks, manufacturer rebates, and management of prescription drug utilization. This section presents PricewaterhouseCoopers' estimates of the magnitude of these savings relative to spending on prescription drugs and in terms of total dollar savings to U.S. consumers and third-party payers.

A. Estimated Percent Savings From Pharmacy Benefit Management

The total savings from pharmacy benefit management varies across health plans and depends on the level of PBM services elected by clients. Some clients contract with PBMs only for administrative services, such as claims and benefit administration. Others adopt a whole range of PBM services, such as formulary, clinical control and disease management. The level of

PBM services utilized depends on the client, which may be an employer, health plan, union, or state or federal government.⁴

Health plans that agree to the narrowest retail networks, tighter formularies, and most aggressive management techniques are able to reduce prescription drug costs by 40 percent or more. Alternatively, plans that have broad networks, completely open formularies, and little management intervention probably save only 15 percent or less, compared to retail purchases with no management. (see Table 2 below).⁵

**Table 2. Savings Generated by PBMs
(Relative to Unmanaged Sales at Average Retail Prices)**

	Level of Management		
	Low	Medium	High
Total Reduction in Costs	15%	25%	40%

Source: PricewaterhouseCoopers.

PBMs rely upon a variety of tools and techniques to help lower the cost of prescription drugs for consumers and health care purchasers:

- Network discounts and dispensing fees.** Network discounts are negotiated by PBMs and are taken at the time the prescription drug is dispensed. Pharmacies may be willing to give discounts in exchange for the increased business that PBMs can bring. Health plans that restrict their enrollees to a relatively small network usually receive the greatest discounts. Offsetting the network discount, PBMs pay retail pharmacies a dispensing fee as part of their retail pharmacy network contracts. The dispensing fees for prescriptions dispensed through mail-service pharmacies are often much lower. Costs are lower in highly managed drug benefit plans, in which clients may choose options such as mandatory mail-service pharmacy for maintenance drugs related to managing chronic conditions. In part because mail-service pharmacies are automated, the cost of dispensing prescriptions is much lower.
- Formularies.** Among the most important tools developed by PBMs to manage prescription drug benefits are formularies. A formulary is a list of prescription drugs approved for reimbursement by the plan sponsor contracting with a PBM. In developing a formulary, the primary considerations are safety, efficacy and clinical appropriateness.

PBMs use panels of experts, called Pharmacy and Therapeutics (P&T) committees, to develop their formularies. P&T Committees are comprised of physicians, pharmacists, and individuals with other appropriate clinical expertise. Often, individuals with special expertise are consulted when considering medications within particular therapeutic classes. Development and maintenance of formularies is an ongoing activity, as they must be continually updated to keep pace with new therapies, recent evidence from clinical research, changes in medical practice, and FDA guidance.

Once a drug is evaluated and classified by the P&T committee, it can be further classified as preferred, non-preferred or generic. Such classification is known as tiering. Tiered formularies are developed based on the needs of the plan sponsor and what co-pay structure and cost sharing they wish to include in their prescription drug benefit. Often, generic drugs are assigned the lowest co-payment, followed by preferred, and finally non-preferred drugs.

- **Therapeutic interchange programs.** PBMs use formularies reviewed by their P&T committees that identify drug pairs that are therapeutically equivalent. PBMs contact the prescribing physician when a non-preferred formulary drug has been written and suggest that the physician authorize the interchange of the original drug to the preferred drug. Therapeutic interchange always requires the approval of the prescribing physician and a new prescription from the physician.
- **Utilization management** – PBMs also rely upon a variety of other tools to help lower the cost of prescription drugs, including generic substitution, prior authorization for classes of drugs that are often prescribed in a manner inconsistent with accepted best medical practice and other specific classes of drugs, drug utilization review, disease management and patient education. Clients seeking greater savings will seek higher levels of intervention by their PBM. Savings in this area require more intervention by the PBM than either network discounts or rebates, both of which come from the client's willingness to put in place certain plan features in the initial plan design. Savings from higher and more intensive levels of management require continual input and monitoring by PBMs to assure appropriate utilization of cost-effective and clinically proven drugs.
- **Rebates** – Rebates lower the overall cost of prescription drugs. Pharmaceutical manufacturers typically provide larger rebates to PBMs for inclusion of a therapeutically equivalent drug on a formulary when other equivalent drug therapy options exist to the PBM. To increase the utilization of a specific drug in a therapeutic class requires that the PBM encourage enrollees to utilize that drug instead of other therapeutic alternatives. PBMs rely upon a variety of approaches, including perhaps placing that drug in a less expensive – and hence more desirable – tier for the enrollee and/or by demonstrating to prescribing physicians that the drug is clinically equivalent, but more cost-effective than others in the same therapeutic class.

Rebates are substantially lower for plans that have “loose” formularies and do not rely upon incentives to encourage the use of specific drugs compared to those plans that have “tighter” formularies and use a wide variety of techniques to encourage utilization of certain specific drugs.

- **Other administrative costs** – Like other businesses, PBMs have other costs in sales and benefit administration and a required return. Some of the functions that PBMs must pay for include call centers, clinical staff, information technology and robotics. In some cases these costs are reimbursed through a direct fee while in other instances PBMs subtract administrative costs from the rebates they receive from pharmaceutical companies before sharing them with clients.

B. Total Savings from Pharmacy Benefit Management Activities, 2005-2014

PricewaterhouseCoopers estimates that the total savings in drug costs from pharmacy benefit management are \$53 billion in 2005 and \$1.3 trillion dollars over the decade, 2005-2014. The details behind this estimate are presented in Table 3 below. (Total savings may not add up due to rounding.)

PricewaterhouseCoopers derived the total savings from PBMs based on the following factors:

- The official estimates of prescription drug spending 2004-2013 from the National Health Accounts as published by the Centers for Medicare and Medicaid Services (U.S. Department of Health and Human Services). CMS forecasts that national spending on prescription drugs will grow from \$234 billion in 2005 to \$567 billion in 2014, for a total over the 10-year period of \$3.9 trillion dollars.⁶
- PricewaterhouseCoopers estimates that prescription drug spending managed by private, third-party payers (that almost universally rely on PBM arrangements) will account for 68 percent of prescription drug spending in 2005, or about \$158 billion. The proportion managed by PBMs will jump to 84 percent when most Medicare beneficiaries enroll in private, prescription drug plans under the MMA.
- PricewaterhouseCoopers estimates that savings in the private plans, as discussed in detail above, is about 25 percent.
- When combined with our estimate of how many dollars are managed by PBMs, PricewaterhouseCoopers estimates that total savings are \$53 billion in 2005, rising to \$88 billion when most Medicare beneficiaries are brought under PBM arrangements in 2006, and reaching \$194 billion in 2014, for a total over the decade of \$1.3 trillion in savings.

**Table 3. Total Savings Generated by PBMs
(In billions of dollars)**

	2005	2005-14
<i>Total Drug Spending</i>		
Total	\$234	\$3,868
Non-Medicare	\$133	\$2,205
Medicare	\$100	\$1,663
<i>Managed Private Spending</i>		
Total	\$158	\$3,220
Non-Medicare	\$106	\$1,749
Medicare	\$52	\$1,470
<i>Managed Private Spending as a Share of Total</i>		
Total	68%	84%
Non-Medicare	79%	79%
Medicare	52%	88%
<i>PBM Discount on Managed Private Spending</i>		
Total	\$53	\$1,288
Non-Medicare	\$36	\$595
Medicare	\$18	\$693

Source: PricewaterhouseCoopers calculations.

The savings generated by PBMs are not only large relative to prescription drug spending, they are also an important element of managing private insurance costs overall. According to the official CMS forecasts, total spending by private insurance companies will total \$25 trillion over the 2005 to 2014 period. Without the savings from PBMs, those total overall health care costs would rise throughout the entire system by about 4 percent and premiums would have to rise correspondingly to cover that increase.

The importance of PBM savings is also illustrated by calculating the per capita costs—roughly, \$268 for each person enrolled in private health plans in 2005. Because Medicare beneficiaries use more prescription drugs, the savings are about \$937 per Medicare beneficiary in private plans in 2005.⁷

IV. Impact of Legislation That Would Restrict Pharmacy Benefit Management Activities

While the tools and techniques PBMs rely upon have been embraced by a broad spectrum of private and public purchasers – most dramatically and recently through the Medicare Modernization Act – some groups have been critical of PBMs. A number of states are considering legislation that would further regulate, restrict, or eliminate PBM operations. The interest that states have in PBMs may well be a reflection of the dominance they have demonstrated in the marketplace. In one form or another, PBMs administer nearly all private drug plans and, increasingly, a larger share of public programs' drug plans. With \$234 billion expected to be spent on pharmaceuticals in 2005, consumers, physicians, pharmacists, health plans, PBMs, small and large employers, labor unions, drug distributors, and drug manufacturers all have a financial interest in how resources are allocated.

As PBMs have emerged in the marketplace, their opponents have lobbied in the legislative arena for restrictions on certain practices of the PBM industry. Some groups argue that PBMs are interfering with the care that providers give to their patients in the interest of controlling costs. Others criticize PBMs for appearing to be more interested in boosting profits over controlling costs on behalf of purchasers. As a result, some states are now considering legislation to place limits on the activities of PBMs, although several states already in 2004 – most notably Florida, Maryland, and Vermont – have rejected legislative proposals calling for additional PBM regulation.

PricewaterhouseCoopers reviewed a range of legislative proposals that have been introduced in various states and developed a list of the most common ones, especially those that would appear to be the most far reaching in terms of impact on savings. Table 4 and the content of this section present PricewaterhouseCoopers' findings with respect to the impact of five illustrative legislative proposals that would place new restrictions on certain pharmacy management activities:

1. Limit Therapeutic Interchange
2. Limit Other Drug Management Techniques
3. Limit Mail-Service Pharmacies
4. Require PBMs to Disclose Contract Terms
5. Require PBMs to Bear Fiduciary Responsibility

We describe each of the options and the basis for our estimates below. Note that in every case, these estimates are consistent with our estimates of the overall savings generated by PBMs, and our estimates assume the legislation will be enacted on a national scale.⁸

Also, note that the impact varies by year for three reasons:

- The baseline share of generic drugs increases over time, and the effects of the legislation is different for generic drugs and brand drugs.
- The increase in mail order is expected to increase over time, affecting the savings.
- The introduction of the MMA drug benefit in 2006 causes a jump in the impact of each proposal. For example, PwC expects rebates to increase significantly for the Medicare population once they are covered by the Medicare benefit. For the legislative proposals that affect rebates (all but Mail Order and Fiduciary w/o disclosure), the impact of the legislation would be larger once the MMA benefit is in effect.

Table 4. Impact of Legislative Proposals on PBM-Managed Drug Costs And Number of Uninsured, 2005

Legislative Proposal	Change in Managed Drug Spending			Change in Uninsured Population, in thousands 2005
	2005 (in billions)	2005-14 (in billions)	Percent Change	
Option 1: Limit Therapeutic Interchange	\$6.9	\$167	5.2%	172.8
Option 2: Limit Drug Management Techniques	\$6.4	\$158	4.9%	158.6
Assuming Therapeutic Interchange included	\$12.9	\$309	9.6%	321.0
Option 3: Limit Mail-Service Incentives	\$4.0	\$97	3.0%	100.7
Option 4: Require PBM Disclosure	\$8.2	\$225	7.0%	204.8
Option 5: Require Fiduciary Responsibility	\$4.1	\$99	3.1%	103.0
Assuming Disclosure required	\$12.6	\$328	10.2%	313.7

Source: PricewaterhouseCoopers calculations.

A. Option 1: Limits on Therapeutic Interchange

Background

PBMs currently use therapeutic interchange to provide maximum flexibility in substituting therapeutically equivalent drugs, often at a cost-savings. Therapeutic interchange programs give patients incentives to try lower-cost alternatives before moving on to a more expensive medicine. Therapeutic interchange programs are a critical component of formulary management because they directly impact the market share of preferred versus non-preferred drugs. These lower-priced treatments may prove successful, saving both the plan and the patient. Critics of this practice believe that PBMs are interfering with the treatment prescribed by physicians.

The actual interchanges often result in lower net costs to health plans (i.e, the discounted price less the associated rebate.) For consumers to move from one drug to another, PBMs must obtain a new prescription from the prescribing physician or other health care provider. While PBMs work to educate, physicians always make the final prescribing decisions.

This legislation would prohibit PBMs from recommending therapeutically equivalent drugs unless all of the following conditions are met:

- The substitution must be made for medical reasons that benefit the patient;
- The substitution must benefit the client;
- PBMs must obtain prior authorization from the prescribing physician or other health care provider;
- The PBM must disclose to the patient and client the cost of both drugs and any benefits or payments directly or indirectly accruing to the PBM because of the interchange.

Finally, if the substitution follows the above standards, the PBM must transfer in full to a covered entity all benefits or payments received because of the substitution under the above requirements.

Cost Impact Analysis

PricewaterhouseCoopers assumes that this proposal would essentially eliminate prescription interchange. This legislation would reduce the incentives for PBMs to encourage consumers to utilize lower-cost drugs by increasing the administrative costs of doing so. The legislation would also limit the ability of PBMs to encourage individuals to move into different therapies and receive rebates from manufacturers whose therapeutically equivalent products are favored by the therapeutic interchanges.

Therapeutic interchange can lower drug spending by as much as 15 percent or more in drug classes where it is utilized. The limiting of therapeutic interchange would also decrease the amount of rebates that manufacturers pay associated with formulary compliance. Taken together, these two effects would lower the average discount on PBM-managed sales by 3.3 percentage points.⁹

- This change results in an increase in drug costs for individuals in PBM-managed plans of 4.4 percent, or \$6.9 billion in 2005.¹⁰
- Over the 2005 to 2014 period, this increase would translate into additional costs of \$167 billion (see Table 4), a 5.2 percent increase. This would increase in 2006 as more Medicare beneficiaries join PBMs.

- Higher prescription drug prices would have wider economic effects. PwC estimates that the 4.4 percent increase in prescription drug costs would increase health insurance premiums by about 0.4 percent in 2005 and lead to nearly 172,800 individuals losing health insurance in 2005.¹¹ Employers who purchase health insurance for their employees and consumers who purchase individual health plans would attempt to avoid the higher costs of health insurance by changing benefits or dropping health insurance coverage altogether.

B. Option 2: Limitation of Drug Management Techniques

Background

PBMs use prescription transmission intervention in a variety of ways, including assuring compliance with the client's formulary and benefit design as well as quality protections such as detecting dangerous drug interaction. For example, the PBM might ask the doctor whether a certain drug is medically appropriate for the condition being treated. PBMs are required to obtain the approval of the prescribing physician in order to affect a therapeutic interchange; however, consumers may or may not need to explicitly approve the interchange, depending on the specific interchange program employed (although they have the right to reject the interchange after it has occurred). Proponents of the legislation argue that this intervention is inappropriate because it interferes with the treatment the prescribing physician believes is the best course of action.

This legislation would restrict the ability of PBMs to manage a prescription by prohibiting any intervention prior to dispensing a prescription. Specifically, the legislation would require that:

- A PBM could not intervene prior to dispensing a prescription without express written authorization of the prescribing health care provider and the insured consumer.
- A PBM could not enter into a contract with a pharmacy or insurer that requires a pharmacist to alter an insured consumer's prescription without the express written authorization of the prescribing healthcare provider and the insured.

This prohibition would hinder the ability of PBMs to review prescriptions in a timely manner to enforce formularies and preferred drug lists. Prohibiting PBMs from intervening in the delivery or transmission of a prescription could affect the following common prescription management tools:

- Clinical prior authorization: Requiring prescribing physician or other health care provider to obtain approval for a particular drug before it is dispensed. Again, this mechanism facilitates the formulary and preferred drug list system by requiring approval for drugs not included on these lists.

- Drug utilization review: Programs designed to review drug-prescribing patterns; provide educational information to health providers on cost-effective therapeutic care; and perform rapid-fire quality checks, such as drug interaction and fraud detection.

Cost Impact Analysis

We assume that this proposal would eliminate the ability of PBMs to use prior authorization requirements and drug utilization reviews to control costs. PBMs believe they are able to suggest alternative treatments, which the prescribing physician may not have considered. Requiring the sign-off of both the physician and the patient would cause undue delay and decrease the likelihood of alternative treatments (which may be more cost effective). Preventing PBMs from encouraging patients to utilize less costly treatments under the benefit design will also limit rebates paid by manufacturers for formulary compliance.

Prior authorization can lower drug costs by up to 80 percent in certain drug categories (the savings would be offset in part by some PBM costs for administering the program). Drug utilization review can also result in significant savings.

- PricewaterhouseCoopers estimates that the elimination of these management techniques would decrease discounts by about 2.5 percentage points, and rebates would also fall by 0.6 percentage points.¹²
- Overall, this provision would increase drug costs for individuals in PBM-managed plans by 4.0 percent, or about \$6.4 billion in 2005.
- Over the 2005 to 2014 period, this increase would translate into additional costs of \$158 billion, a 4.9 percent increase.
- PwC estimates that the 4.0 percent increase in prescription drug costs would increase health insurance premiums by about 0.4 percent in 2005 and lead to almost 158,600 individuals losing health insurance in 2005.

Inclusion of Limiting Therapeutic Interchange

- If this proposal also limited the ability of PBMs to utilize therapeutic interchange, the increase in drug costs would reach 9.6 percent increase, about \$309 billion over the 2005 to 2014 period.¹³
- PwC estimates that the 8.1 percent increase in prescription drug costs would increase health insurance premiums by about 0.4 percent in 2005 and lead to 321,000 individuals losing health insurance in 2005.

C. Option 3: Limit Incentives for Mail Service Pharmacies

Background

PBMs reduce the costs of dispensing drugs by using high-volume, automated mail-service facilities. Mail-service dispensing also makes other tools that PBMs use more effective as well. For example, utilization review and therapeutic intervention with the prescribing physician is easier to do effectively if the patient is not standing at the counter waiting for the drug to be dispensed. To encourage the use of mail service, health plans often charge lower copayments for mail-service prescriptions and allow longer prescriptions (i.e., 90 days instead of 30 days). Some plan designs have moved to a more aggressive model in which members are required to use mail service for prescriptions that treat certain chronic conditions. Some unions have adopted mandatory mail service as a trade-off to retain other healthcare benefits.¹⁴

Proponents of the legislation believe incentives provided to encourage mail-service offer unfair advantages to mail-service pharmacies over retail pharmacies. This legislation would prohibit differential reimbursement or other agreements that encourage mail-service delivery of prescriptions. Specifically, clients would be prohibited from offering economic benefits, or any other incentives, to encourage patients to move their prescriptions away from retail pharmacies to mail order.

Cost Impact Analysis

This proposal would essentially eliminate any incentives PBMs currently use to encourage the use of mail-service pharmacies because few patients will use mail service when they can go to a retail outlet for the same prescription at the same price. We estimate that mail-service discounts are about 11 percentage points higher than discounts on retail drugs, and that mail-service represents about 16 percent of total spending. We expect that this share will increase to 20 percent by 2014.¹⁵

- We estimate that this provision would increase drug costs for individuals in PBM-managed plans by 2.6 percent, or about \$4.0 billion in 2005.¹⁶
- Over the 2005 to 2014 period, this increase would translate into additional costs of \$97 billion, a 3.0 percent increase.
- PwC estimates that the 2.6 percent increase in prescription drug costs would increase health insurance premiums by about 0.2 percent in 2005 and lead to more than 100,700 individuals losing health insurance in 2005.

D. Option 4: Require Disclosure of Contract Terms & Pricing Data

Background

PBMs reduce pharmaceutical costs through direct negotiation with large retail drug stores for discounted reimbursement rates and with pharmaceutical manufacturers for rebates and other retrospective utilization discounts. These negotiations and resulting pricing structures are currently private information and are not publicly available. The parties do not disclose the details of contract negotiations because such information could affect their competitive position in future negotiations.

Proponents of the legislation believe that increasing the transparency of PBM and manufacturer interactions will provide plans and patients with more information that they can use to assess the actual discounts they receive on drugs. Some consumer advocates and third-party payers believe that they have not been paid all the discounts that PBMs have negotiated on their behalf, and they believe that this legislation would give them the necessary information to ensure that they receive all the discounts to which they are contractually entitled.

The type of disclosure mandated in legislation generally is not required of other healthcare organizations. In a competitive environment, the ability to negotiate in confidentiality is paramount. Without such confidentiality, competition, and the benefits derived from it, is eroded. Those benefits include lower costs achieved through a competitive model.

Under this legislation, PBMs would be required to provide to covered entities all financial and utilization information relating to the provision of benefits and services. Specifically, the legislation would require PBMs to disclose publicly the following agreements:

- Negotiated agreement with a manufacturer to provide rebates, discounts, incentives, retrospective utilization discounts, or other economic incentives.
- An agreement with a manufacturer that favors one manufacturer's product over another's product.
- An agreement to place a product on a formulary or preferred drug list.
- An agreement to encourage the prescribing of a preferred drug over another within a given therapeutic class.
- An agreement to bill a client at amounts higher or lower than the amount a PBM reimburses a pharmacy.
- Any other revenue sharing agreements.

Cost Impact Analysis

This legislation would restrict the ability of PBMs and pharmaceutical companies to have a private contractual relationship relating to pricing and incentives. This information would alter the nature and/or structure of those agreements. If required to make their private concessions public, pharmacy networks and drug manufacturers may be less willing to offer terms as generous as they currently do. In addition, if a PBM knows the pricing offered by a competing PBM, the ability to negotiate a lower price is virtually eliminated. As a result, we estimate that the network discounts and manufacturer rebates will decline significantly. The Congressional Budget Office estimated that a similar provision considered as part of the debate on the Medicare prescription drug bill would have increased the cost of the Medicare drug benefit by nearly 10 percent.

- Drug costs for individuals in PBM-managed plans would rise by 5.2 percent or about \$8.2 billion in 2005.
- Over the 2005 to 2014 period, this increase would translate into additional costs of \$225 billion, a 7.0 percent increase.
- PwC estimates that the 5.2 percent increase in prescription drug costs would increase health insurance premiums by about 0.5 percent in 2005 and lead to about 204,800 individuals losing health insurance in 2005.

E. Option 5: Require PBMs to Have a Fiduciary Duty

Background

Currently, PBMs contract with health plans and large employers to manage the prescription drug portion of health benefits offered. Decisions relating to the scope of those pharmaceutical benefits (or indeed, whether to offer them at all), are made by a plan sponsor, normally the employer or union. PBMs serve in an administrative and advisory role for their clients, performing claims processing and other administrative tasks. PBMs are private entities with duties to their shareholders and contractual business relationships with their clients – the covered entities.

This legislation changes those contractual relationships and transforms each PBM into a “fiduciary” of its clients. This state-imposed creation of a “fiduciary duty” is applicable to the entirety of the relationship between the PBM and its clients. In addition, creating fiduciary responsibilities for PBMs will require them to change the way they contract with manufacturers for rebates and other fees and require them to publicly disclose their contract terms.

Imposing such fiduciary duties on PBMs could subject them to broader legal liabilities than under current law because it transforms an arms' length contractual relationship into one where one party is responsible for assets that belong to another, such as a trustee relationship.

In addition, the laws imposing such fiduciary duties also require the PBM to discharge its duties with respect to the covered entity for the "primary purpose of providing benefits to covered individuals." That provision can create inconsistencies between its obligation to its client (the covered entity) to assure that a formulary and choice of drugs is cost-effective versus its obligation to the ultimate beneficiary, where cost-effectiveness is not normally an issue. Further, legislative creation of a fiduciary duty imposes obligations on PBMs to (1) disclose all financial terms and arrangements with manufacturers, pharmacies, and others; and to (2) pass through any payments or benefits to the covered entity, regardless of the terms of the contracts.

Under proposed legislation, specifically, a PBM would have to fulfill the following obligations:

- Act in good faith and in the best interest of a covered entity.
- Show duties of loyalty, care, and reporting to a covered entity.
- Notify in writing to a covered entity any activity, policy, or practice that directly or indirectly presents any conflict of interest with a covered entity.
- Provide to a covered entity financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and financial and utilization information relating to services to that covered entity.

Cost Impact Analysis

Requiring PBMs to owe a fiduciary duty to covered entities would expose PBMs to increased legal risk that may result in the need to adopt defensive business and operating strategies to avoid the threat of litigation. The added cost of increased insurance exposure could drive pharmaceutical costs higher for patients.

Additionally, mandating fiduciary status could lead to the disclosure of proprietary business information and trade secrets. As described under Option 4, such disclosure would dramatically undercut the negotiating advantage of PBMs with drug companies and retail pharmacies, thereby increasing drug costs for health plans and their enrollees. Lastly, mandating fiduciary status for PBMs would require that plan design decisions and authority that currently resides with the health plan be extended to PBMs. The difficulty with these proposals is that they presume PBMs are managing the assets of the payer, rather than two entities operating at arms' length.

Operationally, we believe that an important impact of the legislation may expose PBMs to legal liability for the drug benefits that they manage. PBMs would have to boost their liability insurance and might limit the use of utilization techniques to avoid potential lawsuits.

In 2001, total insurance premiums for liability insurance represent about 1.5 percent of total health spending.¹⁷ We estimate that PBMs would be forced to purchase broader liability insurance and that would lower the average discount by 0.5 percent of spending. Further, we expect that PBMs would be less likely to exercise management techniques, cutting the discount by another 1.5 percentage points.¹⁸

- Overall, we estimate that these effects would combine to increase drug costs for individuals in PBM-managed plans by 2.6 percent, or about \$4.1 billion in 2005.
- Over the 2005 to 2014 period, this increase would translate into additional drug costs of \$99 billion, a 3.1 percent increase.
- PwC estimates that the 2.6 percent increase in prescription drug costs would increase health insurance premiums by about 0.2 percent in 2005 and lead to about 103,000 individuals losing health insurance in 2005.

Fiduciary & Disclosure Combined

- If, additionally, this legislation required PBMs to disclose publicly the results of negotiations with pharmacy networks and drug manufacturers, the overall impact of the legislation in such a case would be the combination of the 2.6 percent increase mentioned above and the 5.2 percent increase estimated for the disclosure legislation, or 7.9 percent, about \$12.6 billion in 2005.
- Over the 2005 to 2014 period, this increase would translate into additional drug costs of \$328.0 billion, a 10.2 percent increase
- PwC estimates that the 7.9 percent increase in prescription drug costs would increase health insurance premiums by about 0.7 percent in 2005 and lead to nearly 313,700 individuals losing health insurance in 2005.

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- ¹ Excluding public programs from the analysis reduces the overall savings attributed to PBMs and probably reduces the lost savings estimates in Section IV but only to the extent that legislation also includes public programs, which in some cases it may not.
- ² Market-share analysis shows changing PBM climate, growth as Medco spins off, Drug Cost Management Report, Aug. 29, 2003.
- ³ Trends in US Healthcare Spending, 2001, Health Affairs, Katharine Levit, Cynthia Smith, Cathy Cowan, Helen Lazenby, Art Sensenig, and Aaron Catlin, January/February 2003.
- ⁴ As noted previously, this report does not include state or federal government use of pharmacy benefit management in its analysis or estimates.
- ⁵ These figures are based on reports and testimony from the General Accounting Office, Congressional Research Service reports, financial reports from PBMs, discussion with industry consultants, conversations with PBMs, and other private research.
- ⁶ CMS estimates for prescription drug spending by source of payment, 2004-2013 can be found on their website at: <http://www.cms.hhs.gov/statistics/nhe/projections-2003/t11.asp>. The National Health Accounts do not include projections for 2014. The growth in prescription drug spending is slowly declining and the projection for 2014 reflects this decline.
- ⁷ As a percent of retail spending without management, the savings from private prescription care management in 2004 is probably about the same in both Medicare and nonMedicare population. The dollar savings is much higher for Medicare beneficiaries because spending per capita is higher for Medicare beneficiaries who are either elderly or else have disabilities.
- ⁸ State regulations generally only apply to plans and entities not covered under Federal ERISA rules. For the purposes of this study, we have assumed that the legislative proposals will be implemented at the national level and therefore apply to all plans managed by PBMs. Once we have calculated the national estimate, we allocate the impacts to the state level. If an individual state were to implement the proposal, the impact on that particular state could differ from our estimates.
- ⁹ We estimate that therapeutic interchange currently saves about 2.7 percent of retail drug costs across all spending in private plans. These savings would be lost under the proposal, as would an additional 0.6 percent from lost rebates from drug manufacturers (we assume half of rebates are driven by movement of market share to particular drugs, and that those rebates would fall by 25 percent, so rebates relative to retail drug costs fall by 0.6 percentage points).
- ¹⁰ Instead of being 25 percent, the overall discount under this proposal would fall to 21.8 percent. Total spending rises by 4.4 percent ($= (1 - 21.8\%)/(1 - 25\%) - 1$).
- ¹¹ Our estimates are based on the assumption that a one percent increase in health insurance premiums causes a 0.3 percent reduction in health insurance coverage. We view this as a

conservative estimate. The Congressional Budget Office estimated that a premium increase of one percent would increase the number of uninsured by about 200,000, a change of about 0.14 percent. However, the CBO estimate specifically addressed the loss of coverage due to a mental health parity mandate, not a change that reflected an increase in premiums with no increase in coverage. This is an important distinction because people are less likely to drop insurance coverage if the increase in cost is accompanied by an increase in benefits as opposed to solely an increase in costs.

In other cases, the Congressional Budget Office assumes an elasticity of minus 0.6 for premium increases not accompanied by increases in benefits. In other words, a 1 percent increase in health insurance premiums leads to a 0.6 percent reduction in the purchase of health insurance. The PwC estimate is based on a minus 0.6 percent elasticity offset by a 33 percent reduction to account for those who would obtain insurance through another family member's employer-sponsored plan, private insurance, or public insurance programs. See *CBO's Estimates of the Impact of the Mental Health Parity Amendment in H.R. 3103* (Washington, DC: May 13, 1996) and *Behavioral Assumptions for Estimating the Effects of Health Care Proposals* (Washington, DC: November 1993).

- ¹² We estimate that the combination of prior authorization and drug utilization review currently saves about 2.5 percent of retail drug costs across all spending in private plans. These savings would be lost under the proposal, as would an additional 0.6 percent from lost rebates from drug manufacturers (we assume half of rebates are driven by movement of market share to particular drugs, and that those rebates would fall by 25 percent, so rebates relative to retail drug costs fall by 0.6 percentage points).
- ¹³ We assume that elimination of therapeutic interchange, prior authorization, and drug utilization review would lower the average discount across all managed drugs by 5.2 percentage points and lower average rebates by 0.6 percentage points.
- ¹⁴ Mail Order Prescriptions Poised for Growth, Bank of America Securities, March 15, 2004.
- ¹⁵ According to a recent Bank of America study, the share of mail-order prescriptions could rise as high as 50 percent, based on current drug utilization patterns. See Bank of America Securities, "Mail Order Prescriptions Poised for Growth," March 15, 2004.
- ¹⁶ The elimination of mail order incentives will eliminate any additional discounts attained currently under mail order. The elimination of the 11 percent differential will lower the overall discount by 1.8 percentage points (an average of 19 percent of drug spending in mail order over the period * 11 percent).
- ¹⁷ A study from the Joint Economic Committee of the U.S. Congress estimated that the direct costs of premiums for medical liability insurance were \$21 billion in 2001 (See Joint Economic Committee, "Liability for Medical Malpractice: Issues and Evidence," May 2003). These premiums represent almost 1.5 percent of total health spending in the National Health Accounts. The ratio must be adjusted to estimate the liability insurance premiums that PBMs would have to pay under the proposal. The ratio sums premiums across all providers, and some providers (such as physicians) face more risk than others, resulting in higher liability premiums. Also, some of the risks PBMs will face under a fiduciary duty will be new risk, but some will be risk that other providers already

faced (and insured against). We feel that PBM premiums of 0.5 percent of drug spending represent a conservative estimate.

¹⁸ Researchers have found that defensive medicine raises health costs by 5 to 9 percent (see Kessler, D. & McClellan, M, “Do Doctors Practice Defensive Medicine,” *Quarterly Journal of Economics*, 111(2): 353-390, 1996). Assuming a similar relationship between the low end of the range and average liability premiums, we estimate that PBMs would adjust their drug management techniques to lower discounts by 1.5 percentage points (5 percent (lower bound of defensive medicine costs) / 1.5 percent (overall liability premium) * 0.5 percent (assumed PBM premium) is approximately equal to 1.5 percent).