Study of Pharmaceutical Benefit Management

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The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Health Care Financing Administration. The contractor assumes responsibility for the accuracy and completeness of the information contained in this report.

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EXECUTIVE SUMMARY

Pharmacy benefit managers (PBMs) have emerged as the national standard for the administration of prescription drug insurance in the United States. Today, in an environment of rising drug costs and utilization, PBMs provide pharmacy benefits to nearly 200 million Americans, including 65% of our country's seniors. The PBM's ability to reduce costs, provide national pharmacy access, and administer benefits that are customized to meet the needs of a wide range of clients in a highly automated environment all attribute to the success of the industry.

The clients of a PBM are primarily major employers, insurers and managed care organizations. The client works with the PBM to decide the pharmacy benefit (i.e., insurance coverage for prescription medication) that it will offer, including the drugs that will be covered, the beneficiary's cost sharing requirements, and the pharmacy network. The client then retains the PBM to administer the pharmacy benefit for its members or employees.

One of the primary reasons clients retain PBMs, is that PBMs reduce the cost of offering a pharmacy benefit. PBMs do this by automating administrative services, obtaining discounts on drugs (ingredient cost), and managing drug utilization. For example, PBMs:

- Reduce administrative cost by using a highly automated environment to electronically process claims at the point of service (e.g., pharmacy where prescription is dispensed). Over 99% of pharmacy claims are processed in this manner, at an average cost of $.30 to $.40 per claim.

- Reduce ingredient cost by obtaining pharmacy-pricing discounts from dispensing pharmacies, and rebates from pharmaceutical manufacturers. These discounts are obtained under contracts, and shared or passed on to clients. The cost of prescriptions, which average around $60.00, can be reduced as much as 30% to 35% by a PBM's programs.

- Manage utilization and favor lower cost medications by using clinical services that influence the behavior of the physicians, pharmacist and patient.

Over the last 10 years the PBM industry has grown dramatically, and undergone several major restructuring trends. These trends include:

- Explosive growth of the PBM industry into the mid-1990s as managed care organizations, insurers and later self insured employers sought to reduce the cost of their pharmacy benefit by contracting with PBMs to receive manufacturer rebates and pharmacy network discounts;

- Acquisition of several leading PBMs by manufacturers in the early 1990s (Merck-Medco, SmithKline Beecham-DPS, and Lilly-PCS). These acquisitions were the result of manufacturer's concern over losing access to the lives managed by the PBM, and were partly prompted by the proposal of healthcare reform under the Clinton Administration. Since the number of lives covered by the PBM drove up the premium paid by the manufacturer, PBMs took on additional lives in an effort to become an attractive acquisition candidate. To do this, PBMs lowered their claims processing fees and rebate retention rates, and in some cases assumed risk for the cost of the pharmacy benefit. As a result of these actions the industry took on unprofitable business.

- In the mid-1990s, the business matured and manufacturers realized they were not receiving the expected value from their PBM acquisitions or rebate payments. Most manufacturers increased the performance criteria for PBMs to earn rebates. PBM profits, already hurt by the acquisition frenzy in the early 1990s, were further impacted by the reduction of rebates from manufacturers. As a result, PBMs introduced expanded services that differentiated them as clinical and pharmaceutical cost managers and began to scrutinize their unprofitable clients.

- In the late 1990s through the present, the PBM industry has been restructuring to restore profits. Lilly and SmithKline Beecham divested their PBMs, and the industry has seen consolidation as the leading PBMs seek to achieve economies of scale and improve profitability, as well as increase their negotiating power with manufacturers and retail pharmacies. The most significant consolidations include Advance Paradigms acquisition of PCS, and Express Script's acquisitions of ValueRx and DPS.

The industry now appears to be stabilizing, and is focused on managing costs and utilization for its clients. Today, there are 4 leading PBMs in the United States (AdvancePCS, Caremark Rx, Inc., Express Scripts Inc., and Merck-Medco Managed Care, L.L.C.) plus several that are owned by insurers (Aetna, Wellpoint) and retail chains (Walgreens, New Eckerd Health Services).

Table 1: Leading PBMs

Segment	PBM	Covered Lives
Large PBMs, managing over 20 million lives	Advance PCS	75,000,000
	Merck-Medco Managed Care, L.L.C.	65,000,000
	Express Scripts, Inc.	42,000,000
	CaremarkRx, Inc.	20,000,000
Insurer owned PBMs	Wellpoint	15,000,000
	Aetna	4,800,000
Retail pharmacy chain PBMs	New Eckerd Health Services	16,000,000
	Walgreens	2,000,000

Macro Trends in Pharmacy Benefits

PBMs are challenged: managing drug costs in a time of rising drug prices. Drug prices are rising faster than inflation, and becoming a larger percentage of our nations overall health care spending. Rising drug prices can be attributed to a number of factors, which include increased drug utilization and the growth in the number of new, more expensive drugs. More specifically:

- The cost of drugs over the next eight years is expected to rise between 10 --15% per year;
- By 2010, it is expected that drug expenditures will be approximately 13.8% of national health expenditures, up from 6.10% in 1995;
- Between 1992 and 2000 drug utilization (unadjusted for changes in population) increased 52%;
- Drugs introduced since 1992 represent 25.4% of all prescriptions, but account for 40.8% of the cost.

Much of the increased utilization is expected to come from seniors. It is generally accepted that seniors need more prescription drugs than non-seniors. Seniors represent approximately 13% of the nation's population, but account for over one-third of the nations drug spending. As a result, this population is expected to continue to contribute disproportionately to the rising use and cost of drugs, especially as "Baby Boomers" near retirement age.

Many of the new drugs being developed reflect the demographic changes driving the U.S. healthcare system. These are drugs designed for geriatric patients or chronic conditions. Other drugs expected to become available target previously untreatable diseases, with a percentage intended to improve the patient's lifestyle (e.g., Viagra). These new drugs will challenge PBMs to continue to educate clients and members and manage utilization and costs, while providing coverage.

PBM Operations

PBMs have large scale, highly automated operations to process claims and provide customer (client, member) service. The services a PBM provides can be categorized as administrative or clinical. Administrative services include benefit administration, enrollment and eligibility administration, pharmacy network administration, mail pharmacy service, claims adjudication, and manufacturer contracting and rebate administration. Clinical services range from formulary management to sophisticated utilization and disease management programs.

PBM services revolve around the drug benefit designed by the client. The benefit design determines the drugs that are covered, and the extent to which generics and formulary drugs are mandated. As a part of the drug benefit, a co-pay structure is developed which determines the cost sharing between the client and its employees or members. PBMs receive enrollment information from their clients, and maintain the pharmacy benefit eligibility files.

PBMs establish and maintain large pharmacy networks with chain and independent pharmacies, through which drugs are dispensed to members. The leading PBMs have over 55,000 retail pharmacies in their networks. In addition, PBMs operate or contract with mail pharmacies, Internet pharmacies, and specialty pharmacies (for high cost drugs) focused on conditions like HIV or organ transplants and new biotech products. Pharmacies contract with PBMs and agree to discount their pricing to gain access to the PBM's members.

Some PBMs operate mail pharmacies to improve member access and help their clients control drug costs. Mail pharmacies offer better pricing than retail pharmacies, but are

limited to providing chronic drugs since there is a delay of several days in the members receipt of the medication.

PBMs offer their clients a highly automated claims-processing environment. Over 99% of all pharmacy claims are electronically adjudicated at the point of service (i.e., the pharmacy where the drug is dispensed) when the claim is entered by the dispensing pharmacist. The claims system tests the member's eligibility and benefit design to determine pharmacy reimbursement and member's co-pay. The claims processing system also applies a series of edits and messages during adjudication to verify the drug is covered and does not conflict with other drugs the patient is taking.

PBMs contract with pharmaceutical manufacturers of branded drugs to receive rebates and administrative fees (rebates are not paid for generic drugs). Manufacturers typically pay these rebates for increases in market share and/or utilization of their products. It is common for PBMs to retain the administrative fees, and share the rebates with their clients. PBMs that operate mail pharmacies may receive extra rebates or better pricing for specific drugs purchased through those pharmacies.

PBMs also provide clinical programs to their clients, which provide the basis for ingredient cost savings. These programs include:

- Formulary management. A formulary is a list of drugs favored by the PBM for their clinical effectiveness and cost savings. Pharmaceutical manufacturers of branded drugs often pay rebates to have their drugs featured on the formulary.

- Therapeutic substitution programs in mail pharmacies. These programs encourage physicians and/or patients to switch to lower cost comparable drugs.

- Disease management programs. These programs identify and categorize patients with chronic conditions and direct them toward an appropriate treatment protocol.

In our discussions with the leading PBMs, there was general consensus that providing services to the Medicare population would not have a significant impact on the industry. This statement is based on the following:

- Most PBM operations are highly automated and relatively insensitive to volume increases;

- All of the leading PBMs have demonstrated a capability to rapidly scale-up operations for new, large clients;

- The PBM industry already manages the drug benefits of approximately 65% of the country's seniors.

The incremental volume to the industry if a Medicare drug benefit is created is expected to be approximately 11 – 14 million lives – roughly the size of a large new client.

PBM Economics

PBMs operate on low profit margins (5% or less), collecting fees from clients and manufacturers. PBM revenues are based on administrative fees for claims processing and may include a portion of the ingredient cost savings achieved for clients. In general:

- Clients pay PBMs as a pass through of ingredient costs (discounted reimbursements to pharmacies) plus a transaction-based claims processing fee;
- PBMs also share or pass through manufacturer rebates with clients; some PBMs retain an administrative fee from the manufacturer for administering the rebate program;
- Clients engaging in clinical programs may pay for the programs on a fee for service or shared savings basis. Under a shared savings arrangement the PBM and the client assume some risk for the cost of the drug program. This approach is an alternative method of paying the PBM, and is based on a percentage of savings that result from the PBM's clinical program.

The fees the PBM receives from its clients and retains from manufacturers are a very small percentage of the total cost of a pharmacy benefit. Clients interested in managing the cost of their drug benefits typically find their best opportunity through restricted plan designs including changes in their member's cost sharing requirements, smaller networks, and the introduction of clinical management programs.

Selecting a PBM

Based on our discussions with the leading PBMs and clients, we expect HCFA's selection of a PBM(s), and implementation of a Medicare drug benefit to take up to 24 months. This includes one year to plan the program and select a PBM, and a second year to implement the program, which includes setting pricing, establishing a network, and notifying and educating beneficiaries.

Proven processes have been established for selecting and retaining a PBM. These processes are based on an RFP that describes a client's objectives, and proceeds through vendor selection, negotiation, implementation, and the on-going monitoring of the PBMs performance. The selection process includes proposal analysis, PBM site visits, and client reference checks.

Once selected, a PBM typically requires 90 days to implement a large client. However, a Medicare benefit could take up to a year after the PBM(s) has been selected before

"going live" due to the size and complexity of the population, and the effort needed to educate the seniors about their benefit. Client implementation includes loading the benefit and eligibility files into the claims processing system, establishing the pharmacy network, educating members about their benefit, and establishing the necessary customer service functions. HCFA may also need to develop new, internal programs to align with the PBM's service. These could include managing enrollment and eligibility, collecting member premiums, as well as monitoring, and possibly managing, utilization and cost.

An overview of the selection and implementation process is provided below.

Diagram 1: Selection and Implementation Timeline

As HCFA (and Congress) pursues this critical initiative for our country's seniors, there are several important steps. The next steps may involve:

- Establishing objectives for the program, including the drugs covered, member cost sharing requirements, network access, mail pharmacy programs and customer service levels. Utilization management and other monitoring processes also need to be addressed.

- Deciding on the pricing, and clinical programs and controls (including formularies) to be used. HCFA has the option to seek legislated pricing similar to that used by Medicaid to obtain manufacturer rebates. HCFA also has the option to either use the PBM's formulary and clinical services, or design its own.

- Selecting a PBM. The selection process begins with development of an RFP to communicate HCFA's goals and objectives, and to provide a standard basis for evaluating responses. Proposal evaluation, site visits to the leading PBMs, and contacting references to discuss critical factors such as implementation and member service should follow issuance of the RFP.

- Planning the implementation of the program, including developing processes to educate beneficiaries as well as enroll members, maintain eligibility and possibly coordinate benefits or collect premiums (functions not typically or routinely performed by a PBM).

In the last 10 years, the PBM industry has grown and repositioned itself: developing ambitious new programs to help clients better manage drug spending and administer benefits. Although the industry faces its challenges, the leading PBMs are generally seeing improved margins and the industry is expected to continue to provide a valuable service. All of the leading PBMs are extremely interested in working with HCFA on this program, and can add great value in helping HCFA achieve its plans and objectives.

1.0 INTRODUCTION

The Health Care Financing Administration (HCFA) contracted PricewaterhouseCoopers LLP (PwC) to prepare a report on the pharmacy benefit management (PBM) industry. The study examines the PBM industry from the perspective of a potential client and is intended to help HCFA effectively respond in the event that Congress extends a drug benefit to Medicare.

This study is based on PwC's consulting experience with the pharmacy benefit management, payer, and pharmaceutical industries, supplemented by literature reviews and interviews with executives from leading PBMs and large employer groups, including Fortune 500 companies and state governments. For ease of understanding, this report is organized into three defining topics:

- ***2.0: Structure Related Issues***
- ***3.0: Operations Related Issues***
- ***4.0: Performance Measurement***

Chapter 2 Structure Related Issues describes the issues and forces that have shaped the PBM industry, provides an overview of PBM operations and industry capacity, describes the regulatory environment, and explains how PBMs service local markets. The section concludes with an overview of PBM financials and pricing mechanism.

Chapter 3 Operations Related Issues describes the administrative and clinical services PBMs provide and the types of contracts into which PBMs routinely enter. It includes explanations of the bidding, vendor evaluation, implementation, and monitoring processes used by clients selecting a PBM.

Chapter 4 Performance Measurement explains the performance indicators, service benchmarks, and guarantees commonly used to evaluate PBMs. This section also includes an evaluation of the PBM industry's performance against the aforementioned measures, based on recent surveys.

2.0 STRUCTURE RELATED ISSUES

During the 1990s, PBMs evolved into organizations that provided an array of administrative and clinical services to help their clients manage drug benefits. Today, PBMs manage the drug benefits of approximately 70% of the United States, including approximately 65% of our country's seniors, in an environment of rising drug costs and utilization.

PBMs operate in a competitive consolidating market constantly challenged by their clients and manufacturers to reduce drug costs and utilization, and to influence the drug selection by patients, doctors, and pharmacists. Moreover, its' operations and contractual relationships are subject to federal and state regulations.

PBMs service a complex system that includes pharmacies, manufacturers, clients, physicians, and members. Most PBM operations are highly automated and not especially sensitive to significant increases in volume. As a result, the leading PBMs believe the industry could quickly respond to accommodate a Medicare drug benefit.

PBMs maintain national pharmacy networks to provide members with access to drugs, and derive revenue from clients and manufacturers.

This section describes the issues and forces that have shaped the PBM industry, provides an overview of PBM operations and industry capacity, describes the regulatory environment, and explains how PBMs service local markets. The section concludes with an overview of the financials and pricing that underlie PBMs.

2.1 Industry Structure Overview

In the last 10 years, the PBM industry has repositioned and is developing ambitious new programs to help clients better manage drug spending. During this time, a group of leading PBMs has emerged to dominate the industry. This group includes AdvancePCS, Caremark Rx, Inc., Express Scripts Inc., and Merck-Medco Managed Care, L.L.C.

Drug costs are rising faster than inflation, and have become a large percentage of the overall healthcare spending. Increasing drug costs can be attributed to a number of factors, which include increased drug utilization, the growth in the number of new, more expensive drugs, and advances in science and medicine.

The rise in overall healthcare cost, and in particular drug cost, have political and regulatory implications. Given their role in the pharmacy and healthcare industries, PBMs are subject to myriad federal and state regulations and laws. These laws often overlap in scope, and in many instances have yet been tested in the courts. Presently, legislation concerning patient privacy and rights – whose impact on PBMs is unclear – has become a concern of the industry.

Besides the political and regulatory realities, the major forces shaping the industry today include consolidation, the struggle to maintain rebates, increased pressure to more effectively manage drug costs in a time of rising drug prices, and responding to increased regulations.

This section describes the evolution and dynamics driving the industry, macro trends in drug spending and utilization, profiles of the leading PBMs, the major challenges to the stability of the industry, and the regulatory environment governing PBMs.

2.1.1 Structural Evolution and Market Dynamics Driving the PBM Industry

PBMs work with their clients to administer drug benefits and control costs. As part of their service, PBMs secure substantial discounts from retail pharmacies and rebates from drug manufacturers; they offer their clients a highly automated claims-processing environment. Moreover, 99% of all pharmacy claims are electronically adjudicated at the point of service (POS), i.e., at the pharmacy where the drug is dispensed.

PBMs establish and maintain large pharmacy networks with chain and independent pharmacies, from which drugs are dispensed to members. These networks include retail pharmacies, mail pharmacies for chronic drugs, and in some cases specialty pharmacies for high cost specialty drugs (e.g., HIV and organ transplant medications). Pharmacies contract with PBMs and agree to discount their pricing to gain access to PBM members.

PBMs contract with manufacturers of branded drugs to receive rebates and administrative fees. Manufacturers typically pay these rebates for increases in market share and/or utilization. PBMs may also receive additional rebates for administering certain disease-management or counter-detailing programs that are not tied to specific branded drugs, and/or money or non-cash benefits. It is common for PBMs to retain the administrative fees, and share the rebates with their clients. PBMs that operate mail pharmacies may receive extra rebates or better pricing for specific drugs purchased through those pharmacies.[1]

[1] "Report to the President on Prescription Drug Coverage, Spending, Utilization and Price," Office of Health Policy with the Office of the Assistant Secretary of Planning and Evaluation, April 2000.

PBM Clients and Services

PBM clients include HMOs (35%), employer groups (33%), and insurers (21%). In addition, PBMs provide services for other clients (11%) such as "consumer cards" for the uninsured (Diagram 3). Employer groups include corporations, state and local government, trade unions, and others. Insurers include commercial health insurers and Blue Cross/Blue Shield clients. Other clients are predominantly consumer card clients such as consumer organizations or associations like AARP. These programs offer a pharmacy discount whereby members pay the cost of drug minus a contracted percentage off retail prices (typically 5 to 10%). [2]

PBMs may provide administrative services, clinical services, or both types of services to their clients, and may manage the retail pharmacy, mail pharmacy, or "integrated" (mail and retail) benefit. Administrative services include client service, pharmacy network administration, mail pharmacy, claims adjudication, member services, and manufacturer contracting and rebate administration. Clinical services range from formulary management to sophisticated disease management programs.

In general, self-insured employers and insurance carriers outsource both administrative and clinical services to a PBM. Managed care organizations (MCOs) (e., g., health plans) and some insurers may elect to retain formulary and clinical control, including manufacturer contracting, and outsource only administrative services such as claims processing and benefit administration to a PBM.

It is noteworthy that several large insurers and MCOs, such as Foundation Health Systems, Oxford Health Plan, and BCBS of California, have recently outsourced the administration of their drug benefits to PBMs, but retained formulary and clinical control. These insurers are attempting to reduce cost by taking advantage of lower claims processing and other administrative fees.

PBM services revolve around the drug benefit designed by the client. The benefit design determines the therapeutic categories that are covered --including whether cosmetic, lifestyle, and over-the-counter (OTC) drugs are reimbursed, and the extent to which generics and formulary drugs are mandated. As a part of the drug benefit, a co-pay structure is developed which determines the cost sharing between the client of a PBM and the individual members of healthcare programs. PBMs use co-pays as a mechanism to shift some responsibility of utilization to the member by making them sensitive to the

[2] Scott, Miriam Basch, "Rx trends: Market shows strong growth rate; makers consolidate, PBMs emphasize managed care," Employee Benefit Plan Review, April 1, 1998.

cost of their utilization.[3] Co-pays are also used to provide incentives to encourage the use of generics or formulary drugs.

PBMs use formularies to encourage the use of specific branded (and generic) drugs, which are typically the basis for rebates (and administration fees) paid by manufacturers. Rebates typically represent a discount of 5 to 15% of a drug's cost and administration fees an additional 1 to 3%.

Formulary management services allow a client to use the PBM's formulary and share manufacturer rebates. A formulary is an approved list of branded (and generic) drugs developed by the PBM, or the client. In general, employers and insurers have the least restrictive drug programs and will use a PBM's formulary, while MCOs have the most restrictive formularies and are more likely to develop their own list of approved drugs. Manufacturers pay rebates to have their drugs listed on formularies. Drug formularies can be open, incented, or closed.

- An open formulary is a list of recommended drugs. Under this structure, most drugs are reimbursed irrespective of formulary status. However, the client's plan design may exclude certain drugs (e.g., OTC, cosmetic and lifestyle drugs). Physicians, pharmacists, and members are encouraged by PBMs via mailings, electronic messaging, and other means to prescribe and dispense formulary drugs.

- An incented formulary applies differential co-pays or other financial incentives to influence patients to use, pharmacists to dispense, and physicians to write prescriptions for formulary products.

- A closed formulary limits reimbursement to those drugs listed on the formulary. Non-formulary drugs are reimbursed if the drugs are determined to be medically necessary, and the member has received prior authorization.

In addition to formulary management, PBMs offer their clients other clinical services. These programs often include a shared savings arrangement between the PBM and the client. These services include disease management, utilization management programs such as drug utilization review (concurrent and retrospective), and prior authorization, as well as brand and generic therapeutic substitution programs. In some cases, HMOs seeking greater clinical control may develop additional programs

Evolution of PBMs

[3] Kreling, David, "Cost Control for Prescription Drug Program: Pharmacy Benefit Manager (PBM) Efforts, Effects, and Implications," August 2000. This was a background paper prepared for the Department of Health and Human Services' Conference on Pharmaceutical Pricing Practices, Utilization and Costs.

HCFA Study of the Pharmaceutical Benefit Management Industry

The PBM industry began when managed care principles, such as co-pays and provider networks were applied to the pharmacy benefit in an effort to control costs. Growth in the industry was driven by manufacturer rebates, manufacturer acquisition of PBMs, and self-insured employers seeking to reduce drug costs. Recently, the industry has focused on clinical services and consolidation in an effort to improve margins, as well as negotiating power with retail pharmacies and manufacturers. The evolution of the PBM industry can be categorized into four major phases, which are summarized below.

- Phase I: Inception (1980 – 1990) - Beginnings of the PBM industry as managed care organizations carved out the pharmacy benefit, and mail service and claims processing companies emerge;

- Phase II: Dramatic Growth (1990 – 1994) - Rapid growth in enrollment of managed care clients, penetration of the employer segment, emergence of rebates, and manufacturer acquisitions of PBMs;

- Phase III: Scrutiny and Saturation (1994 – 1998) - Manufacturers divest PBM operations, rebates begin to diminish, and a large percent of the privately insured population contracts with PBMs;

- Phase IV: Consolidation and Repositioning (1998 – Today) - Industry consolidates to improve margins and market power and to realize economies of scale, while facing increased pressure to manage client's drug spending and comply with new regulations.

The active stakeholders and trends that emerged in one phase of evolution often overlapped with the next phase because of the significant transition in this market.

Phase I: Inception (1980—1990)

The PBM industry originated as a result of several developments occurring throughout the 1980s. These developments included managed care organizations that "carved-out" the pharmacy benefit, and companies that provided mail-pharmacy or claims-processing services.

In the 1980s, in an effort to control costs, managed care organizations split out specific benefits such as pharmacy, mental health, and dental from their overall medical benefit. Coupled with electronic claims adjudication to reduce claims processing costs, MCOs applied managed care principles, such as co-pays and provider networks, to the pharmacy benefits. This represented a significant shift from the previous administration of the pharmacy benefit under indemnity insurance. With indemnity insurance, the member paid the full cost of the prescriptions, and then submitted a paper claim to their insurer for

reimbursement. Indemnity plans typically covered 80% of prescription costs over a set deductible.

The new managed care pharmacy carve-outs became some of the early PBMs. For example, United Healthcare created Diversified Pharmaceutical Services (DPS), and New York Life created Express Scripts Incorporated. These PBMs managed the drug benefits for the insurers managed care plans. Initial PBM savings were realized through administrative cost savings via electronic claims adjudication and negotiated discounts in pharmacy networks. Also, clinical services were beginning, generally focused on promoting generics.

As managed care organizations began using PBMs, several companies emerged that offered electronic claims processing, networks discounts, and mail services to help control the cost of drugs and improve member convenience. These companies included Caremark and Medco. At the time it was formed, Caremark primarily serviced Baxter Healthcare Corporation's employees.

Another leading PBM that emerged at this time to provide pharmacy benefit services was PCS. PCS began as a claims processor serving self-insured employers, and also offered network discounts and electronic adjudication.

Phase II: Dramatic Growth (1990—1994)

During this period, the PBM industry experienced significant growth, culminating with the acquisition of several leading PBMs (Medco, DPS, and PCS) by pharmaceutical manufacturers. This growth was partly fueled by the introduction of formulary rebates. (A formulary is an approved list of both branded and generic drugs developed by the PBM or the client of a PBM.)

In the early part of this phase, a few manufacturers began to pay rebates for access to the formularies utilized by the managed care organizations. These manufacturers generally paid rebates out of fear that they would lose access to the individuals (commonly referred to as lives) within the MCOs. As managed care organization and PBMs became more prominent, more manufacturers began to aggressively offer rebates to these managed care entities. In addition, the impetus of the Clinton Health Care Reform Proposal fueled manufacturer concerns over the influence of managed care. This proposal encouraged and would have accelerated the use of managed care, particularly among employer groups, and probably served to drive their acceptance of employer plans for rebates.

As PBMs gained experience using rebates to attract managed care organizations, they decided to expand their efforts and target the vastly untapped self-insured employer market. During this time, much of the employer market population was still under indemnity insurance plans. While PBMs were already providing claims-processing services to many of these employers, they weren't managing the employee lives through a formulary. Diversified Pharmaceutical Services (DPS) made the initial strategic move by encouraging manufacturers to participate in a National Drug Formulary designed specifically for self-insured employers.[4] At the same time, PCS combined with Clinical Pharmacy Advantage and was able to offer a proven formulary to their existing self-insured clients. Large mail-order pharmacies such as Medco and Caremark developed formulary programs to achieve savings for their clients.

Using pharmacy discounts and manufacturer rebates as an incentive, PBMs demonstrated to employers the savings generated from a managed drug program: Manufacturers began to pay rebates for the self-insured employer claims covered by PBMs. As pharmacy discounts and manufacturer rebates increased, PBMs demonstrated to employers that the savings generated from a managed program would more than outweigh the additional claims volume that would result from elimination of the "shoe-box" effect. The "shoe-box" effect refers to the increase in pharmacy costs that results when online adjudication, under which all covered claims are reimbursed by the payer, replaces paper claims. Paper

[4] Decision Resource, "PBMs in the Managed Care Marketplace: An HMO Perspective," *Spectrum Pharmaceutical Industry Dynamics* (October 28, 1994).

claims not submitted by the patient were said to be in the "shoe-box," with the cost of these drugs paid by the patient, not the payer of the drug benefit.

The PBMs success with employers result for several key reasons:

- First, employer groups were generally less sophisticated than HMOs and insurance carriers on the topics of healthcare benefits and rebates. In later phases, this would change as employer groups hired the services of benefits consultants to advise them on contracting with PBMs.[5]

- Second, PBMs demonstrated a real value to the employer groups illustrating for them that network discounts and formulary rebates would more than offset the "shoe-box" effect .[6]

- Third, PBMs showed impeccable timing as healthcare benefit costs for employers were spiraling out of control and garnering serious attention from the senior management of most employers. Moreover, the application of accrual accounting to retiree medical benefits added to such concerns. Many employers recognized that some action was needed and made the decision to empower PBMs to manage the pharmacy benefit.[7] Enlisting the services of a PBM appeared to be a good start and an easy decision for most employers.

The PBMs experienced substantial increases in the number of lives they covered as a result of at least two important factors: enrollment increases in MCOs coupled with the PBMs own ability to extend services into the self-insured employer market.

Manufacturer acquisitions of PBMs represented another major force behind the life growth. Such acquisitions of PBMs were a logical extension and natural evolution of the defensive posture manufacturers had taken in paying rebates to ensure access to the lives managed by PBMs. From 1993 to 1994, three manufacturers acquired PBMs for substantial premiums over market value (several billion dollars each), and many other manufacturers entered into expanded alliances with PBMs in order to remain competitive (see Table 1). These actions were at least partly prompted by the proposal of healthcare reform under the Clinton Administration. If healthcare reform was to be a reality, manufacturers would need to have access to formulary managed lives.

[5] "Get the Most Out of Your PBM," *Business & Health* 12 No. 11 (November 1994): 37.
[6] Ibid., 37
[7] Coopers & Lybrand, Appendix B, *Summary of Employer Rebate Experiences 1993–1995*, Chicago: Coopers & Lybrand 1996.

Table 2: Key Manufacturer PBM Acquisitions and Alliances (1993–1994)

Manufacturers Acquire PBMs	Manufacturers Ally with PBMs
▪ Merck-Medco; July 1993; $6.6 billion ▪ SKB-DPS; May 1994; $2.3 billion ▪ Lilly-PCS; July 1994; $4.0 billion	▪ Caremark Drug Alliance Program; Spring 1994; Pfizer, BMS, RPR, Lilly ▪ ValueHealth-Pfizer Joint Venture; May 1994; $50 million each

Manufacturers hoped to realize two additional benefits: access to utilization data, and an opportunity to move closer to their real customers -- the patients taking their drugs and the organizations paying for them. Among other things, manufacturers were interested in understanding the profiles of patients taking their drugs, as well as their concomitant medications, dosing regimes, and physician prescribing patterns. Collection of such data, along with access to formularies, would enable manufacturers to optimize the strategic positioning of their products.[8] [9] [10]

The number of lives that PBMs covered drove up the premium paid by the manufacturers. Manufacturers acquired PBMs at a cost of $80 to $175 per covered life, (while PBMs acquired each other at a cost of $22 to $34 per covered). This fueled more growth as PBMs took on unprofitable business and lives from the uninsured population.

In an effort to garner additional lives and become an attractive acquisition candidate, PBMs lowered their claims processing fees and rebate retention rates, and began to take on unprofitable business. Regarding its management of a large employer (Ford Motor Company), Value Health commented in 1994: " We nursed that account along, because of course if a pharmaceutical manufacturer wanted to pay us for the asset value of that account, if you will, it was worth continuing."[11]

One technique used to drive growth in lives and acquisition values was to include the uninsured segment of the population; i.e., the cash-paying customer. PBMs signed on these unfunded lives through consumer card programs. These programs essentially offered small discounts on certain formulary products to patients at the point of service, to encourage the use of formulary products. At the time, manufacturers were not

[8] Decision Resource, "PBMs in the Managed Care Marketplace: An HMO Perspective," *Spectrum Pharmaceutical Industry Dynamics*, (October 28, 1994)
[9] Financial Times/Coopers & Lybrand, "Adapting an Innovative Product/Service Strategy to a Geographically Varied Market Positioning," paper read at the World Pharmaceuticals Conference, March 1995.
[10] Financial Times/Coopers & Lybrand, "Healthcare Data—Getting the New Currency that Drives Strategy and Success," paper read at the World Pharmaceuticals Conference, March 1995.
[11] "Value Health Seeking 'Significant Rate Increase' From Captitated Ford Contract; Decision Not to Sell PBM Due to Decreased Vertical Integration Interest." *FDC Reports* December 5, 1994,

especially discriminating about the quality of a PBM's clientele. These unfunded lives added to the PBM's overall value.

These trends increased the sales volume throughout the formulary management business. With few barriers to entry and manufacturer rebates as a new revenue source, more PBMs entered the market. This larger number of PBMs were now covering substantially more lives and generating record numbers of rebatable claims.

Rebate payments however were reaching record levels, attracting the attention of senior management at pharmaceutical manufacturers. By the end of this phase of growth, most manufacturers began to conclude that paying rebates for access to formularies did not add value to their financial statements. Manufacturers, including those who purchased PBMs, began to realize that their sales volume through PBMs were increasing primarily because of the life growth in the PBMs customer base, and that in most cases the PBMs were unable to influence the brand of drugs dispensed to their open formulary clients.

Phase III: Scrutiny and Saturation (1994—1998)

By 1994, the PBM business began to mature, and manufacturers were generally not recognizing the anticipated value from their contracting practices, despite the dramatic increases in total rebate payments. At the same time, pricing litigation placed manufacturers under scrutiny and caused them to become more discerning about conditions under which rebates would be paid. As a result, manufacturers made a fundamental change in their approach to contracting with PBMs. In general, rebate-pricing criteria were changed so that PBMs would have to deliver increases in market share before all or most of the rebate would be paid.

Manufacturers also began to exercise their right to audit PBMs and exclude certain plans from rebate eligibility. By 1995, all of these changes represented a fundamental shift in manufacturer philosophy regarding formulary management programs, causing a precipitous decline in the average rebate paid per claim, and the number of claims on which rebates were paid. Partly as a result of their better understanding of PBMs, SKB and Lilly divested their PBM operations (DPS and PCS, respectively) for significantly less than they were acquired.

In response to these trends, PBMs introduced expanded services that differentiated them as clinical managers as well as pharmaceutical cost managers. Increased use of restrictive formularies and the addition of intervention programs offered tools for PBMs to better influence the products dispensed to their members. As a result, PBMs were partially able to restore rebate revenues and continue to share them with their clients. In addition, PBMs began to scrutinize their unprofitable clients, and either increased their fees,

changed the rebate allocation, or exited the relationship. Claims processing fees increased, although not to the level that had historically existed.

During this period, the PBM market became saturated as a very large percentage of the privately insured population used PBMs or other third-party payers to administer their pharmacy benefits. By 1998, approximately 65% of all retail drug purchases were administered through PBMs or other third party administrators at the point of sale; this is up from 49% in 1995 and 30% in 1992 (Diagram 4). During this same period, Medicaid payments for drug purchases remained stable.[12]

[12] IMS Health Retail Method-of- Payment Report™, 1999. Based on data from Hoechst Marion Roussel (1998), approximately 92% of HMOs and 78% of PPOs use a PBM to administer their drug benefit. Thus, it assumed that a large percentage of the growth in third party payers is attributed to the growth of PBMs.

Phase IV: Consolidation and Repositioning (1998—Today)

The major forces shaping the industry today include industry consolidation, the struggle to maintain rebates, increased pressure to more effectively manage drug costs in a time of rising drug prices, and responding to increased regulations.

Partly as a result of consolidation, a group of leading PBMs has emerged to dominate the industry. These include AdvancePCS, Caremark Rx, Inc., Express Scripts Inc., and Merck-Medco Managed Care, L.L.C. The PBM industry is consolidating in an effort to realize economies of scale and as a means to increase market power and negotiating strength with manufacturers and network pharmacies.

The PBM industry has repositioned itself beyond administrative services, and is developing ambitious new programs to help clients better manage drug spending. These include plan designs that provide incentives for the use of less expensive, preferred medications and clinical programs that reduce cost, encourage appropriate utilization, and improve patient care.

PBMs are also facing proposed regulations, such as those mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which could hinder their ability to help clients manage drug cost by restricting the use of patient and prescriber data. Complying with these regulations could also be costly, as systems and business processes are modified.

The challenges facing the PBM industry will be discussed in Section 2.1.4 (Industry Stability and Major Challenges Facing the PBM Market).

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2.1.2 Macro Trends in Drug Spending and Utilization

Drug Cost Trends

Drug costs are rising faster than inflation, and becoming a large percentage of the overall healthcare spend. By 2010, it is expected that drug expenditures will be approximately 13.8% of national health expenditures, up from 6.10% in 1995 and 8.2% in 1999 (Diagram 5).[13]

[13] Heffler, Stephen, et al., "Health Spending Growth up in 1999; Faster Growth Expected in the Future" *Health Affairs20*, no. 2, (March/April 2001): 194.

The cost of drugs over the next eight years is expected to rise between 10--15% per year. By 2008, national expenditure on drugs is expected to be $243 billion, up from $61 billion in 1995, a 299% increase (Diagram 6).[14] On a per capita basis, drug costs are estimated to increase to $800 per year by 2008, an increase of 257% from 1995 (Diagram 7). [15]

[14] National Health Statistics Group, Office of the Actuary, HCFA: National Health Accounts.
[15] Ibid.

Rising drug costs can be attributed to a number of factors, which include increased drug utilization, the growth in the number of new, more expensive drugs, and advances in science and medicine.

Increased utilization by patients of all ages is contributing to rising drug costs. Since 1992, drug utilization (unadjusted for changes in population) has increased 52% from approximately 2 billion prescriptions dispensed per year to an estimated 3.15 billion in 2000.[16] It is estimated that nearly 4.0 billion prescriptions will be dispensed by 2004 (Diagram 8). It is generally accepted that seniors need more prescription drugs, and this population is expected to contribute disproportionately to rising utilization, especially as the Baby Boomers near retirement age.

[16] IMS and National Association of Chain Drug Stores (NACDS) Economics Department. 2000 and 2004 estimates are from NACDS.

Seniors account for approximately 13% of the total population, but account for over one-third of the nation's drug expenditures.[17] The typical Medicare beneficiary (over the age of 65) spends $516 per year on drugs, which is 235% greater than individuals under 65 years of age, who spend approximately $154 per year (Diagram 9).[18] Recent survey data reported that 80% of retired persons take a prescribed drug every day, and the average Medicare beneficiary used 19.6 prescriptions in 1996.[19]

[17] "Medicare Fact Sheet," The Henry J. Kaiser Family Foundation, March 2000.
[18] *Report to the President on Prescription Drug Coverage, Spending, Utilization and Price*, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. Data source is the Bureau of Labor Statistics, Consumer Expenditure Survey Data as analyzed by the Office of the Actuary, HCFA.
[19] Davis, Margaret, et al., "Prescription Drug Coverage, Utilization and Spending Among Medicare Beneficiaries," *Health Affairs* 18, no. 1, (January/February 1999): 237.

HCFA Study of the Pharmaceutical Benefit Management Industry

New more expensive drugs are being introduced and taking market share from drugs that are coming off patent and being replaced by less expensive generics. In 1999, drugs introduced since 1992 represented 25.4% of all drugs prescribed in 1999 and 40.8% of the drug costs (Diagram 10).[20] However, it is expected that the impact of new drugs on overall drug costs will be partially offset by the expiration of patents on branded products, allowing the use of less expensive generics. This represents a loss of approximately $30 billion in revenues to pharmaceutical companies.[21]

A recent study published in *Health Affairs* identified two underlying drivers of increasing drug cost that go beyond price and utilization. The study proposes that new science and better medical practice have contributed significantly to increases in drug costs. As a result, the number of patients diagnosed and undergoing treatment is increasing at the same time the efficacy of treatment is improving. For example, advances in the treatment of AIDS patients have dramatically increased their life expectancy.[22]

[20] *1999 Drug Trend Report*, Express Scripts, June 2000

[21] Mullin, Daniel, et al., "Projections of Drug Approvals, Patent Expirations and Generic Entry 2000 to 2004," Prepared for U.S. Department of Health and Human Services' Conference on Pharmaceutical Pricing Practices, Utilization and Costs.

[22] Dubois, Robert, et al, "Explaining Drug Spending Trends: Does perception match reality?," *Health Affairs* 19, no. 2 (March 1, 2000): 231-239.

Medicare Trends

As of 2000, approximately 66% of Medicare beneficiaries had some form of drug coverage through employer sponsored health plans such as Medicaid, Medicare HMOs, or Medigap insurance (Diagram 12)[23], down from 1998 when 73% of seniors had drug coverage (Diagram 11).[24] The trend is due in large part to employers reducing or eliminating pharmacy benefits for retirees.

[23] Kaiser Commission on Medicaid and the Uninsured. Data Source: Actuarial Research Corporation projections, based on 1998 Medicare Current Beneficiary Survey.

[24] Poisal, John and Lauren Murray, "Growing Differences Between Medicare Beneficiaries with and without Drug Coverage," *Health Affairs* 20, no. 2 (March/April 2000): 77. Data based on the 1998 Medicare Current Beneficiary Survey.

In some cases the Medicare beneficiary received a partial drug benefit. For example, Medigap coverage is limited (only three of ten Medigap plans offer a prescription drug benefit), and requires significant cost sharing with the beneficiary. These plans require the beneficiary to pay 100% up to a $250 deductible and then 50% of the cost up to a maximum benefit typically between $1,250–$3,000. Nearly 25% of those receiving Medigap coverage received it for only part of the year. Also, while approximately one-half of U.S. states offer indigent seniors programs, the programs do not cover all drugs, and service only a small percentage of the total senior population that lacks coverage.

Medicare beneficiaries without drug coverage utilize fewer prescriptions per year, and have higher out-of-pocket expenditures than beneficiaries with drug coverage. Seniors without drug coverage average 16 prescriptions per year while those with coverage average 21.1 per year. Non-seniors with insurance averaged 6.8 prescriptions per year and 2.0 for those individuals without insurance coverage (Diagram 13).[25]

[25] Ibid.

2.1.3 PBM Profiles and Landscapes

The PBM market is led by AdvancePCS, Caremark Rx, Inc. (Caremark), Express Scripts Inc.(Express Scripts), and Merck-Medco Managed Care, L.L.C. (Merck-Medco), with the remainder of the market split between smaller PBMs such as, Prescription Solutions, insurer owned PBMs such as, Wellpoint, and PBMs operated by retail chains such as Walgreens Health Initiatives, (Table 3).

It is estimated that the top four PBMs control 195 million covered lives, more than half the population of the United States. The total number of reported covered lives by PBMs (400,000,000) significantly exceeds the total population of the U.S, primarily because of double counting. For example, a state government with 3 million members may contract with one PBM for retail services and another PBM to provide mail service. In this case, both PBMs count the same 3 million members.

Table 3: PBM Market Segments

Segment	Description	PBM	Covered Lives
Tier 1	> 20 million covered lives.	AdvancePCS	68,000,000
		Merck-Medco	65,000,000[26]
		Express Script	42,000,000
		Caremark Rx	20,000,000
Tier 2 and Retail	Smaller PBMs and those owned by retail chains	New Eckerd Health Services	16,000,000
		Prescription Solutions	5,000,000
		Restat	2,000,000
		Walgreens Health Initiatives	2,000,000
Captives	Insurer-owned PBMs.	Wellpoint	15,003,377[27]
		Aetna	4,800,000
Other	Other PBMs		160,196,623
		Total	400,000,000[28]

The top four PBMs (in terms of covered lives) each manage greater than 20 million covered lives, own mail pharmacies, and have extensive retail pharmacy networks with national coverage. PBMs are low margin companies with the leading PBMs operating at

[26] Includes 10.5 million covered lives from United Healthcare.
[27] Namovic-Peat, Susan, *HMO& PBM Strategies for Pharmacy Benefits*(Atlantic Information Services (AIS), 1999): 78. Reflects 1998 membership total.
[28] Ibid., p. 120.

a profit margin of less than 5.0% (Table 4)[29] . However, over the last couple of years, PBMs, through increased clinical and formulary control, are seeing their margins increase.

Table 4: Profile of Top Four PBMs

	AdvancePCS	Merck-Medco	Express Scripts	Caremark
Covered Lives	• 68 million	• 65 million	• 42 million	• 20 million
Claims Processed	• 450 million	• 500 million[30]	• 260 million	• 70 million
Mail Claims Processed	• 10 million	• 61 million	• 15 million	• 14 million
Number of Mail Pharmacies	• Three (3)	• Thirteen (13)	• Five (5)	• Three (3)
Number of Retail Pharmacies	• 57,000	• 57,000	• 56,000	• 54,000
Internet Pharmacy	• Yes	• Yes	• Yes	• Yes
Geographic Market	• National	• National	• National	• National
Ownership	• Independent	• Merck	• Independent	• Independent
Other Alliances	• Drugstore.com • Consumer Health Interactive	• CVS Procare	• PlanetRx.com	• CTS
Market Capitalization[31]	1,192,000,000	• N/A	2,893,000,000	2,340,000,000

[29] Data obtained from Dow Jones Interactive. Profit margin and revenue reflect most recent 12-month period as of October 31, 2000.
[30] Latanich, Terry, "Issues in Managing Prescription Drug Benefits for Retirees-The PBM Perspective," November 20, 2000. Paper read at Issues in Managing Prescription Drug Benefits for Retirees Conference. Estimate based on company reported data for 2001.
[31] Market capitalization data reflects most recent reported data (varies by company), typically 3rd Quarter 2000 numbers.

2.1.4 Industry Stability and Major Challenges Facing the PBM Market

As mentioned previously, the major challenges shaping the PBM industry today include industry consolidation, the struggle to maintain rebates, increased pressure to more effectively manage drug cost in a time of rising drug prices, and responding to increased regulations.

The pharmacy benefit management industry has undergone consolidation as the leading PBMs seek economies of scale and an increase in their negotiating power with retail pharmacies and manufacturers. Currently, the top four PBMs manage the drug benefits for approximately 70% of the United States population. Recent examples of consolidation activity include the following:

- In 2000, Rite Aid sold PCS Health Systems to Advanced Paradigm, forming the largest PBM in the U.S., AdvancePCS (68 million lives);

- Express Scripts, Inc. grew from the sixth largest PBM to the third in 1999 with the acquisitions of ValueRX and Diversified Pharmaceutical Services (DPS);[32]

- Merck-Medco has routinely acquired small PBMs such as Systemed in 1996 and Provantage in 2000; and

- Over the past few years, Caremark has shed its affiliation with MedPartners and has announced its intent to purchase several smaller PBMs.

The rest of the PBM market (approximately 100 companies), composed of insurer-owned PBMs, retail network–owned PBMs, and small independents, continues to compete for the remaining 30% of available covered lives. Although most of these "other PBMs" maintain national retail networks, they tend to focus on smaller or regional clients. Consolidation and acquisition activity among these smaller, privately held PBMs is not well reported in the trade publications and is not perceived to be a driving force in the industry.

While continued market consolidation is a concern for the PBM industry, it is believed that in addition to the potential of lowering administrative costs, a consolidated market should enhance the presence and market power of the remaining PBMs with respect to retail pharmacies and manufacturers. The concentration of market share should give the PBMs more leverage with retail pharmacies in negotiating discounts, and to negotiate

[32] Albertson, David, "Express Scripts – ValueRx Deal a Strong Declaration of Independents," *Employee Benefit News*.

better rebates with manufacturers. [33] From the perspective of clients and members, consolidation has had minimal impact, and looks more like a change in service provider (e.g. new cards issued).

As previously discussed, manufacturers have been requiring more performance from PBMs in order to receive rebates. In response to this, PBMs continue to offer more restrictive formularies and intervention programs to their clients to move market share to preferred branded products and generics. With the exception of HMOs and some employer groups, most clients have historically been adverse to moving their members to more restrictive drug benefit plans (e.g. closed plans) for fear of alienating their members and physicians.

Over the next five years, PBMs will have to manage a significant change in the drug market: the so-called "blockbuster" (i.e. greater than $1 billion in annual revenue) drugs that are rebated are expected to lose (or have lost) their patent protection, and will be replaced by a new generation of drugs.

The existing blockbuster drugs comprise a significant percentage of current PBM rebates, and include Lipitor, Prozac, and Pravachol. Between 1998 and 2004, it is expected that approximately $30 billion in manufacturer revenue will be lost from branded products losing their patent protection (Diagram 14). [34] As these products lose their patent protection, PBMs will likely lose rebates as their clients use generics, or manufacturers eliminate rebates for these products.

[33] "Industry Consolidation," *PBM News* 5, no. 3 (Fall 2000): www.pbmi.com

[34] Mullin, Daniel, et al, " Projections of Drug Approvals, Patent Expirations, and Generic Entry 2000 to 2004." Prepared for U.S. Department of Health and Human Services' Conference on Pharamaceutical Pricing Practices, Utilization and Costs.

Over the next five years it is also expected that approximately 643 new drugs will enter the market. [35] Based on our discussions, the leading PBMs anticipate rebates for these new drugs to offset those lost from aforementioned blockbuster drugs. These new drugs will probably increase rebates in therapeutic categories not previously competitive, or in classes that are altogether new. This trend, in conjunction with the aging population and the expected higher utilization of drugs, will contribute to the overall increase in drug costs.

Many of the new drugs developed will reflect the demographic changes driving the U.S. healthcare system (e.g. drugs designed for geriatric and chronic conditions).[36] Other drugs will target previously untreatable diseases, while a large percentage will be lifestyle drugs (e.g. Viagra). This will place a heavier burden on the PBMs whose clients will expect them to continue to control drug costs and utilization while providing access and coverage to many of these new drugs.

In light of these challenges, PBMs have been looking for opportunities to improve their profitability while helping their clients better manage drug spending. As a result, PBMs are increasingly segmenting their client base when contracting with manufacturers, and receiving higher rebates for those clients willing to provide incentives for member behavior changes, either through three-tiered co-pays or more restrictive plan designs. PBMs are also offering, and charging for, clinical and disease management programs intended to control utilization and cost. Many of these programs feature risk-sharing arrangements that allow the PBM to retain a percentage of the savings realized by the client.

PBMs are also facing increased regulatory pressure. Of prime concern to the PBMs we interviewed are the recent HIPAA regulations governing patient privacy, and pending state legislation that prohibit clients from implementing certain restrictive plan design features. PBMs are wary that these regulations could hinder their ability to effectively help their clients manage drug cost and utilization by limiting the use of patient data in developing clinical programs. In addition, the PBMs believe upgrading their systems and operations to become HIPAA compliant could be costly.

[35] Ibid. It is not expected that all 643 drugs will make it to market due to later clinical trials demonstrating lower efficacy and unfavorable side effects.
[36] *Prescription Drug Trends in the U.S. 2000*, PCS HealthSystems, p. 24.

2.1.5 PBM Legislative and Regulatory Environment

Given their role in the pharmacy and healthcare industries, PBMs are subject to a myriad of federal and state regulations and laws. These laws often overlap in scope, and in many cases have not been tested in the courts. In addition, there is pending legislation (including HIPAA) whose impact on the industry remains to be seen. Table 5 outlines the key regulations that impact and govern the PBM industry.

Table 5: Key Regulations Impacting and Governing the PBM Industry[37]

Regulatory Issue	Description
Privacy	Federal and state laws that control access, distribution, and use of a patient's private medical and pharmacy information.
Benefit and Plan Design	Proposed and existing state laws that prohibit clients from implementing certain restrictive plan design features.
Anti-Remuneration/ Fraud	Federal and state laws that prohibit the receipt of financial incentives to induce referrals of persons covered by federally funded healthcare programs.
Drug Dispensing	Federal and state laws designed to control the clinical care patients receive, with specific laws precluding commercial activity that interferes with a patients well-being (e.g. mail pharmacy regulation, generic substitution laws and therapeutic substitution laws).
Network Access	State laws that affect a PBM's ability to offer less restrictive retail pharmacy networks, and a PBM's ability to remove retail pharmacies from their network.
Licensure Issues	State laws requiring a mail pharmacy to be licensed in the state it is located, or the states it services.
Drug Pricing	Federal and state laws governing the price manufacturers can charge. State-sponsored programs to provide drug benefits to indigent seniors.

[37] Ranked in descending order of perceived impact on PBM operations.

Privacy

PBM operations require the receipt and use of a member's confidential pharmacy information. Often, PBMs are required to electronically transmit this information to their clients. Out of concerns related to the transmission and use of private, confidential medical information, the federal government and most states have enacted patient confidentiality laws, placing restrictions and imposing standards on the use and transmission of medical information by healthcare organizations.

Health Insurance Portability and Accountability Act (HIPAA) of 1996

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA) to address problems and issues related to the privacy, confidentiality, and security of healthcare-related data and information. On Dec. 28, 2000, the Department of Health and Human Services (HHS) published a final rule creating new federal privacy rights for personal health information. The rule became effective April 13, 2001, and all healthcare providers, health-related companies, and PBMs are required to become compliant by April 15, 2003. Going forward, the President has granted the Secretary of Health and Human Services authority to change the rule for the purpose of clarification.

These regulations establish security standards to protect all electronic health data from improper access, alteration, or loss, and impose "extensive restrictions" on the use and disclosure of individually identifiable health information. [38] [39]

All healthcare providers, health-related companies, and PBMs are expected to comply with HIPAA, or face severe penalties. The final HHS rules are likely to require PBMs to make significant changes to their information systems, policies, and procedures to protect patient privacy and the security of data. This could impact long-term profitability

PBMs are concerned about the impact of HIPAA and the final regulations due to:

- The imprecise definition of healthcare and healthcare related operations;
- The lack of national standards;
- The administrative burdens and increased costs;
- Liability issues; and

[38] Banahan, Benjamin, and Suzy Buckovich, "Patient Privacy, Confidentiality and Security," *Drug Topics* 144, no. 4 (February 21, 2000): 77.
[39] ESI, Inc., "10-K Report to the Securities and Exchange Commission" (1999), p. 22.

- The authorization requirements to transmit or release a member's personal healthcare data and information.

HIPAA supercedes any state laws that are less restrictive; however, it does not preempt any state laws that are more restrictive. Currently, most states have enacted privacy laws that established standards regarding patient confidentiality and have regulated access to medical records.

PBMs are evaluating the potential impact these final regulations will have on their operations. It is unclear whether the final regulations will allow PBMs to access and use health information for utilization review, quality assessments, audits, and other routine healthcare operations. Based on our interviews with the leading PBMs, they felt that these regulations could hinder their ability to effectively help their clients manage drug cost and utilization, by limiting the use of patient data in developing clinical programs.

Benefit and Plan Design

At least six states, including New Jersey and Virginia, have enacted or proposed legislation that prohibits clients from implementing certain restrictive benefit design features. For example, some states prohibit or restrict a PBM's clients from using therapeutic substitution programs, require coverage of all FDA approved drugs, and prohibit the denial of coverage for non-FDA approved uses of approved drugs.

These types of laws and regulations are not directly applicable to PBMs, but do impact the type of drug benefits their clients can implement. The PBM industry believes that if these laws were to become broader in scope and universally adopted, then they could impact the efficacy of PBM cost reduction programs; this could have a significant impact on PBM operations and profitability.[40]

Anti-Remuneration/Fraud

Federal law prohibits, subject to certain exceptions and "safe harbors, " the receipt of financial incentives to induce referrals of persons covered by federally funded healthcare programs (i.e. Medicare and Medicaid) or the purchase of items or services for which payment may be under federal programs. [41] In addition, some states have enacted similar laws that go beyond the requirements of the federal statutes. Due to the federal statutes' broad scope, Safe Harbors have been established which limit liability. Safe Harbors exist for certain properly reported discounts, certain investment interests, certain properly

[40] Ibid., p. 17
[41] Ibid.

disclosed payments made by vendors to group purchasing organizations, and certain discount and payment arrangements.[42]

The Office of the Inspector General and other governmental entities have begun to investigate PBMs and companies that have contractual relationships with PBMs. Issues of concern include the development of drug formularies, therapeutic substitution programs, and the rebates PBMs receive from manufacturers. The leading PBMs we interviewed all believe that their policies, procedures, and practices are in compliance with the anti-remuneration and fraud statutes, and defined Safe Harbors. However, they recognize that they could be subject to scrutiny under these laws, which could have adverse effects on the PBM industry.

Drug Dispensing

PBMs are affected by a variety of state and federal drug dispensing laws and regulations. Regulation of mail pharmacies, generic substitution laws, and regulation of therapeutic substitution programs can impact PBM mail pharmacy operations and the effectiveness of their clinical programs.

Mail Pharmacy Regulation

PBMs are subject to state and federal laws and regulations that impact the operation of their mail pharmacies. PBMs must comply with statutes that govern the operation of mail pharmacies, repackaging of drug products, dispensing of controlled substances, and medical waste disposal. Federally controlled substance laws require PBMs to register pharmacies with the Drug Enforcement Administration (DEA).

The Federal Trade Commission requires mail pharmacies to engage in truthful advertising, to stock appropriate inventory levels, to fill orders within 30 days, and to provide refunds to members as appropriate. In addition, the United States Postal Service currently has statutory authority to regulate and restrict mail service of drugs. However, to date, the Postal Service has not exercised such authority.[43]

Generic Substitution Laws

After passage of the Waxman-Hatch Act of 1984, which removed many of the impediments to market entry facing manufacturers of generic equivalents of branded drugs, all states enacted generic substitution laws.[44] These laws, replacing earlier anti-

[42] Ibid.
[43] Caremark, "10-K Report to the Securities and Exchange Commission" (1999), p. 4
[44] "The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change," Federal Trade Commission, pp. 19–20.

substitution laws, were designed to promote the substitution of lower-priced generic drugs for higher-priced branded drugs. Under the new laws, a pharmacist can dispense a generic drug even when a brand-name drug is specified, as long as the physician does not specify "dispense as written." These laws have had a significant impact on the price of branded drugs, and have contributed to lower drug costs.

Therapeutic Switch Laws

In contrast, therapeutic switch programs, in which PBMs switch the drug a physician has written for a drug preferred by the PBM, have faced challenges in many states. These challenges have been made largely on the grounds of consumer protection. In particular, a mail pharmacist's incentive to act as a "good agent" for members could change under the influence of therapeutic substitution policies.[45] Mail pharmacies that receive rebates for specific branded drugs could steer patients toward these drugs, even though members may have been prescribed a low-cost or high quality alternative. Although most therapeutic substitutions programs require a physician's approval, physicians may lack the necessary information to make the best decisions for members. Hence the laws to regulate therapeutic substitution programs, which could encourage drug switches that may not be in the best interest of a member.

Network Access

Most states have enacted regulations and laws that affect a PBM's ability to offer more restrictive retail pharmacy networks, and their ability to remove retail pharmacies from networks. These types of laws, also referred to as "any willing provider" laws, require PBMs to include any retail pharmacy in their network willing to meet a PBM's negotiated price and other terms for network participation.[46]

Access laws do not significantly impact PBMs, because most PBMs maintain national networks. In general, PBMs include any "duly licensed pharmacy" in their network that meets and adheres to their participation criteria, which typically include adequacy of insurance, minimum hours of operation, and the absence of disciplinary actions by relevant state and federal agencies.[47]

Licensure

Most states have enacted licensure and registration laws that govern a wide spectrum of healthcare organizations. The scope of these laws varies from state to state and the application is often ambiguous as it relates to PBM operations. Most PBMs will comply with these laws on a state-by-state basis, as appropriate. For example, some states have

[45] Ibid.
[46] Caremark, "10-K report to the Securities and Exchange Commission" (1999), p. 8.
[47] ESI, "10-K report to the Securities and Exchange Commission" (1999), p. 19.

increased the regulatory requirements of prior authorization programs, typically administered by HMO clients. In response, some PBMs have obtained state utilization review licenses.

PBMs must be licensed in each state in which it operates a mail pharmacy. Some states require mail pharmacies that deliver drugs to members in their state to be licensed by its board of pharmacy. Generally, many states permit the dispensing pharmacy to follow the laws of the state within which the dispensing pharmacy is located.[48] However, some states have enacted laws and/or regulations designed to prohibit or limit the operations of out-of-state pharmacies. Typically these states require the mail pharmacy to comply with all state laws irrespective of whether these laws conflict with the laws of the state where the mail pharmacy is located.

Drug Pricing

The federal and state governments use a variety of laws and regulations to regulate prescription drug costs and prices. In order for a manufacturer to receive reimbursement under Medicaid, Federal Supply Schedule (FSS), or Public Health Services (PHS), they must participate in all three of these programs at the same time. Key laws governing drug pricing include:

- State laws that provide prescription assistance programs to low-income seniors;
- State unitary pricing programs, which mandate that all drug wholesalers have access to the same pricing and discounts;
- Medicaid best price laws, which stipulate that a manufacturer participating in a state Medicaid program must give the state the lower of the best price available to any third party payer or a legislated discount; and
- The Federal Supply Schedule, which regulates drug prices paid by Federal agencies, such as Veterans Affairs, the Department of Defense, the Coast Guard, and indigent hospitals (Public Health Services).

[48] Caremark, "10-K report to the Securities and Exchange Commission" (1999), p. 7

Indigent Senior Drug Programs

As of February 2001, 26 states offered prescription assistance programs that provide coverage low-income seniors.[49] Many of these indigent senior drug programs receive manufacturer rebates, which are calculated in a similar fashion to the Medicaid rebates.

Most states have income limits for eligibility of between 170–225% of the poverty level. In addition, many assistance programs provide limited access for a small percentage of Medicare beneficiaries, ranging from 0.2% in Minnesota to 18% in Rhode Island. [50] A recent study by the White House Office of Management and Budget claims that only 45% of eligible Medicare beneficiaries are enrolled. This is believed to be due to the stigma associated with low-income programs and the lack of awareness of the availability of these programs.

State Unitary Pricing—The Maine Model

Maine (other states have proposed legislation) recently passed a prescription drug pricing law that allows the state to negotiate lower prices on drugs for the uninsured and ultimately to impose price controls if negotiations are unsuccessful. The law requires drug companies to offer unitary pricing plans, in which discounts must be based on volume, not the type of customer. Maine became the first state to enact such a law.

In order to have access to the Maine Medicaid program, manufacturers are required by Maine law to offer the same pricing and rebates to all wholesalers. The state passes these rebates on to pharmacies, which discounts drugs purchased by seniors. Currently, 21 other states are considering similar legislation. Pharmaceutical groups have countered that this legislation would ultimately lead to reduced access and rationing, and could impact research and development, slowing the development of new life-saving drugs.[51]

Currently, PBMs are unaffected by Maine's unitary pricing laws. However, if these laws are enacted in a state with a mail pharmacy, then a PBM's ability to negotiate discounts for drugs dispensed through their mail pharmacy will be limited. In addition, some manufacturers will not pay PBMs rebates for clients located in Maine.

[49] "State Senior Pharmaceutical Subsidy Proposals, 2001", National Conference of State Legislatures website, March 21, 2001.
[50] "State Rx Plans Enroll From .2% to 18% of Medicare Beneficiaries, GAO Say," *The Pink Sheet*, 62, no. 30 September 18, 2000
[51] Moskowitz, Daniel, "Federal and State Laws and Regulations Affecting Managed Care", *Drug Benefit Trends* 12, no. 8 (August 2000): 23-24.

Medicaid Best Price

The Omnibus Budget Reconciliation Act of 1990 established the Medicaid rebate program, which requires manufacturers to pay the states and the federal government a rebate to equal to at least 15.1% of the average whole acquisition cost for sales to Medicaid beneficiaries. In 1996, this program reduced total Medicaid drug expenditure from $11 billion to $9 billion.[52]

Medicaid rebates may exceed 15.1%, because of the "best price" provisions that guarantees Medicaid access to the lowest price paid by any private purchaser of a manufacturer's branded products. However, PBMs rarely receive rebates from manufacturers greater than 15%, because manufacturers rarely extend their best prices to PBMs. These prices are typically reserved for large, closed model HMOs such as Kaiser Permanente. Additionally, manufacturers are obligated to pay a "penalty rebate" if their pricing increases exceed CPI-U (consumer price index--urban).

Veterans Health Care Act (VHCA) of 1992 and the Federal Supply Schedule (FSS)

The Veterans Health Care Act (VHCA) of 1992 established the Federal Supply Schedule (FSS). Prices paid to drug manufacturers by federal agencies, such as the Department of Veterans Affairs and the Department of Defense, are set by the FSS.

Generally, the FSS price may be no higher than the lowest contractual price charged by the manufacturer to private purchasers. FSS prices are approximately 60% below the nonfederal average wholesale price.[53] Manufacturers have an incentive to comply with the FSS, because they want access to federal facilities and many physicians receive their training from VA hospitals. From sales and marketing perspective, manufacturers want VA trained residents to be familiar with their drugs. For certain drugs sold to the VA, the Department of Defense, the Public Health Service, and other agencies, a manufacturer must charge the lesser of the FSS and federal ceiling prices. The federal ceiling price is set at 24 % of the average wholesale price charged to nonfederal purchasers, and may be higher or lower than the FSS.

[52] Cook, Anna, "Pricing Mechanism Used by the Federal Government to Contain Prescription Drug Costs," August 2000. Prepared for U.S. Department of Health and Human Services' Conference on Pharamaceutical Pricing Practices, Utilization and Costs.

[53] *Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices*, Department of Health & Human Services, April 2000.

2.1.6 Important Trade Organizations

The PBM industry relies on several key trade organizations to provide legislative support, develop industry standards, promote the exchange of data and information, and provide representation for the industry in a variety of public and private forums. These organizations include:

- **American Academy of Managed Care Pharmacist (AMCP) -** AMCP is a professional association of pharmacists and associates whose goal is to serve patients and the public through the promotion of wellness and rational drug therapy by the application of managed care principles. The mission of AMCP is to serve as an organization through which the membership pursues its common goals; to provide leadership and support for its members; to represent its members before private and public agencies and health care professional organizations; and to advance pharmacy practice in managed health care systems.

- **Health Distribution Management Association (HDMA)** - HDMA is the trade association that represents pharmaceutical and related healthcare product distributors throughout the Americas. HDMA was formerly known as the National Wholesaler Druggists Association (NWDA).

- **National Association of Chain Drug Stores (NACDS)** – NACDS represents the views and policy positions of member chain drug companies. This purpose is accomplished through the programs and services provided by the association which emphasize ensuring the community retail pharmacy perspective is communicated to and understood by legislators and policy-makers; creating a favorable political and business climate in which NACDS member companies can carry out their business plans; providing appropriate forums for retailers to interact with their suppliers and business partners; and developing and promoting policies and programs aimed at improving merchandise distribution and retail operations efficiency.

- **National Council of Prescription Drug Programs (NCPDP)** – NCPDP is a non-profit ANSI-accredited Standards Development Organization. Their mission is to create and promote data interchange standards for the pharmacy services sector of the health care industry, and to provide information and resources that educate the industry and support the diverse needs of our members.

2.2 Industry Capacity Overview

PBMs operate in a complex system that includes pharmacies, manufacturers, clients, members, and physicians. The largest PBMs are serving 20 million or more members, using a highly automated operation that is relatively insensitive to volume increases.

PBMs today administer drug benefits for 65–70% of our nation's seniors, and the leading PBMs we interviewed do not expect a Medicare drug benefit to have a significant impact on industry capacity.

This section describes the administrative and clinical services PBMs provide. In addition, an analysis of PBM services that could be impacted by the addition of a large Medicare population is included.

2.2.1 PBM Operations

PBMs provide their clients administrative and clinical services, as shown in the following table.

Table 6: PBM Services

Overview of PBM Services	
Administrative Services	Client Services • Benefit Administration • Eligibility Administration • Reporting
	Pharmacy Network Administration
	Mail Pharmacy Operations
	Claims Adjudication
	Member Services
	Manufacturer Contracting and Rebate Administration
Clinical Services	Formulary Management
	Therapeutic Substitution Programs
	Utilization Management
	Disease Management
	Emerging Clinical Programs

PBM Administrative Services

Administrative services that PBMs provide their clients include client services, pharmacy network administration, mail pharmacy operations, claims adjudication, member services, and manufacturer contracting and rebate administration.

Client Services

Client services are comprised of benefit administration, eligibility administration, and reporting.

Benefit administration involves setting up and maintaining the drugs that are covered or excluded from the benefit. Most clients have different drug benefit designs to cover different employee/member groups (e.g. exempt, non-exempt, and retirees). A drug benefit design also includes the maximum benefit levels, co-pay, co-insurance, and deductible requirements. In addition, the drug benefit design may establish prior authorization requirements for specific drugs and/or therapeutic categories.

Eligibility administration is the enrollment, and ongoing maintenance, of members and their dependents. PBMs receive enrollment information from clients and maintain eligibility files. They are not responsible for the enrollment of members; the client handles this task. PBMs assign a client service team to support their larger clients. This team is the primary contact for the client to coordinate enrollment, administer benefits, and resolve issues.

Reporting includes standard (monthly, quarterly, and annual) and ad hoc report packages PBMs offer to their clients. Typical reports focus on drug utilization, drug cost, and PBM service levels.

Pharmacy Network Administration

Pharmacy network administration is the maintenance of the PBM's extensive network of pharmacies, and includes services such as network development and maintenance, network contracting, reimbursement and pharmacy audits. The pharmacy network specifies which pharmacies are approved for members, and includes retail, mail, and in some cases specialty pharmacies. PBMs routinely audit retail pharmacies in order to detect and prevent fraudulent or erroneous activities.

Mail Pharmacy Operations

In addition to retail networks, all the leading PBMs own and offer a mail pharmacy service to improve member access and help their clients better control costs. Mail order pharmacies are used for chronic medications, since there is a delay of several days in the

receipt of medications. They also typically dispense a 90-day supply of drugs (versus 30 days in retail).

Claims Adjudication

Claims adjudication is the online processing of a prescription drug claim. Most claims are submitted electronically at the point of service (the retail or mail pharmacy) when service is rendered. Paper claims (less than 1% of all claims) are manually entered into the claims processing system by the PBM. The claims system tests the member's eligibility and coverage to determine pharmacy reimbursement and member's co-pay. In addition, these systems apply a series of messages and edits to ensure the clinical appropriateness of the drug dispensed, and to drive appropriate utilization.

Member Services

Member services provide call center support to members and pharmacists. Member education and questions related to their benefits, pharmacy access, and adjudication issues are handled by member services. In addition, member services provide a "welcome" packet, which typically includes the member's drug card, drug coverage, required co-pays, benefit limits, information on how to access their pharmacy network, use the mail pharmacy, and submit a paper claim. Some of the leading PBMs have provided special training to their customer service representatives that interact with seniors. This training includes identifying emergent medical situations and offering clinical programs.

Manufacturer Contracting and Rebate Administration

Manufacturer contracting and rebate administration works directly with manufacturers to develop contracts, submit rebate claims, and allocate rebates to clients. Manufacturers pay rebates and administration fees to PBMs, because PBMs can influence the drugs that their members use. Manufacturer rebates are usually shared with or passed completely on to clients, while administrative fees are retained by the PBM. It is common for large clients to receive 100% of rebates.

PBM Clinical Services

PBMs use a variety of clinical services to help their clients control the cost and utilization of their drug benefit. The most common clinical services used by PBMs include formulary management, therapeutic substitution, utilization management, and disease management.

Formulary Management

Formulary management is the process of developing and maintaining a formulary. A formulary is a continually updated list of branded (and generic) drugs favored by the PBM (or its clients). Formulary development is managed through the PBM's Pharmacy and Therapeutics (P&T) Committee. A formulary works in concert with the member's drug benefit to determine which drugs are covered and the member's co-pay. PBMs typically develop a national formulary and will often customize formularies for specific clients. A PBM may also administer a formulary developed by its client.

Therapeutic Substitution Programs

Therapeutic substitution programs are typically operated in mail pharmacies to encourage physicians and patients to switch to lower cost comparable drugs. Therapeutic substitution can occur when a new medication becomes available, when drug formularies change, or when a manufacturer offers more favorable rebates for a new drug.[54]

Utilization Management Programs

PBMs use utilization management programs and to encourage the use of generics or preferred products. These programs include services such as prior authorization, drug utilization review (concurrent and retrospective), academic detailing programs, and patient education. PBMs have also developed specific edits for the senior population. These edits include identifying drugs that are not appropriate for a member's age (e.g., oral contraceptives), or dosing regimes that are not adjusted for an elderly metabolism.

Disease Management Programs

PBMs develop disease management programs to identify and categorize patients (especially those with chronic conditions) and to direct these patients towards a specific treatment protocol. Disease management programs are usually provided at additional cost to clients, beyond the PBMs standard service offering. Compliance programs, especially for severe/high cost conditions such as transplants, fall into this category.

Emerging Clinical Programs

Some emerging clinical programs offered by PBMs include contracting with specialty pharmacies, the use of the Internet as a portal for member and physician education, and enhanced access to mail and retail pharmacy services. PBMs are enhancing their Web capabilities, offering personalized, comprehensive services to members via their

[54] Fish, Leslie and Barbara Edelman-Lewis, "The Impact of a Therapeutic Interchange Program in a Managed Care Organization," *Journal of Managed Care Pharmacy* 5, no. 5 1999: 438-444.

Websites such as health content and benefit design. Another recent focus is enhancing physician connectivity to PBMs and pharmacies to improve formulary and clinical control at the time the prescription is written, and to reduce translation errors when pharmacists dispense the drug.

2.2.2 PBM Capacity Considerations

In our discussions with the leading PBMs, there was general consensus that extending a drug benefit to the Medicare population would not have a significant impact on the industry. PBMs already administer drug benefits for 65–70% of this population through employer groups (e.g., retiree plans) and health plans. Thus, the incremental volume to the industry is expected to be approximately 11–14 million lives—roughly the size of a large new client. This would be an increase of 6–7% in the lives currently covered by the four leading PBMs.[55]

Most PBM operations are highly automated and relatively insensitive to volume increases. The leading PBMs have all demonstrated capability to rapidly scale-up operations for new, large clients. Examples of this include the following:

- Merck-Medco recently completed an agreement with United Healthcare to provide PBM services to United's 10 million covered lives, which is expected to increase Merck-Medco's covered lives to 60 million. [56]

- AdvancePCS signed a ten-year agreement to provide PBM services to Foundation Health Services' 6 million covered lives.

- Over a two-month period in 2000, AdvancePCS signed agreements with several clients totaling 5 million covered lives.

- Caremark signed agreements with Oxford Health Plan and Coventry Health Care for a total of 3 million covered lives over a two-month period in 1999.

There are, however, some aspects of a PBM that are volume sensitive, but which can usually be scaled up quickly. These include administration of benefit design, new enrollee education, and call center and mail pharmacy operations.

In the event of selecting a PBM, HCFA may request the PBMs provide detail on how their operations and service levels will change to accommodate Medicare volume, and what their projected service levels will be as a result of these changes.

[55] Total covered lives of Top 4 PBMs = 195 million * 1.06 = 207 million lives, a net increase of 12 million lives.
Total covered lives of Top 4 PBMs with Non-covered Medicare population = 206 million – 209 million
Percent change = 6%- 7%

[56] "Express Scripts will Lose UHC Contract One Year After DPS Acquisition, " *Pink Sheet*, 61, no. 7February 15, 1999.

Administration of the Benefit Design

The administration of the benefit design is sensitive to the number of different plan designs that need to be set up, and any ongoing changes to these plans. PBMs are accustomed to administering a large number of complex plan designs, which require ongoing maintenance. For example, large insurer or employer groups can have upwards of 300 plan designs in effect, which vary by type of employee or retiree. The impact of a Medicare drug benefit on the benefit design administration operations of a PBM depends on the complexity and number of plan designs offered, and the extent to which these plans are changed once they have been implemented.

Member Education and Support Services

The member services operation of a PBM is sensitive to the number of new enrollees, complexity of the benefit design, and the effort required to educate new members about their benefit and answer questions. If a Medicare benefit was extended, educating beneficiaries about their drug benefit will be very important, given the size of the senior population and the complexity in meeting their clinical and administrative needs. With some seniors receiving a pharmacy benefit for the first time, and others moving from private coverage to Medicare, PBMs will invariably have to respond to increase calls. The leading PBMs we interviewed were in general consensus that educating beneficiaries posed the greatest risk to successfully implementing a Medicare drug benefit.

To meet the needs of the Medicare population, the leading PBMs anticipate a need to add dedicated member service personnel, and to ensure they have sufficient capacity (headcount and technology) in their call centers to handle the anticipated call volume and talk times, especially during the open enrollment periods. Based on a survey of the major PBMs, senior talk times are approximately 6–8 minutes, more than double that of non-seniors (3–4 minutes). This will likely require building and fitting out new facilities, and investing in additional information and telecommunication support systems.

Mail Pharmacy Operations

Depending on whether and how a mail pharmacy service is extended to the Medicare population, a large senior population could impact the mail pharmacy operations of the leading PBMs. Since many seniors suffer from chronic conditions, they have the potential to become heavy users of mail pharmacies. This could impact a mail pharmacy's logistics and fulfillment operations. As a result, PBMs may need to evaluate the capacity of these operations, and scale up accordingly. All of the leading PBMs we interviewed stated that their mail pharmacy operations are scalable, such that they could quickly increase capacity to meet increased demand.

2.3 Local Market Structure and Roles of Pharmacy Networks

All PBMs maintain national pharmacy networks to provide members with access to drugs. Networks include leading national and regional retail pharmacy chains supplemented by independent, mail, and specialty pharmacies. A PBM's pharmacy network determines its geographic coverage, not the PBM's location.

Most PBMs maintain several "standard" pharmacy networks that cover all 50 states, plus the territories of Puerto Rico and Guam. The average PBM has 42,000 pharmacies in its network.[57] AdvancePCS and Merck Medco have the largest pharmacy networks with approximately 57,000 pharmacies (98% of all pharmacies in the U.S.).[58]

PBMs routinely design custom networks to provide better pricing through more restricted access for their clients. A customized network allows a client with *regional* or *unique* needs to receive deeper price discounts than the PBM usually offers through its standard network. However, such discounts typically come with some inconvenience to the members. In general, the deeper the discount, the fewer the pharmacies are willing to participate in the network and the farther a member will have to travel to get a prescription filled. Custom networks can also be designed to better align with a client's geographic requirement.

The contracts a PBM holds with the pharmacies participating in its network vary. PBMs generally receive less favorable pricing discounts with rural and remote pharmacies than with urban and suburban pharmacies. This is due to the lower volume a PBM is able to drive into rural or remote pharmacies, and their scarcity.

PBMs use geo-access-mapping software to evaluate the coverage of their pharmacy network. Most PBMs provide access guarantees to clients, and often have to contract with independent pharmacies in rural areas to meet their obligations.

A chain pharmacy is typically contracted through the chain's corporate office and is more likely to contract with a PBM at a lower rate of reimbursement to capture a PBM's significant market share. For example, a chain pharmacy that comprises 50% of all pharmacies in a specific region may contract with a PBM for reimbursement rates of branded products at average wholesale price (AWP) minus 14% (instead of the usual AWP – 13%) if they are one of two chain pharmacy providers within that region. These savings are then passed on to the clients. However, many clients elect to maintain broader networks in order to avoid member dissatisfaction that may result from limiting the retail network.

[57] Peat, Susan, *HMO & PBM Strategies for Pharmacy Benefits* (AIS, 1999), p. 36.
[58] PCS pharmacy data obtained from PCS Website (www.pcs.com).

Independent pharmacies contract either individually or through a Pharmacy Services Administrative Organization (PSAO). Contracting through a PSAO improves contract efficiency and enables independents to improve pricing through group purchasing. With better pricing, independents are able to contract with the PBMs at reimbursement rates that are comparable to those contracted by chain pharmacies.

2.4 Overview of PBM Financials and Pricing

PBM's derive revenue from clients, manufacturers, and in some cases pharmacies, while administering the financials and pricing of drug benefits (Diagram 15). Please refer to Sections 3.2 and 3.3 for a more detailed analysis of PBM financials, pricing and contracting.

In general:

- Clients are charged an administrative fee for services like claims processing. PBMs may also charge a small transaction fee for claims processing to the pharmacies participating in their network.
- PBMs reimburse dispensing pharmacies for the ingredient cost plus dispensing fees less co-pay for drugs dispensed to members, and then pass this cost on to clients.
- PBMs receive rebates and administration fees from manufacturers. PBMs typically retain the administrative fee, and share the rebates with their clients.
- PBMs may receive additional money from manufacturers for the sale of data, maintaining clinical programs, or other services. Clients may be charged for clinical management programs, or other "custom" services such as ad-hoc reporting or providing dedicated customer service teams. PBMs may also make a small profit from their mail pharmacy operations.

One of the primary reasons clients retain PBMs, is that PBMs reduce the cost of offering a pharmacy benefit. PBMs do this by automating administrative services, obtaining discounts on drugs (ingredient cost), and managing drug utilization. As shown in Table 7, the average prescription costs $59.17 in an unmanaged market (e.g., fee for service). Through a PBM this cost is reduced to $38.96, or 34% less than the fee for service cost.

Table 7: FFS versus PBM Cost Savings [1-7]

Factor	Average Dollar Value Per Prescription
AWP	**$54.79**
FFS Cost Per Prescription to the Patient (AWP + 8%)	**$59.17**

PBM cost per prescription to the client	
Ingredient Cost (AWP – 27%)	$40.00
Dispensing fee	+ $2.50
Administrative/claims processing fee	+ $0.30
Manufacturer rebates	- $1.10
Utilization management	- $2.74
PBM Cost per prescription	**$38.96**
FFS versus PBM	**$20.21** **(34% lower than average cost per script under FFS).**

1. Based on internal PwC documents for an actual client.
2. AWP estimated at $54.79
3. FFS cost estimated at AWP + 8%.
4. AWP is a blended number based on a 65/35 brand to generic ratio.
5. Retail discount is a blended number based on a 65/35 brand to generic ratio. The average branded retail discount was assumed at 14% off AWP, and the average generic retail discount assumed at 50% off AWP. Retail discount assumed at 27%.
6. Ingredient cost equals AWP less average retail discount (27%)
7. PBM cost per prescription is net of total rebates/savings per claim.

The flow of money and pricing between PBMs and their business partners varies according to the type of contract. There are three types of contracts PBMs hold with their clients: fee-for-service, shared savings, and capitated.

2.4.1 Fee-For-Service Contracts

Fee-for-service contracts are the most common pricing arrangements PBMs have with their clients. Under these contracts, PBMs are paid for the administrative services they provide (claims processing). The PBM retains the manufacturer-paid administrative fees and, depending on the client, some percentage of the rebates. With this type of contract, the PBM does not assume risk for the cost of drugs dispensed (ingredient cost); this cost is passed through to the clients.

PBMs contract with their clients and pharmacy network for retail pricing for branded and generic drugs, for drugs dispensed from a mail pharmacy, and in some cases, specialty pharmacies. Pharmacists are reimbursed the discounted ingredient cost, plus a dispensing fee. Ingredient cost is typically the lower of average wholesale price (branded), maximum allowable cost (generic), or usual and customary (price-charged cash-paying customers). The member also pays pharmacists a co-pay.

Certain PBMs guarantee clients an overall price (e.g., AWP – 12% + $2.50 dispensing fee), and then manage the pharmacy network based on negotiated prices, which on average are comparable to the prices guaranteed to clients. In some cases, the PBMs may generate a small profit off their network pricing.

PBMs receive claims processing fees from clients on a per transaction basis for a bundled package of services that typically includes: basic administrative and clinical services, such as claims adjudication, drug utilization review (DUR), member communications, member ID cards, provider directories, standard reports, fraud protection, and on-site claim audits. PBMs may also charge separate administrative fees for additional services not included in the bundled package such as prior authorization, disease management, and customized reports. These additional services are paid either on a per transaction basis or as a quarterly/monthly flat fee.

2.4.2 Risk Sharing (Shared Savings) Contracts

PBMs also maintain shared savings arrangements with clients. An effective way to manage pharmacy cost is through a shared savings arrangement, where the client and the PBM share the savings. These arrangements provide incentives for both sides to collaborate and run the pharmacy benefit program effectively.[59]

Under these arrangements, PBMs guarantee clients minimum rebates, generic prescription dispensing rates, and discounts from average wholesale prices. Failing to meet these targets trigger financial penalties for the PBM. In return, PBMs expect clients to sign long term contracts in order to realize potential reductions in utilization and costs. Under shared savings contracts, the flow of revenue and drug pricing is similar to fee-for-service contracts. However, PBMs will reconcile on a quarterly/monthly basis any drug costs savings with the client.

2.4.3 Capitated Contracts

Capitated pricing, tested by the PBM industry in the early-1990s, is essentially non-existent today since PBMs generally lost money through these arrangements. For example, ValueRx (now Express Scripts) signed a capitated contract with Ford Motor Company in 1994 for Ford's unionized workers. Due to significant losses, ValueRx was forced to renegotiate this contract a year later.

In a capitated pricing arrangement, the PBM agrees to assume financial risk for a client's drug spending. Capitation is a set dollar amount, established by analysis of pharmacy claim data, used to cover the prescription costs for a member. The amount is usually a per member, per month (PMPM) rate; the client is responsible for monthly payments to the PBM. With this type of contract, the PBM functions in a capacity similar to that of an insurer. As a result, PBMs assuming risk are required to have an insurance license.

Under a capitated arrangement, the PBM receives a PMPM payment from the client. This payment (or premium) is expected to cover the PBM's cost of providing pharmacy benefits to the client's members, as well as the administrative and clinical services provided by the PBM. If the PBM is able to effectively control utilization and spends less than the PMPM payment (plus any overhead allocation), then the PBM profits. However, PBMs that manage large volumes of patients with catastrophic illnesses may, in fact, lose money.

This type of contract is risky, given unpredictable factors such as the release of new branded drugs, escalating drug prices, direct-to-client (DTC) advertising and higher

[59] Manieri, Elaine, "Vendor Contracting for PBM Services: How to get more than you paid for?" *Employee Benefit Plan Review* 53 no. 10 (April 1, 1999): 22.

prescription utilization rates. In addition, PBMs do not have risk arrangements with physicians; nor can they benefit from the tradeoff of drugs versus medical costs. PBMs have only indirect influence on drug volume, such as physician interventions or through increases to member co-pays.[60] Also, pharmaceutical manufacturers have not been willing to underwrite the risk of PBM's that enter capitated arrangements.

[60] Etheredge, Lynn, "Purchasing Medicare Prescription Drug Benefits: A New Proposal," *Health Affairs* 18 no. 4 (July 1, 1999): 7.

3.0 OPERATIONS RELATED ISSUES

The services a PBM provides can be categorized as either administrative or clinical.

Administrative services include client services, pharmacy network administration, mail pharmacy operations, claims adjudication, member services, and manufacturer contracting and rebate administration. Clinical services include formulary management, therapeutic substitution, utilization management, disease management programs, and some emerging clinical programs.

PBMs derive most of their revenue from clients via administrative fees, and from manufacturers via rebates and administrative fees. PBMs contract with clients using three types of contracts: fee-for-service, risk sharing, and capitated. Manufacturer contracts are usually based on the PBMs' ability to build or maintain a drug's market share.

Prior to contracting with a PBM, clients typically engage in a comprehensive bidding and selection process. The bidding process encompasses the time from the decision to request a bid through PBM selection.

This first section of this chapter describes the administrative and clinical services PBMs provide. The second section describes PBM financials and pricing, and includes a description of administrative fees, pharmacy reimbursement and the cost of pharmaceuticals, and rebate administration and payment. The third section provides an overview of the types of client contracts. The last section presents the major components of the bidding and selection process and provides examples of the processes and methodologies used by clients today.

3.1 Services

PBMs provide their clients administrative and clinical services.

Table 8: PBM Services

Overview of PBM Services	
Administrative Services	Client Services • Benefit Administration • Eligibility Administration • Reporting
	Pharmacy Network Administration
	Mail Pharmacy Operations
	Claims Adjudication
	Member Services
	Manufacturer Contracting and Rebate Administration
Clinical Services	Formulary Management
	Therapeutic Substitution Programs
	Utilization Management
	Disease Management
	Emerging Clinical Programs

3.1.1 PBM Administrative Services

Client Services

Client services include benefit administration, eligibility administration, and reporting.

Benefit Administration

Benefit administration is the administration of drug benefit designs. It includes setting up and maintaining drug coverage and exclusions, setting limits on drug coverage, and defining member cost sharing requirements (co-pays).

Benefit plan designs specify the prescription drugs that are covered. A drug benefit plan typically covers ethical pharmaceuticals. Ethical pharmaceuticals are drugs approved by the Food and Drug Administration (FDA) for treatment of specific disease states specified by the FDA. Ethical pharmaceuticals require prescriptions. Cosmetic and lifestyle drugs such as Retin A and Rogaine, and over-the-counter (OTC) medications such as Tylenol, are generally excluded from the drug benefit (members pay for excluded medications themselves). Biotech injectables, infused medications, and other medications dispensed at an inpatient setting are typically covered under the medical benefit, and not included in the drug benefit.

Clients may maintain several drug benefit plans. This allows them to offer different coverage for populations with different needs (e.g. exempt, non-exempt, retirees and their dependents). Clients can vary benefit design by employee type, such as exempt versus non-exempt or part-time versus full-time. Clients may extend pharmacy and medical benefits to qualified retirees. Typically, retirees' cost sharing requirements and coverage limits differ from active employees. Coverage is typically extended to members and dependents of active employees. Dependents are typically defined as a member's spouse and their children. Coverage of children can vary by age and whether or not the child is in college. Beyond a defined age limit, children are no longer considered dependents and are excluded from coverage under their parent's pharmacy benefit.

Benefit plans also specify how members share the cost of their drug benefit with their employer or group (co-pays, co-insurance, and deductibles). These cost sharing arrangements are often used to encourage members to select generics or lower priced drugs. Co-pays are fixed amounts that members pay for every prescription. Co-pays can vary depending on whether the prescription is dispensed from a mail pharmacy or retail pharmacy, whether a brand or generic is dispensed (i.e. a two-tier structure), and whether the drug is featured on the formulary (i.e. a three-tier structure).

Coordination of benefit (COB) programs – the practice of coordinating coverage for members eligible for more than one pharmacy benefit – are not typically administered by

PBMs because the cost savings have proven insufficient to warrant the administrative cost and burden to the member. COB programs typically require members to submit paper claims to their primary insurer. Once the primary insurer has paid and provided an explanation of benefits, the member is then required to submit a paper claim to the secondary payer for any outstanding amount. Most clients functioning in the secondary payer capacity choose to pay whatever out-of-pocket expenses the primary payer has not covered, but some apply their own co-pay amounts.

Most of the leading PBMs offer a COB program. As stated above, none of these programs are administered on a "real time" basis (e.g., at the time a claim is submitted from the point of service for adjudication), but rather rely on paper claims. There is typically an added administrative charge for COB programs.

During our discussions, several leading PBMs stated there appears to be increasing interest in COB, as clients look for ways to stem the rising costs of drugs. In general, clients with the "richest" benefit plans (e.g., broad drug coverage, low co-pays) and employees eligible for drug benefits elsewhere, stand to benefit the most from implementing a COB program

While some drug benefit plans still use a single co-pay structure (e.g. $5–$10) for all prescriptions, some use a two-tier differential co-pay structure that differentiates branded drugs from generics. Under this structure, members pay lower co-pay amounts (e.g. $5–$15) for generic drugs and higher co-pay amounts ($10–$25) for branded drugs. In addition, some drug benefits plans include a three-tier co-pay structure that differentiates branded, generic, and non-formulary. Under this structure, members not only pay differential co-pay for brand ($10–$25) versus generic ($5–$15), but also pay higher co-pay for using non-formulary drugs ($15–$50). Non-formulary drugs are usually branded drugs for which the PBM does not receive manufacturer rebates. In the spring of 2000, 80% of pharmacy benefit plans offered three-tier co-pays, a significant increase from 36% in the spring of 1998.[61] An emerging trend by some clients is the use of a fourth co-pay tier for lifestyle and/or "biotech" drugs. Clients often require a 50% co-insurance for drugs in this tier, thereby requiring the member to pay one-half the cost of the drug. (The most restrictive plan designs only cover formulary-listed products, and typically require a generic be dispensed if available. Non-formulary drugs are excluded from the benefit. These plans are favored by HMOs that have assumed risk for the cost of their members' drug benefit.

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[61] "Managed Care Co-pays: Higher and Higher; More HMOs and Pharmacy Benefit Managers Using Three-Tier Cost Control Measures," *Business Wire*, August 7, 2000. Article used data from Scott-Levin Spring 2000 Managed Care Formulary Drug Audit.

Co-pays are usually comparable for mail and retail, even though retail pharmacies typically fill a 30-day supply of prescriptions. Mail pharmacies fill a 90-day supply of the same prescription for the same co-pay or one that is only modestly higher (typically twice retail); the overall cost to the member is generally one-third lower through the mail pharmacy. For example, a member with $10 co-pay for generic drugs, using a retail pharmacy, will pay $30 for three 30-day prescriptions. However, by using the mail pharmacy they typically pay $20 for a 90-day supply, saving $10. This encourages the member to use the mail pharmacy, where deeper discounts off the ingredient cost are found than in retail pharmacies, thereby reducing the cost of the pharmacy benefit.

With co-insurance, members pay a fixed percentage of the cost of each prescription. Typically, the co-insurance percent (usually 20%) is fixed irrespective of the type of drug dispensed (brand, generic, or non-formulary). However, many clients are moving toward differential co-insurance based on the category of drug. For example, members pay 10% for generics, 20% for branded and 30% for non-formulary. This form of cost sharing has been a traditional feature of indemnity programs, but not widely used in PBM administered plans.

Deductibles—the amount of money a member has to pay out-of-pocket before the drug benefit program begins—may be used in conjunction with co-insurance and co-pays. For example, some drug benefit plans include a $50 annual deductible. The member is responsible for all drug costs equal to $50 or less. Once annual drug cost exceeds $50, the member only pays the relevant co-pay or co-insurance. Pharmacy costs are often included as part of a member's total medical benefit. Clients may establish maximum annual benefit limits on the amount they will pay for medical (and pharmacy) costs per year (e.g. $1 million).

Eligibility Administration

Client services include enrollment and eligibility administration services that assist clients in registering their members and dependents for the drug benefit. PBMs generally do not register members and their dependents for their drug benefit. The clients handle this process, as well as the collection of member premiums, and provide the PBM with enrollment and eligibility information. Key information a PBM receives from its clients for an eligible member includes name, unique identifier, age, sex, date of birth, and benefit plan. An eligibility file is created from this information, which is used to verify the member's eligibility for coverage during claims adjudication.

Enrollment activity for the PBMs peaks in June and December, as these months are typically the enrollment periods prior to the beginning of a client's new benefit plan year. Eligibility updates are provided on an ongoing basis for major life events (marriages, births, and deaths), and to account for new and terminated employees. PBMs typically

require several weeks to map and load a new enrollment file, and one or two days to administer eligibility changes.

Currently, no industry standard exists to support enrollment or eligibility maintenance processes. PBMs receive enrollment information in a variety of formats, including floppy disk, magnetic tape, and hard copy. Although PBMs generally require the same information (e.g., name and date of birth), each PBM has developed its own standard. In addition, clients often provide this information in their own formats, requiring the PBM to map the data into the eligibility file used during claims adjudication.

Reporting

As an aspect of client services, PBMs provide their clients monthly, quarterly, and annual reports that focus on drug utilization, drug cost, and service issues. The client and the PBM, to anticipate and manage utilization trends and costs, use these reports and combine them with information about trends in drug development (new drugs on the market, patent losses, etc.).

Monthly reports provided to clients typically include standard cost, utilization, and performance indicators. These include claims data such as total drug cost, total ingredient cost, total cost sharing, total cost savings from generic and therapeutic substitution programs and denied claims, and reports that list the top pharmacies by cost, top prescribers by cost, and top drugs by cost. Quarterly executive summary reports often provide trend data that includes member demographics, plan cost sharing averages, average ingredient costs, brand/generic dispensing rates, retail network performance, and mail pharmacy performance. Annual reports typically summarize the plan's performance during the year, and often include a statistical summary of cost, utilization, and service indicators. In addition, these reports provide a more detailed analysis of the effectiveness of specific programs, such as maximum allowable cost (MAC) pricing and utilization and formulary management programs. PBMs will provide ad-hoc or customized reports to clients for an additional cost. PBMs typically charge per hour fees for computer programming and other resources required to produce these reports.

Client Service Support

PBMs assign a client service team to support their largest clients (smaller clients are typically assigned an account coordinator). The client service team is the primary contact for the client to coordinate enrollment, benefit set up, and administration, member communications, and issue resolution. Client service teams can be dedicated or non-dedicated. Dedicated teams exclusively service specific clients for an additional cost; non-dedicated teams provide general support to many clients.

Pharmacy Network Administration

Pharmacy network administration maintains the PBM's extensive network of pharmacies. This includes network development, network contracting, reimbursement, and pharmacy audits.

Network Development

To fill their members' prescriptions, PBMs develop and maintain a network of chain and independent retail pharmacies, supplemented by mail and specialty pharmacies. PBMs offer their clients a choice of a standard pharmacy network, or a customized network. A standard network provides national coverage, and is the network frequently selected by clients. A customized network allows a client with *regional* or *unique* needs to receive deeper price discounts than the PBM offers through its standard network, but at some inconvenience to the members (Table 9). In general, the deeper the discount, the fewer the pharmacies that are willing to participate in the network and the farther a member will have to travel to get a prescription filled.

Table 9: A Leading PBM's Pharmacy Network Pricing

Network Type	Branded Discount Off AWP	Number of Pharmacies in Network
Standard	12%	57,000
Custom (restricted)	13.5%	50,000

Pharmacy networks are designed to provide good access to retail pharmacies at the lowest cost. The more restrictive a network (less access), the better the discounts. In some cases PBMs can reduce the number of retail pharmacies in the network by 20%, obtain better pricing, yet still meet their contractual obligations regarding pharmacy access—typically 1–5 miles from a member's home in urban and suburban areas.

Most PBMs require their network pharmacies adhere to the policies and procedures of the PBM, such as reasonable hours of operation, promotion of generic substitution, adhering to a pricing formula, submission of U&C charges. Additional requirements typically include:

- Submission of electronic claims, using the latest NCPDP format;
- Active membership in the National Association of Boards of Pharmacy (NABP) (The numeric identification number assigned to the pharmacy is verified by the NCPDP);

- State licensure of the pharmacy and pharmacists, with the licenses clearly displayed at the pharmacy;
- Evidence of a valid tax ID number and an active DEA number;
- Proof of professional liability insurance;
- Demonstration that all prescriptions are dispensed in accordance with applicable state laws;
- Maintenance of a customer signature log; and
- No claims, settlements or judgments outstanding.

Network Contracting and Reimbursement

PBMs contract with pharmacy chains at the national level and with independent pharmacies directly, or through Pharmacy Services Administrative Organizations (PSAOs). PSAOs are group purchasing organizations for smaller, independent pharmacies. PSAOs improve contracting efficiency for independent pharmacies, and allows them to contract with PBMs at discount rates that are comparable to those received by larger, retail chains. Key terms of these contracts include the pharmacy reimbursement rates and timing, the PBM's right to audit, and minimum performance requirements, such as generic dispensing rates.

Pharmacies are reimbursed (with the cost passed onto PBM clients) the ingredient cost of the drug dispensed plus a dispensing fee, less the member's co-pay by the PBMs. As a result, the PBM is not at risk for the cost of the drugs. Retail pharmacies are reimbursed either every week or every other week. At the time of claims adjudication, the claims processing systems sets the amount the pharmacist will be reimbursed.

PBMs typically guarantee an overall pharmacy network reimbursement rate for their clients, and separately negotiate reimbursement rates to pharmacies that allow them to meet client commitments. The actual rates the PBM receives will vary by pharmacy chain and network. The PBM may contract with certain pharmacy networks for deeper pricing discounts and lower dispensing fees than it is obligated to provide its clients. In other cases, the pharmacy discounts are less favorable relative to the contracted rates a PBM receives from its clients. If the PBM is successful, it retains the margin while meeting its contractual obligations.

Pharmacy Audits

PBMs retain the right to audit retail pharmacies participating in their PBM network. This enables the PBM to monitor, deter, and recover fraudulent or erroneous claims. The right to audit is stipulated in the contract the pharmacy holds with the PBM. Studies have found that approximately 3% of claims submitted to PBMs from retail pharmacies are fraudulent, and 2% are claims for which payment should have been denied.[62] Audits of retail pharmacies are a standard service PBMs provide their clients

Pharmacies with higher than normal "abuse indicators" are typically targeted for an on-site audit.[63] PBMs use a variety of utilization and cost reports to identify likely abusers and then target them for audit. Indicators of abuse include high average prescription price, high refill percentages, and high volumes and utilization.

Audits can be categorized into "off-site," which includes "desk-top" and "real-time," and "on-site."

Desktop audits identify and detect patterns of abuse using statistical probabilities for 20–30 key indicators. Examples of these indicators include the brand to generic dispensing ratio and the average pills dispensed per script. Desktop audits are used to monitor the pharmacy network, and prioritize pharmacies for on-site audits.

Real time audits enable PBMs to quickly identify erroneous or fraudulent claims and mitigate the potential for overpayment. For example, a pharmacy that submits two prescriptions for the same drug at the same time as opposed to one prescription could receive a phone call questioning whether this should be submitted as one prescription, thereby reducing the dispensing fees paid and co-pays collected. Real time audits save the PBM the time and expense of an on-site audit, and have a sentinel effect on the pharmacy network; they also act as a bulwark against wider fraud and abuse. Criteria for real time audits are built into the claims adjudication process. Claims selected for audit are routed to the retail pharmacy operations group, from which the outbound phone call is placed.

On-site audits are limited to pharmacies suspected of heavy abuse. These audits are expensive for the PBMs, and often require the use of outside auditors and consultants. During an on-site audit, the prescription records maintained by the pharmacy are reviewed and compared to the information provided via the claims processing system.

The leading PBMs we interviewed each perform 30,000–40,000 desktop audits and 500 – 1,500 field audits annually. These audits resulted in the annual removal of between 5 and

[62] "The Auditor Cometh," *Drug Topics*, 141, no. 20, September 20, 1997. 72.
[63] Ibid.

15 retail pharmacies from the PBM's network, and the recovery of millions of dollars from false or erroneous claims. Most of the PBMs sent the recoveries back to their clients; however, some of the PBMs retained a portion of the recovered monies to cover their costs.

Details regarding PBM audits and results are considered proprietary and confidential to the PBMs. HCFA should request additional information on this topic as a part of the PBM evaluation process.

Mail Pharmacy Operations

Most pharmacy benefit plans offer a mail pharmacy service as a way to promote cost savings and improve access. The cost savings and convenience of mail pharmacies are particularly attractive to seniors with chronic conditions that require long term medications. Since there is a delay in receipt of medications via mail pharmacies, mail pharmacies are appropriate for long-term medication for chronic illnesses. PBMs own most mail order pharmacies, allowing the PBM to promote cost savings for its clients and members, increase formulary control, and drive compliance. Members may be encouraged (through the co-pay) or required to use mail pharmacies when appropriate.

Mail pharmacies also enable PBMs to promote cost savings for their clients through logistic and fulfillment economies of scale: economies of scale include lower acquisition cost due to volume purchasing, larger dispensing quantities, and therapeutic substitution programs. The pricing discounts offered through mail pharmacies are larger and the dispensing fees lower than those offered through retail pharmacies. Mail pharmacies also provide the PBM an opportunity to intervene with therapeutic substitution programs before a prescription is filled, thereby facilitating the use of less expensive medications (Table 10).

Table 10: Retail and Mail Discounts and Dispensing Fees

	Brand		Generic	
	AWP Discount %	Dispensing Fee	Discount %	Dispensing Fee
Retail	12–15%	$2.00–$3.00	MAC	$2.00–$3.00
Mail	18–23%	$0–$2.00	50–60%	$0.–$2.00

Mail order pharmacies typically dispense a 90-day supply of drugs at two-thirds the co-pay for three 30-day supplies at retail. For example, consumers who use mail pharmacies will often pay $10 for a 90-day supply for a generic drug, but will pay $5 per prescription or a total of $15 for three 30-day prescriptions at retail pharmacies.

Mail pharmacies also offer members the convenience of direct delivery to home or another desired location. For seniors that have more than one address, the mail pharmacy helps eliminate the need for the paper claims that may result from using a non-network pharmacy in remote locations. In addition, members can easily request refills via the phone or Internet.

The major processes in a mail pharmacy are receipt, translation, therapeutic substitution, and fulfillment. An overview is provided in Diagram 16; the functions are described below.

In the typical mail-order program, the member mails their prescription and co-pay, along with the necessary forms, to the mail pharmacy. The mail pharmacy receives and opens the mail, and deposits the co-pay into a banking account. Co-pay remittances are typically restricted to money orders, credit cards, or checks. This first process is commonly called receipt. The next step in the process is translation. Here the prescription is entered into the claims processing system for adjudication. If the prescription is illegible, the mail pharmacy will call the prescriber for confirmation.

Once in the claims processing system, the prescribed drug is evaluated to determine whether a less expensive drug within the same therapeutic class can be substituted. If a substitute is available and clinically appropriate for the member, the prescriber is contacted and asked if a switch can be made. Claims for which drugs have been switched are re-adjudicated. Once the drug to be dispensed has been determined, the mail pharmacy can then pick, pack, and ship the order. This process is called fulfillment. State-of-the-art mail pharmacies rely heavily on robotics to automate this process. The larger PBMs fill between 10 and 60 million mail prescriptions annually, with very low error rates (less than 0.01%). On average, the members receive their prescription in about 10 days. Prescriptions are typically mailed by an overnight delivery service.

Prescription refills follow a similar process. Prescriptions can be refilled over the phone or via the Internet. In addition, members can request that refills be mailed to a different address than the original prescription.

Claims Adjudication

One of the key services PBMs provide is the online adjudication of drug claims commonly referred to as claims processing. This process examines the member's eligibility and drug coverage to determine the pharmacy's reimbursement and member's co-pay. In addition, edits are applied to ensure the clinical appropriateness of the drug dispensed, and to drive appropriate utilization.

In general, claims are processed at the PBM's corporate location. However, as a result of growth through mergers and acquisitions, a portion of claims may be processed at the legacy company's corporate headquarters site. In general, PBMs own and operate their claims processing systems.

At the point of service (POS), which can be either the retail or mail pharmacy, the claims adjudication process begins. Upon receipt of the prescription, the pharmacist enters it into the computer along with information from the member's drug card. This information is then sent to the PBM's claims processing system via a switch vendor. A switch vendor is an independent company that maintains the mailbox routing information necessary to send a claim from a pharmacy to the appropriate PBM. Leading switch vendors include Envoy Corporation, MedEAmerica, and National Data Corporation. Switch vendors typically charge the pharmacy a transaction based fee for their service.

Once the PBM's claim processing system receives the claim, the claim is adjudicated and the pharmacist sent an electronic message confirming the member's eligibility and drug coverage, and stipulating the amount the pharmacy is to be reimbursed and the co-pay to be collected. The PBMs paid claims file stores the transaction for reporting and audit purposes.

During claims processing, the information submitted by the pharmacy is checked against the eligibility file to validate the member's name, benefit plan, and birth date. Upon confirming eligibility, the prescription is then checked against the benefit design to confirm drug coverage and the relevant co-pay/co-insurance to be paid by the member. The claims processing system also determines the type of network pharmacy submitting the claim (either mail or retail), and then calculates the appropriate reimbursement of ingredient costs and dispensing fee the pharmacy will receive.

During the adjudication process, a series of edits are applied to the claim, with corresponding messages sent to the pharmacist. These edits are intended to ensure the clinical appropriateness of the drug dispensed, and to drive appropriate utilization. The edits can be either "soft," in which case the pharmacist can override the edit, or "hard," in which case the pharmacist must take the appropriate action or the claim will not be reimbursed.

Soft edits are advisory messages, which the pharmacists can act on or ignore. Many pharmacists ignore soft edits because of a lack of time and/or incentives to counsel patients or call physicians. An example of a soft edit is a message indicating the dispensing of a non-formulary drug.

Hard edits are messages that the pharmacist cannot override, and are an effective way to control a drug benefit. The pharmacists or member assumes the cost of prescriptions

filled contrary to a hard edit. Examples of hard edits include, but are not limited to, messages indicating the prescription is being refilled too soon, or that the drug being prescribed is subject to an "NDC lock out."

An NDC lock out is commonly used by PBMs to control the dispensing of drugs marketed under more than one name (e.g. Calan and Isoptin). The PBM typically contracts for rebates with the manufacturer of one of the drugs, and uses an NDC lockout to prevent their members from receiving the non-contracted drug. NDC lockouts are an effective way for a PBM to receive higher rebates for the preferred drug, without clinically impacting their member's drug benefit.

The PBM industry uses a standard format for the electronic transmission of claims for processing. This standard was created and is maintained by the National Council for Prescription Drug Programs (NCPDP), and is available for a small fee. All PBMs and chain and independent pharmacies use this standard. Moreover, chain and independent pharmacies have also developed preferred relationships with switch vendors to route claims to the appropriate PBMs for processing.

Nearly all PBMs report that their claims processing systems have an uptime of 98–99%, excluding scheduled downtime periods. All PBMs schedule downtime, typically a few hours every week or other week for system maintenance.

Approximately 1% of all claims processed are paper claims. Paper claims are appropriate when unique circumstances arise that prevent a claim from being processed electronically. For example, paper claims may be required for new employees who are not in the PBM's eligibility system, or if a member is on vacation in a remote area without a network pharmacy. In the case of a paper claim, the member pays for the drug out-of-pocket and then submits the claim to their health plan for direct reimbursement, minus the appropriate co-pay. Paper claims are entered directly into the claims processing system by the PBM. PBMs charge for the administration of paper claims. Clients typically pay $0.25–$0.40 per electronic claim processed. While many PBMs do not charge retail pharmacies claims processing fees, some do charge retail pharmacies $0.02–$0.03 per processed claim. For paper claims, clients are typically charged between $1.00 and $1.50 per claim processed.

Details regarding the edits and controls applied during claims adjudication are considered proprietary and confidential to the PBMs. HCFA should request additional information on this topic as a part of the PBM evaluation process.

Member Services

Shortly after enrollment, PBMs provide their members an information packet to help them understand their drug benefit. This welcome packet typically includes the member's drug card, drug coverage, required co-pays, benefit limits, and list of local network pharmacies, as well as information on how to access their pharmacy network, use the mail pharmacy, and submit a paper claim. PBMs may also provide the member a copy of the formulary. PBMs typically produce the members drug cards, and allow their clients to customize the drug cards with a private label.

PBM's operate a member services call center that provides a 24-hour toll-free help line to answer benefit questions, locate network pharmacies, or request additional forms and ID cards. The member services department can provide dedicated or non-dedicated support.

PBMs also provide 24-hour toll-free support to pharmacies in their pharmacy network. Pharmacists call the PBM's retail customer service area for assistance in entering the information needed for claims adjudication, requesting prior authorization, and to ask questions that better help the member understand their drug benefit or the pharmacist understand their reimbursement. Typical phone wait time for retail customer service is less than 30 seconds. The call center and customer service representatives providing member support are typically the same staff that supports the retail pharmacy network.

Manufacturer Contracting

PBMs contract with the manufacturers of branded drugs to receive rebates and administrative fees, in return for the preferential treatment and increased market share of these drugs. Manufacturers pay rebates and administration fees to PBMs, because PBMs can influence the drugs that their members use. At a minimum, to be eligible for rebates and administration fees, manufacturers typically require PBMs to include the contracted drugs on the formulary with no restrictions; the manufacturers may also require PBMs to increase market share for their specific drugs above the national average. Additional requirements may exist -- such as restrictions concerning competitor products or the implementation of promotional programs (e.g. PBMs sending mailings to physicians and members encouraging the use of a specific product). -- depending on the drug and the manufacturer. Generic drug manufacturers do not enter into these types of contracts because the PBM does not influence which generic brands are carried at the retail pharmacy.

Rebates and administrative fees are commonly paid as a percent of the drugs wholesale acquisition cost (WAC)—which represents the manufacturer's sale price—with rebates typically ranging from 5–15% of WAC, and administration fees from 1–3%. Rebates greater than 15% are rare, since manufacturers may set a new Medicaid Best Price, and are then required to rebate Medicaid claims at this level. Rebates and administration fees are paid monthly or quarterly. Once a rebate claim is received, the manufacturer has 30–90 days to process and pay the rebate.

The allocation of rebates to the client is dependent on the clients' contract with the PBM. Some clients receive all or a fixed percentage of the rebates collected. Other clients may receive a guaranteed rebate the PBM is obligated to provide. PBMs are increasingly contracting with manufacturers for various rebate levels —typically open, incented, and closed—by type of drug benefit used by the client. For example, open formulary clients with limited control over the drug benefit might be offered a 3% rebate while a closed formulary client is extended a 7% rebate.

PBMs also typically contract for pricing discounts and/or rebates for generic products (and some multi-source branded drugs) stocked in their mail pharmacies. These pricing concessions are reflected in the mail pharmacy pricing that the PBMs offer their clients.

3.1.2 PBM Clinical Services

PBMs use a variety of clinical services to help their clients control the cost and utilization of their drug benefit. These techniques can influence the choice of prescriber, pharmacist, or patient, and can be performed prospectively, concurrently, or retrospectively. Clinical services are intended to work in concert with each other, and with the clients' drug benefit. The most common clinical services used by PBMs include formulary management, therapeutic substitution, utilization management, and disease management.

PBMs use a variety of methods to engage patients, physicians and pharmacists in clinical services. Telephone calls, written correspondence and faxes are the most common methods. In some cases e-mails and face-to-face meetings (academic detailing) are used. In addition, pharmacies are routinely sent electronic messages during claims adjudication.

Formulary Management

Formulary management is the process of developing and maintaining a list of preferred drugs, with the intent of promoting cost-effective clinical care.[64] A drug's position on a formulary is typically a prerequisite for that drug to be eligible for rebates. The PBM or the client may manage the formulary.

A formulary is a continually updated list of branded (and generic) drugs favored by the PBM (or its clients). Formularies often contain relative cost indices for comparable drugs, highlight preferred brands, and include treatment protocols, usage guidelines, and other clinical information. Formularies are typically distributed to primary care physicians, but patients and pharmacists may also receive them. Electronic messages are often sent to pharmacists during claims adjudication indicating products that are non-formulary. Formularies are typically produced yearly or every other year, with quarterly updates distributed during the interim.

The PBM's or the client's Pharmacy and Therapeutics (P&T) committee decides which drugs are included on a formulary, with the intent of discouraging the use of marginally cost-effective drugs.[65] All PBMs have a P&T committee comprised of physicians, pharmacists, and other clinicians. Given the constant introduction of new drugs and the multiplicity of drugs in the same therapeutic categories, P&T committees meet regularly to keep the formulary current. The first consideration of these committees is the clinical effectiveness and safety of a drug. However, when multiple drugs exist with similar

[64] "Concepts in Managed Care Pharmacy Series: Formulary Management," The Academy of Managed Care Pharmacy, April 30, 1998. www.amcp.org . Link to Concepts in Managed Care Pharmacy.
[65] Ibid.

clinical results, issues such as cost-effectiveness and maximizing manufacturer rebates determine which drugs are included on the formulary.

The formulary works in concert with the member's drug benefit to determine which drugs are covered and the member's co-pay. Drug formularies vary in their degree of influence and are classified as open, incented, or closed. An open formulary is a list of the drugs preferred, but not mandated, by the PBM. Under this structure, all drugs are reimbursed regardless of formulary status. An incented formulary applies three-tier co-pays (e.g., generic, formulary brand, and non-formulary brand) or other financial incentives to influence patients to use formulary products. A closed formulary limits reimbursement to formulary drugs, and may require generics be dispensed when available. Non-formulary drugs typically require prior authorization (based on medical need) to be reimbursed.

Clients can develop their own formulary or customize the PBM's national (e.g., standard) formulary to develop one that better meets the needs or preferences of their practitioners. This is typically done by health plans that have their own P&T committee. When customizing a formulary, PBMs encourage their clients to consider the impact that deviations from the PBM's national formulary can have on their rebates. PBM's routinely administer customized formularies on behalf of their clients. Some clients with customized formularies, especially large MCOs, negotiate rebates directly with manufacturers and administer their own rebate programs.

Therapeutic Substitution Programs

Therapeutic substitution programs are typically operated in mail pharmacies to encourage physicians and patients to switch to lower cost comparable drugs. In 1996, Prescription Solutions reported that its therapeutic substitution program for Medicare mail-order customers achieved an 80% success rate in getting maintenance prescriptions changed to less expensive therapeutic alternatives for some categories over a six month period.[66]

Therapeutic substitution programs are used for two reasons:

- The P&T committee may have identified one drug as superior, and not a therapeutic equivalent to the other drugs in a particular therapeutic category; or
- The PBM has a contract with a manufacturer for rebates making one drug more cost-effective than other drugs in the same therapeutic category.[67]

[66] Ibid., pp. 20–21.
[67] Namovicz-Peat, Susan, *HMO and PBM Strategies for Pharmacy Benefits* (AIS Inc, 1999), p. 20.

Therapeutic substitution requires the prescriber's permission, because the substituted drug may have different side effects and drug interaction profile than the drug originally prescribed. Prescribers are contacted via auto-fax or by phone. The patient's permission is also typically requested, but not required, prior to substitution. For members that object, the PBM usually provides the originally prescribed drug at no extra charge.

Most PBMs focus their substitution programs on new prescriptions received in their mail pharmacy, as opposed to refills or retail prescriptions. PBMs target new scripts in the mail pharmacy due to the high cost of chronic-illness medications, and the amount of time needed to switch the drug. Most PBMs fill prescriptions received by their mail pharmacy within 72 hours. Given the time required to administer therapeutic substitution programs, and the acute nature of most drugs dispensed in a retail setting, retail pharmacists do not typically engage in this practice. PBMs also target new scripts due to the low success rate of repeatedly contacting a prescriber after they have denied the initial request, as well as the risk of switching a patient that has been successfully maintained on a drug for an extended time.

Some PBMs have attempted to develop therapeutic substitution programs for retail pharmacies. With these programs, PBMs provide a financial incentive for the pharmacist to contact the physician and request a substitution, with additional monies paid if the product is switched. The incentives are typically paid in the form of higher dispensing fees. The time needed to contact physicians and the acute nature of many of the medications dispensed make administering retail therapeutic substitution programs problematic.

Utilization Management

PBMs use a variety of utilization management programs to lower drug costs and drive appropriate utilization. These programs include prior authorization, drug utilization review (concurrent and retrospective), academic detailing, and patient education.

Prior Authorization

Certain drugs require prior authorization before they are covered under the drug benefit. Prior authorization is the pre-approval of a drug by the PBM before a pharmacy can dispense it. Currently, prior authorization of prescriptions is used only for a few chosen drugs. These are drugs that are very expensive and have major off-label uses not approved by the Food and Drug Administration, such as growth hormones, or drugs that require medical justification before coverage is approved, such as Viagra and Cox-2 Inhibitors. Before authorizing prescription of one of these drugs, the benefit manager asks the physician about diagnostic tests, symptoms, and other clinical measures that would establish the appropriateness of the drug according to evidence-based protocols.[68] According to a recent study by Scott-Levin the 10 therapeutic classes with the highest number of plans requiring prior authorization include antifungals, migraine treatments, select pain medications, antidepressants, cholesterol reducers, alpha-blockers, antiulcer/ulcer combinations, calcium channel blockers, sympathomimetic antiasthmatics, and macrolides.[69]

Drug Utilization Review

Concurrent drug utilization review (CDUR) occurs at the point of sale. During the claims adjudication process, a series of clinical edits are applied to the claim that compares information about the member (e.g. age and sex), the drug to be dispensed, and concomitant medications the member is taking (from the paid claims file). Examples of CDUR edits include drug-drug interaction, drug-age conflict (drug not appropriate for the age of member), and drug-gender conflict (e.g. male and birth control pills). The appropriate message(s) are then sent to the pharmacist.

Retrospective drug utilization review (RDUR) is the systematic analysis of prescribing patterns and utilization based on past claims data. These programs assist PBMs in identifying physician-prescribing patterns, identification of pharmacy fraud and abuse, and inappropriate or dangerous utilization patterns of members. RDUR programs can help PBMs better target patient and physician education programs and disease management programs. In addition, physicians are often sent letters highlighting how their prescribing practices compare to their peers.

[68] Clemmitt, Marcia, "Will We Try to Manage Care Again? This Time, for Drugs?" *Medicine and Health* 54, no. 25 (June 19, 2000): 1.
[69] "Audit data outline targets for pharmacy cost control," *Employee Benefit News*, April 15, 1999. Data obtained form Scott-Levin's Fall 1998 Managed Care Formulary Drug Audit.

Academic Detailing and Patient Education

PBMs make educational materials on specific diseases and wellness available to their members. These materials range from simple monographs to Web-based, interactive programs. Typical education topics include diabetes, thyroid conditions, heart disease, and asthma.

PBMs have developed clinical consulting and academic detailing programs in an effort to influence physicians' prescribing patterns. Detailing is the practice of directly promoting drugs to physicians, a practice commonly used by manufacturers to promote new branded products on the market. PBMs have modified these programs to educate physicians about their prescribing patterns and to focus on the cost-effectiveness of alternative drugs. AdvancePCS has developed an academic detailing program that focuses on physicians' prescribing habits, comparing them relative to their peer group. Focusing on high cost therapeutic categories, pharmacists meet with physicians to educate them about their utilization patterns and discuss cost saving strategies.[70]

Disease Management Programs

PBMs use disease management programs as a proactive tool to control overall healthcare costs for members with dominant, chronic conditions. Approximately 75% of PBMs offer disease management program to their clients.[71] The goal of disease management programs is to maximize the cost-effectiveness of drug therapies and outcomes, while minimizing the total cost of treating the disease. Disease management programs may result in higher drug costs due to increased compliance and persistency, but are touted as lowering the client's overall healthcare expenditure. Most PBMs offer disease management programs for common conditions such as asthma, diabetes, and congestive heart failure. Manufacturers often support these programs, because they tend to increase drug utilization.

Nurses and pharmacists, hired by the PBM, administer these programs. These clinicians engage in an ongoing dialogue with the patient concerning their condition, the disease's progress, and the patient's compliance with their treatment regimen. Members are often sent education material and tools to help them remain compliant. Members are required to sign-up for these programs with the client billed for the service, or in some cases through a shared savings arrangement. PBMs charge for these services in a variety of ways that typically include:

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[70] "PBMs Deliver Drug Cost Savings Through Education, Substitution," *Physician Manager*, December 3, 1999.
[71] Kreling, David, "Cost Control for Prescription Drug Programs: Pharmacy Benefit Manager PBM Efforts, Effects, and Implications," HHS' Conference on Pharmaceutical Pricing Practices, Utilization and Costs, August 8–9, 2000.

- Per employee per month basis (approximately $2 PEPM);
- Per participant per year (PPPY) basis (approximately $600 - $650 PPPY);
- Per prescription basis (approximately $0.01/Rx) for each selected program (e.g., congestive heart failure, hypertension). Services billed in this manner are intended to identify patients that may benefit from the initiation of additional medications to their drug regimen, as recommended in national guidelines and medical literature, with an overall goal of reducing total health care spending (e.g., medical and drug).
- Per case per year (PCPY) basis for patient care management (approximately $300 PCPY) for selected diseases (e.g., diabetes, asthma). Patient care management is intended to help patients improve their health through lifestyle changes, drug education, and the optimal utilization of medical services.

Disease management programs are an additional cost to clients, beyond the PBMs standard service offering.

Emerging Clinical Management Programs

Emerging clinical management programs offered by PBMs include contracting with specialty pharmacies, as well as the use of the Internet as a portal for member and physician education and to provide pharmacy related services and physician connectivity.

PBMs have been developing relationships with specialty pharmacies or have developed there own specialty pharmacy operations in order to provide more comprehensive services to clients and members. Specialty pharmacies dispenses high cost, low volume drugs that target specific patient populations with chronic, potentially life threatening diseases such as HIV/AIDS, multiple sclerosis, cystic fibrosis and cancer. These drugs typically require infusions or injections administered by a health-care professional, and are very expensive ranging from $10,000 - $200,000 per year. Specialty pharmacies contract directly with manufacturers to deliver products to patients, physicians, and specialized clinics. In addition, they typically handle insurance billing and offer customer service, which includes reimbursement counseling and 24-hour pharmacist assistance.

PBMs have also expanded their services to the Internet offering clinical information for patients, physicians, and other care givers via their websites. Members using a PBM's mail pharmacy can have their prescriptions filled or refilled directly over the Internet. In addition, some PBMs have developed strategic alliances with Internet pharmacies, which enables members to purchase OTCs and other health and beauty related products via Internet links to these sites.

As an example of PBMs' use of the Internet, Merck-Medco's websites offers personalized service to its members. The site is organized into four sections:

- My Page – includes a message center, service alerts, refills reminders, important benefit information, and client specific messaging;
- My Health – offers personalized health content based upon the member's preferences and/or the client's preferences;
- My Benefits – includes information regarding the member's benefit design, co-pays, and formulary; and
- My Prescriptions – enables members to refill and renew prescriptions.

Another recent focus of some PBMs is physician connectivity. PBMs are developing systems, operated through hand held devices, that connect PBMs, prescribers, and pharmacists. These systems provide the physician access to formularies, the Physician's Desk Reference and drug utilization review edits at the time of prescribing. Once the prescription is written, it is transmitted electronically to the pharmacist. Through this technology, PBMs hope to help physicians prescribe preferred medications, thereby improving formulary and clinical compliance. The PBMs also hope to reduce dispensing errors through incorrect pharmacist translation. Ultimately, physician connectivity is intended to reduce costs while increasing physician, pharmacist, and PBM productivity.

For example, in February, 2001 Advance PCS, Express Scripts, Merck-Medco and recently announced an agreement to form RxHub LLC, to develop an electronic exchange that allows physicians using electronic prescribing technology to link to pharmacies, PBMs, and the health plans of their patients.

3.2 Financials and Pricing

As stated earlier in Section 2.4, PBM's derive the majority of their revenue from clients and manufacturers. PBMs typically receive an administrative fee -- on a per-claims basis -- from their clients that covers the majority of services they provide. In addition, the PBM retains the administrative fees paid by manufacturers and a portion of the rebates. PBMs pass the cost of the drug benefit to their clients. PBMs may also have a shared savings arrangement with clients, where the client and the PBM share the savings. These arrangements provide incentives for both sides to collaborate and run the pharmacy benefit program effectively.

3.2.1 Administrative Fees (Claims Processing)

PBMs charge their clients an administrative fee based on the number of claims processed. Client administrative fees are approximately $0.30 - $0.40 per processed claim. This fee typically covers the PBM's administrative services, as well as basic clinical services like formulary management, therapeutic substitution, and utilization management. PBMs may charge additional fees for dedicated client or member service teams, ad-hoc reporting, special clinical programs (e.g. disease management, prior authorization, etc.) customized educational material, or other services.

Major insurers or HMOs that have outsourced their drug benefit to a PBM typically charge *their clients* for PBM services on a per member per month (PMPM) basis, and may list the PBM services as a separate charge or combined with their medical administrative charge. Major insurers or HMOs do not sell PBM services as a stand-alone product.

3.2.2 Pharmacy Reimbursement and the Cost of Pharmaceuticals

Pharmacies are reimbursed by the PBMs (as a pass through from clients) for the ingredient cost of the drug dispensed plus a dispensing fee, less the member's co-pay or co-insurance. Ingredient cost is based on the lowest of three calculations, depending on the drug dispensed: AWP, maximum allowable cost (MAC), or usual and customary (U&C). Reimbursement rates vary depending on the network.

Ingredient cost for branded drugs under patent is typically reimbursed at AWP minus a discount percent (usually 12–15%). AWP for all pharmaceuticals is calculated and maintained by the third party data vendor Medispan/First Databank. Dispensing fees for branded drugs are typically $2.00–$3.00 per prescription.

Ingredient costs for generic drugs are commonly based on MAC pricing typically 50–60% below AWP. MAC prices are typically set at the regional or Metropolitan Statistical Area (MSA) level to reflect variations in cost of living across the country. PBMs can either set the MAC prices themselves, or use the MAC prices set by HCFA for Medicaid beneficiaries. PBM-set MAC prices are usually higher than those set by HCFA to encourage pharmacies to participate in their network. Compared to the HCFA MAC, the PBM MAC also covers more drugs and is updated more frequently. Some PBMs offer higher dispensing fees for generics to encourage the pharmacist to substitute a generic equivalent for a branded drug. Dispensing fees for generics are typically $2.00–$3.00 per prescription.

To ensure their clients receive the lowest possible price for drugs, pharmacies are contractually obligated to limit their reimbursement to the price they would charge a cash-paying customer. This price is called usual and customary (U&C), and is determined by the pharmacy. For example, if a retail pharmacy charges a cash-paying customer $20 for a drug, the retail pharmacy cannot invoice the PBM for an ingredient cost greater than $20, regardless of the AWP discount or MAC price in effect for that drug.

Using the example of a branded drug in Diagram 17, the member has its prescription filled for Drug ABC at a retail pharmacy, and pays the required $10.00 co-pay. The pharmacy is then reimbursed $14.25 for the ingredient cost (AWP – discount) of the drug plus the dispensing fee, less the co-pay [AWP ($25) – 13% + a dispensing fee ($2.50) – co-pay ($10)].

For generic drugs, the member pays a $5.00 co-pay to the retail pharmacy (Diagram 18). Given that the MAC price for this drug is set at $6.00, the retail pharmacy is reimbursed $4.00 [MAC ($6.00)+ dispensing fee ($3.00) – co-pay ($5.00)].

Pharmacies do not typically receive discounted pricing (or rebates) on branded drugs. In some cases, generic manufacturers will provide pricing incentives to pharmacies based on volume, market share, or exclusivity. Retail acquisition cost for branded drugs is typically 20%-25% below average wholesale price (AWP), which is the wholesalers mark-up from WAC (wholesale acquisition cost). In some cases, retail chain distribution centers may pay WAC.

3.2.3 Rebate Administration and Payment

PBMs contract with the manufacturers of branded drugs to receive rebates and administrative fees. Rebates are usually shared with clients; administrative fees are retained by the PBM. Manufacturers pay administrative fees to PBMs for administering formulary rebate contracts. These fees range between 1% - 3% of WAC (WAC is the cost to the wholesaler for buying the drug from the manufacturer and is typically used as the reference price for calculating rebates and administration fees). Typically, manufacturers pay rebates and administrative fees for all contracted products dispensed to qualified members. The amount of rebate shared with the client is a negotiable point and can range from 100% for very large clients to zero for small clients.

Using Diagram 19 as an example, the WAC for this drug is $20. After all claims for drug ABC have been submitted by the pharmacy for reimbursement for an entire month or quarter, the PBM submits a claim to the manufacturer for payment. For the current period and assuming an incented formulary, the PBM achieved 20% market share, which makes them eligible for a 10% rebate in addition to the 2% administrative fee for all prescriptions processed by the PBM.

Typically, manufacturers pay higher rebates when the market share of a drug exceeds the market share in the unmanaged market (e.g. national market share). In some cases, manufacturers rebate differently depending on the client's degree of control over pharmacy benefit. For example, closed formulary clients might receive better rebates than open formulary clients for the same market share.

PBMs typically pass rebates through to their clients and retain 100% of administrative fees. Continuing with the example in Diagram 17, the PBM received a $2.00 rebate and a $0.40 administrative fee for each prescription from the manufacturer. The PBM's contract with their clients stipulates that the PBM will pass through 80% of the rebates to the client. In some cases, PBMs may guarantee their clients a rebate/claim.

3.3 Contracts

Section 3.3 provides an overview of the types of PBM contracts currently used by clients. Sample contracts collected from PBMs participating in this study as well as actual contracts employers hold with PBMs were reviewed. The main features of the contracts are described, compared, and contrasted. In addition, material differences (if any) between contracts used in the public and private sector, or contracts between a PBM and an employer versus a managed care organization (insurer, HMO, etc.), are highlighted.

3.3.1 Types of Contracts

PBM contracts can be classified into the following three types:

- Fee-for-service contracts;
- Risk sharing or shared savings contracts; and
- Capitation contracts.

Although PBM contracts contain client specific language and services, the differences across contracts can be broadly defined as follows:

- The organization "at risk" for the cost of the prescription drug benefit;
- The payment methodology for the cost of prescription drugs;
- The pricing and payment of administrative fees; and
- The allocation of rebate dollars between the parties to the contract.

Regardless of contract type, PBMs generally provide their clients very similar services.

Fee-for-Service Contracts

Fee-for-service is the most common type of PBM service contract used by large clients. In a fee-for-service arrangement, the client is at risk for all claims and associated administrative expenses incurred while the contract is in effect. The PBM acts as a claims adjudicator, utilization manager, and customer service provider for this portion of a client's health plan. Fee-for-service contracts are also commonly referred to as administrative services only (ASO) contracts. Significant features of a fee-for-service contract include:

- The client is responsible for the cost of prescription drug claims. Typically, prescription drug claims (including ingredient costs and dispensing fees) are billed to the client by the PBM weekly, biweekly, or semi-monthly, with payment due electronically (wire transfer or automated clearing house (ACH) transfer) within 48 hours. The PBM reimburses the retail pharmacy for the drug costs.
- Administrative fees are typically billed by the PBM to the client on a monthly basis. Basic administrative fees apply to claims processing costs (billed usually on a cost per paid claim or cost per processed claim basis). Some large insurance companies will bill for administrative services on a per employee per month (PEPM) basis. Other administrative fees that cover items such as special reports, custom services, cost management programs, etc., which are not a direct function of prescription volume, are also billed on a monthly basis.
- Formulary rebates due to the client are typically credited to invoices or paid to the client within the first 6 months after the end of the period (e.g., a calendar quarter).

The client's share of total rebates usually varies based on the size of the client. Large clients typically receive 100% of the rebates.

Risk Sharing or Shared Savings Contracts

In a risk sharing or shared savings agreement, the client and the PBM both assume some risk for the total cost of the prescription drug program. The agreement may be for the total cost of the program or for a particular service within the program. Drug utilization review, prior authorization programs, and drug substitution (i.e., generic or therapeutic intervention) programs are the most common program elements involved in a shared savings arrangement. Key features of a risk sharing arrangement include:

- The estimation by the PBM of expected costs (claims plus base administrative fees) for the contract year. Parameters are set around the expected costs (e.g., 80–90% of expected costs, 90–100% of expected costs, etc.). During the contract year, the client pays the PBM either on a fee-for-service or a PEPM basis. At the end of the contract year, an accounting is made to compare actual program costs with expected costs. The PBM and the client share in the positive or negative experience within each parameter based on a predetermined risk sharing percentage formula. PBMs usually limit their financial exposure to the total of their administrative fees. A few large employers and payers have negotiated contracts with no limit on a PBMs negative exposure. Risk sharing arrangements may be set up on either paid claims or an incurred claims basis.

- Formulary rebates may be either part of or separate from the risk sharing arrangement, but usually are treated separately. Rebates due to the client are typically credited to invoices or paid to the client within the first 6 months after the end of the period (e.g. the calendar quarter).

Risk sharing may also apply to only a portion of the employer's prescription drug costs, such as to a particular cost management program. This type of risk sharing, typically referred to as a shared savings program, is used in one or more of the following situations:

- The shared savings approach is used as an alternative method of paying the PBM for its expenses in administering the program, rather than paying the PBM on a per transaction basis. The client will pay the PBM a set percentage of all demonstrated savings from the PBM's various drug utilization review (DUR) management programs. The PBM guarantees a minimum level of savings, with additional savings shared on a predetermined basis. For example, the PBM guarantees a minimum 7%

saving from DUR. DUR savings above 7% will be shared 75% by the client and 25% by the PBM.

- For a new program, trial program, or a program developed or installed at the insistence of the client, any savings above the initial development costs are shared on a predetermined percentage basis. In some cases, the client may also be liable for the initial program development costs.

Capitation Contracts

Under a capitation arrangement, the PBM is at risk for all claims and basic administrative fees incurred. As previously discussed, capitated pricing is essentially non-existent since PBMs have historically lost money through these arrangements. As a result, capitation for prescription drugs on a stand-alone basis (not included with total medical claims) is rare, if not non-existent, in the market today. There are several factors that limit a PBMs ability to assume risk. PBMs are not licensed as insurance organizations, and are therefore limited in their ability to accept risk. One method used to provide the equivalent of capitation is to write a fee-for-service or a risk-sharing contract with a stop-loss limit. The PBM then arranges for a reinsurance company to accept the risk above the stop-loss limit. This effectively provides the same protection to the client as a capitation arrangement.
Stop-loss policies are uncommon for pharmacy benefits. In the few cases where these have been used, the client paid the cost of the stop-loss policy, and was at risk for the cost of the drug benefit up to the limit. Once the limit has been reached, the re-insurance company assumes risk for the cost of the drug benefit.

Another factor limiting the use of capitation contracts is the inability of most clients to provide the detailed pharmaceutical data required for a PBM to accurately calculate PEPM fees. In discussions with various PBMs, most required at least one full year (preferably two years) of detailed claims data (utilization at the individual drug level) to even consider a capitation agreement. Some clients and PBMs have discussed contracting on a fee-for-service basis for one or two years, capturing the required data, and then agreeing to discuss the concept of a full or partial capitation agreement.

Other factors impacting the PBMs assumption of risk include their inability to control the release of new branded drugs, drug prices, and demand driven through direct to consumer advertising. Also, PBMs lack risk sharing arrangements with physicians, cannot benefit from reductions in medical costs as a result of drugs, and have been unable to convince pharmaceutical manufacturers to underwrite their risk.

In instances where capitated contracts have been tested, these contracts generally contained the following features:

- The payment of a PEPM fee by the client to the PBM for both prescription drug and basic administrative services. Non-standard administrative fees are usually billed separately on a fee-for-service basis. Some capitation contracts specify a limit on the coverage of claims paid after the incurred period. For example, claims paid more than six months after the end of the contract year will be the client's responsibility on a fee-for-service basis.

- Capitation contracts may be written for multiple years (typically three). These contracts may state the PEPM for each year, or may specify a formula for calculating the PEPM after the first year, either as a function of actual first year experience, or as a function a specific index, (e.g. prescription drug inflation index). Based on the recent escalating trend in the cost of prescription drug costs, the majority of capitation contracts have their PEPM rates adjusted on a yearly basis.

- Formulary rebates may be either part of or separate from the capitation arrangement; they are usually treated separately. Rebates due to the client are typically credited to invoices or paid to the client within the first 6 months after the end of the period (e.g., the calendar-quarter).

3.3.2 Comparative Analysis of PBM Contracts

This section provides an overview of the key sections of a common PBM contract (Tables 11-15). A table containing the standard contract sections and a brief description of the contents of each section is provided. Following the contract table is a discussion of significant variations that occur between a public and private sector PBM contract, and between an employer contract and managed care or payer contract.

Common Aspects of PBM Contracts

Contracts between clients and PBMs vary based on the individual needs or purchasing requirements of each client. However, there are certain features commonly found in most contracts. Based on the contracts obtained from the clients and PBMs participating in this study we have categorized the common features of a PBM contract as follows:

- Contract terms and conditions;
- PBM duties;
- Client duties;
- Pharmaceutical pricing and administrative fees; and
- Compliance and security issues.

Table 11: Contract Terms and Conditions

Item	Standard
Identification of parties and definitions	Detailed list of standard definitions of all terms relevant to pharmaceutical items, identification of all persons or entities covered by the contract and all program functions addressed in the contract. Especially important is the definition of any terms used to describe cost, savings, or performance guarantee calculations.
Contract term	Initial term is usually 3–5 years, automatic 1-year extensions thereafter. PBMs prefer a longer contract term especially if the client requests customized programs or services.
Access to and ownership of records	Each party shall have access to confidential and proprietary information owned by the other party. Each party reserves all rights to its proprietary information. PBM will maintain claims information for a stated number of years (usually 7 years from dispensing date). Most contracts describe the actual ownership of the patient records by the client. Specific rules are established for the use and release of any client specific information by the PBM. Terms describing the return or future use of client claims data by the PBM upon termination of the contract are described.
Termination and assignment	PBM will make available to the client or successor PBM all materials necessary to continue the administration of the plan.
Notice	Six months notice of termination without cause by either party. Termination with cause (e.g. default) on 60 days notice. Conditions for default include breach of contract, non-payment, or insolvency.

Table 12: PBM Duties

Item	Standard
Customer service	PBM will maintain a toll free customer service telephone line (dedicated or non-dedicated). Line will be operational 6 days per week, minimum 12 hours per day weekdays, 10 hours weekends. Some large clients are now demanding customer service coverage 24 hours per day, 7 days per week. The largest PBMs are complying with this request. Written communications materials on all programs will be provided to members, with client's prior approval. ID cards and claim forms will be provided initially and periodically thereafter as part of base administrative fees. Section 3.1.1 provides a detailed overview of PBM administrative services.
Claims administration	PBM will adjudicate claims in accordance with the contractual provisions (including pharmaceutical pricing) and within contractual performance guarantees. Separate pricing may apply to: • Retail Brand • Retail Generic • Mail Order Brand • Mail Order Generic • Section 3.2.2 provides a detailed description of pharmaceutical pricing. Separate performance standards apply to: • Retail Electronic claims • Retail Paper claims • Mail Order claims • Section 4.0 provides a more detailed description of common performance guarantees. This section also contains a description of the denied claims appeal process (both written and verbal) along with a description of the various reports to be provided by the PBM.
Network composition and access	PBM will maintain selected network intact each year with no material changes in composition or member access. Provider directories will be maintained and updated periodically in written form and continually via the Internet and through a toll-free customer service line. Notification to the client of any major change in the network (e.g. loss of a significant pharmacy chain or pharmacy access in a specific geographic area) is mandated. The duties of the participating pharmacies in relation to the collection of co-pays, services to members, and payment are described. Pharmacies are usually required only to collect the applicable co-pay for covered pharmaceuticals.
Utilization and cost management	All utilization and cost management programs will be described in detail in the contract. Additional fees, if any, will be clearly itemized. Programs include, but are not limited to: • Drug utilization review • Prior authorization • Generic dispensing • Therapeutic intervention and switching • Disease management. Section 3.1.2 provides a more detailed description of these services.
Formulary management	PBMs are the ultimate developers and owners of any formularies used in the prescription drug program. PBMs usually retain the right to change the content of the formulary as they see fit. Some client contracts require that the PBM notify the client of any pending change in the formulary although approval of the change by the client is usually not required. Section 3.1.2 provides additional information on formulary management.

Table 13: Client Duties

Item	Standard
Duties/responsibilities of the client	This section contains the specific responsibilities of the client, including: • Eligibility information (method of transmission, frequency, and file format), • Plan design (establishment of plan design, plan design changes and required notification of change), • Payment terms and methodology, and • Other duties including distribution of ID cards and educational materials.

Table 14: Pharmaceutical Pricing and Administrative Fees

Item	Standard
Pharmaceutical pricing – Retail	Pricing and rebates: • Brand: AWP minus a % discount + a dispensing fee, or Usual & Customary, whichever is less • Generic: AWP minus a % discount + a dispensing fee, or Maximum Allowable Cost + a dispensing fee, or Usual & Customary, whichever is less • Rebates: a percentage of all rebates (both direct and market share) to client, may include a dollar minimum guarantee per prescription. Discounts and dispensing fees are dependent on the retail network selected. Rebate share varies by size of client. Sections 3.2.2 & 3.2.3 provide additional information on rebates, discounts, and administrative fees. Payment terms by the client to the PBM for the actual cost of dispensed prescriptions is described. Clients reimburse PBMs for the cost of drugs through wire transfer or ACH on either a weekly, biweekly, or semi-monthly basis in fee-for-service contracts. In a capitation or risk sharing agreements the specifics of the PEPM premium charged or parameters of the risk sharing arrangement are described.
Pharmaceutical pricing – Mail	Pricing and rebates: • Brand: AWP minus a % discount + a dispensing fee • Generic: minus a % discount + a dispensing fee • Rebates: a percentage of all rebates (both direct and market share) to client. Discounts, dispensing fees and rebate share vary by client size. Typically, large employers receive 100% of the rebates attributable to their drug spend. Sections 3.2.2 & 3.2.3 provide additional information on rebates, discounts and administrative fees.
Administrative fees (Base Services)	Retail: set amount per prescription, varies by client size. Mail: set amount per prescription (negotiable, some PBMs charge $0). Section 3.2.1 contains additional detail on administrative fees. Administrative fees in a fee-for-service agreement are usually billed monthly with payment required within 30 days of receipt of invoice.

Table 15: Compliance and Security Issues

Item	Standard
Insurance requirements	PBM are required to maintain comprehensive general liability insurance in amounts of $1M per occurrence, $3M in aggregate, often listing the client as an additional insured. Contracts also contain language concerning the maintenance of liability insurance by the individual pharmacies. Specific limits are usually not stated.
Indemnification	Many contracts contain dual indemnification clauses with each side indemnifying the other for one party's negligence.
Performance guarantees (including monitoring and audits)	Monetary penalties for non-performance up to 50% of total administrative fees. Some large clients are now negotiating performance guarantees in amounts up to 100% of administrative fees. Section 4.0 provides additional information on performance guarantees.
Right to audit	Clients maintain the right to conduct an audit of the PBMs performance. The audit is the final determinant of PBM compliance with any performance guarantees. The cost of the audit is borne by the client with the PBM agreeing to provide claims data or other information required to complete the audit. Most PBMs request 60 days notice prior to commencing an audit. Claims audits require significant preparation by both parties and therefore are not practical on an "unannounced" basis. Section 3.4.3 contains additional information on the various types of audits.

Employer versus Managed Care or Payer Contracts

The PBM contract of a single large employer is similar in many ways to the PBM contract of a MCO or insurer. The major differences are usually contained in the scope of services provided by the PBM and the risk sharing arrangements.

PBM services

An employer typically contracts with the PBM to completely manage their drug benefit. Some MCOs prefer to maintain responsibility for various aspects of their prescription drug program. Typical services performed by the MCO include:

- Client service;
- Member service;
- Manufacturer contracting and rebate administration; and
- Formulary management.

Risk Sharing Arrangements

Large MCOs are more likely to negotiate significant risk sharing arrangements than an employer is. This is due to the MCOs desire to work collaboratively with the PBM in managing such items as plan design features, cost management and clinical programs. Risk sharing arrangements include guarantees on:

- Per member annual drug spending;
- Annual trend in drug spending;
- Specific targets for generic utilization or utilization within each tier of a three-tier drug co-pay plan design; and
- Other risk/reward programs based on the results of various utilization management programs.

Public Versus Private Client Contracts

Public employer (state employee health benefit program) contracts are also very similar to private client contracts. The main differences in public employer contracts usually center on an increase in regulatory issues and stricter contract terms. Listed below are aspects of a common public employer contract that differ from a typical private client contract:

- Contract term – Public contracts usually have a set contract term with a mandatory re-bid of the contract at the end of the term. Private client contracts usually remain in-force until cancelled by one of the parties.

- Incorporation of the RFP and RFP response into the contract – Public contracts routinely incorporate the RFP, the PBMs proposal, and material correspondence during the bid process into the contract. This requires that the PBM have legal review of their entire proposal, lengthening the response time required by the PBM to prepare their proposal.

- Fidelity bonds – Many public clients require that the PBM obtain a fidelity bond to protect the client from theft or other misuse of public funds by an employee of the PBM.

- Open records regulations – These regulations do not allow the PBM to maintain the confidentiality of some of its financial proposals, which may deter a PBM from proposing its most aggressive financial arrangements.

- Choice of law – Most private contracts are adjudicated under the laws of the state, in which the PBM resides. Most public contracts are adjudicated under the laws in the state in which the public entity resides.

- Availability of funds – Many public employer contracts are contingent upon the availability or appropriation of funds by the governing legislature or board. This will occasionally lead to a PBM requiring the client to establish an impress fund for the payment of drug costs and administrative fees. Required impress funds range from two weeks of estimated claims to 30 days of estimated claims and administrative expenses.

Overall, PBM contracts are similar regardless of the type of entity involved.

3.4 Bidding Rules and Selection Criteria

The procurement of PBM services is a major endeavor for all clients. For this reason, most clients follow a comprehensive bidding and selection process. Section 3.4 presents the major components of the bidding and selection process and provides examples of the processes and methodologies used by major clients today. Diagram 20 represents a sample timeline for the bidding and selection process. This timeline is more indicative of a new versus renewal bidding process, although the steps are very similar for both. In addition, no two employers follow exactly the same steps in exactly the same order. For example, some may develop the scoring methodology in conjunction with the development of the RFP while other follow the schedule listed below.

Diagram 20: Sample Bidding and Selection Timeline

3.4.1 Bidding Overview

The bidding process encompasses the time from the initial decision to begin a market bid process to the actual selection of a PBM vendor(s). The process varies by client type and may or may not include the preliminary step of issuing a non-binding request for information. There is a wide range of complexity and formality involved in the process among employers and payers, with a greater degree of formality present among public (government) employers.

Components of the Bidding Process

The bidding process involves a number of key components, with varying levels of importance to clients. The timeframe for the bidding process will be discussed in a later section; however, it should be stated at this point that the timeframe is heavily dependent on both the complexity of the process and the number of individuals and/or departments involved.

Key components of the bidding process

The establishment of goals and objectives is usually the first step in the bidding process. This is accomplished when the client establishes the "reasons" they are pursuing a PBM market bid and outlines the major services, products, and PBM functions. Typical reasons given for conducting a bid process include:

- Management or reduction in pharmacy cost;
- Achievement of a greater level of access to pharmacies;
- Improvement in member/client services; and
- Achievement of a greater array of pharmacy related services (e.g., mail order, Internet pharmacy, etc.).

Clients' review past PBM experience, such as the frequency of customer services issues. After this, they may develop a "wish list" of services, prioritizing items in categories such as "must have," "nice to have," etc. In addition, they may look at what other clients are doing in this area. Finally, they may examine applicable legislation regarding PBMs. Objectives for minimum vendor requirements; geographic coverage, ownership issues, etc. are also developed.

Minimum Vendor Requirements

Common minimum vendor requirements for large clients include:

- Five years of service as a PBM;
- The provision of a pharmacy network meeting the stated access requirements of at least 90% of the designated members;
- A current client with at least 100,000 covered lives; and
- Acceptable financial results (a client's financial officer usually establishes what they believe is necessary for a vendor to meet this objective. Some only require a positive audit letter while others review certain financial ratios).

Government entities often include compliance with specific governmental requirements as minimum vendor requirements.

The development of procurement rules and standards—the specific rules and procedures governing the process—are determined and prepared in written format for inclusion in the request for information (RFI) and/or the request for proposal (RFP). Private clients are far less restrictive, more flexible in applying the rules that govern their market bid process, while government clients have more rules and regulations and are characteristically stricter and less flexible in applying such rules and procedures.

As an initial step in the procurement process, many large clients include the development of a RFI. The purpose of the RFI is to eliminate some vendors based on minimum vendor requirements, services, or coverage. An RFI identifies only those vendors who can reasonably meet a client's needs and thus are eligible to receive the comprehensive RFP.

The development of a request for proposal (RFP) is the formal procurement document for both clients. Typically, RFPs are sent and received in an electronic format, although hard copy RFPs are still prevalent. In general, a RFP is presented to potential vendors in a way that makes the needs of the client easily understood. The RFP usually contains the following broad sections:

1. *Background information* – The key information concerning the client and its covered population. This section identifies who the client is, a brief description of the demographic and geographic make-up of the covered population, and any pertinent client history.

2. *The goals and purpose of the RFP* – A succinctly written statement that sets the context for the RFP.

3. *A description of the benefit plan design and program features* – This section explains to the potential bidder the exact product they are bidding on. Type of program financing (ASO, capitation, etc.), desired services such as prior authorization, various forms of utilization management, and the management of the formulary are described. This section also lists requirements for customer service, reporting, and other administrative functions.

4. *Minimum vendor requirements* – The list of requirements that a vendor must meet in order to be considered. Requirements may include years of operation, size of current clients under contract, geographic coverage, etc.

5. *Bidding rules and timeline* – This section discusses any pertinent rules for the bidders to follow and includes information on submitting vendor questions, contact with client staff, etc. A timeline outlining key dates in the bidding process is also presented.

6. *Questionnaire* – This section includes various information requests including:

- General information and organizational background;
- Network operations and coverage;
- Plan design, quality assurance, and formulary issues;
- Client/member services;
- Claims administration;
- System capabilities and interface;
- Pharmaceutical pricing and rebates;
- Reporting and data analysis;
- Utilization management;
- Legal and liability issues;
- Implementation support;
- References;

- Financial-related questions and banking issues; and
- Contract compliance and performance measures.

7. *Administrative fee quote* – The PBM's cost for providing services to the client. Most administrative fees are based on a per prescription basis, but some insurers (e.g. CIGNA, Aetna) base their administrative fees on a PEPM basis. Usually, the outline of a financial exhibit is provided in the RFP. The PBMs fill in the exhibit with their administrative fee quotes and describe the basis of the quote (e.g. per script). Separate quotes are obtained for electronic and paper claims, along with both retail and mail order claims.

   The PBM is asked to identify all services included in their base administrative fee and to provide the cost and the cost basis (e.g. per prior authorization review) of any additional services. Many employers request administrative fee guarantees for the initial term of the contract (usually 3–5 years) and include a question dealing with the PBM's willingness to guarantee its rates in this section.

Information Provided to Bidders

Demographics

In order for bidders to respond to the potential client's questions, they must be provided with information that will enable the bidders to develop credible responses. At a minimum, bidders are supplied with member demographic information, the total number of covered lives, their residence zip codes, and an age/sex listing. Bidders use this information to perform geo-access analyses that determine the percent of a potential client's covered lives within a specific number of miles from the closest network pharmacy.

Utilization/cost management

Most bidders desire two years of claims data and any statistics available on service utilization such as the number of telephone calls to customer service, number of prior authorizations, etc. This information is needed to generate a fee quote and to estimate customer service personnel requirements. For an ASO bid, there will be less of a need for the bidders to receive claims information; bidders will not be at risk for the drug spend. Most ASO bidders can use demographic information to forecast their administrative costs.

System interfaces

System requirements are important if the PBMs need to communicate with the various parties involved with the PBM. These parties might include the client's third party administrator for the medical benefits and/or the client's data management vendor. Potential PBMs need to know the record layouts and the means of communicating with the client's other vendors.

Contract issues

Many clients will include a copy of a proposed contract in the RFP in order to give the bidders the opportunity to suggest changes or to indicate their inability to meet certain contractual obligations. Some clients use the PBM's comments concerning adherence to the proposed contract as a selection criterion. It is common for government entities to include these contracts, citing specific aspects of the contract that must be adhered to in order to do business with them. Government entities, particularly states, may also include any applicable regulatory language.

3.4.2 The PBM Selection Process and Criteria

The Composition of the Selection Team

The composition of the selection team can be critical in accurately assessing the best PBM for a specific client's needs. The private and public sectors rely on varying levels of expertise in analyzing competing proposals.

Many private sector clients understand the PBM industry and feel comfortable in reviewing the various proposals. Other private sector clients rely on the expertise of employee benefits consultants to review all aspects of the proposals or to review the more technical components of the proposal such as utilization management, pharmaceutical pricing, rebates, and administrative fees.

Public sector clients also review proposals using a variety of personnel. Some will form multi-disciplinary review teams with personnel from various departments within the entity (employee benefits personnel, systems personnel, medical personnel, finance personnel, etc.), while others will have the review contained within a single department. Again, some public sector clients use consultants to analyze all aspects of the proposals (or specific sections) and recommend the best choice.

In general, a mix of clinical personnel, financial personnel, systems personnel, and operations personnel are required to adequately review a PBM proposal. While all of

these areas are important, a number of clients we interviewed view a familiarity with the benefits structure that the PBM will be operating in as most important. This is particularly important for clinical personnel, who should also be familiar with issues such as formulary management or therapeutic switching methodology. Financial personnel should understand the underpinnings of the PBM industry, and how PBMs make money. Systems personnel are especially important if the PBM will need to interface with other vendors.

If a capitation or significant risk sharing agreement is being considered, additional personnel including actuarial and underwriting personnel should be involved in the selection process.

The Scoring and Analysis of Proposals

As stated earlier, clients employ a variety of approaches in evaluating potential PBM vendors. The scoring and analysis of proposals is no exception to this. Some use an elaborate scoring matrix while others use none at all. For those that use a scoring matrix, it is usually developed in a manner that assigns various weights to identified sections of the RFP based on their relative importance to the client. The scoring matrix can be electronically tied to the proposal received if an appropriately written electronic version of a RFP is issued.

Within each section, the question or data elements are assigned a maximum score. The score may be the same for each element, or each item may be assigned a different maximum score based on its importance within the section. The importance of each section is based on individual client needs and preferences and will vary by client. The importance (weight) assigned to each section usually is in line with the stated goals and objectives of the bid process.

Generally, private clients use a less detailed, less complex scoring methodology than public sector clients do for two reasons. First, private clients tend to have adequate knowledge about the industry to evaluate the non-price aspects of the proposals, and may want to focus their attention on pricing issues and network composition. Second, public clients may be bound by a more formal bidding process, which requires a quantitative scoring method.

If an RFI is not used to eliminate some vendors, then the scoring methodology can be developed to eliminate bidders who do not receive a minimum score on a specific section or combination of sections of the RFP. Minimum vendor qualifications, compliance with contractual issues, and geographic network coverage are the usual areas that are used to initially eliminate bidders.

Many clients further pare the list of bidders through the selection of finalists. Depending on the number of overall bidders, there are usually 2–4 finalists selected. One method of selecting finalists is to establish a target score for finalists; those vendors reaching the target score or higher are considered finalists. Vendor presentations, site-visits, and reference verifications are usually reserved for finalists.

Standard RFP Sections, Weighting and Evaluation Criteria

Table 16 compares the weighting by component contained in recent PwC PBM market bids with the average overall importance ranking based on information gathered during PwC's discussions with PBM clients for this study. The RFP weighting emphasizes the overall importance of the pharmaceutical discounts and rebates due to their material impact on the cost of a prescription drug benefit. The significant weighting on discounts and rebates also is indicative of most clients' concern about the cost of the prescription drug benefit.

Table 16: Relative Importance of RFP Sections

RFP Section	RFP Weighting	PBM Client Ranking
Pharmaceutical Pricing and Rebates	35%	1
Administrative Functions	20%	4
Performance Guarantees	15%	6
Retail Pharmacy Access	8%	2
Clinical/Utilization Management	5%	5
Administrative Pricing	5%	3
Quality Indicators	5%	7

In PwC's discussions with clients, price and access were the two most important considerations. While performance guarantees are often an integral part of the bidding and selection process, they rank next to last in importance. This is probably the case for two reasons: 1) they are generally measured only periodically (many times just once a year); and 2) clients are more interested in receiving high quality service than collecting fees that will not offset the harm caused by a vendor's inferior performance.

Network pharmacy access has a relatively low weight in the RFP process, even though it is important to the PBM's clients, because almost all major PBMs have very extensive

networks and therefore there is very little differentiation in this area among the national PBMs.

Administrative pricing also has a low weight due to the fact that the cost of administering the pharmacy benefit is minimal compared to the actual cost of the pharmaceuticals dispensed. Administrative services are weighted higher in the PwC model, as the administration of the benefit plan is the main function of the PBM. The fact that it ranked lower in importance may be a sign that PBMs, in general, perform their functions well and that level of service has come to be expected by the PBM's clients. Most clients, with whom PwC held discussions, believed that the administrative pricing and administrative functions were very similar in importance.

The individuals PwC spoke with were asked whether the criteria used in selecting a PBM to serve a primarily senior population would vary from their own criteria. The general feeling was that while cost would remain the overriding issue, customer service for the elderly will increase significantly in importance. In addition, mail order capabilities may become more important, given the presence of chronic conditions found in the elderly population. While some tout online capabilities as important for seniors, others feel that at the present time the senior population is not ready to rely on online services.

The sub-sections that follow identify key issues and statistics commonly used in evaluating the pharmaceutical pricing, pharmacy access, and administrative fees contained in a bid response from a PBM. The remaining evaluation areas are less uniform in the criteria used for evaluation, and vary based on the goals of the client.

Pharmaceutical pricing

Pharmaceutical pricing in both the retail and mail order environment is usually not based on the actual price of a specific pharmaceutical, but on the discount scheme proposed by the PBM. Discounts on brand pharmaceuticals are usually bid as a percentage off the pharmaceutical's average wholesale price (AWP). Generic pharmaceuticals are usually proposed based on their MAC cost, but may also be stated as a percentage discount from AWP. A requirement that the lesser of the negotiated discount price or the pharmacy's "usual and customary" (U&C) price is analyzed in this area.

Based on recent PwC market bids the average discounts are as follows:

- Retail brand: AWP – 12% to 15%
- Mail order brand: AWP – 18% to 23%

- Generics: most generic pharmaceuticals use a MAC pricing schedule. The combination of generic pharmaceuticals with MAC pricing and those without MAC pricing average discounts of approximately AWP – 50% to 60% for both retail and mail order pharmaceuticals.

- Many PBMs use the HCFA MAC pricing schedule, while most of the largest PBMs have developed their own MAC pricing schedule.

Dispensing fees

Pharmaceutical pricing in the retail environment also includes a dispensing fee that is in addition to the discounted cost of the pharmaceutical. Dispensing fees in the retail environment for most large clients usually range from $2.00–$3.00 per prescription. Some governmental entities may pay in excess of $4.00 for dispensing fees and a small number of MCOs will pay below $2.00 for dispensing fees.

Some PBMs charge a dispensing fee for their mail order services; this is a negotiable point. Mail order dispensing fees range from $0–$2.00 per prescription.

Manufacturer rebates

PBMs provide rebate guarantees averaging between $0.85–$1.25 per prescription to their clients. The pharmaceutical manufacturer actually pays the rebates to the PBMs based on percentage of the drug cost and the PBMs "pass through" the rebates to their clients based on their agreed upon terms. PBMs may vary the way they "pass through" rebates to their clients. Rebates can be on all prescriptions, some propose a guarantee based on all retail prescriptions, some propose rebates based on all brand prescriptions, some provide rebates for only formulary prescriptions, and some vary the level of rebate between retail and mail order.

Pharmacy access

Pharmacy access is analyzed (scored) based on established access criteria and the percentage of members meeting the access requirement when compared to a PBM's proposed network. Most PBMs offer extensive networks and this is generally not a differentiating factor in selecting a PBM. Clients generally look at whether the PBM has the major retail chains in its network for its relevant service areas. Clients with members in more rural areas look to the PBMs' flexibility in adding non-chain pharmacies in local communities. Section 4.2.3 provides a description of standard pharmacy access standards.

Administrative fee arrangements

Administrative fees in the retail environment are most commonly based on a per prescription basis. Most clients prefer a bundled administrative fee with a majority of the basic administrative services included in the per prescription fee. Additional administrative fees may be charged for specialty programs such as disease management, prior authorization programs, some levels of utilization management, and ad-hoc reporting. Statistics are developed from prior client experience or based on industry norms for each administrative category in order to assure an equal comparison of the vendors' proposals and a fair analysis.

Administrative fees for mail order prescriptions vary by PBM with some charging no administrative fees for mail order. A detailed description of administrative fees is contained in Section 3.2.1 of this report.

Other Components of the Selection Process

Vendor presentations, site visits, and reference verifications generally take place after the client has identified a set of finalists or semi-finalists. These presentations are used to provide vendors the ability to discuss their services in person. In addition, these presentations can be used to: 1) verify the information presented in the RFP; 2) gauge the interpersonal relationship between the vendor and the client; and 3) solicit "best and final" offers. Potential clients usually request that the vendor's account management team is present at interviews, rather than the vendor's sales representatives.

Site visits to operations centers, mail order facilities, etc. are used to verify that the services described in the RFP are actually in operation and working as described. Clients view site visits with varying levels of importance. Aside from onsite verification, the visits can serve as an educational tool in learning about the latest technologies at both call centers and mail order facilities. However, some potential clients feel that they have sufficient knowledge about the PBM industry to avoid the expense of site visits.

Finally, reference verifications are used to verify the service performance of a vendor. While private clients certainly view this as an important step in the process, public clients may incorporate references into the selection scoring process. In addition, private clients may utilize their "network" of counterparts working in similar functions at other clients to discuss the service provided by various PBMs.

Bidding and Selection Timeline

The bidding and selection timeline illustrated in Diagram 17 is for a large, complex PBM client. The size of the Medicare population, the number of regions to be bid and the requisite approval requirements within the HCFA procurement process will impact this timeline. During our discussions, clients and PBMs were asked to estimate the HCFA bidding and selection process. The general feeling was that the process would take 9–12 months, given the potential scope of the program and the vendor selection requirements inherent in a federal program.

The total process outlined in Diagram 17 can take anywhere from 4 months to a year, depending on a number of factors, with most large clients falling in the 4–8 month range. Factors affecting this timeline are described below:

- Establishment of goals and objectives – This can take longer than 30 days when multiple decision-makers are involved in the process, or when a public oversight board is involved.

- Issuance of RFI – In some cases, a client will place more emphasis on the RFI and include a more comprehensive list of questions, which will take more time to produce.

- Development of RFP – As is the case with step one, if multiple parties are involved and board approval is required, the development process can take longer.

- Issuance of RFP and receipt of proposals – If the RFP is complex or requires capitation or significant risk sharing, vendors must be given more time to respond. In addition, if the RFP and the PBM's proposal will become part of the contract, additional time is required by the PBM to obtain all necessary legal review of their proposal.

- Development of scoring methodology – The more detailed the scoring is, the longer it will take to develop.

- Analysis (scoring) of proposals – In some instances, multiple parties must be involved in the scoring process, which will stretch out the process.

3.4.3 Implementation Process

Implementation Time Line

The typical large client implementation time line is 90 days from contract acceptance to "going live" with the benefit. PBMs commonly state that they can implement a program within 60–90 days for large clients. However, government entities usually require a six-month implementation schedule due to their size and complexity. At a recent workshop, many PBM representatives estimated that due to the complexity of the Medicare program it may take as long as one year to adequately implement a prescription drug benefit. This estimate was reinforced in discussions with clients and PBMs, during which a number of respondents stated that it would take at least one year to implement the program. Diagram 21 displays a typical 90-day implementation timeline for a private PBM client.

Diagram 21: Typical 90-Day Implementation Schedule - January 1 Start-Up

Factors Affecting the Implementation Timeline

There are a number of key milestones in the implementation process that need to be achieved in order to for a PBM to be implemented. This information was augmented by PwC's discussions with clients. Factors affecting the implementation timeline are discussed below, with an emphasis on large client implementations, as these more closely resemble HCFA's size and complexity.

Information systems and interconnectivity

One of the more important drivers in the implementation process is the installation of the system(s) used to administer the plan. These systems must be set up to accommodate the plan parameters, pricing arrangements, and integrate with functions such as eligibility, billing, and reporting. The information technology capabilities of both the client and vendor can impact the implementation time.

Benefit plan design

Multiple plan designs increase the required implementation time for this set of tasks. Employers with multiple subdivisions and plan designs can take longer to implement. Insurers with a multitude of options must be comfortable with the PBMs ability to deal with these complexities. Several entities participating in the study suggested that HCFA could simplify the system installation step in the process by limiting the number of drug plan design options it offers Medicare beneficiaries.

Coordination with Existing Employer Benefit Plans

Currently Medicare coverage is secondary when coverage from an employer's benefit plan is in force. Through legislation or policy the classification of the Medicare prescription drug benefit as primary or secondary will need to be established. An internal PwC report on the Medicare prescription drug benefit proposed by the Clinton Administration indicated that approximately 25% of employers would drop their prescription drug benefit if Medicare implemented a prescription drug benefit. The remaining employers may alter their existing benefit thereby pushing a majority of the cost into the Medicare program.

The degree (if at all) to which the Medicare program coordinates benefits with existing employer plans will need to be determined and the appropriate systems established within the selected PBM to accommodate the agreed upon procedures.

Eligibility

The eligibility verification and transfer processes are important components of the system installation process. Interfaces must be developed which take into account functions such as claims processing, card production, and the mailing of communication materials to members. It is much simpler to work with a centralized eligibility file than multiple files from multiple sources. The complexity of a client's eligibility files can also have a major impact on the implementation timeline. Based on discussions with clients and PBMs, it was suggested that HCFA attempt to consolidate eligibility data in a single source of transmission to the PBM.

Member communications and customer call center

Member communications are another important implementation step. Most clients interviewed were comfortable with the process and did not personally experience any major stumbling blocks. However, when asked about the implications of introducing a prescription drug plan to Medicare beneficiaries, the consensus was that a comprehensive communication plan should be developed for beneficiaries and network pharmacies.

Legal/contract

Several clients commented that the process of executing a contract with a PBM could be a long, drawn-out process. All applicable plan design requirements, performance guarantees, and other specifics for the program must be spelled out and agreed to by both parties. Public clients tend to have vendor-contracting requirements that reduce flexibility in reaching a mutually agreeable document. The contracting process could become especially time consuming in dealing with a program of the size and scope of Medicare.

Pharmacy network, management reporting and financial requirements

Several clients mentioned other factors that could affect the implementation timeline. First, any required changes to the PBM's pharmacy network to accommodate a new program could affect the speed of implementation. This is common when a client wishes to minimize employee disruption in terms of pharmacies utilized. Second, the PBM and the client must agree on the type of reports generated for the client's program, including both standard and ad hoc reports both of which provide an easy interpretation of areas such as the status of program costs and utilization factors. Finally, the PBM and the client must work out details of the medium, format, and accounting requirements of the invoices sent to the client by the PBM.

Client responsibilities

While it is ultimately the PBM's responsibility to meet implementation deadlines, the ability to implement a new program is also heavily dependent on a client's responsiveness to the PBM's requests. Factors that are particularly important, as stated in PBM proposals, include: 1) the availability of technical staff to assist with system setup; 2) the timely provision of eligibility information; 3) the availability of business staff to answer PBM questions and respond to information requests; and 4) the ability of the client to make timely decisions. It is equally important for the PBM to clearly understand the client's specific needs.

Given the magnitude of the Medicare program, HCFA would need to ensure that the factors stated above are addressed, and that an adequate number of qualified individuals be assigned to the implementation team.

Member Communications Timeline

The timeline for member communications during the implementation process, from establishing the communication's requirements to mailing member packets, averages 90 days for clients, and starts at the beginning of the implementation schedule. Key milestones include:

- The identification of client-specific communications requirements;
- The creation of an announcement letter, informing members of the upcoming change;
- The preparation of a mail service profile, spelling out the parameters of the types of mailings, timing, quantities, and any other special mailing instructions;
- The creation of toll-free member and pharmacy numbers (often client-specific);
- The design of an ID card;
- Client sign-off on materials for distribution; and
- The mailing of materials 15 days prior to implementation.

As stated earlier, the member communications timeline would need to be expanded well beyond 90 days for the Medicare population, and may also need to include a public relations and/or advertising campaign.

The Effect on Implementation of the Number of Members in a Plan

Based on client interviews, the number of members did not routinely affect an implementation timeline. However, it was stated that a program as large, and possibly complex, as Medicare would likely have an impact on the time required for implementation. For example, the customer service function of the PBM(s) contracted would likely require expansion and special training to deal with the senior population. Mail order volume could grow significantly. Other functions such as ID card production and aspects of member communications could also be impacted.

The degree of impact the Medicare population has on the implementation timeline is somewhat dependent on the number of PBMs selected to administer the program. Splitting the Medicare population across several PBMs would be likely to have less of an impact than concentrating the business in one PBM.

The Member's Effect on the Implementation Process

Member demographics and a member's prior experience with drug benefits can impact the implementation timeline. Member demographics (language, education level, etc.) may affect member communications vehicles, ID card production, and customer service requirements. A member's prior experience with drug benefit programs can dictate the amount of up-front member education. The individuals interviewed for this study agreed that special consideration would need to be made in addressing the needs of the senior population, particularly in the areas of member communication and customer service.

Another consideration is the multi-lingual composition of the Medicare-eligible population. Most PBMs have Spanish-speaking representatives on-site at their call centers. Some PBMs state that they will "work closely" to develop and implement specific programs targeted to non-English-speaking populations. Others utilize a language line service such as AT&T, which has translators available in 140 languages.

Implementation Issues and Success Factors

Listed below is a summary of key implementation tasks that are important to a timely and successful implementation:

- Ongoing implementation review meetings to assess goals, schedules, and deliverables;
- Internal account team status meetings to discuss program requirements with operations managers;
- Implementation status reports every two weeks; and

- Bimonthly internal post-implementation problem resolution meetings.

A number of other insights were gained during our discussions with clients. One client stated that the most important factor is having the right people on the implementation team, including those who have the authority to get additional resources if needed. Communication between the vendor and client is critical, and they need to understand each other's terminology. Communicating via e-mail is seen as a recent improvement in the process.

Several clients stated that a primary reason they considered their PBM implementation to be successful was that the PBM was staying one step ahead in the process, providing the client with timely reminders of upcoming deadlines and responsibilities. Finally, if the client has online access to the PBM's system, then adequate training in using the system is very important.

Implementation incentives

It is common practice for PBMs to agree to implementation incentives (bonds, guarantees, etc.). These can either be imposed by the potential client, or asked for as part of the bidding process. Performance incentives range from a set dollar amount ($100,000 in the case of one state government) to daily or weekly fees for missing the start date. The magnitude of the guarantee is based on number of covered lives.

Other clients require PBMs to agree to penalties for missing specific implementation milestones. Generally penalties range from $5,000 per milestone, with a maximum of $25,000 for implementation guarantees. On the high end, one PBM offered to pay $10,000 to $30,000 per milestone, and up to 20% of annual administrative fees.

Implementation credits

Some PBMs offer an implementation credit to a client to cover specific costs related to the implementation process. Costs covered include a client's staff time, consultant's fees, system upgrades, and other related costs. This credit is based either on a per employee basis or a flat amount. Per employee credits range from $1.00–$1.50 per employee. Flat amounts will vary based on the size of the client. The credit is usually offered when a potential customer switches from another vendor to the PBM offering the credit.

Post Implementation Monitoring

As described in Section 4.2.1 ("Administrative Performance Benchmarks and Guarantees"), PBMs monitor their own performance utilizing a number of techniques, ranging from automated call monitoring systems to mail surveys. However, many clients hire third party auditors to assist in post-implementation monitoring.

Client claims audits are the most common form of external measurement of PBM performance. Guidelines for these audits are frequently established in the service contract between the PBM and the client. The client usually hires a third party to conduct the audit.

The protocols established in the contract between the client and the PBM generally provide the details for how the client and the third party auditor will interface with the PBM. PBMs usually require 60-day notice of an audit and may exclude a time period such as December–January. Clients may try to negotiate the reimbursement for conducting the audit, but PBMs prefer to have it stipulated in their contract that audit expenses are borne by the client.

The third party auditor develops a systematic approach to conducting the audit. Claim audits fall in the general category of discovery audits, and are the preferred type of audit because they: 1) require relatively minimal time and financial investment; 2) validate/invalidate vendor relationships; 3) uncover areas for process improvement; 4) satisfy the plan sponsors' financial and fiduciary objectives; and 5) allow for modification of audit size and scope to meet the budgetary constraints of plan sponsors of any size.[72]

Typically, the audit helps to uncover:

- Inappropriate discounts off the average wholesale price and dispensing fees;
- Ingredient cost errors stemming from inaccurate conversions of units of measure for products like inhalers, topicals, and compounded medications;
- Coverage of non-covered drugs;
- Routine coverage of drugs requiring prior authorizations without proper documentation; and

[72] Peard, Susan, et al, "Taking Stock of your PBM," *Business and Health* 18 no. 3 (March 2000): 43-47.

- Eligibility problems, such as ineligible employees receiving coverage, claims being filed under the wrong members, and in some cases, legitimate enrollees being denied coverage.[73]

Rebate verification audits may also be conducted during the course of the discovery audit described above or as a separate audit. Contracts between drug manufacturers and the PBM are reviewed and the PBM's accounting procedures are checked to ensure that the appropriate rebates are being received.[74] Audits are generally conducted once every 1–3 years, based in part on the performance of the PBM. Due to the size of the Medicare population, more frequent rebate audits may be necessary.

In general, rebate audits include:

- A review and analysis of the methodology used by the PBM to allocate rebates to its clients;

- Identification of the top manufacturers (usually 3 or 4) that represent a majority of the rebates due a client;

- Performance of a detailed analysis of the PBM's contracts with the top manufacturers;

- A review and verification of the PBM's calculations concerning the rebates owed by the manufacturers and the allocation of those rebates to the client; and

- Verification of the PBM's compliance with any contractual performance guarantees relating to rebates.

The overall goal of the rebate audit is to assure that the client is receiving the appropriate amount of rebate dollars and to verify contract compliance. Due to the degree of data and information required to conduct a rebate audit, the audit is usually scheduled well in advance and not performed on an unannounced basis.

[73] Ibid., 44
[74] Ibid., 47

3.4.4. Medicare Selection/Implementation Schedule

In discussions with clients and PBMs, most agreed that due to the size and complexity of the Medicare program an elongated selection and implementation process would be required. Most believed it would take up to two years for Medicare to complete the vendor selection and program implementation process. Based on the discussions with clients and PBMs, PwC prepared a sample twelve month bidding/selection timeline and a twelve month implementation timeline. Diagrams 22 and 23 on the following pages illustrate the combined twenty-four month timeline.

Diagram 22: Sample Medicare Twelve Month Bidding/Selection Timeline

Diagram 23: Sample Medicare Twelve Month Implementation Schedule

Medicare Bidding and Selection - Additional Time Required

The twelve-month timeline recognizes that additional time may be needed to finalize the RFP and to perform a complete analysis of the proposals received. The twelve month timeline (Diagram 22) varies from the ninety-day timeline (Diagram 21) in the following ways:

- Expands the time allocated for the issuance of the RFI and receipt of responses from the PBMs. The additional time will be used to answer PBM questions concerning the RFI and to allow the PBMs more time to submit their response.

- Allows for additional RFP preparation time. Additional time may be required to obtain the necessary reviews of the RFP and approval to issue the RFP.

- Provides for additional time to perform the analysis of the proposals received from the PBMs. The additional time will be needed to clarify the responses from the PBM, pose follow-up questions, allow for multiple site visits to call centers and mail order facilities and in general to provide additional time to complete the analysis and obtain required approvals.

Medicare Implementation – Additional Time Required

The twelve-month Medicare timeline (Diagram 23) is significantly longer that the usual 90-day implementation timeline (Diagram 21). The longer timeline is indicative of the belief that implementing a Medicare prescription drug benefit will require extensive member and pharmacy communications and that the success of the program will be dependent on a successful communications program. The twelve-month timeline varies from the 90-day timeline in the following ways:

- Significant expansion of the time allocated for both member and participating pharmacy communication. A significant communications effort will be required to assure that the members and the pharmacies are well versed on the program's benefits and the claims submission procedures.

- Allows for additional time to finalize and test the claims submission systems and procedures.

- Provides for additional time to finalize the PBM contracts and obtain required approvals.

- Anticipates that additional time will be required by the PBM to hire and train their customer service personnel. Anticipates additional training will be required to orient customer service personnel to the needs and challenges of a senior population.

The actual time needed to bid, select and implement a Medicare drug benefit is dependent on the number of PBMs evaluated, complexity of the drug benefit, and beneficiary criteria. In addition, HCFA may require additional time to develop new, internal programs to align with the PBM's service. These could include managing enrollment and eligibility, collecting premiums, as well as monitoring, and possibly managing, utilization and cost.

4.0 PERFORMANCE MEASUREMENT

Performance measurement is a key function for clients as they assess their ongoing relationship with their PBM. Traditionally, performance measurement is divided into the following two categories:

- Cost and utilization; and
- PBM service performance.

Cost and utilization performance measurement includes such metrics as the number of prescriptions dispensed per member, average ingredient cost per prescription and per member, generic use rates, and rebates. Cost and utilization results may vary significantly by client based on the client's demographics and the client's overall benefit plan design.

Conversely, PBM service performance measurements are more uniform. Clients have established a series of benchmarks and service guarantees to measure the overall service performance of a PBM. Many of the service guarantees were derived from the guarantees used by medical claims administrators. Service guarantees deal primarily with the administrative aspects of a PBM's performance, as this is the main service provided by the PBM. Since PBMs do not manufacturer, prescribe and dispense drugs (with the exception of mail order), the service performance measurements are the main "quality" measurement for a PBM. In almost all cases, the monitoring of performance measures is performed and paid for by the PBM.

This section includes an overview of common cost and utilization statistics and PBM service performance measurements routinely used by clients today. A description of some of the variables that may impact these statistics is also provided. In addition, an overall evaluation of the PBM industry's performance, based on recent survey material, is presented.

4.1 Cost and Utilization Measurements

Most clients monitor similar cost and utilization statistics. The statistics are monitored to determine trends in drug utilization and the impact of various plan design changes. Common measurements used to monitor a prescription drug benefit program include:

- Number of prescriptions dispensed per member;
- Generic use rate;
- Average ingredient cost per prescription; and
- Average annual cost per member (after co-pay and including dispensing fee).

Although the statistics monitored by clients is similar, the results achieved vary greatly based on the demographics of the client's covered population and the overall benefit plan design. As a result, it can be difficult to compare statistics. Table 17 provides a range of results achieved during 1999 by various clients with whom PwC held discussions.

Table 17: Range of Results for Common Cost and Utilization Measurements

Measurement Statistic (per year)	Range of Results (1999 Data)
Number of Prescriptions per Member	10.4 – 13.6
Generic Use Rate (% of total drugs dispensed)	37.2% – 38.4%
Average Ingredient Cost per Prescription	$33.83 - $44.65
Average Annual Cost per Member (after copay and including dispensing fee)	$130.68 - $381.73

As mentioned above, population demographics and plan design can have a significant impact on comparative statistics. Below are some of the causes for these variations.

Number of Prescriptions per Member – The age and sex of the population along with various adjusters for the general health of the population will impact the number of prescriptions dispensed on an annual basis. The statistics in Table 17 represent a mix of active personnel, pre-65 retirees and post-65 retirees. It is probable that a post-65 population will have a higher use rate.

Specific statistics on post-65 retirees were either not available or considered proprietary by the clients with whom PwC held discussions.

Generic Use Rate – The benefit plan design will have the most impact on the use of generic pharmaceuticals. Benefit plan features that impact generic use include:

- The variance in the co-pay or coinsurance between generic and branded drugs;
- The use of a mandatory generic policy, either in all cases or in cases where a physician does not specifically write " Dispense as Written" (DAW) on the prescription;
- The provision of incentives (usually through higher dispensing fees) to pharmacists to dispensing generic pharmaceuticals with the approval of the patient and/or the patient's physician; and
- The use of various patient and physician educational programs on the availability and cost benefit of generic pharmaceuticals.

Average Ingredient Cost per Prescription – Both the demographics of the population and the benefit plan design will impact the average ingredient cost per prescription. A more senior population will probably have a higher use rate of more costly medications (i.e. cardiac and arthritis pharmaceuticals). A benefit plan design that does not include the proper incentives (level of copays and coinsurance) for the use of generics and preferred branded (three-tier benefit plan design) pharmaceuticals will probably have higher utilization of more costly brand name pharmaceuticals and thereby, a higher average ingredient cost.

Average Annual Cost per Member – The same factors that impacted the average ingredient cost per prescription along with the overall health of the population will impact the average annual cost per member.

In addition, clients will also monitor their average dispensing fees (if variable dispensing fees are used) and the amount of rebates received from the pharmaceutical manufacturers through their PBM. Rebates may be measured as an amount per all prescriptions, an amount per brand prescriptions, an amount per formulary prescription or other methods agreed upon between the client and the PBM. Table 10 in Section 3.1.1 provides an average range of dispensing fees while average rebate guarantees are described below.

Dispensing Fees – Dispensing fees will be impacted by the methodology agreed upon between the client and the PBM. Some clients prefer a set dispensing fee while other use their dispensing fee to incent pharmacists to dispense generic pharmaceuticals.

Manufacturer Rebates - The rebate payment schedule is often monitored, with rebates paid to the client on a quarterly basis and within six months of the quarter in which rebate was earned.

The level of rebate payments is usually expressed as a dollar amount per prescription. Industry average rebate guarantees are approximately $0.85—$1.25 per prescription.

Attention must be paid to the basis of the rebate guarantee. Some PBMs offer rebate guarantees on all prescriptions, some propose a guarantee based on all retail prescriptions, some propose rebates based on all brand prescriptions, some provide rebates for only formulary prescriptions, and some vary the level of rebate between retail and mail order. The PBMs offer the guarantees to their clients even though the actual rebates are paid by the manufacturers and "passed through" the PBM to the client.

The level of rebates will depend on the structure of the plan design including the level of copays/coinsurance, the number of tiers, the structure of the formulary, and negotiations between the client and the PBM. Most large clients receive 100% of the manufacturer rebates due them while smaller clients may only receive a percentage of the rebates. Rebates range from 2% to 5% of total pharmacy benefit plan costs based on the factors listed above.

4.2 PBM Service Performance Indicators and Benchmarks

4.2.1 Administrative Performance Benchmarks and Guarantees

Table 18 displays the administrative performance benchmarks and guarantees that are commonly used in contracts between clients and PBMs.

Table 18: Administrative Service Performance Benchmarks

Performance Criteria/Guarantee Level	Expected Outcomes
System availability – system available for access to contracted pharmacies Availability of the PBM's systems to electronically adjudicate claims from retail pharmacies.	99% system availability is the minimum acceptable outcome with a penalty assessed for failing to meet this minimum standard.
Paper claim turnaround time Time required to process a paper claim after receipt.	99% of all paper claims processed within 10 days is the minimum acceptable level with a penalty assessed for each percentage below the 99% level.

Table 18: Administrative Service Performance Benchmarks (continued)

Performance Criteria/Guarantee Level	Expected Outcomes
Claim accuracy Payment of the claim in accordance with the benefit plan parameters and financial accuracy.	Online claims – 100% Paper claims – 99% The above levels are the minimum acceptable levels for claims accuracy with penalties assessed for achieving less than the minimum level.
Phone answer time The time it takes for the PBM to answer a customer service call. Connection to a PBM's decision tree or other electronic phone answering mechanism is considered answering the phone.	95% of all calls are expected to be answered within 30 seconds. Measured through the review of PBM supplied reports, there is a penalty assessed for failing to meet the minimum 95% level.
Phone call abandonment The rate at which calls are abandoned due to excessive answering time or other telephone problems.	3% is the minimum acceptable level with a penalty assessed for failing to meet the minimum. Usually judged based on PBM supplied reports.
Mail order turnaround time Time it takes the PBM's mail pharmacy to dispense/distribute product after receipt of the prescription. It does not include delivery time.	95% are expected to be processed in two days for cases not requiring intervention. 95% are expected to be processed in five days for cases requiring intervention. Interventions include attempts at generic or therapeutic switches, reviews for drug interactions, and the gathering of additional information required to dispense the pharmaceutical. The levels listed above are the minimum acceptable levels with penalties assessed for failing to meet the minimum.

Table 18: Administrative Service Performance Benchmarks (continued)

Performance Criteria/Guarantee Level	Expected Outcomes
Program satisfaction	At least 85% of respondents are expected to service as excellent or good with penalties assessed for failing to meet these levels.
ID card delivery	Minimum acceptable level requires ID cards to be mailed within 5 days of receipt of eligibility update with penalties assessed for failing to meet these levels.
Accurate and timely update of eligibility files	Minimum acceptable level requires eligibility files to be 100% accurate and updated within 5 days of receipt with penalties assessed for failing to meet these levels.
Preparation of clinical or financial reports	Minimum acceptable level requires reports to be delivered within 21 days of request. Some contracts contain alternative report delivery dates (e.g., 15 days after the end of a quarter) based on the needs of the client with penalties assessed for failing to meet these levels.
Delivery of routine financial/management reports	Minimum acceptable level requires delivery within 30 days of the period to which they apply (slight variation in the number of days contained in contracts) with penalties assessed for failing to meet these levels.

4.2.2 Pricing Benchmarks and Guarantees

Discount Guarantees

Discount guarantees ensure that the client's contracted discount off AWP (e.g., ingredient cost) is achieved. The measurement of the realized discount includes the AWP discount, Usual and Customary, and MAC pricing reimbursed to network pharmacies.

Certain components of this discount are fixed in advance. For example, the PBM and the client generally fix the retail and mail discounts, for brand and generic drugs, as a percentage discount off AWP.

The discounts offered on retail pharmacy networks are consistent across the larger PBMs. There is some variance in the discounts guaranteed for mail order. In general, PBMs have consistently met or exceeded their discount guarantees.

PBMs will not usually provide specific discount quotes outside of a formal bid process. This will be an area for HCFA to explore during its process to evaluate and select a PBM.

DUR Cost Savings

DUR guarantees are rare. This is a result of the difficulty in quantifying the guarantee and resultant savings, and a perceived lack of accuracy and credibility in the measurement of results. A number of factors can effect the measure of DUR cost savings including manufacturer price changes, changes in treatment protocol and usage guidelines, and new medications.

If a DUR guarantee is included in a client's contract, it is a common practice to guarantee savings on yearly basis, with greater savings in year one. PBMs measure program savings and guarantees, on a dollar for dollar basis with savings guarantees of 4-5 percent of net plan cost in Year One, 3-4 percent of net plan cost in Year Two, and 2-3 percent of net plan cost in Year Three. For each full percentage point below the guaranteed target, the PBM makes up 100 percent of the shortfall on a dollar for dollar basis usually up to an agreed upon cap.

In many cases, the cost of the DUR programs is included in the overall administrative fee. Some PBMs charge separately for DUR pharmacy management (approximately $1 per employee per month) and guarantee that plan savings will at least equal the DUR administrative fee. Any savings over and above the DUR administrative fee are shared equally between the client and the PBM.

Shared Savings Guarantees

Shared savings guarantees are a type of risk sharing agreement between the PBM and the client. As with DUR cost savings guarantees, these arrangements are rare in client contracts due to the difficulty in monitoring/auditing the actual results. Historically, PBMs did not have much success in predicting overall costs under risk-sharing arrangements. This was due to their inability to predict the factors affecting prescription drug costs, and their overly optimistic estimates of savings from utilization management programs. As a result, PBMs experienced significant underwriting losses, and have become much more conservative and hesitant to engage in significant risk sharing programs.

The reluctance to enter into risk sharing programs continues today. The increasing inflationary trend along with the rapid emergence of new pharmaceuticals is causing PBMs to refuse to enter into new risk sharing arrangements and to phase out existing programs. In general, PBMs will not even consider this type of arrangement without at least two years of detailed cost and utilization data for the proposed covered population. In addition to data, PBMs will require significant input into the proposed benefit plan design parameters and control over areas such as generic substitution, therapeutic substitution and other clinical programs within the pharmacy benefit.

PwC found only one occurrence of a shared savings agreement during our discussions with PBMs and clients. The details of the agreement are considered proprietary, but included the availability of significant amounts of data and significant control by the PBM over the benefit plan design and the clinical programs.

4.2.3 Access and Network Performance Benchmarks and Guarantees

As discussed throughout Section 3.4 of this report, pharmacy access is an important criterion in selecting and monitoring a PBM vendor. Today, with geo-access mapping software, it is relatively easy to determine a member's access, measured by distance, to the nearest network pharmacy. After implementation is complete, access guarantees are established to monitor the overall percent of members within a set distance from a pharmacy.

Clients use access rates such as one pharmacy within 1, 3, or 5 miles of a member's home. Instead of a uniform measurement for all members, some clients vary the access rate by urban, suburban, or rural as portrayed in the example below:

- Urban – one pharmacy within 1 to 2 miles of a member's home
- Suburban – one pharmacy within 3 to 5 miles of a member's home
- Rural – one pharmacy within 6 to10 miles of a member's home

Access standards may also vary based on the size of the retail network and whether the member population is urban or rural. Typical standards require that at least 90–95% of the covered population have access to a retail network pharmacy within the specified mileage requirement. Additional guarantees may be put in place to ensure that specific retail chains remain in the network.

Even with the increasing use of mail order, access to a local pharmacy is still an important consideration. Many individuals still have an "attachment" to their local pharmacy and will strongly desire access to their pharmacy. Some clients are now starting to perform a disruption analysis that concentrates on the pharmacies the covered population utilizes more than on the distance test.

In general, the larger PBMs have extensive networks that meet or exceed the requirements listed above.

4.2.4 Mail Order Dispensing and Retail Pharmacy Benchmarks and Guarantees

Given the potential ramifications of errors committed in the dispensing of drugs, very high standards are set for a PBM's mail order facility in the dispensing of pharmaceuticals. A common standard for mail order dispensing is 99.99% of all prescriptions filled accurately. Self reported statistics indicate that the PBMs contacted by PwC are meeting this standard.

PBMs are also obligated in the majority of cases to perform audits of their network pharmacies. A common standard is that 4% of pharmacies within a PBM's network are audited on an annual basis. PBMs will usually return 100% of recovered claims due to errors by the pharmacy to the client. Errors include the failure to price the drug at the lessor of the discount rate or the usual and customary (U&C) rate, the application of the wrong AWP, etc. However, in the case of on-site audits, PBMs may retain a small percentage (10–20%) of recovered claims to cover their costs.

Because new pharmaceuticals are constantly being introduced, PBMs are obligated to inform clients of new drugs and the potential implications to their plan at least quarterly, with individual updates at least 30 days prior to the release of expensive new drugs.

4.2.5 Levels of Guarantees and Incentive Payments

Penalties for not achieving established guarantees are usually capped at between 20–50% of total administrative fees. Some large clients have negotiated guarantees that place 100% of a PBM's administrative fees at risk; one large client has no cap on the PBM's liability for failing to meet certain cost guarantees. Each guarantee is assigned a specific guarantee amount (e.g. 2% of administrative fees for claims turnaround or a set dollar amount) with the total not exceeding the cap.

Some clients also provide incentives for exceeding certain guarantee amounts. The most common incentives are for exceeding the generic substitution rate, member satisfaction, and financial accuracy. For example, a client and a PBM may agree that for each percentage point the PBM raises the generic substitution rate, the client and the PBM will each split the estimated savings. The split may be an even 50% - 50% split or with larger clients, the split would more likely be a 70% client, 30% PBM split. Fixed dollar bonuses or bonuses based on a percentage of base administrative fees are more common incentives for member satisfaction and financial accuracy.

4.2.6 PBM Performance in Relation to Guarantees and Benchmarks

During discussions with clients, they were asked whether a series of performance standards and guarantees are included in their contracts with PBMs. In addition, the clients were asked whether the standards set forth were being met. Table 19 on the following page displays the various standards and the prevalence of their inclusion in contracts. The percentage listed under the "Included in Contract" column indicates the percentage of clients contacted by PwC that had the specific guarantee in their current PBM contracts.

In addition, clients were asked to report on the recent performance of their PBM with respect to meeting these standards. In areas where performance was measured, these standards, without exception, were currently being met by the PBM. Most clients that had recently switched to a new PBM did so due to price considerations. However, two of the seven clients participating in this study, sited dissatisfaction with service or network access provided by their prior PBM.

Table 19: Typical Performance Guarantees and Performance of PBMs

Standard/Guarantee	Included in Contract	Recent Performance
System availability – system available for access to contracted pharmacies 99% of the scheduled time (measured on an annual basis).	80%	Met
Paper claim turnaround time – 99% of all claims processed within 10 days.	60%	Met
Claim accuracy: online claims – 100% Paper claims – 99%.	80%	Met
Phone answering time – 95% within 30 seconds.	100%	Met
Phone call abandonment – 3% or less.	100%	Met
Mail order dispensing accuracy – 99.99%.	80%	Not reported
Mail order turnaround time: No intervention – 95% in two days. Intervention – 95% in five days.	60%	Met
Pharmacy audits – perform audits of 4% of pharmacies annually and return 100% of errors uncovered to employer.	60%	Not reported
Program satisfaction is expected to be by 85% of respondents as excellent or good in surveys conducted by the PBM.	20%	Not reported
ID card delivery – mailed within 5 days of receipt of eligibility update.	60%	Met
Rebate payments – rebates paid to employer on a quarterly basis and within six months of quarter in which rebate was earned.	80%	Met
Inform client of new drugs and potential implications to employer's plan – quarterly updates and individual updates at least 30 days prior to release of expensive new drugs.	60%	Met
Preparation of ad-hoc clinical or financial reports – delivered within 21 days of request.	40%	Met
Discount guarantees – guarantee that the discount from AWP listed in proposal is actually achieved.	80%	Met
DUR cost savings – document cost savings associated with DUR programs.	20%	Not reported
Delivery of routine financial/management reports within 30 days of period to which they apply.	40%	Met
Network access – number of pharmacies or distance/time to a pharmacy.	60%	Met
Shared savings guarantees – documented achievement of proposed savings.	20%	Met

Guarantees in the areas of satisfaction surveys, ad-hoc reports, routine reports, DUR cost savings, and shared savings were included in less than 50% of the contracts of the clients contacted by PwC. Possible reasons for the lack of inclusion in client contracts are listed below:

Satisfaction Surveys – Many clients prepare a comprehensive member satisfaction survey covering all facets of employee benefits or services including PBM services. They do not want to pay the additional expense for a PBM specific survey.

Ad-hoc Reports and Routine Reports – Clients expressed the belief that due to the varying nature and difficulty of the reports requested, a standard delivery schedule would not be appropriate.

DUR Cost Savings – Due to the rare nature of this type of guarantee and the difficulty in delineating the savings, only a few clients contacted by PwC had this type of guarantee.

Shared Savings – These types of programs are rare and becoming more so.

4.3 Performance Expectations and Administrative Requirements for a Senior Population

Given that the senior population has different needs than the non-senior population, performance guarantees should reflect the requirements needed to effectively service this population. During discussions with clients, the question of how guarantees or standards should be altered to best service the Medicare population was raised, and several suggestions were made.

First, the general perception is that the customer service function will be more important for seniors, and that performance requirements for areas such as telephone service and communication be strengthened. The suggestion was also made that requirements be established mandating the training of customer service reps on issues and sensitivity concerning the elderly.

Second, because seniors are significantly higher users of maintenance drugs, they should be encouraged to use mail order services. Standards should be established to steer beneficiaries to mail order services. Similarly, significant savings can be gained by substituting generics for branded drugs. Standards should be established with respect to the percent of prescriptions dispensed as generics.

4.4 Overall PBM Performance Assessment

One of the best means of tracking overall PBM performance is by conducting annual customer satisfaction surveys. The Pharmacy Benefit Management Institute, Inc. (PBMI) conducts such a survey, and their *The 2000 Pharmacy Benefit Manager Customer Satisfaction Survey Report* presents data on current satisfaction levels, as well as trends over time. Significant findings of this survey are reported throughout this section.

Overall Satisfaction Over Time

Current satisfaction with overall service and performance of PBMs is relatively high, and these ratings have increased over time. It should be pointed out that while the majority of respondents are very satisfied, approximately 40% of respondents gave their PBM a rating of 7 or less on a scale of 1–10. [75]

Table 20: Overall Client Satisfaction with PBM Performance

Satisfaction Level	1995 % Rating	1998 % Rating	2000 % Rating
High (8–10)	49	60	61
Medium (5–7)	40	32	33
Low (1–4)	11	9	6
Average rating	7.1	7.4	7.5

Satisfaction versus Implementation Year

When satisfaction is evaluated according to the employer's start date with a PBM, employers who implemented a new PBM during the current year are least satisfied. The average rating of 7.3 for those starting with a PBM in 2000 is well under the rating score of 7.7 for employers whose plans have been in place since 1997.[76] This implies that the implementation process can be difficult.

Satisfaction with Individual Functions—Current Satisfaction Levels

Respondents to the PBMI survey were asked to rate their satisfaction with the quality of service for 18 specific functions and performance indicators. There is a relatively wide gap (2.5 rating points) between the average rating for the highest-rated function

[75] *The 2000 Pharmacy Benefit Manager Customer Satisfaction Survey Report* (Pharmacy Benefit Management Institute, Inc., October 2000): 4.
[76] Ibid., 4

(pharmacy network quality and size) and the lowest-rated function (disease management programs). Table 21 displays the five highest and lowest rated functions. [77]

Table 21: Client Satisfaction with Specific PBM Functions

Highest Rated Functions	Average Rating*
Pharmacy network quality and size	8.8
Claim processing	7.7
ID card production & distribution	7.6
Eligibility data management	7.4
Value for administrative costs	7.4
Lowest Rated Functions	**Average Rating***
Disease management programs	6.3
Utilization & benefit management consulting	6.4
Proactive account management	6.6
Dollar amount of manufacturer rebates	6.7
Plan implementation/changes	6.8

*Scale = 1-10

Satisfaction Level Trends

The PBMI survey compared the 2000 satisfaction ratings with 1999 ratings for specific functions and performance indicators. Table 22 documents the greatest changes in average rating, and indicates that the average rating for mail service pharmacy experienced the greatest decrease in customer satisfaction.[78]

Table 22: Comparative Performance 1999 versus 2000

Function	Change in Average Rating*
Mail order vendor quality and performance	–0.35
Delivering promised services	–0.18
Claim processing	–0.10
Delivering promised savings	0.11
Utilization & benefit management consulting	0.12
Disease management	0.13
Formulary management	0.14

*Scale represents difference for two years on 1-10 rating displayed in Table 19

[77] Ibid.,5
[78] Ibid.,8

5.0 CONCLUDING COMMENTS

PBMs have emerged as the national standard in the administration of pharmacy benefits in the United States. Today, in an environment of rising drug costs and utilization, PBMs manage the drug benefits of approximately 70% of the United States, including 65% of the country's seniors. The PBM's ability to reduce costs, provide national pharmacy access, and administer benefits that are customized to meet the needs of a wide range of clients in a highly automated environment attribute to the success of the PBM industry

In our discussions with the leading PBMs there was consensus that extending a drug benefit to the senior population would not have a significant impact on the industry. For the most part, PBM operations are highly automated and relatively insensitive to volume with the leading PBMs all demonstrating an ability to rapidly scale up their operations for new, large clients.

The Medicare population does however, present Congress, HCFA and the PBM industry with a set of unique challenges and opportunities. Characteristically, seniors place higher demands on PBMs than non-seniors, and have different, more complex needs. In our discussions with the leading PBMs, we found agreement on the following:

- A Medicare benefit will take longer to implement than a non-Medicare benefit. This is partly due to the effort and time expected to educate seniors on their benefit;
- Seniors take more medications than non-seniors, and use more chronic medications;
- Seniors have higher service costs than non-seniors. This is partly due to longer "talk times" into the call centers, and the need for specially trained, dedicated customer service reps;
- Seniors have different clinical needs than non-seniors. For example, drug dosing regimes and the prevalence of certain disease states change as people age.

As the possibility of extending a Medicare drug benefit moves through legislation, Congress and HCFA will need to decide how to obtain discounted pricing, the benefits and services it will offer, and whether it will use the PBM's formulary and clinical services or design its own. Ultimately, Congress will need to decide the role of HCFA and that of the PBM.

Several strategies are available to obtain discounted pricing for the Medicare population. These strategies include contracting with a PBM on a fee-for-service, risk sharing arrangement, or legislation on special pricing. Congress (or HCFA) may have the option,

to pursue legislation on special pricing for Medicare similar to that used by Medicaid to fix rebate amounts.

Among the key decisions that will need to be made is what benefits and services will be included in a Medicare drug benefit. This includes deciding the drugs that are covered, member cost sharing requirements and benefit limits (if any), size of the pharmacy network, and whether a mail service will be provided.

Opportunities to manage Medicare drug costs should also be considered. Beyond restricting pharmacy networks, limiting drug coverage and mandating generics, the benefit can be designed to incent behavior that reduces cost. For example, tiered co-pays can be structured that favor preferred medications or use of a mail pharmacy where deeper pricing discounts are available. Wellness and disease management programs, and senior specific utilization edits can also be used to control costs, improve patient care, and help prevent over prescribing.

A decision will also need to be made as to whether a Medicare formulary will be established, in lieu of using the PBM's formulary. Better rebates and admin fees could result from the creation of a Medicare formulary. Negotiating with manufacturers for position on such a formulary would likely leverage the senior population most effectively, and provide the most favorable contracts. This would also help to ensure the clinical needs of this population were met.

As it decides on the role of the PBM, HCFA (and Congress) has the opportunity to retain control over the value added, differentiating aspects of a Medicare benefit. These include formulary management and clinical control, member services, and manufacturer contracting. Medicaid and some larger insurers and managed care organizations do this. This would allow HCFA to control member services, and to ensure the value of the senior population was maximized by capitalizing on the high utilization and possible restrictive plan design of this population, thereby maximizing price discounts and rebates. In this scenario, a PBM would be contracted for administrative services such as claims processing and network administration.

The opportunity also exists to take advantage of emerging programs designed to reduce administrative costs. For example, the leading PBMs are using the Internet to provide a variety of member services such as benefit information and help locating network pharmacies. In addition, IVR (intelligent voice recognition) technology is being used to check prescription status in mail pharmacies, refill prescriptions, request forms, and meet other member needs.

Moving forward, HCFA should plan on a PBM selection process that will take 9 – 12 months. This includes establishing a selection team and clearly defining HCFA's goals and objectives. Once these steps are completed, the team will need to develop and issue an RFI, followed by an RFP. Proposal analysis, vendor presentations, site visits and reference verifications will follow, culminating in selection of the PBM.

In the last 10 years the PBM industry has grown and repositioned itself: it is now developing ambitious new programs to help clients better manage drug spending and administer benefits. Although the industry faces its challenges, the leading PBMs are generally seeing improved margins; the industry overall is expected to continue to provide valuable services to its clients. All leading PBMs such as AdvancePCS, Caremark Rx, Inc., Express Scripts Inc., and Merck-Medco Managed Care, L.L.C., insurer owned PBMs like Wellpoint, and retail chain owned PBMs like New Eckerd Health Services, as well as others, are viable candidates to help HCFA administer a Medicare drug benefit.

APPENDIX A: LIST OF EXHIBITS

APPENDIX B: GLOSSARY OF TERMS

Administrative Fees - Per claim fees paid by clients to PBMs for services like claims processing. Also used to denote the fees paid by manufacturers to PBMs for administering formulary rebate contracts.

Average Wholesale Price (AWP) – A published suggested wholesale price for a drug, based on the average cost of the drug to the pharmacy. AWP is often used by pharmacies to price prescription drugs.

Benefit Administration – The administration of drug benefit designs. It includes setting up and maintaining the drug coverage and exclusions, setting limits on drug coverages, and defining member cost sharing requirements.

Capitated Contract – A very rare contract among PBMs. It is used when a PBM agrees to assume financial risk for a client's drug spending. Capitation is a set dollar amount, established by analysis of pharmacy claims data, used to cover the prescription costs for a member, usually set at a per member per month rate (PMPM).

Claims Adjudication – The online processing of a prescription drug claim. Most claims are submitted electronically at the point of service (the retail or mail pharmacy).

Client – A MCO, employer, or insurer that contracts with a PBM to administer their drug benefits and cost control programs.

Co-pay – A fixed dollar amount paid for every prescription.

Co-insurance – The fixed percentage members pay of the cost of each prescription.

Deductible – A specific annual dollar amount that a member must pay out-of-pocket for prescription drugs before the drug benefit program begins.

Disease Management Programs – Programs developed by PBMs to identify and categorize patients (especially those with chronic conditions) and to direct these patients towards a specific treatment protocol.

Fee-for-Services Contract – The most common pricing arrangement PBMs have with their clients. Under the contract, PBMs are paid for the administrative services they provide, and they do not assume the risk for the cost of the drugs dispensed.

Formulary – An approved list of branded (and generic) drugs developed by the PBM, or the client.

- **Open Formulary** – A list of recommended drugs. Under this structure all drugs are reimbursed irrespective of formulary status. However, a client's plan design may exclude certain drugs (OTC, cosmetic, and lifestyle drugs).

- **Incented Formulary** – An incented formulary applies differential co-pays or other financial incentives to influence patients to use, pharmacists to dispense, and physicians to write formulary products.

- **Closed Formulary** – A closed formulary limits reimbursement to those drugs listed on the formulary. Non-formulary drugs are reimbursed if the drugs are determined to be medically necessary, and the member has received prior authorization.

Health Care Financing Administration (HCFA) – the federal agency that administers Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP).

Ingredient Cost – The cost to the pharmacy for dispensed drugs (AWP – discount %)

Mail Pharmacy – Mail pharmacies dispense a 90-day supply of drugs through the mail; typically used for chronic conditions. Most pharmacy benefit plans offer a mail pharmacy service as a way to promote cost savings and improve access.

Managed Care Organization (MCOs) – A broad term encompassing a variety of healthcare delivery systems utilizing group practice and providing an alternative to fee-for-service health plans. The primary goal of a MCO is to create incentives to use a prepaid and organized healthcare system that serves a defined population.

Manufacturer – A company that manufacturers branded and/or generic pharmaceuticals.

Maximum Allowable Cost (MAC) – The price basis for generic drugs which is typically 50–60% below AWP. PBMs can either set the MAC prices themselves, or use the MAC prices set by HCFA for Medicaid beneficiaries.

Member – A covered individual within a health plan.

PEPM – Per employee per month

PMPM – Per member per month; in an employer plan includes employees and their covered dependents.

Pharmacy Benefit Manager/Management (PBM) – A company providing administrative and clinical services through a complex system that includes retail pharmacies, manufacturers, clients, physicians, and members. These companies administer drug benefits and drug cost control programs for their clients, and secure substantial discounts from retail pharmacies and drug manufacturers. PBMs establish and maintain large pharmacy networks with chain and independent pharmacies. Also, PBMs contract with manufacturers of branded products to receive rebates and administrative fees.

Pharmacy Network – Specifies which pharmacies are approved for members, and includes retail, mail, and in some cases specialty pharmacies.

Prior Authorization – A prior approval process that allows prescription drugs to be dispensed to members only when specific conditions have been met.

Shared Savings Contract – A contract between a PBM and a client that provides incentives for both sides to collaborate and run the pharmacy benefit effectively and to share in the overall cost savings.

Therapeutic Substitution Programs – Typically operated in mail pharmacies to encourage physicians and patients to switch from the drug prescribed to lower cost, comparable drugs. Substitution requires physician and typically member permission.

Rebates – Paid by manufacturers to PBMs for the sale of branded drugs to PBM members.

Usual and Customary (U&C)– The price pharmacies charge to cash paying customers for prescription drugs.

Utilization Management Programs – Programs designed to lower drug costs and utilization and to encourage the use of generics or preferred products. These programs include services such as prior authorization, drug utilization review (concurrent and retrospective), academic detailing programs, and patient education.

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APPENDIX D: PBM Customer Satisfaction Survey Tool

THE 2000 PHARMACY BENEFIT MANAGER CUSTOMER SATISFACTION SURVEY

Please identify your current Pharmacy Benefit Management Company (PBM):_____

When did you start using this PBM:_____

The number of beneficiaries (employees, retirees, dependents) covered by this PBM?_____

Do you contract with this PBM directly or through a medical plan administrator such as an HMO, TPA or insurance company (circle one): **PBM / OTHER**

Rank each category by importance: LOW HIGH				**PBM Service Categories**	Rank each category by importance: LOW HIGH									
1	2	3	4	Overall service & performance	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Value for administrative cost	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Cost of the drug benefit	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Proactive account management	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Utilization & benefit management consulting	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Plan implementation/changes	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Pharmacy network quality and size	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Eligibility data management	1	2	3	4	5	6	7	8	9	10
1	2	3	4	ID card production and distribution	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Customer and member services	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Claim processing	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Management reports	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Drug utilization management	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Disease management programs	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Formulary management	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Dollar amount of manufacturer rebates	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Delivering promised savings	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Delivering promised services/capabilities	1	2	3	4	5	6	7	8	9	10
1	2	3	4	Mail order vendor quality and performance	1	2	3	4	5	6	7	8	9	10

THE 2000 PHARMACY BENEFIT MANAGER CUSTOMER SATISFACTION SURVEY

Are you (Circle one): **Extremely Dissatisfied Somewhat Dissatisfied Netural**

Somewhat Satisfied Extremely Satisfied

In what areas has your PBM shown the greatest improvement during the last year?

_____

_____

In what areas has your PBM's performance declined most during the past year?

_____

_____

Please provide additional comments about issues related to your satisfaction and PBM performance:

_____

_____