



# HOUSE JOINT MEMORIAL 98 A STUDY ON THE NEED TO REGULATE PHARMACY BENEFIT MANAGERS

A REPORT TO THE INTERIM LEGISLATIVE  
HEALTH AND HUMAN SERVICES SUB-COMMITTEE  
2005



October 19, 2005

# **The New Mexico Health Policy Commission**

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October 19, 2005

Dear Honorable Danice Picraux, New Mexico House of Representatives, Chairperson and Members of the Interim Legislative Health and Human Services Committee:

The New Mexico Health Policy Commission presents this report on House Joint Memorial 98 to the Legislative Health and Human Services Sub-Committee on pharmacy benefit managers and their impact on New Mexico. The thirteen member task force researched and discussed the memorial's resolutions to study the need to regulate PBMs, and made its recommendations following six intensive work meetings.

The Health Policy Commission thanks the legislature for giving us the opportunity to convene the task force and to lead this research task force.

We also thank the task force members, who committed their time to participate fully and worked diligently on this controversial and difficult topic to arrive at a solution that would best serve New Mexicans.

Sincerely,

A handwritten signature in black ink, reading "Patricio C. Larragoite DDS".

Patricio C. Larragoite, DDS  
Executive Director

A handwritten signature in black ink, reading "Leticia M. Rutledge".

Leticia M. Rutledge  
HJM 98 Project Coordinator

**HOUSE JOINT MEMORIAL 98  
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Denise Cuellar	National Association of Chain Drug Stores
Luis Hernandez	Consumer
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## EXECUTIVE SUMMARY

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During the 2005 Regular Session of the Forty-Seventh Legislature, the legislature adopted House Joint Memorial 98 (HJM 98) which directed the Health Policy Commission (HPC) to convene a task force to study the need for regulation and oversight of pharmacy benefit management (PBMs) companies. PBMs administer and manage prescription drug benefit programs for managed care organizations, employers, unions, preferred provider organizations, Medicaid, and other state programs. The task force members represented various stakeholders: pharmacy benefit managers, consumers, state agencies, health plans, retail chain pharmacies, and independent pharmacists.

Through several presentations, research, and sharing of literature, the task force educated itself on the healthcare role of PBMs - their value and impact for employers, health plans, consumers, and pharmacies. Local and national perspectives were presented, some objective and some subjective. The task force addressed PBM-related legislation from other states, current litigation facing several large PBMs, issues of confidentiality, and contract responsibilities.

In order to gather client insights and experiences of working with PBMs, the HPC staff invited small and large employers to participate on the committee as members or to provide presentations during the meetings. Except for a few PBM-related experiences as reported by one of the presenters, an insurance broker that represented several small employers, other small employers contacted by the HPC said that they did not contract directly with PBMs. The three major managed care organizations were contacted, of which the two that responded said that their own internal PBMs provided satisfactory services. Several rural and urban community health centers were contacted of which only one center responded; saying that they did not contract directly with PBMs. Several state agencies were contacted, and agreed that the task force representative from the General Services Division represented their interests as well.

For the purpose of gaining a national perspective, the HPC contacted several states in which PBM legislation had been introduced and received personal responses from North Dakota and South Dakota.

During its work, the task force offered strong evidence on the positive and negative aspects of implementing new or expanding current regulations. Some members strongly believed that regulation of PBMs is necessary, and other members strongly believed that regulation is not necessary. In the end, the task force could not reach a consensus on whether or not to regulate pharmacy benefit managers.

Part of the reason that the task force could not reach a consensus might be attributed to the lack of strong evidence in which to make that decision. During the task force process, certain issues became evident as problematic. First, there was ongoing confusion on where to place the accountability and responsibilities for prescription drug coverage concerns, e.g., health plans/employers versus PBMs. Second, task force members agreed that contract negotiations between potential clients and PBMs could be confusing and that some clients might not realize their options and/or rights in the negotiating process. The task force could never learn from existing sources exactly how many PBMs actually have business in New Mexico, and with whom. Due to lack of sufficient time, the task force could not determine the extent in which current New Mexico laws might already be providing

sufficient protection for PBM clients and consumers, i.e., the Department of Insurance and the Board of Pharmacy have some regulations in place that may directly or indirectly relate to PBMs.

Based on these findings, the task force asks the 2005 Legislature to consider the following recommendations:

- Develop and implement a registry of active pharmacy benefit managers in New Mexico.
- Educate the general public to reduce confusion between the responsibilities of a health plan/employer and the responsibilities of pharmacy benefit managers.
- Promote education on available negotiating options between contractors and pharmacy benefit managers.
- Delegate, through a future memorial, that the Health Policy Commission further research and analyze PBM activities and existing federal and state laws that regulate PBMs.

The Health Policy Commissioners support the task force recommendations in addition to adding the following:

- All PBMs should be registered in New Mexico through an application process which would include: 1) a description of how PBMs will educate the public about their role and the prescriptions that are covered, 2) disclosure of administrative costs and profits.
- PBMs should develop a standardized formulary.

## BACKGROUND

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Pharmacy benefit managers initially entered the healthcare market as service oriented companies, hired to manage pharmacy benefits and to reduce pharmacy costs through price breaks on volume discounts. As the “middle man” between pharmaceutical companies and employers, it was anticipated by PBM clients that PBMs would be able to hold down drug prices through negotiated discounts and their pharmaceutical networks. According to various sources, an estimated forty to sixty PBMs administer drug plans nationwide of which three companies control approximately seventy percent of the business (Caremark Rx, Express Scripts, Inc., Medco Health Solutions).<sup>1234</sup>

Today, many PBMs are a strong competitive force, owning their own profitable mail order companies and expanding their business beyond administering claims processing. As drug prices continue to climb PBMs are being critically questioned about the savings they claim to be producing for their clients. Viewpoints are strong from both factions on the benefits of PBMs and the potential harm they may be creating. In order to gain a better understanding of PBMs and their impact on consumers, House Joint Memorial 98 was introduced and assigned to the New Mexico Health Policy Commission to study the pros and cons of PBMs and whether there is a need to regulate them in this state.

HJM 98 was a result of insufficient clarity on what role PBMs may have in the rising costs of prescription drugs and their subsequent effects on New Mexico constituents. To elucidate the role between pharmaceutical companies, pharmacy benefit managers and their clients, the volunteer HJM 98 task force was asked to address the following directives:

- Evaluate the various administrative and corporate structures of pharmacy benefit managers;
- Identify and create a graphic representation of the pricing structure of prescription drugs, including the various levels at which rebates, discounts and other incentives are offered;
- Evaluate the necessity for regulation of pharmacy benefit managers;
- Study the extent to which pharmacy benefit managers interact with covered individuals and the value and propriety of those interactions;
- Evaluate the positive and negative aspects of disclosure of financial and utilization information;
- Include a complete listing of the approaches other states have taken in regulating the pharmacy benefit manager business, including the status of current legal actions.

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<sup>1</sup> US Action, “Pharmacy Benefit Managers: Health Care Cost Containment or Consumer Rip-Off?” Corporate Truth Squad Alert #12. 13 August 2004. Found at [http://www.usaction.org/site/pp.asp?c=eiJPJ5\)VF&b=139398](http://www.usaction.org/site/pp.asp?c=eiJPJ5)VF&b=139398)

<sup>2</sup> Russell C. Ring, “PBM Industry Overview.” Presentation to the HJM 98 Task Force, 7 July 2005.

<sup>3</sup> Robert Atlas, “The Role of PBMs in Implementing the Medicare Prescription Drug Benefit,” *Health Affairs*, 28 October 2004.

<sup>4</sup> “Improving Health Care: A Dose of Competition.” A Report by the Federal Trade Commission and the Department of Justice. July 2004.



## ENVIRONMENTAL SCAN

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### Literature Research

The literature on pharmacy benefit managers appears to be evenly distributed between the positive and negative aspects of the services PBMs provide. The literature across the board, whether for or against PBMs, acknowledges the value of the administrative support services they provide to their clients. Of the 40 to 60 PBMs in business, three of them own at least seventy percent of the PBM business as a whole and it is primarily the three larger PBMs that have received the most attention regarding their business practices. The major concern surrounds financial transparency. The larger PBMs (Medco Health Solutions, Caremark Rx, and Express Scripts) are perceived by some as withholding pertinent financial information from clients, pharmacists, consumers and others. There is an increasing trend among various PBMs toward greater financial transparency based on client demand. Several small and larger PBMs advocate and provide fuller access to a fully transparent model.

PBMs administer prescription benefit programs for health management organizations, government (state, federal and local), employers, unions, preferred provider organizations and other health plans. They also develop drug formularies to help manage and control costs.<sup>5</sup> PBM revenues are generally derived by administering the prescription benefit portion of health plans (e.g., processing and paying claims), disease management and drug utilization reviews (DUR), and specialty pharmacies. Revenues are also generated through profits from the mail-order prescription drugs they sell and from pharmaceutical company rebates.<sup>6</sup>

The literature shows that during the last decade, PBMs have evolved into a new realm of business that has become increasingly profitable for them. According to the Pharmaceutical Care Management Association (PCMA), PBMs not only administer drug benefits, some also own and manage mail-order pharmacy services, provide real-time electronic claims adjudication, and negotiate discounts from pharmaceutical manufacturers and pharmacies. According to a recent report by the Federal Trade Commission, a survey conducted for annual years 2002 and 2003 of 26 PBM-health plan sponsor contracts resulted in the FTC's conclusion that PBM-owned mail order pharmacy drug costs were typically lower than at non-PBM-owned mail order pharmacies, and that PBM-contracted plan sponsors generally paid lower prices for drugs purchased through PBM-owned mail-order than through non-PBM retail or mail order services.<sup>7</sup> The FTC cites other PBM services include drug utilization reviews and education programs designed for physicians and consumers to reduce costs and add quality to drug management.

Concerns about PBMs surround their business practices, mergers and consolidations, which has resulted in three national firms dominating the PBM market; Caremark Rx, Medco Health Solutions, and Express Scripts, Inc. Their combined revenues in 2004 were approximately \$80 billion<sup>8</sup> An

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<sup>5</sup> Remarks by the Pharmaceutical Care Management Association to the House Committee on Ways and Means, 18 March 2004

<sup>6</sup> Coalition for Quality Healthcare, found at [www.pharmacychoices.org/PFAQ.html](http://www.pharmacychoices.org/PFAQ.html)

<sup>7</sup> "Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies." Federal Trade Commission. August 2005.

<sup>8</sup> Robert Atlas, "The Role of PBMs in Implementing the Medicare Prescription Drug Benefit," *Health Affairs*, 28 October 2004.

estimated 200-250 million Americans receive prescription drug benefits managed by the three PBMs, according to the PBM representatives on the task force. PBMs own, manage, and profit from their own mail order prescription drug services; conduct utilization reviews; and provide recommendations for health plan formulary list decisions based on recommendations by their Pharmacy and Therapeutics (P&T) committees. Another concern is that, unlike other healthcare professionals and businesses, PBMs, while regulated in certain aspects, are not regulated as a whole by the federal government.

The following publications written by nationally recognized sources support the thesis that PBMs provide cost-effective prescription drug benefits, which subsequently benefit the consumer. Other than a small reference of the estimated impact of PBMs in New Mexico in a 2004 PricewaterhouseCoopers report, no other studies were found regarding the activities and impact of PBMs in New Mexico.

1. The 2002 Congressional Budget Office (CBO) report, Issues in Designing a Prescription Drug Benefit for Medicare, concluded, among other findings in their analysis of four prescription drug proposals, that PBMs could save up to 30% in total drug spending relative to unmanaged purchases of prescription drugs through the use of discounts, rebates and other utilization management tools.
2. The 2003 U.S. Government Accountability Office (GAO) report, Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies, found that PBMs save a substantial amount of money through pharmacy price discounts, rebates from pharmaceutical manufacturers, and cost/care management techniques.
3. The 2004 PricewaterhouseCoopers (PwC) analysis, The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation, estimated that PBMs save private benefit plans 25% of costs through their management interventions.
4. The 2004 U.S. Federal Trade Commission report, Improving Health Care: A Dose of Competition, recommended that states should consider the potential costs and benefits of regulating PBM transparency, supporting "vigorous competition in the marketplace" to "arrive at optimal level of transparency" rather than regulation of transparency.
5. A 2004 response by the U.S. Federal Trade Commission to a request for comments on the competitive effects of California Assembly Bill Number 1960 concluded that mandating disclosure of information by PBMs could undermine competition and increase the cost of pharmaceuticals and health insurance premiums which would create a burden on consumers.
6. A similar response was provided in 2005 by the U.S. Federal Trade Commission on North Carolina House Bill 1374, regarding disclosure of financial information regarding rebates and other incentives received from pharmaceutical companies. The Commission stated that the passage of the bill could result in hindering competition, which could penalize consumers who might not be able to obtain the drugs or health insurance they need due to the cost increases that would result. The Commission stated that there was no evidence to prove that revealing aspects of cost structure would improve market outcomes, and that the risk of collusion among pharmaceutical companies could be more likely if they learned of the amount of rebates being offered by their competitors.

### **Challenges to the reports**

The above mentioned literature provides scientific evidence that PBMs provide a wealth of valuable services and cost savings to their clients and consumers. The healthcare industry acknowledges the value of PBMs, yet there are widening concerns that PBMs may be abusing the system they are trying to serve. The validity of the findings in the GAO and PwC reports has been challenged by

task force members and the National Community Pharmacists Association (NCPA) as skewed data or conflict of interest. A study by Robert I. Garis, a grant recipient of an NCPA research grant, challenged that mail order pharmacies “may not be a ‘bargain’ when compared with community” pharmacies<sup>9</sup>, and that PBMs may be practicing “spread pricing” – charging their clients “a higher price for a drug than the PBM pays the pharmacy for the same drug.”<sup>10</sup>

The GAO admittedly used selected data that was provided by the PBMs and stated in its report that it “did not independently verify information provided by the plans, PBMS or pharmacies.” The GAO study did not investigate rebates that the PBMs receive, did not verify any prices, and stated that it did not “address the overall PBM industry and how it operates, including special economic relationships that may exist between some manufacturers and PBMs.” As assigned, the report focused on federal employee health plans and not on a large fraction of PBM covered populations that have non-federal coverage.

Other challenges by task force members include that the PwC analysis was conducted under contract with the Pharmaceutical Care Management Association (PCMA), the trade association of the PBM industry. The 2004 U.S. Federal Trade Commission report on improving healthcare makes reference to the GAO report in reaching its own conclusions. While the GAO report may be a well respected report, as said earlier, the report itself admits to certain research limitations.

The National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS) have taken a stand that PBMs need to be regulated due to documented claims of PBMs issuing prescription drug substitutions without prescribers’ authority among other allegations and investigations.

Ten state legislators, members of the National Legislative Association on Prescription Drug Prices (NLARX), wrote to the Federal Trade Commission concerning its advocacy against state regulation of PBMs, stating that, “Unfortunately the FTC has chosen to either stay on the sidelines or advocate on behalf of the PBM industry, instead of consumers.”<sup>11</sup>

Rapidly rising healthcare costs - prescription drug prices in particular - and the attempt to understand the causes behind those costs, has stimulated questions and suspicion among consumer advocates, legislators, pharmacists, and others as to how much of the increases might be related to PBMs and their interactions with pharmaceutical manufacturers. Allegations and concerns have surfaced that, while PBMs state that they contractually offer their clients the best prices that they can, concerns that PBMs do not provide financial transparency raises suspicions that PBMs might not actually be providing them with the best possible price. While PBMs insist that they offer financial transparency to the clients they serve if the contracts indicate that specification, several task force members asserted that, according to claims from their stakeholders, PBMs make this process a difficult and time consuming effort for them. HJM 98 task force members maintain that this results in clients giving up and giving in. Some legislators and consumer advocates argue that PBMs favor more expensive drugs over generics, or less expensive drugs, to reap the rebate benefits provided by

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<sup>9</sup> Robert I. Garis, RP, MBA PhD, Alladin Mohammed, PharmD (Candidate), “Mail Order Prescription Pricing: A Critical Examination.”

<sup>10</sup> Robert I. Garis, RP, MBA PhD, Farrukh Syed, PharmD (Candidate). “Spread Pricing in the Prescription Benefit.”

<sup>11</sup> “Legislators Write FTC Urging Regulation of Prescription Drug Middlemen,” National Legislative Association on Prescription Drug Prices. Media Release. 6 May 2005

pharmaceutical companies, yet it appears that the FTC's report on PBM-owned pharmacies may negate this claim. Retail pharmacies contend that PBMs pay "too little for both dispensing and ingredient costs" and that PBMs steer prescription volume to mail-order pharmacies.<sup>12</sup>

## Approaches of Other States

Several states have taken steps in recent years to ensure that pharmacy benefit managers are working in the best interest of their clients. While regulations are in place in some states to control violations such as inappropriate drug switching, allegations of unscrupulous PBM business practices continue to be made public, spurring the desire on the part of some interest groups to implement more stringent laws to control future allegations of such practices. Legislative initiatives include regulations that mandate fiduciary responsibilities, state and/or pharmacy board oversight and monitoring, and disclosures of financial terms and arrangements to ensure more accountability.

Georgia, Maine, Maryland, North Dakota, South Dakota, and Washington, D.C. have passed new laws or modified existing laws to regulate various aspects of PBM operations. Regulation bills failed to pass in 2005 and previous years for numerous states: Colorado, California, Connecticut, North Carolina, Texas, Pennsylvania, Mississippi, Illinois, Louisiana, Florida, Hawaii, Michigan, Alabama, Arkansas, Minnesota, Iowa, New Jersey, South Carolina, and Vermont.

The six states that have recently introduced or appended laws to regulate PBMs and/or improve reporting measures appear to share similar regulation language among them. The District of Columbia, Maine, and North Dakota require PBM fiduciary and/or administrative responsibilities. PBM licensure or registration is required in Georgia, North Dakota, and South Dakota. Notification of any conflict of interest is required in the District of Columbia and Maine. Disclosure of financial and discount information is required in the District of Columbia, Maine, North Dakota, and South Dakota. Protection of disclosed information by PBMs is classified as confidential in District of Columbia, Maine, North Dakota, and South Dakota. Other language covers auditing procedures, guidelines for substituting drugs, provisions for options, and providing status reports to the legislature or other designated entity on an annual or other designated time schedule. An interim injunction against the District of Columbia was filed by the Pharmaceutical Care Management Association in December 2004 which halted implementation of the law. Maine also faced a preliminary injunction but the Court later ruled in favor of the State. See Appendix B.

Limited evidence of studies was found on PBM related bills in other states. Of numerous states that were contacted by the HPC regarding their legislative process, only two personally responded. A spokesperson in South Dakota said that a study would be conducted in late 2005, after the fact that their PBM bill was signed by the Governor. A Division of Insurance spokesperson in North Dakota cited frustrating issues related to communication and financial transparency requests with PBMs during their insurance benefit negotiations that eventually led to legislation.

A report written by the Colorado Department of Regulatory Agencies analyzed and evaluated the need to regulate PBMs in Colorado. The Department conducted its study similar to the methods used by the HJM 98 task force. In addition, the study included a survey of physicians and pharmacists. It appears that concerns about PBMs in Colorado were similar to concerns in New

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<sup>12</sup> Robert Atlas, "The Role of PBMs in Implementing the Medicare Prescription Drug Benefit," *Health Affairs*, 28 October 2004

Mexico. The conclusions of the report indicated that there was no evidence of harm being done to Colorado residents, physicians or pharmacists, and that sufficient protections existed through current laws and regulations.

Reasons for and against regulation are many, but financial transparency issues seem to be at the heart of concerns. PBM legal representatives argue that “contemplating imposing fiduciary and disclosure requirements on PBMs (is) unworkable, invalid, and unconstitutional.”<sup>13</sup> The Pharmaceutical Care Management Association has said that disclosing contract deals between PBMs and pharmaceutical manufacturers “violates PBMs’ trade secret rights.”<sup>14</sup> The National Community Pharmacists Association states that transparency would identify potential conflicts of interest and provide a clear roadmap on any savings earned through rebates and discounts.<sup>15</sup>

In addition to legislative initiatives, coalitions have formed in recent years to empower employer’s access to PBM pharmaceutical purchasing and discount information. Rx Collaborative encourages financial transparency in PBM contracts, and began with six employers in the summer of 2004 and has grown to 30 employers as of spring 2005.<sup>16</sup> The Wall Street Journal reported in August 2005 that the coalition of 52 out of approximately 200 employers, representing over five million beneficiaries, united to endorse a purchasing model for PBMs that would standardize the reporting of acquisition costs and rebates for mail order and generic prescriptions. Vendors willing to conduct business under the purchasing model include Walgreens Health Initiatives, Inc., MedImpact Healthcare Systems, Inc., and Aetna Pharmacy Management<sup>17</sup>.

## Status of Current Legal Actions

The nation’s largest PBMs are facing litigation and/or investigation related to issues such as the federal false claims act, antitrust and unfair competition, deceptive practices, and their roles as fiduciaries. While PBMs claim that many of these suits are untrue allegations and unsubstantiated, a number of private and public companies have sued or are suing PBMs. Among the suits are allegations of wrong doing that took place with AdvancePCS prior to being acquired by Caremark Rx, Inc. A settlement was reached on September 8, 2005, with no implications of misconduct and no admission of wrongdoing by AdvancePCS or Caremark Rx.<sup>18</sup> Some of the other plaintiffs include:<sup>19</sup>

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<sup>13</sup> Pharmaceutical Care Management Association, “US District Court Blocks PBM Disclosure-Fiduciary Requirements of DC’s Access Rx Act from Taking Effect. Injunction Protects District Residents from 10 Percent Hike in Prescription Drug Costs,” Press Release, 22 December 2004. Found at [http://www.pcmnet.org/newsroom/pr\\_04/pr\\_122204.htm](http://www.pcmnet.org/newsroom/pr_04/pr_122204.htm).

<sup>14</sup> Managed Care Magazine, “Transparency Catches Eye in Coalition’s Deal with Medco,” Managed Care March 2005. Found at [www.managedcaremag.com/archives](http://www.managedcaremag.com/archives) on August 2005.

<sup>15</sup> Reginia Benjamin, Presentation to the NM Health Policy Commission Pharmacy Benefit Managers Task Force. 29 July 2005.

<sup>16</sup> Managed Care 2005. “Transparency Catches Eye in Coalition’s Deal with Medco.” Found at [www.managedcaremag.com/archives](http://www.managedcaremag.com/archives) in August 2005

<sup>17</sup> HR Policy Association, “HP Policy Association Pharmaceutical Purchasing Coalition.: 8 August 2005. Found at [www.hrpolicy.org](http://www.hrpolicy.org)

<sup>18</sup> Business Wire. “Caremark Rx, Inc. Subsidiary AdvancePCS Settles with U.S. Government with no Admission of Wrongdoing,” 8 September 2005.

<sup>19</sup> Pharmacy Benefit Management Companies Attempt to Scuttle Consumer Choice, Alexandria, Virginia - Press Release, August 03, 2005 The National Community Pharmacists Association (NCPA)

- State attorneys general from 20 states (sued Medco Health Solutions for drug switching practices)
- American Federation of State, County & Municipal Employees
- National Community Pharmacists Association and the Pharmacy Freedom Fund
- Peabody Energy Corporation
- Northwest Airlines Health Plans
- United States Attorney, Eastern District, Pennsylvania
- The State Teachers Retirement System of Ohio
- Chicago District Council of Carpenters Welfare Plan
- The Vermont State Auditor

Medco Health Solutions reached an agreement with the 20 state attorneys general by adopting or expanding its business practices to be more cognitive of, among other issues, the need for its clients and consumers to be aware of any therapeutic interchanges (i.e., switching from one brand drug to another brand drug or to a chemically distinct generic drug). There was no admission or finding of inappropriate business conduct. The state attorneys general were quoted as being satisfied with the outcome, saying that they hoped that a “gold standard” was being set on how PBMs should operate.

According to a press release by Kaisernetwork.org on June 1, 2005, Arkansas, Florida, Tennessee, and Texas were joined by the Department of Justice in a lawsuit that alleged that Caremark Rx “knowingly” avoided or decreased reimbursements for dual-coverage Medicaid beneficiaries, According to the article, Caremark Rx officials refute the claims.

California Public Employees’ Retirement System (CalPERS), second to the federal government as the biggest buyer of health care benefits, is involved in a false-claim lawsuit with Caremark Rx for illegally restocking returned drugs and reselling them. Other charges include “secretly delaying, changing and canceling drug orders, then falsifying turnaround time to avoid contract penalties for slow service.”<sup>20</sup>

Facing a New York suit, Express Scripts denied allegations that it had defrauded New York state employees out of over \$10 million, saying that they had saved the state \$2 billion since 1998.<sup>21</sup>

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<sup>20</sup> The National Community Pharmacists Association (NCPA). “Pharmacy Benefit Management Companies Attempt to Scuttle Consumer Choice,” Press Release, 3 August 2005.

<sup>21</sup> Robert Atlas, “The Role of PBMs in Implementing the Medicare Prescription Drug Benefit,” *Health Affairs*, 28 October 2004

## The Extent to Which Pharmacy Benefit Managers Interact With Covered Individuals and the Value and Propriety of Those Interactions

PBMs generally do not contract directly with covered individuals; instead they contract with commercial health plans, private and public employers, insurers, unions and other entities that are providing prescription drug benefits to their employees or members.

All interactions with covered individuals are governed by the terms of the contracts between the PBMs and their clients. The clients determine what programs they want to offer to their employees/members, what activities they want the PBM to undertake, and what communications they want their employees/members to receive about those programs, and whether those communications will come from the PBM or the client. The clients have approval rights as specified in the contract before any information materials are sent out.

Some clients maintain their own customer service centers and handle all customer service-related inquiries from covered individuals related to the pharmacy benefit that the PBM is managing, other clients contract with the PBM to handle all customer service inquiries. Covered individuals generally have access to customer service representatives and relevant information through a toll-free number and/or a website.

If the client has contracted with the PBM to provide mail-order pharmacy services, then those services are provided by mail order service pharmacies which are usually subsidiaries of the PBM parent company. These mail order pharmacies are licensed as domestic pharmacies by the Boards of Pharmacy in the states in which they're located, and as non-resident pharmacies by those states that have such statutory requirements (including New Mexico). The prescriber or the covered individual submits a new prescription to the mail order pharmacy, which verifies for eligibility, potential drug interactions, and other checks, and then the pharmacy dispenses the drug. This is true for any pharmacy. The covered individual usually has multiple options for ordering any refills that the prescriber has authorized through toll-free customer service numbers, websites, fax or mail.

According to the PBM task force members, in the course of dispensing the prescription, the pharmacist at the mail service pharmacy may have various interactions with the covered individual and the prescriber, including determining appropriate therapy (*e.g.*, to avoid potentially harmful drug interactions) and formulary compliance. All such interactions are conducted in accordance with applicable pharmacy practice acts, the client contracts and/or other applicable legal or regulatory requirements.

In addition to the client contracts and state pharmacy laws, interactions between PBMs and covered individuals are also subject to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and any applicable state privacy laws. All pharmacies, hospitals, and healthcare providers are required to comply with HIPAA

## The Positive and Negative Aspects of Disclosure of Financial and Utilization Information

The task force provided the following opinions about the positive and negative aspects of disclosing financial and utilization information. The opinions do not necessarily reflect a consensus.

### Factors in Disclosing Financial Information

Positive Aspects	Negative Aspects
Understanding financial trails (money flow)	Placing requirements on PBMs that are not required by other entities
Freedom of choice	Confidentiality loss for PBMs and clients
Increase consumer's decision making	Trade secret loss for PBMs and clients
Increase access to medication	Negotiating loss for PBMs and clients
Recognize conflicts of interest	Unknown benefit to consumers
Validate rebates	Concerns of contracts interference as a matter of law
Increase satisfaction of clients	Increased costs for pharmaceuticals
Actual costs of services, products and drugs	
Understand mechanism for discounts	

### Factors in Disclosing Utilization Information

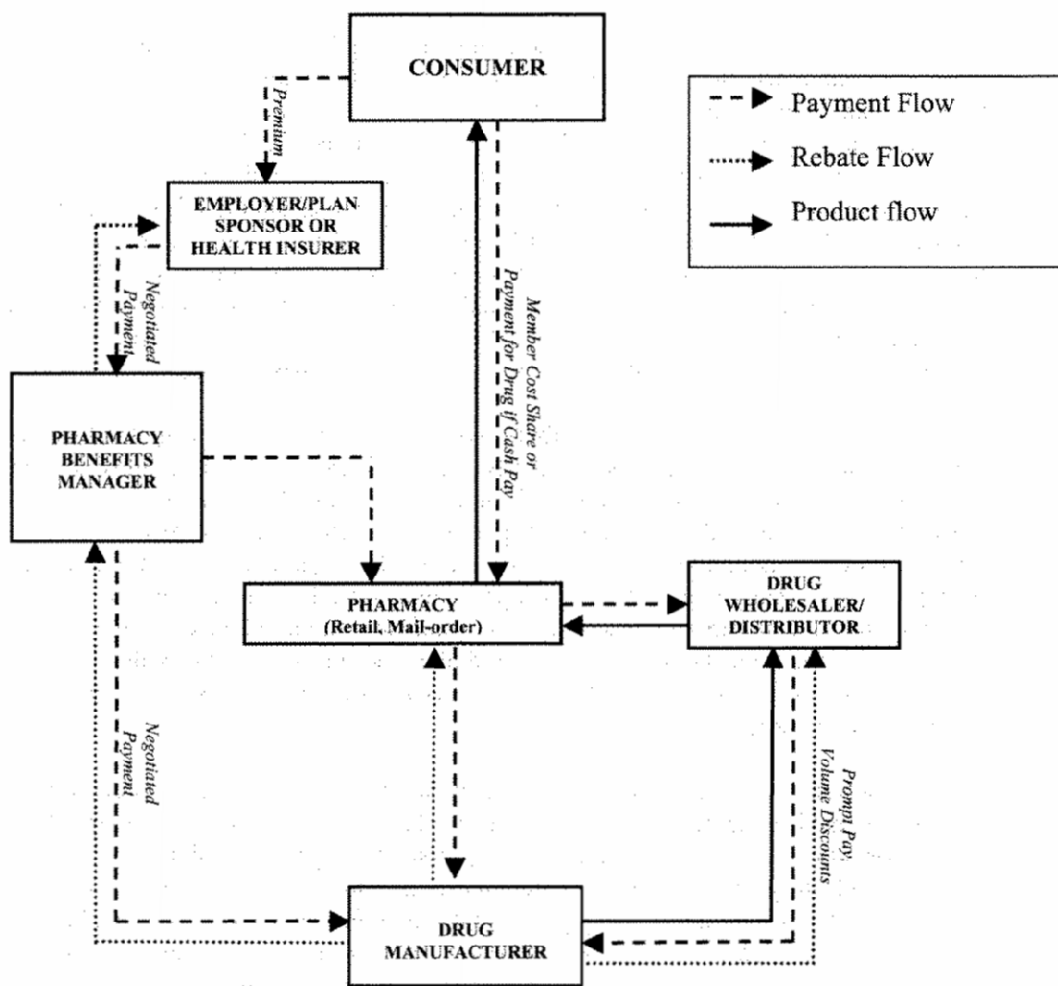
Positive Aspects	Negative Aspects
Coordination and quality of care	Potential HIPAA conflict
Managing health disease	Limited benefit without financial utilization
Managing effectiveness of treatments	Potential misuse/misinterpretation by stakeholders
Identifying provider over/under utilization	
Appropriateness of drug use	
Evaluate customer education/outreach	
Program effectiveness	

## A Graphic Representation of the Pricing Structure of Prescription Drugs, Including the Various Levels at Which Rebates, Discounts and Other Incentives are Offered

Every pharmacy benefit manager company has its own variety of structure, rebate mechanisms, incentives and discounts. Below are two generic samples of how PBMs may generally be structured.

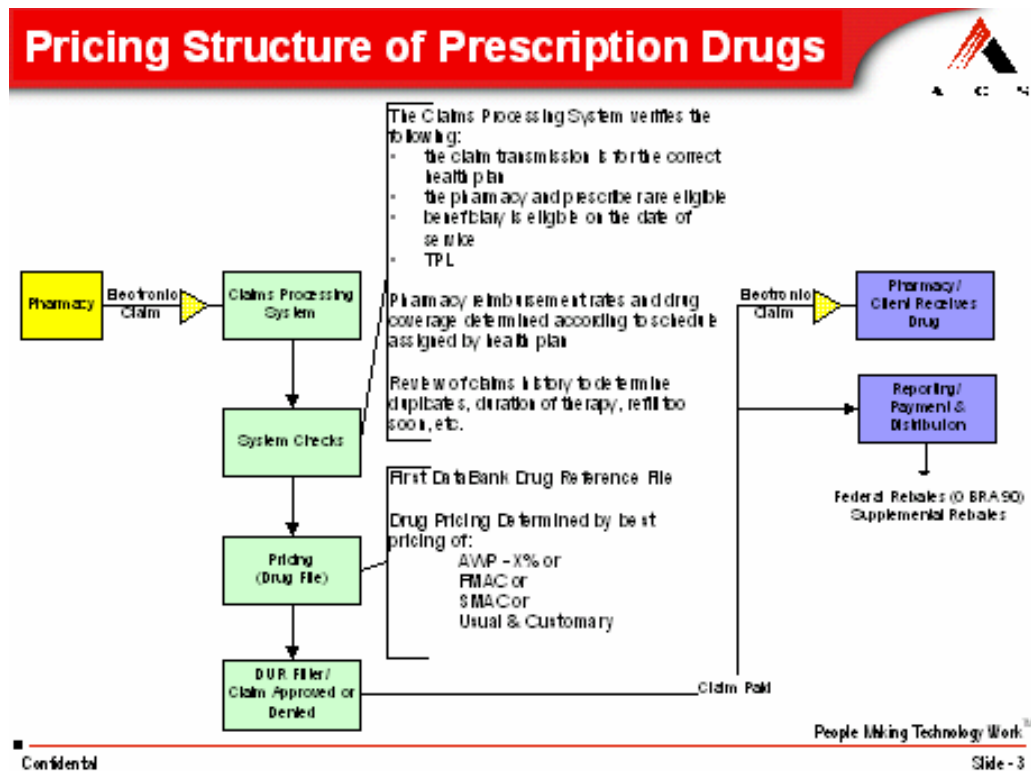
The graph below borrowed from “Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain” for the Kaiser Family Foundation, March 2005.

**Exhibit 1. Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain**



Source: The Health Strategies Consultancy LLC

Graph courtesy of ACS Government Healthcare Pharmacy Benefit Management, Presentation to the HJM 98 Task Force, July 7, 2005



See Glossary for definitions of abbreviated terms.

Based on the request of fellow task force members, one task force member offered this explanation of available rebate structures between PBMs and their clients.

#### Typical Manufacturer Rebate Contracts

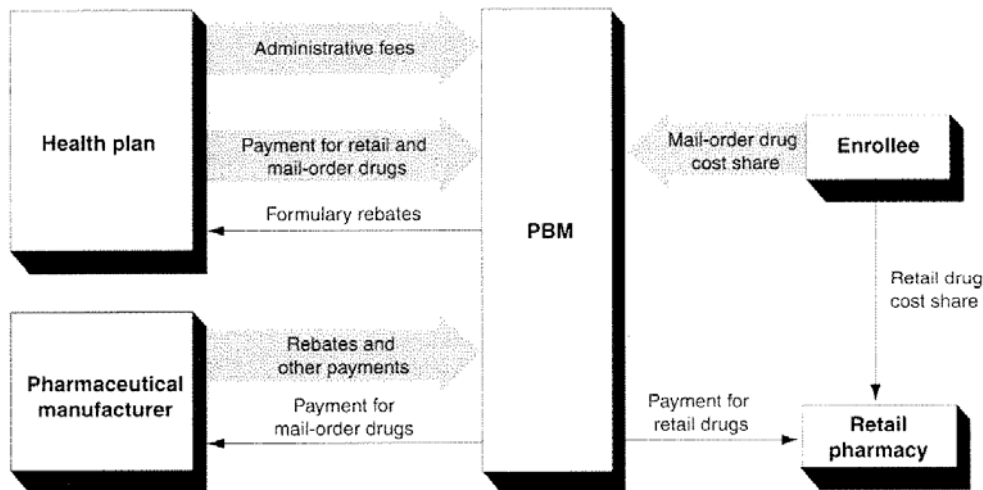
- **Access Rebates:** Apply to any drug that is included on the drug formulary.
- **Access Contracts:** Require only that the PBM place the product on the formulary. These are used by PBMs to promote appropriate utilization of high cost or over utilized drugs and may include quantity limits or step therapy programs. These contracts may make future formulary changes more difficult once the contracted drug gains market share and new, less costly products enter the market.
- **Market Share Incentive Based Contracts:** Provide for a greater return based on the level of market share achieved. Contracts are frequently associated with limited placement restrictions. Contracts may require PBMs to implement programs to help move market share of the product. Drugs with this type of contract need to be clinically sound and not over priced in the class.
- **Limited Placement Contracts:** Require the PBM to limit the number of competitor products on the formulary to receive the rebate.
- **Bundled Contracts:** Stipulate that rebates for a particular drug are provided only with the addition of other drugs to the formulary. Failure to add to these products could result in total loss of rebates or loss of incentive rebates.

## The Various Administrative and Corporate Structures of Pharmacy Benefit Managers

There are an estimated 40 to 60 PBMs operating in the U.S. today, each with varying levels of administrative and corporate structures. None of the PBMs are owned by pharmaceutical companies. Some PBMs own and manage mail order companies through subsidiaries. Some large insurers and/or managed care plans manage pharmacy benefits internally, rather than contracting those services out to an independent PBM. Examples include Kaiser, Aetna, Cigna, Wellpoint and PacifiCare. A number of retail chain drug stores operate PBMs which includes but is not limited to PharmaCare Management Services (a subsidiary of CVS Corp.), RxAmerica (a subsidiary of Longs Drug Stores Corp.), and Walgreen's Health Initiative (a subsidiary of Walgreen Co). Independent pharmacists have gone into the pharmacy benefit management business through their national trade association, the National Community Pharmacists Association (NCPA).

The following graph, borrowed from the GAO report on pharmacy benefit managers<sup>22</sup> is a representation of compensation and payment processes.

**Figure 3: Overview of PBMs' Compensation and Payment Sources**



Source: GAO analysis of plans and PBMs reviewed.

Note: The extent to which a PBM receives compensation and payments from any one of these sources varies based on its contractual arrangements with plans and manufacturers. For example, some PBMs may contract with a separate entity to provide mail-order services.

<sup>22</sup> United States General Accounting Office (GAO) report to the US Senate. Federal Employees' Health Benefits; Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies. January 2003

With the passage of the Medicare Modernization Act (MMA) of 2003, organizations may seek the services of pharmacy benefit managers to administer this new prescription drug benefit, also known as Medicare Part D. The federal government will contract with private entities manage the prescription drug benefit on behalf of the federal government. The prescription drug benefit is a voluntary prescription drug program for those who are eligible for Medicare. The level of involvement for PBMs may be as a stand alone private drug plan (PDP), partner with insurance company as PDP, participate as a health plan owned PBM (within PBM corporate structure may use own insurance license), or support Managed Medicare plan or stand alone PDP.

Under the MMA, states may license Medicare Part D plans as risk bearing entities eligible to offer health insurance or health benefits coverage.

## The New Mexico Experience

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Scientifically based data and research specific to New Mexico on the number of lives covered by PBMs and the relationships between PBMs and their clients is difficult to obtain. Based on presentations given by state, county and private small employer representatives, the task force learned the following:

- According to a PricewaterhouseCoopers report an estimated 1,063,000 New Mexicans will receive PBM administered prescription drugs in 2005
- The Interagency Benefits Advisory Committee (IBAC), a coalition of four large New Mexico state organizations, covers approximately 174,175 lives.<sup>23</sup>
- Small employers rarely conduct business directly with PBMs; generally depending on their selected health insurer to choose the PBM for them. Based on data from a local insurance broker, approximately 1,000 small Santa Fe area business employers provide coverage for an estimated 10,000 lives, of which all receive prescription drug benefits.
- San Juan County provides healthcare coverage for an estimated 500 county employees. Including family members, an average of 1,300 lives have prescription drug coverage through the county's benefits.
- The number of Medicaid clients utilizing a PBM is 415,922.

Two different government and state agencies, the General Services Division (GSD) Risk Management Division and San Juan County, said they are unaware of problems experienced with their PBMs; provision of services has been good, and few employee complaints have been filed. GSD reported that during the past year they received 10 appeals for a specific issue, all of which were resolved through member and/or provider education. According to the insurance broker, a small number of employers have filed complaints and/or grievances with the Department of Insurance, but the majority of insurance contracts have been able to accommodate the needs of their clients.

Since local data is scarce, positive testimonies and negative concerns stemmed from personal experiences, second hand or anecdotal information, references to published reports and documented out-of-state allegations and litigation. Unlike in some other states, neither the New Mexico Board of Pharmacy (BOP), or the Department of Insurance (DOI), or any other government entity have any direct regulation or monitoring authority over PBMs other than indirect regulation through managed care organizations (DOI) and regulatory control over pharmacists and mail order companies (BOP). Consumers, pharmacists and other health professionals might make complaints to various boards, associations, and offices, but it appears that complaints generally do not go beyond those initial places because there may be no definitive regulation or standard or centralized forum in which PBM issues can be addressed; there might not be a clear understanding of available legal platforms to enforce or monitor compliance; and the petition process can be arduous and resource-consuming. So, while these cases can be described as anecdotal, they do exist and give cause to consider regulation and monitoring of PBMs.

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<sup>23</sup> IBAC members include General Services Department Risk Management Division, Public School Insurance Authority, Retiree Health Care Authority, and Albuquerque Public Schools.

According to a Board of Pharmacy inspector, independent rural pharmacies, which are generally small in terms of resources and staff, have recently reported to the Board that they perceive that harm is being done to their businesses and to their clients by the actions of PBMs. According to the complaints, numerous claims have been denied due to the PBMs' perceptions of contract violations or discrepancies in documentations upon PBM auditing of pharmacy records. According to some of the complaints, reimbursement for certain prescriptions are denied or processed slowly, which induces financial hardship to the pharmacist that is forced to purchase some drugs from suppliers using cash on delivery payment. Rural pharmacists have reported cases of having to turn away clients with certain insurance plans knowing that the PBM will deny their claims. Other complaints say that some clients must travel to larger out of community pharmacies to get the drugs they need. While pharmacies can undertake a grievance against the PBMs, the process is said to be time consuming and expensive, which can be a hardship for small and/or rural pharmacies. An example given was: filing a particular grievance against a PBM's allegation or denial of claims might require that the pharmacists, to argue its case, contact dozens to hundreds of practitioners to solicit and receive letters written on letterhead stationary stating that they either wrote a specific prescription or telephoned in a specific prescription to those pharmacists.

The opinion of many independent rural pharmacists is that forcing their clients to travel to other communities to get pharmacy services when their local pharmacy can not process claims will result in the loss of rural pharmacies and would allow the PBM to increase mail order pharmacy services, which could be a financial incentive for PBMs.

On the other hand, arguments against these claims are that the health plans or employers, not PBMs, are responsible for the denial of claims. Other arguments against the independent pharmacy's claims about the undue financial hardships inflicted by PBMs is that independent pharmacies are going into the pharmacy benefit management business through their national trade association, the National Community Pharmacists Association. It would appear that the independent pharmacists would soon be in competition with the established PBMs, and their arguments may seem to be self-serving.

## Task Force Activities and Issues

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HJM 98 task force members represented almost a full spectrum of the prescription drug industry. Representatives included pharmacy benefit managers, consumers, state agencies, health plans, retail chain pharmacies, and independent pharmacists.

Presentations were given by individual task force members and their national representatives to highlight the interests and concerns of the organizations they represented in regards to PBM business practices and interactions, contracting policies, and other related issues. See Appendix D. Outside presenters were invited to provide other perspectives, including entities that contract with PBMs. Articles and current PBM-related press releases were exchanged on a regular basis via electronic mail and during meetings.

Based on presentations and discussion by the task force, a summary of the pros and cons of PBM services are provided below. Please note that the following lists are based on individual opinions and do not reflect a consensus of the entire task force.

### **PBM Benefits and Services**

A sample of services offered by PBMs might include:

- An array of customized time saving administrative services and service options
- Flexibility to meet the needs of the clients they serve
- Full price disclosure of negotiated terms to their clients based on written contracts
- Information and education for health professionals and consumers on the types and effectiveness of available drugs
- Expedient electronic prescription processing
- A proven record of knowledge and experience
- Integration of clinical and analytical expertise to determine safe and appropriate drugs
- A pool purchasing ability of millions of consumers to negotiate lower drug prices
- Protections in place through state regulations in which they are domiciled
- Quality monitoring and oversight
- Rebates and discounts

### **Challenges with the PBM System**

- Conflict of interest by providing preferred deals to PBM-owned pharmacies and mail order companies
- Confusing and complicated channels for reimbursement
- Confusing and complicated contract negotiations
- Difficult and time consuming processes to make contract revisions
- Perception of a lack of timely communication
- Differential pricing for not using network or maintenance drugs
- Indirectly regulated and primarily on claims processing, utilization review and third party administration – not for the services they provide
- Various levels of full disclosure on rebates and discounts
- Lack of accredited standards except for mail order companies that are regulated under state pharmacy laws

- Concerns of potential conflict of interest; some smaller PBMs more likely to accept transparencies
- PBMs sued for not being conducive to needs of clients, drug switching, PBMs driving utilization to higher priced drugs
- Concerns of PBM business practices over formulary, pharmaceutical and therapeutic committees, etc.
- Drug substitutions based on PBM's own P&T committee recommendations versus the best choice of the patient's physician or pharmacist

### **PBM member concerns**

- There is no need for further regulation of pharmacy benefit managers.
- There has been no demonstration of any harm to citizens of the State of New Mexico that would warrant further regulation of this industry.
- Whether owned by PBMs or not (*e.g.*, drugstore.com), non-resident mail service pharmacies are already regulated under state law (§61-11-14.1 of the New Mexico Statutes Annotated) as well as the pharmacy practice acts in their states of domicile.
- The state already regulates the benefits that insurers and managed care organizations offer to their members, and the PBMs that contract with those entities to manage the prescription benefit must assist their clients in meeting their regulatory requirements, such as coverage mandates (*e.g.*, §59A-46-44 regarding coverage for prescription contraceptive products) and “any willing provider” requirements (see §59A-46-35). Because of federal pre-emption under the federal ERISA statute, states cannot regulate the benefit that employers offer to their employees.
- The Federal Trade Commission has submitted several letters to legislators in states that were considering PBM regulation bills (Rhode Island, California, North Carolina, North Dakota), pointing out how the bills being considered would likely increase the cost of pharmaceuticals in the state and could lead to an increased number of citizens without prescription drug coverage as a result, and how the bills would be likely to undermine competition in the marketplace rather than promote it.
- There is no need for the state to become included in contracts between two private entities.
- Numerous objective, non-partisan studies by federal government agencies (the Government Accountability Office, the Congressional Budget Office, and the Federal Trade Commission) have analyzed PBMs and the services that they provide in terms of savings and quality. The most recent FTC study concluded that the allegations of a conflict of interest raised by industry critics are simply “without merit.”

### **Concerns of other members include:**

- The Department of Insurance (DOI) regulates prescription drug benefits in health insurance products but does not regulate PBMs.  
*Mandate: 13.10.13 NMAC Managed Health Care – regarding prescription drug coverage by HMOs to include the right of enrollees to obtain drugs not on the formulary when the drugs on the formulary are proven to be not effective or could cause adverse reactions. HMOs are subject to mandated benefits such as the mandate requiring coverage for prescription contraceptive drugs and devices.*
- PBMs are not directly regulated through existing laws. Generally state laws that regulate managed care plans are not interpreted to apply to PBMs.
- PBMs should be regulated to avoid

- potential conflicts of interest
- provide needed financial transparency of rebates and other drug manufacturer fees
- establish standards for relationship between PBM and its clients
- establish protections regarding drug therapy switches
- Misaligned Incentives? Critics questioning whether PBMs are cooperating with the Pharmaceutical Research and Manufacturers of America (PhRMA) to maximize their own profits rather than serving the cost saving interest of their clients.
- Contractual agreements with PhRMA
- Take-it-or-leave-it contracts for pharmacies
- Delaying reimbursement for between 45-60 days when pharmacies must pay wholesalers within 14 days.
- Abusive audit practices
- Delays in price adjustments to the pharmacy, but immediate price increases to the employer's bill.
- PBMs influence health plan choices
- Would like to have an improved ability to participate in contracts (open networks)



## Conclusion and Recommendations to the New Mexico Legislature

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The task force members were polarized on the need to regulate pharmacy benefit managers in New Mexico. It was difficult to determine which standing laws may already be adequately regulating PBMs. Also not clear was how many of the current issues or problems associated with PBMs in this state are actually health plan related. Local data was not available from which to draw conclusions indicating the number of PBMs that operate in New Mexico or the number of people that are being served by PBMs.

Individual task force members offered their opinions on the need to regulate PBMs, including the Office of the Attorney General, who issued a statement to the committee. See Appendix C. Other members disagreed on the need for regulation. The committee could not reach a consensus on the need for regulation.

The HJM98 task force did reach a consensus on PBM-related topics and asks the 2005 Legislature to consider the following recommendations:

- Develop and implement a registry of active pharmacy benefit managers in New Mexico.
- Educate the general public to reduce confusion between the responsibilities of a health plan/employer and the responsibilities of pharmacy benefit managers.
- Promote education on available negotiating options between contractors and pharmacy benefit managers.
- Delegate, through a future memorial, that the Health Policy Commission further research and analyze PBM activities and existing federal and state laws that regulate PBMs.

The Health Policy Commissioners support the task force recommendations in addition to adding the following:

- All PBMs should be registered in New Mexico through an application process which would include: 1) a description of how PBMs will educate the public about their role and the prescriptions that are covered, 2) disclosure of administrative costs and profits.
- PBMs should develop a standardized formulary.



## Appendix A

### House Joint Memorial 98

A JOINT MEMORIAL  
REQUESTING A STUDY OF THE NEED FOR REGULATION AND OVERSIGHT OF  
PHARMACY BENEFIT MANAGEMENT COMPANIES.

WHEREAS, the cost of prescription drugs continues to be a huge component of the cost of health care in the nation and the state; and

WHEREAS, the cost of prescription drugs in New Mexico is estimated to have been eight hundred four million dollars (\$804,000,000) in 2004; and

WHEREAS, New Mexico state government pays for prescription drugs for more than five hundred thousand people covered through the Medicaid program, for those incarcerated in our state prisons and for state employees and retirees; and

WHEREAS, pharmacy benefit managers are private companies that administer and manage the purchase and dispensing of and reimbursement for prescription drugs for public and private insurance plans; and

WHEREAS, many pharmacy benefit managers also own and operate their own mail order pharmacies; and

WHEREAS, in the United States, pharmacy benefit managers handle prescription drug benefits for an estimated ninety-five percent of all patients with prescription drug insurance; and

WHEREAS, the state is among many entities that rely on the services of pharmacy benefit managers to negotiate discounted prices for prescription drugs, develop formularies of covered drugs, establish and maintain adequate networks of pharmacies and manage utilization of drugs through prior authorization or utilization reviews; and

WHEREAS, the extremely complex system of prescription drug pricing involves many different prices, rebates and discounts and involves many different parties in the purchasing and dispensing of the product; and

WHEREAS, it is in the best interest of the state to have full knowledge of the pricing structure, negotiated discounts and supplementary payments that pharmacy benefit managers receive from prescription drug manufacturers in order to ensure that the lowest possible prescription price is passed along to beneficiaries; and

WHEREAS, it is similarly important for the state to have knowledge that beneficiaries are receiving drugs that are the most medically appropriate and of the lowest cost; and

WHEREAS, pharmacy benefit managers are credited with assisting health insurers and states to achieve savings on prescription drugs; and

WHEREAS, disclosure of financial arrangements and conflicts of interest and sharing of data about utilization management is generally covered in contracts between entities and should not be required by state law; and

WHEREAS, there are conflicting opinions regarding the impact of requiring price transparency on prescription drug prices; and

WHEREAS, the administrative activities of this important industry are largely unregulated, except for regulations governing the operation of pharmacy businesses; and

WHEREAS, recent state and federal lawsuits have been filed alleging the possibility of serious conflicts of interest, understated savings from deals with prescription drug manufacturers and the use of information about utilization and prescribing patterns for marketing purposes rather than for benefiting patient health; and

WHEREAS, the nature and purpose of regulation is highly controversial, and the outcome of regulation is uncertain;

NOW, THEREFORE, BE IT RESOLVED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO that the New Mexico health policy commission be requested to convene a task force to study the need for regulation of pharmacy benefit management companies; and

BE IT FURTHER RESOLVED that the task force include representation from the human services department, the department of health, the office of the attorney general, the insurance division of the public regulation commission, the risk management division of the general services department, members of statewide organizations representing retail pharmacists and retail chain pharmacies, representatives of the pharmacy benefit manager industry, consumers and others as appropriate; and

BE IT FURTHER RESOLVED that the study evaluate the various administrative and corporate structures of pharmacy benefit managers; and

BE IT FURTHER RESOLVED that the task force identify and create a graphic representation of the pricing structure of prescription drugs, including the various levels at which rebates, discounts and other incentives are offered; and

BE IT FURTHER RESOLVED that the necessity for regulation of pharmacy benefit managers be evaluated; and

BE IT FURTHER RESOLVED that the task force study the extent to which pharmacy benefit managers interact with covered individuals and the value and propriety of those interactions; and

BE IT FURTHER RESOLVED that the task force evaluate the positive and negative aspects of disclosure of financial and utilization information; and

BE IT FURTHER RESOLVED that the study include a complete listing of the approaches other states have taken in regulating the pharmacy benefit manager business, including the status of current legal actions; and

BE IT FURTHER RESOLVED that the findings and recommendations of the study be presented to the interim legislative health and human services committee at its October 2005 meeting; and

BE IT FURTHER RESOLVED that copies of this memorial be transmitted to the director of the New Mexico health policy commission, the secretaries of human services, health and general services, the chief of staff of the public regulation commission and the attorney general.



## Appendix B

### State Laws Regulating Pharmacy Benefit Managers

**State Laws Regulating Pharmacy Benefit Managers  
Provided by the National Community Pharmacists Association, 2005**

State	Law	Summary of Pharmacy Benefit Manager Law
District of Columbia*	Title 48, Subtitle II, Chapter 8A, Subchapter II. Transparent Business Practices Among PBMs	<p>Requires a PBM to</p> <ul style="list-style-type: none"> <li>• act as a fiduciary</li> <li>• notify the covered entity of any practice that is a conflict of interest</li> <li>• pay in full to the covered entity any payments/benefits received from a drug manufacturer/labeler based on volume of sales or market share</li> <li>• provide information on all rebates, discounts and other similar payments upon request by the covered entity</li> <li>• disclose, upon request by the covered entity, all financial terms and arrangements for remuneration of any kind between the PBM and a drug manufacturer or labeler including formulary management, drug substitution programs, educational support claims processing and data sales fees <ul style="list-style-type: none"> <li>- PBMs may designate the information provided as confidential</li> </ul> </li> </ul> <p>Establishes guidelines for substituting prescriptions including obtaining the approval of the prescriber.</p> <ul style="list-style-type: none"> <li>• PBMs must disclose the costs of both drugs to the covered individual and the covered entity prior to switching. Any benefit or payment received as a result of the substitution must be transferred to the covered entity. <ul style="list-style-type: none"> <li>- Violations are subject to a fine of not more than \$10,000.</li> </ul> </li> </ul> <p>Effective: 05/18/04 (Effective date suspended by Court Interim Injunction.)</p>
Georgia	Title 26, Chapter 26-4.110.1	<p>Requires a PBM to be licensed as a pharmacy, with a few exceptions, if it provides the services of benefits that constitute the practice of pharmacy.</p> <p>The Pharmacy Board can inspect a licensed PBM's premises whether they are located within or outside the state.</p> <p>Effective: 05/22/02</p>

Maine	Title 22, Chapter 603, Subchapter 4, Section 2699 Prescription drug practices	<p>Requires that a PBM</p> <ul style="list-style-type: none"> <li>• owe a fiduciary duty to a covered entity and must discharge that duty in accordance with the provisions of state and federal law</li> <li>• perform its duties with care, skill, prudence and diligence in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims</li> <li>• notify the covered entity of any practice that is a conflict of interest</li> <li>• must provide, upon request by the covered entity, all financial and utilization information relating to services to that covered entity</li> <li>• may designate any information provided to the covered entity as confidential and the information may not be disclosed without the permission of the PBM except that disclosure may be ordered by a court - does not limit the Attorney General's use of its investigative authority</li> <li>• transfer in full to the covered entity any benefit or payment received as a result of a substitution</li> <li>• disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the PBM and any drug manufacturer or labeler, including formulary management, drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees <ul style="list-style-type: none"> <li>○ The PBM may designate the information as confidential. However disclosure may be ordered by a court and this provision does not limit the Attorney General's use of its investigative authority.</li> </ul> </li> </ul> <p>Provides that a violation of the Act is an unfair trade practice and subject to a fine of not more than \$10,000.</p> <p>Applies to contracts executed or renewed on or after September 13, 2003.</p> <p>Effective: 6/3/03 (Effective date suspended by Court Preliminary Injunction.) 04/13/05 Court ruled in favor of State of Maine.</p>
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Maryland	Title 15, Subtitle 10B, Section 15-10B-20 Private Review Agents	<p>Requires the Insurance Department to conduct an examination of any PBM registered as a private review agent at least once every three years.</p> <p>Requires the (Insurance) Commissioner to issue a report based on the examinations.</p> <p>Effective: 5/13/03.</p>
North Dakota	Chapter 26.1-27 North Dakota Century Code	<p>Requires that a PBM</p> <ul style="list-style-type: none"> <li>• Is defined as an administrator</li> <li>• Be registered as an administrator</li> <li>• Discloses ownership interest by an insurer or a pharmaceutical manufacturer</li> <li>• Notify the Insurance Commissioner in writing within five business days of any material change in the PBM's ownership</li> <li>• Comply with statutory provisions concerning substitution of one drug for another</li> <li>• May not exclude an otherwise qualified pharmacy from its network if the pharmacy accepts the terms, conditions and reimbursement rates of the PBM's contract</li> <li>• May not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract</li> <li>• Must offer to the covered entity options for the covered entity to contract for services that must include: <ul style="list-style-type: none"> <li>○ a transaction fee without a sharing of a payment received by the PBM,</li> <li>○ a combination of transaction fee and a sharing of the payment received by the PBM or</li> <li>○ a transaction fee based on the covered entity receiving all of the benefits of payments received by the PBM</li> </ul> </li> </ul> <p>Agreement between the PBM and the covered entity must include a provision allowing the covered entity to audit the PBM's books, accounts and records as necessary to confirm that the benefit of a payment received by the PBM is being shared as required by the contract</p> <ul style="list-style-type: none"> <li>• During an examination of a covered entity, the Commissioner may examine any contracts between the covered entity and the PBM in order to determine whether payments received from the PBM are being applied to reduce the covered entity's rates or have been distributed to covered individuals</li> <li>• PBM must disclose annually the benefits of the payments received and describe how the PBM applied those benefits toward reducing rates or distributed them to covered individuals</li> <li>• Any information disclosed to the Commissioner is considered a trade secret</li> </ul> <p>Legislative Council was directed to study the PBM industry and make a report and recommendations, together with legislation required to implement the recommendations to the next assembly</p> <p>Effective: 08/01/05</p>

<p><b>South Dakota</b></p>	<p>Chapter 58-29E Pharmacy Benefits Management</p>	<p>Requires PBMs to</p> <ul style="list-style-type: none"> <li>• Be licensed as a third party administrator</li> <li>• Perform its duties by exercising good faith and fair dealing toward the covered entity</li> <li>• Give the covered entity the option to request information on rebate revenues and retrospective utilization discounts.</li> <li>• Gives the covered entity the option to request information on the nature, type and amount of all other revenue received from a pharmaceutical manufacturer or labeler with respect to programs that the covered entity offers to its enrollees</li> </ul> <p>Prohibits a PBM from contacting a covered individual without express written permission of the covered entity.</p> <p>Provides that information disclosed to the covered entity shall be confidential and proprietary information; however insurance department may request information but it will be considered confidential and privileged and not open to public inspection or disclosure.</p> <p>Provides that the covered entity may audit the PBM's records as they relate to rebates and other information described in this Chapter.</p> <p>Prescription may be substituted if it is a lower priced generic or if the substitution is for medical reasons but PBM must obtain prior approval from the prescriber.</p> <p>Allows the Division of Insurance to promulgate rules.</p> <p>Applies to contracts entered into or renewed after June 30, 2004. Effective: 03/09/04</p>
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\* The Pharmaceutical Care Management Association filed an interim injunction seeking to enjoin the enforcement of this law. On 12/21/04, the U.S. District Court for the District of Columbia granted the interim injunction. The District of Columbia plans to appeal the interim injunction.



## Appendix C

### Statement from the New Mexico Attorney General

**Statement from the Office of the Attorney General**

Attorney General of New Mexico



**PATRICIA A. MADRID**  
Attorney General

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Fax (505) 827-5826

**STUART M. BLUESTONE**  
Chief Deputy Attorney General

The Attorney General supports legislation regulating pharmaceutical benefit managers because the legislation would benefit New Mexico businesses that purchase health care coverage for their employees, benefit State Government when we purchase prescription drugs, benefit New Mexico patients, New Mexico's pharmacists, and honest fair dealing Prescription Benefit Managers.

PBM's are the latest chapter in a long time trend in health care financing, which is to re-combine in new ways in new business organizations the various elements of traditional health insurance organizations. A PBM combines elements of traditional health insurance, HMO's and PPO's. Legislation would do no more than extend existing regulatory approaches to these new combinations of old businesses.

The result of no legislation has been a series of charges against PBM's, lawsuits-by the federal government, the states, and business organizations, and subpoenas. The New Mexico Attorney General's Office has been involved in many of these matters and others that are ongoing and has seen first hand the harm caused by a lack of regulatory oversight.

Legislation would establish clear expectations for all parties and a process so any future conflicts can be addressed administratively rather than only through our courts and grand juries.

Legislation can be drafted to protect the proprietary and competitively sensitive information of the PBM's, but also makes certain that the buyer can determine what he is buying and whether it was honestly delivered by the PBM or not.

Attorney General Madrid believes that health care is about the patient. Legislation governing PBM's provides protection for the patient without frustrating legitimate efforts at cost containment.

Appendix D  
List of Presentations

## Presentations to the Task Force

Copies of the listed presentations were provided by the presenters. Topics were selected by the task force and appropriate presenters were invited to address these selected topics. The following presentations can be viewed on the New Mexico Health Policy Commission website:

[www.hpc.state.nm.us](http://www.hpc.state.nm.us)

PBM Industry Overview

Russell C. Ring, SVP-Government Relations, Caremark RX

ACS Government Healthcare Pharmacy Benefits Management

Dan Hardin, ACS

DOI Regulation of Pharmaceuticals in Insurance

Mike Batte, Department of Insurance

Retail Pharmacy Contracting with Pharmacy Benefit Managers

Denise Cuellar, MBA, RPh, Regional Clinical Manager, Walgreen Co.

Pharmacy Benefit Managers Need for Regulation

Diane Darvey Pharm.D., JD, Director, State Pharmacy Affairs, National Association of Chain Drug Stores

NCPA, the National Community Pharmacists Association

Reginia Benjamin, Associate General Counsel & Director of Government Affairs, NCPA

Dale Tinker, Executive Director, New Mexico Pharmacists Association

The Impact of Drug Utilization, Marketshare, and Rates on Formularies

Doug Lohkamp, R.Ph, BCBSNM, Manager of Pharmacy Services

Pharmacy Benefit Manager, State of New Mexico General Services Department, Risk Management Division, Employee Benefit Bureau

Nancy Bearce, Benefit Analyst, Audit & Compliance

Other presenters included:

Anne Sperling, CSA, National Association of Health Underwriters

Stewart Logan, Benefits/Compensation Manager, San Juan County

Robert Newcomb, Alamo Navajo Health Center

## Glossary of Key Terms\*

Average Wholesale Price (AWP) - A national average of list prices charged by wholesalers to pharmacies. AWP is sometimes referred to as a “sticker price” because it is not the actual price that larger purchasers normally pay. \*

Drug and Utilization Review (DUR) –A method for evaluating or reviewing the use of drugs to determine the appropriateness of the drug.

Maximum Allowable Cost (MAC) - MAC is a cap set by payers on reimbursement for certain generic and multi-source brand products. States and private payers with MAC programs typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which the program will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing for drugs on a MAC list.\*

Wholesale Acquisition Cost (WAC) - The price paid by a wholesaler for drugs purchased from the wholesaler’s supplier, typically the manufacturer of the drug. Publicly disclosed or listed WAC amounts may not reflect all available discounts.\*

Pharmaceutical Research and Manufacturers of America (PhRMA) - Represents pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.

Pharmacy and Therapeutics Committee (P&T) – The primary responsibilities of P&T committees are to ensure high-quality drug therapy for patients and act as a liaison between medical staff and pharmacies. The P&T maintains a formulary of medications approved for routine patient care, reviews drug use and adverse drug reactions, and establishes procedures for prescribing. (PubMed, [www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list\\_uids=1](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=1))

\*Terms from the Health Strategies Consultancy LLC, for the Kaiser Family Foundation. “Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain” March 2005

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