2004 SUNRISE REVIEW

Colorado Department of Regulatory Agencies
Office of Policy, Research and Regulatory Reform

Pharmacy Benefit Managers

October 15, 2004

STATE OF COLORADO

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Bill Owens
Governor

October 15, 2004

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado Department of Regulatory Agencies has completed its evaluation of the sunrise application for regulation of pharmacy benefit managers and is pleased to submit this written report. The report is submitted pursuant to section 24-34-104.1, Colorado Revised Statutes, which provides that the Department of Regulatory Agencies shall conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

The report discusses the question of whether there is a need for regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm, and whether the public can be adequately protected by other means in a more cost-effective manner.

Sincerely,

Tambor Williams

Tambor Williams
Executive Director

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The Sunrise Process

Background

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:

> (I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
>
> (II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence; and
>
> (III) Whether the public can be adequately protected by other means in a more cost-effective manner.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation. Applications received by July 1 must have a review completed by DORA by October 15 of the year following the year of submission.

Methodology

DORA has completed its evaluation of the proposal for regulation of pharmacy benefit managers (PBMs). During the sunrise review process, DORA performed a literature search, reviewed the laws of other states and interviewed representatives of the applicant, PBMs, professional and trade associations and consumer groups. In order to determine the number and types of complaints filed against PBMs in Colorado, DORA contacted representatives of the Colorado Division of Insurance, the Denver District Attorney's Office, the Denver/Boulder Better Business Bureau, the Office of the Attorney General Consumer Protection Section, the Colorado Board of Pharmacy and the Colorado Board of Medical Examiners. Additionally, DORA surveyed a random sample of Colorado-licensed physicians and pharmacists.

Proposal for Regulation

Rx Plus (Applicant), an association of independent pharmacies, has submitted a sunrise application to the Department of Regulatory Agencies (DORA) for review in accordance with the provisions of section 24-34-104.1, Colorado Revised Statutes (C.R.S.). In connection therewith, the Applicant provided two drafts of proposed legislation to DORA, the second presumably intended to replace the first. The second draft of proposed legislation is actually a model act prepared by the National Community Pharmacists Association. A copy of this model legislation may be found in Appendix A on page 32.

The application proposes state certification of pharmacy benefit managers (PBMs) as the appropriate level of regulation to protect the public. The Applicant states that certification is recommended because it will have minimal impact upon commerce, can be accomplished without an impact on the current state budget, and will work within an existing state regulatory framework.

The application defines a PBM as either: 1) an entity that administers the prescription drug or device portion of a health benefit plan on behalf of the plan sponsor, insurance company, union, or health maintenance organization; or 2) any arrangement for the delivery of pharmacist's services in which an entity undertakes to pay for or reimburse any of the costs of pharmacist's services on a prepaid or insured basis and that: a) contains incentives intended to influence the cost or level of pharmacist's services; and b) requires or creates a benefit payment differential based on whether the customer uses a retail or mail order pharmacy. Thus, PBMs are usually entities, not individuals.

The Applicant proposes that the Colorado State Insurance Commissioner (Commissioner) issue certificates of authority to PBMs that submit certain, enumerated documents:

- The PBM's organizational documents;
- The PBM's bylaws or other documents outlining the internal affairs of the PBM;
- The names, addresses, positions and professional qualifications of the PBM's directors, officers, partners, members or other individuals that are responsible for the management of the PBM;
- A Certificate of Compliance issued by the Colorado State Board of Pharmacy (Pharmacy Board);
- Annual financial statements for the previous three years;
- The name and address of the PBM's agent for service of process;

- A detailed description of the claims processing services, pharmacy services, insurance services, other prescription drug or device services, audit procedures for network pharmacies or other administrative services to be provided;

- All incentive arrangements or programs such as rebates, discounts, disbursements or other similar financial arrangements entered into with any pharmaceutical manufacturer;

- The posting of a fidelity bond in an amount equal to at least 10 percent of the amount of funds handled or managed annually by the PBM;

- Other documents the Commissioner may require; and

- A $5,000-filing fee.

The Applicant's proposal discusses a certificate of compliance to be issued by the Pharmacy Board, but the proposed legislation merely directs the Pharmacy Board to promulgate rules regarding, among other things, the requirements for annual filings without providing the Pharmacy Board with any direction as to the purpose of the certificate or what types of issues should be considered in deciding whether to grant or deny such a certificate.

The legislation proposed by the Applicant would also, among other things:

- Mandate a formula by which a PBM must calculate the rate at which it reimburses pharmacies for the dispensation of covered drugs;

- Require a PBM to adopt an "any willing provider" approach to pharmacy networks through which a PBM would offer a standard contract to all pharmacies in a given region and those pharmacies could either sign or not sign such a contract, but the PBM could not refuse to contract with a pharmacy willing to sign;

- Require a PBM to obtain the approval of the Commissioner for all contracts entered into with pharmacies;

- Require a PBM to act as a fiduciary of the pharmacies and pharmacists with which it contracts;

- Prohibit a PBM from terminating a contractual relationship with a pharmacy if that pharmacy engages in certain, enumerated acts, such as commenting negatively to a customer on the PBM's medical policies or decisions;

- Prohibit a PBM from mandating that a pharmacy change a covered person's prescription unless the prescribing physician and the covered person agree to the change;

- Prohibit a PBM from offering lower co-payments to covered persons for using mail order pharmacies, as opposed to retail pharmacies (which would effectively negate part of the definition of "PBM" relating to payment differentials);

- Require a PBM to remit reimbursements to pharmacies within seven days; and

- Require a PBM to inform covered persons of the PBM's identity and the fact that PBMs are regulated by the Commissioner and the mailing address of the Commissioner.

Finally, the proposed legislation would authorize the Commissioner to suspend or revoke a PBM's certificate of authority if the PBM is found to, among other things:

- Be in an unsound financial condition;

- Have used methods or practices that are harmful to covered persons or the public;

- Have failed to pay any judgment entered against it in Colorado within 60 days of judgment;

- Have violated any rule or order of the Commissioner;

- Have refused to allow the Commissioner to examine its books and records;

- Have refused, without just cause, to pay any proper claims;

- Have failed to reimburse any pharmacy or pharmacist in a timely manner;

- Have advertised in an untrue, misrepresentative, misleading deceptive or unfair manner; or

- Have been suspended or revoked in another state.

The Applicant's proposed legislation would also provide for the imposition of administrative fines in lieu of suspension or revocation. Such fines would be in the amount of $1,000 for each "nonwillful" violation, with a maximum of $5,000 for all nonwillful violations arising out of the same action, and $5,000 for each knowing and willful violation, with a maximum of $25,000 for all knowing and willful violations arising out of the same action.

The proposed legislation does not specify where certification fees or funds realized through fines are to be deposited, whether in the state's General Fund or in a cash fund.

Profile of the Industry

PBMs are entities that work with their clients to administer the drug benefit portion of health plans in an attempt to control drug costs. Clients primarily consist of insurers (21 percent), self-insured employers (33 percent) and managed care organizations (35 percent).[1] Additionally, beginning in June 2004, clients may also now include Medicare beneficiaries who obtain Medicare discount drug cards. Regardless of who the client may be, costs are primarily controlled through obtaining discounts from retail pharmacies and rebates from drug manufacturers.

Modern PBMs perform many more functions than early PBMs. The PBM industry emerged as a distinct market niche in the 1970s and 1980s, as managed care organizations, seeking to control costs, split out the drug benefits they offered to clients. As a result, mail order service and claims processing companies emerged whereby these fledgling PBMs acted as intermediaries between the pharmacy and the managed care organization. PBMs developed sophisticated computer systems that adjudicated prescription drug claims.

In a typical, albeit simplified, scenario, a patient would take a prescription to the pharmacy and the pharmacist would enter the patient's information into a computer. The pharmacy's computer would communicate with the PBM's computer, which would adjudicate the claim by either allowing or denying it. The pharmacy would then fill the prescription and the patient would pay a co-payment, a type of cost-sharing mechanism. The managed care organization would then reimburse the pharmacy according to previously contracted rates, and it would also pay to the PBM a transaction fee, typically one or two dollars.

As the industry evolved, however, the manner in which PBMs realized cash flow also changed. PBMs discovered that they could provide pharmacies with access to more covered lives than individual health plans or managed care organizations and that they could leverage this market of consumers to extract even greater concessions from pharmacies than could their individual clients. The retail pharmacies, in return, would benefit from increased store traffic and sales volume through inclusion in the PBMs' networks.

As a result, the PBMs' role expanded to include direct payments from the PBMs' clients to the PBM, which then reimbursed the pharmacies for prescriptions filled. The PBM could then retain the difference between the client's reimbursement rate and the retail pharmacy's contract rate. Health plans were able to reduce their costs, retail pharmacies increased their sales and the PBMs became more profitable and less dependent on transaction fees.

Throughout the 1980s and into the 1990s, the PBM industry grew rapidly as more managed care organizations out-sourced the administration of their prescription drug benefits and as self-insured employer groups began to contract with PBMs as well.

[1] *Study of Pharmaceutical Benefit Management*, by PricewaterhouseCoopers, L.L.C. for the U.S. Health Care Financing Administration (HCFA) (HCFA Contract No. 500-97-0399/0097), June 2001, p. 17.

PBMs also began expanding into formulary design, a function previously left to the PBMs' clients. A formulary is a list of "preferred" drugs. Under a closed formulary design, drugs on the formulary are considered "covered." That is, the enrollee (consumer) pays only the co-payment to obtain the drug. Drugs that are off the formulary are not covered, so the patient must absorb the entire cost of the prescription out of pocket. Tiered formularies operate on a similar principal, except that most drugs are covered, but the amount of money the enrollee pays out of pocket varies depending upon which tier the drug is placed. As of 2002, 57 percent of enrollees who had prescription drug coverage were covered by a tiered formulary.[2]

As a result of the PBMs' entry into formulary design, drug manufacturers began to offer rebates and discounts to PBMs for inclusion on the formularies because inclusion leads to greater access to enrollees and, thus, to increased sales. The introduction of rebates as a source of positive cash flow allowed the PBMs to reduce their transaction and other charges to their clients, thus increasing competition among the PBMs. Formulary design and the pursuit of manufacturer rebates became all important.

Finally, by the mid-1990s, drug manufacturers realized that a more efficient means to assuring inclusion on the formularies was to control the PBM itself. As a result, a number of drug manufacturers purchased PBMs.

Within just a few years, however, those drug manufacturers that had purchased PBMs came under scrutiny as the healthcare industry began to question whether the PBMs were looking out for the best interests of enrollees or for the best interests of their drug manufacturer parent companies.

Furthermore, drug manufacturers changed the drug rebate structure. Rather than offering a rebate on each sale, manufacturers offered rebates to PBMs based on market share. The more market share for a particular drug a PBM could deliver, the higher the rebate.

As a result of all of these changes in the industry, by the late 1990s, most drug manufacturers that had, just a few years earlier, acquired PBMs, had divested themselves of those PBMs.

[2] "The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending," by H. Huskampt, P. Deverka, *et al*, *The New England Journal of Medicine*, Dec. 4, 2003, p. 2225.

According to a 2001 study conducted by PricewaterhouseCoopers for the U.S. Health Care Financing Administration (the precursor to the Centers for Medicare and Medicaid Services), by 2001, 70 percent of all drug purchases were administered by PBMs,[3] up from 65 percent in 1998, 49 percent in 1995, and 30 percent in 1992.[4] In August 2003, the Pharmaceutical Care Management Association reported that fully 80 percent of all prescription drug transactions were managed by PBMs.[5] According to the Applicant, this figure is consistent with its estimates for drug purchases in Colorado.

Although there may be as many as 60 PBMs operating across the United States,[6] after a consolidation boom during the late 1990s, four major PBMs emerged: AdvancePCS, Medco Health Solutions, Express Scripts and CaremarkRx, which, together, administer the pharmacy benefit for between 195 million[7] and 200 million Americans,[8] or half of the U.S. population.[9] Further consolidation occurred in March 2004, when CaremarkRx acquired AdvancePCS, leaving just three major PBMs. This market consolidation, some argue, has empowered the surviving PBMs to exert more leverage in negotiating better discounts and rebates from manufacturers and pharmacies.

Not surprisingly, the scope of the PBM industry has evolved considerably from its origins, which focused primarily on claims processing. Today, most PBMs offer, though not all clients contract for, a variety of services, including, client services (benefit and eligibility administration), pharmacy network administration, mail order pharmacy operations, claims adjudication, manufacturer contracting and rebate administration, formulary management, therapeutic substitution programs, and utilization and disease management.

Finally, while many PBMs are independent entities, some are subsidiaries of health plans or are operated by large, retail drug store chains.

[3] PricewaterhouseCoopers at 14.
[4] Id. at 25.
[5] *Pharmacy Benefit Mangers (PBMs): Tools for Managing Drug Benefit Costs, Quality and Safety*, by Health Policy Alternatives, Inc. for Pharmaceutical Care Management Association, p. 1 (citing "Health Spending Projections for 2002-2012," by Heffler, Stephen, *et al*, *Health Affairs*, February 7, 2003).
[6] *Improving Health Care: A Dose of Competition*, a joint report by the Federal Trade Commission and the U.S. Department of Justice, July 24, 2004, Chp. 7, p. 14.
[7] PricewaterhouseCoopers at 35. Citied figures may include double counting on the part of the PBMs. Each PBM reports the number of lives it covers and individuals may have prescription drug coverage from more than one source, such as health insurance, union benefits, etc.
[8] Letter dated April 5, 2004, from B. Levy of the Pharmaceutical Care Management Association to B. Harrelson of the Colorado Department of Regulatory Agencies. Citied figures may include double counting on the part of the PBMs. Each PBM reports the number of lives it covers and individuals may have prescription drug coverage from more than one source, such as health insurance, union benefits, etc.
[9] PricewaterhouseCoopers at 35. Citied figures may include double counting on the part of the PBMs. Each PBM reports the number of lives it covers and individuals may have prescription drug coverage from more than one source, such as health insurance, union benefits, etc.

Some of the major complaints regarding PBMs concern drug switching and the overall lack of transparency of PBMs. Put simply, drug switching occurs when a patient receives a drug other than the drug the patient's physician originally prescribed. In a typical scenario, a patient's physician prescribes Drug A and the patient takes that prescription to the pharmacy. The pharmacist enters the order into a computer, which transmits the order to a PBM for confirmation of benefits. If Drug A is on the formulary, then Drug A will be allowed. However, if Drug A is not on the formulary, but Drug B is on the formulary and is in the same therapeutic class as Drug A, the PBM contacts the pharmacist, by phone, fax or electronically, informing the pharmacist that Drug B will be covered, but Drug A will not be covered. The pharmacist then contacts the prescribing physician to obtain permission to switch the prescription to Drug B. If the physician agrees, then the patient gives the pharmacy a co-payment and takes home Drug B. If the physician refuses to change the order, then the patient may pay full retail price for Drug A. In either case, the consumer may become confused because the patient receives Drug B when the patient had expected Drug A, or the patient may become angry with the pharmacist, the physician, the health insurance carrier, or all three because all the consumer is told is that Drug A is not covered.

The reasons behind drug switching drive the second major concern regarding PBMs – a substantial lack of transparency in the industry. As discussed above, a major source of revenue for PBMs are the rebates they receive from drug manufacturers for delivering market share for various drugs. This is accomplished by including certain drugs on the PBM's formulary and excluding other drugs in the same therapeutic class. This more or less forces enrollees to purchase the covered drug, which increases the market share delivered by the PBM for that drug, which increases the rebate paid to the PBM by the drug manufacturer.

This scenario has led many to allege that formulary design is motivated not by the safety and efficacy of the various drugs involved, but rather by the rebates paid by the drug manufacturers to the PBMs.

Because PBMs consider their rebate agreements to be trade secrets, they have historically refused to allow their own clients (along with everyone else) access to those agreements. As a result, most contracts between PBMs and their clients have not, historically, included rebate-sharing provisions because there was no way for the client to ensure that the PBM was sharing the appropriate amount of revenue with the client.

Rather, and as a direct result of this lack of transparency, many clients agree to certain, pre-established fees for each drug on the formulary. What the client often does not know is that the cost of the drug on the formulary may be higher than other drugs in the same therapeutic class. This, in turn, may increase the client's costs, which are ultimately passed on to enrollees in the form of higher premiums, higher co-payments, or both. In some cases, these extra costs can even force the client to reduce coverage or even eliminate benefits altogether.

This logic concludes by finding that drug switching occurs because PBMs attempt to direct consumers away from non-formulary drugs and toward formulary drugs so that the PBM can realize greater rebates. Thus, the transparency issue raises concerns as to in whose best interests the PBMs act: the patients', the clients' or the PBMs'.

Summary of Current Regulation

The Colorado Regulatory Environment

Whether and the extent to which pharmacy benefit managers (PBMs) are regulated at the state and federal levels are subjects of great contention. Beyond question, however, is the fact that neither Colorado nor federal law directly regulates PBMs. However, many of the functions of PBMs are directly addressed by existing Colorado statutes.

During the 2003 legislative session, Senate Bill 03-142 (SB 142) was introduced in an attempt to directly regulate PBMs. Senate Bill 142 would have required PBMs doing business in Colorado to obtain from the State Board of Pharmacy (Pharmacy Board), a certificate of authority. While the bill contained numerous provisions to protect pharmacies and pharmacists from PBMs, it also required PBMs to disclose to the Board, pharmacies, insurance carriers and consumers the rebates that the PBMs obtain from drug manufacturers.

Senate Bill 142 was postponed indefinitely by the Senate Committee on Appropriations, effectively ending this effort to directly regulate PBMs. As indicated earlier, however, PBMs are nevertheless regulated to one degree or another in Colorado.

Under Colorado law, a mail order pharmacy that mails prescription medications to a Colorado consumer falls within the jurisdiction of the Pharmacy Board and must be properly registered as a nonresident pharmacy. Similarly, the pharmacists working in such a pharmacy must be duly licensed in the jurisdiction in which the mail order pharmacy is physically located. These types of pharmacies are located outside of Colorado, but Coloradans may mail, fax or otherwise transmit valid Colorado prescription orders to such pharmacies for filling. The filled prescription, which typically consists of a three-month supply, is then mailed to the Colorado consumer. The services of mail order pharmacies are typically utilized for filling medications that treat chronic conditions and co-payments are generally lower when compared to the co-payments assessed for the use of retail pharmacies.

To the extent that a PBM offers disease management services, such services may fall within the jurisdiction of the Colorado State Board of Medical Examiners (BME). “Disease management” is a broad term and can include services as trivial as reminders to take and refill prescribed medications, but it can also rise to the level of providing education and consultative services to enrollees. Depending on the disease management services rendered, those rendering such services may be required to possess a license issued by the BME.

To the extent that a PBM has a contractual relationship with a Colorado-licensed health insurance carrier, various aspects of Colorado insurance law also apply to PBMs. These provisions include, but are not necessarily limited to, network adequacy, uniform disclosures, prompt payment of claims, prescription transfers and procedures for appealing the denial of benefits.

Colorado law regarding network adequacy requires plans that maintain networks, including pharmacy networks, to ensure, among other things, that the size and scope of the network is sufficient to assure reasonable geographic access. Thus, PBMs that contract with Colorado-licensed health insurance carriers must maintain pharmacy networks that satisfy the needs of the carrier's various plans.

Colorado insurance laws also require health insurance carriers to maintain mechanisms by which providers, such as pharmacists, can access information on the covered services. In this area, PBMs provide electronic connectivity so that pharmacists have immediate access to the details of a patient's drug benefit and co-payment structure.

Colorado insurance law also establishes the procedures for developing "open" and "exclusive" pharmacy networks.

Under yet another section of the Colorado insurance laws, a health insurance carrier must disclose to enrollees whether a prescription drug formulary is to be used in the plan as well as a contact to which questions may be addressed.

PBMs that contract with Colorado-licensed health insurance carriers are also subject to the state's prompt payment of claims provisions, which require claims to be either paid or denied in a prompt manner. Additionally, procedures must be in place for the consumer to appeal the denial of a claim.

This is but a partial description of the Colorado laws to which PBMs are subject when they offer their services under contracts with Colorado-licensed health insurance carriers. However, according to the Colorado Division of Insurance, only about one-third of Coloradans are covered by such plans. Nearly one-third is covered by self-insured employers and the final third of Coloradans are covered by Medicare or Medicaid, or they have no insurance at all. These final two-thirds of Coloradans are not protected by the Colorado insurance laws discussed above.

The federal Employee Retirement Income Security Act of 1974 (ERISA), in general, covers employer-funded benefit plans, including health plans. Whether and to what extent PBMs are subject to the requirements of ERISA when they contract with such plans is the subject of considerable legal debate. Nevertheless, it is discussed in this sunrise review to better provide the General Assembly with a background of the issues involved.

First, it is important to note that if PBMs are subject to ERISA, then the doctrine of federal pre-emption applies. That is, ERISA specifically prohibits the states from passing laws that directly impact ERISA-covered plans.

Regardless, ERISA requires covered plans to provide enrollees summary plan descriptions that outline the covered benefits of such a plan, including pharmacy benefits. ERISA-covered plans must also provide mechanisms for appealing denied claims.

More importantly, however, ERISA imposes upon covered plans a fiduciary duty with respect to enrollees. This means that an ERISA-covered plan must place the welfare of enrollees above the plan's own interests. This would necessarily be a factor in an ERISA-covered plan's contract with a PBM.

Thus, although PBMs are not directly regulated at either the state or federal levels, there is considerable indirect regulation that offers some public protection value.

Regulation in Other States

Colorado is not alone in its struggle to determine whether and how to regulate PBMs. Since 2002, no fewer than 34 bills have been introduced in the legislatures of at least 25 states, plus Washington, DC. There has been no great rush to regulate, however. Only three states (Maine, Maryland and South Dakota) and Washington, DC, have enacted legislation to regulate PBMs to one degree or another.

Maine

In 2003, the legislature of Maine passed S.P. 194 – L.D. 554. This legislation imposes a fiduciary duty on a PBM to the benefit of the PBM's client, referred to in the bill as "covered entity." As such, the bill imposes upon the PBM a responsibility to disclose to its client any potential conflicts of interest as well as any financial or drug utilization information the client may request.

Additionally, the bill outlines the steps that must be taken for drug substitutions. It also mandates that any savings realized by a PBM based on sales volume must be passed on to the PBM's client. More importantly, however, the Maine act requires PBMs to disclose all terms and arrangements for remuneration between a particular PBM and drug manufacturers.

The Maine act was scheduled to take effect on September 13, 2003, but on September 3 of that year, the Pharmaceutical Care Management Association (PCMA), an association whose membership comprises PBMs, filed a petition in the U.S. District Court seeking to enjoin implementation of the act. Citing the likelihood that PCMA would prevail on the merits, the court granted a preliminary injunction on March 9, 2004, effectively suspending Maine's act until final resolution at trial. Crucial to the court's decision was the provision in the Maine act that PBMs disclose their financial relationships with drug manufacturers. Both the PCMA and the court characterized such information as "trade secrets," which, if disclosed, could permanently harm PBMs' ability to compete with one another.

The court also found that the Maine act imposes internally inconsistent legal obligations on PBMs by creating a fiduciary duty on PBMs to the benefit of their clients, while at the same time prohibiting the substitution of a drug unless such a substitution would benefit both the client and the individual enrollee. It is conceivable, the court found, for the interests of the client on the one hand and the enrollee on the other hand, to be adverse, leaving it unclear as to what a PBM in such a situation would be required to do.

Maryland

Also in 2003, Maryland's legislature passed House Bill 410, which directs PBMs to register with Maryland's Insurance Commissioner as private review agents. Under Maryland law, a private review agent is a person or entity that performs utilization reviews for a health insurer, nonprofit health service plan, health maintenance organization, or other third party that pays for, provides, or administers health care services to individuals in the state. Registration as such is accompanied by mandatory examinations at least once every three years.

The Maryland act took effect on October 1, 2003.

South Dakota

In 2004, the South Dakota legislature passed House Bill 1311, which requires PBMs operating in that state to be licensed as third party administrators. The South Dakota law also provides that clients may request rebate and revenue information from their PBM and those clients may have PBM books audited. Finally, the South Dakota law directs that a prescription drug may be substituted for a more expensive drug only for medical reasons that benefit the individual enrollee.

The South Dakota law applies to PBM contracts entered into or renewed after June 30, 2004.

Washington, DC

In 2004, the Council of the District of Columbia passed a law that is substantially similar to the law passed by Maine in 2003, in that it imposes a fiduciary duty on PBMs in favor of PBMs' clients and requires considerable transparency in PBM business dealings with drug manufacturers.

In addition to the four laws discussed above, Georgia is frequently mentioned as a state that has instituted regulation of PBMs. However, the 2001 Georgia law simply requires PBMs to obtain licensure as pharmacies if they offer mail order pharmacy services. In this respect, the Georgia law is substantially similar to Colorado's nonresident pharmacy registration provision.

Analysis and Recommendations

Public Harm

The first sunrise criterion asks:

> Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument.

When discussing pharmacy benefit managers (PBMs), how harm is measured is critical to determining whether harm occurs. Consumers may suffer several types of easily recognizable harm as the result of PBM actions, such as physical harm from drug switching, higher prescription drug costs and not receiving drugs from mail order pharmacies. More tenuous forms of harm could include higher overall healthcare costs, loss of or reduction in healthcare coverage, and higher costs for non-prescription products purchased at pharmacies.

Regardless of how harm is measured, the Applicant has failed to produce any specific instances of harm suffered by Coloradans. Indeed, the Applicant has merely lodged accusations based on anecdotal evidence that cannot be confirmed.

Perhaps the single most important type of harm alleged by the Applicant involves drug switching. This is the process whereby a physician prescribes Drug A, which is in the same therapeutic class as Drug B. Drug B is on the formulary, but Drug A is not, so when the pharmacist seeks PBM-approval of Drug A, the PBM instructs the pharmacist to contact the physician to switch the prescription to Drug B. The pharmacist does this and the patient, expecting to receive Drug A, instead receives Drug B.

The Applicant alleges that in receiving Drug B rather than Drug A, the consumer is harmed because the physician's first choice had been Drug A. Although both drugs may be in the same therapeutic class, they are different at the molecular level and the physician had reason to prescribe Drug A rather than Drug B.

This hypothesis is questionable, however, for it presumes that the physician had valid clinical reasons for prescribing Drug A. This may be the case in some instances, but research shows that it is not necessarily the case in all instances.

While there is a lack of comprehensive research into why physicians prescribe the drugs that they do, there is considerable research regarding the effects on physician prescribing habits from drug manufacturers' direct to consumer and direct to physician marketing efforts.

A 1994 article in the *New England Journal of Medicine* stated:

> Pharmaceutical companies are waging aggressive campaigns to change prescribers' habits and to distinguish their products from competing ones, even when the products are virtually indistinguishable. . . . Victory in these therapeutic-class wars can mean millions of dollars for a drug company. But for patients and providers it can mean misleading promotions, conflicts of interest, increased costs for health care, and ultimately, inappropriate prescribing.[10]

Direct to consumer and direct to physician marketing can take several forms. For example, direct to consumer marketing includes television, radio and print advertisements lauding the virtues of particular drugs. A 2003 report published by the Kaiser Family Foundation found that almost 25 percent of Americans have asked their physicians about particular brand name drugs as the result of such marketing efforts.[11] Another study found that patients who ask their physicians for particular drugs are nearly 17 times more likely to receive prescriptions for those drugs than those patients who do not ask.[12]

This phenomenon led researchers writing in the *Journal of the American Medical Association* to conclude in 2003 that direct to consumer advertising has "fundamentally transformed the physician and patient roles in prescribing decisions."[13]

Direct to physician marketing plays an important role in prescribing habits also. In 2004, *The New York Times* reported that drug manufacturers routinely pay physicians up to $10,000 to participate in "drug trials," which essentially amount to physicians agreeing to prescribe one drug over another.[14] Although The Kaiser Family Foundation reported that only 12 percent of physicians admitted to receiving financial incentives from drug manufacturer representatives, 61 percent admitted to receiving free meals, tickets to events or travel. Additionally, 92 percent reported receiving free samples of prescription drugs.[15]

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[10] "Therapeutic-Class-Wars – Drug Promotion in a Competitive Marketplace," by D. Kessler, J. Rose, R. Temple, R. Schapiro and J. Griffin, *The New England Journal of Medicine*, Nov. 17, 1994, p. 1350.

[11] "Demand Effects of Recent Changes in Prescription Drug Promotion," by M. Rosenthal and E. Berndt, *et al*, for The Kaiser Family Foundation, June 2003, p. 1.

[12] "How Does Direct-to-Consumer Advertising (DTCA) Affect Prescribing? A Survey in Primary Care Environments With and Without Legal DTCA," by B. Mintzes, M. Barer and R. Kravitz, *et al*, *Journal of the Canadian Medical Association*, Sept. 2, 2003, p. 410.

[13] "Direct-To-Consumer Advertising and Shared Liability for Pharmaceutical Manufacturers," by M. Mellow, M. Rosenthal and P. Neumann, *Journal of the American Medical Association*, Jan. 22/29, 2003, p. 477.

[14] "As Doctors Write Prescriptions, Drug Company Writes a Check," *The New York Times*, June 27, 2004.

[15] "National Survey of Physicians – Part II: Doctors and Prescription Drugs," *The Kaiser Family Foundation*, March 2002.

Thus, no one can say for certain what leads a physician to prescribe Drug A over Drug B. While it is comforting to believe that prescribing decisions are based on clinical evaluations and determinations, the prevalence of prescription drug marketing to both physicians and consumers casts doubt on such beliefs.

This is important when discussing drug switching because, if Drug A was originally prescribed due to successful marketing efforts, rather than due to clinical determinations, what harm does the consumer truly suffer as a result of receiving Drug B?

As part of this sunrise review, the Department of Regulatory Agencies (DORA) surveyed five percent of Colorado-licensed physicians and 10 percent of Colorado-licensed pharmacists. With an overall response rate of 39 percent, the results of the survey may be considered reliable.

One question on the survey, which can be found in Appendix B on page 47, asked whether the physician or pharmacist was aware of any physical harm as a result of drug switching. Twenty-four percent of respondents that reported knowledge of drug switching did not know whether their patients had suffered physical harm as a result of the switch, and another 24 percent reported that no physical harm had occurred. Even more telling, however, is the fact that only five percent of respondents reported that they knew of physical harm.[16] Thus, it is difficult to determine the extent to which drug switching results in physical harm.

It is not even clear from the survey results that drug switching is as common of a practice as the Applicant asserts. Only 56 percent of respondents reported having been contacted by a pharmacist or a PBM to change a prescription, and this occurs, on average, only 11.6 times per month. Interestingly, more physicians (62 percent at an average of 3.9 times per month) report this occurring than pharmacists (47 percent at an average of 9.0 times per month). In other words, the survey indicates that while more physicians are contacted regarding drug switches, they are contacted less frequently than pharmacists.

Since the Applicant failed to provide specific instances of physical harm to consumers resulting from drug switching and since DORA's own survey reveals that if physical harm does result from drug switching, it happens relatively infrequently, regulation cannot be recommended based on the premise of preventing physical harm.

However, it is also argued that PBMs influence a system that results in higher prescription drug prices that ultimately harm consumers, employers and health insurance carriers. This argument revolves around the lack of transparency regarding the manner in which PBMs receive rebates from drug manufacturers.

[16] Numbers do not add up to 100 percent due to rounding and because not all survey respondents who reported having knowledge of drug switching answered the survey question regarding physical harm.

Although a very complex issue, it can be explained in relatively simple terms. Recall that PBMs administer drug benefits that are based on formularies. Drugs that are listed on the formulary are considered "preferred," and thus the consumer's co-payment or cost-sharing obligation is generally lower than for non-formulary or "non-preferred" drugs. A co-payment is a fixed dollar amount that the consumer pays to the pharmacy when the prescription is filled. Cost-sharing obligations include co-payments, but can also include an arrangement whereby the consumer pays a percentage of the cost of the drug. Under both arrangements, the healthcare plan pays whatever the consumer does not. Throughout this report, "co-payment" is used generically, to refer to co-payments and cost-sharing obligations.

Some formularies are "closed," meaning that drugs are either preferred or non-preferred. Some formularies are "tiered," meaning that there are varying levels of preference. For example Tier 1 may comprise generic drugs, Tier 2 may comprise preferred branded drugs and Tier 3 may comprise all other branded drugs. Under this scenario, Tier 1 would have the lowest co-payment and Tier 3 would have the highest co-payment, with Tier 2's co-payment laying somewhere in between.

Thus, as far as the consumer is concerned, preferred drugs are less expensive than non-preferred drugs. In this manner, the formulary, through the imposition of varying co-payments, encourages the use of preferred drugs.

This is particularly important when discussing drugs in the same therapeutic class. These are drugs that ostensibly do the same thing, such as reducing blood serum cholesterol, but are produced by different manufacturers. In order to receive patents, such drugs, often referred to as "me too drugs," must be molecularly different from one another, which also means that one may work better than another under certain circumstances, or one may have different or more severe side-effects than another. It is the competition between drugs in the same therapeutic classes that drive drug manufacturer marketing efforts.

In this sense, placement on PBM formularies is all-important. Since there is such a large number of drug manufacturers, each with relatively small market shares, even a "me too" drug with a small market share can generate tens of millions of dollars in sales.[17]

One way to increase the market share of a particular drug is to secure placement of that drug on as many formularies as possible because then the PBMs, through their formularies, will steer consumers towards the preferred drugs and away from the non-preferred drugs, thus generating greater market share for the manufacturer of the preferred drug.

[17] Kessler, *et al.* at 1351.

In order to secure placement on formularies, drug manufacturers offer financial incentives, in the form of rebates, to the PBMs. Since both PBMs and drug manufacturers refuse to disclose their agreements with one another regarding the structure of these rebates, speculation reigns. This is the root cause of complaints regarding lack of transparency among PBMs.

While it is impossible to determine the prevalence of one rebate structure over another, it is possible to summarize the various structures. The simplest rebate is one where the drug manufacturer pays the PBM for each prescription filled. "Market share" rebates are structured such that the PBM receives increasingly greater payments for the more market share of a particular drug that PBM delivers.

Given this, the incentive to engage in drug switching becomes apparent. Since the PBM receives a rebate for preferred drugs and not for non-preferred drugs, the PBM has a monetary incentive to switch its enrollees from non-preferred drugs to preferred drugs. While this raises obvious conflict of interest concerns, as the discussion above concluded, there is little evidence that such practices are resulting in physical harm to consumers.

Whether such practices result in higher costs, however, is another question entirely. This question deserves analysis from at least two different perspectives: 1) consumers and 2) health plan sponsors, including employers and health insurance carriers.

There is no direct evidence that PBM practices result in higher prescription drug prices for consumers. In fact, quite the opposite is true. According to the survey DORA conducted in connection with this sunrise review, 57 percent of physicians and 54 percent of pharmacists that reported having been contacted by a PBM or a pharmacy regarding a drug switch also reported that the new drug was less expensive than the originally prescribed medication. Only five percent of physicians and nine percent of pharmacists reported that the new medication was more expensive, and 30 percent of physicians and 31 percent of pharmacists reported that they did not know the cost differential. Therefore, at least half the time, the consumer pays less for the preferred drug than for the non-preferred drug. This is exactly how the use of formularies is intended to keep down the cost of prescription drugs.

The out of pocket cost to the consumer at the pharmacy, however, is not the only cost involved. Recall that when a prescription is filled, the PBM reimburses the dispensing pharmacy according to a contracted rate. Additionally, PBM clients pay the PBM for its services on either a per-transaction basis, or on a per-enrollee basis. Thus, in addition to rebates from drug manufactures, PBMs may earn profit by "playing the spread" between what the client pays the PBM and what the PBM pays the pharmacy.

This is another place in which formulary design is critical. PBMs maintain that they do not design the formularies. Rather, they assist their clients in designing the formularies. The Applicant asserts that while this may technically be true, it is somewhat misleading because in most cases, the PBM presents a client with a baseline formulary from which the client may deviate. Due to rebate considerations, the PBM may attempt to dissuade tampering with the pre-developed formulary.

In this type of situation, the Applicant argues, the PBM asserts that the average wholesale price (which is a controversial figure itself) on Drug A is $100 for a 30-day supply, but it can provide Drug A to its client for $90. To the client, this appears to be cost effective, so the client agrees to include Drug A on the formulary. Throughout this process, the PBM does not tell the client that the manufacturer of Drug A will pay a rebate of $20 to the PBM for each prescription filled, which reduces the PBM's actual cost of the drug to $80, thus generating a profit for the PBM of $10.

While some view this as legitimate profit for the PBM, the conclusion of this line of reasoning is cause for concern, for what the PBM did not tell the client is that Drug B, a therapeutic equivalent, could have been provided for $85. Thus, the client, which is an employer or health insurance carrier, ends up paying five dollars more than necessary.

In this manner, PBM profit potential, rather than clinical considerations, determine which therapeutically equivalent drugs secure positions on formularies and which do not. According to this line of reasoning, if the market were truly allowed to operate, purely monetary considerations would lead to greater use of Drug B, because Drug B is less expensive. In the end, this would reduce the speed at which prescription drug spending is increasing.

Additionally, the consumer may, in the end, pay more for health care under the current situation because higher prescription drug costs will ultimately lead to increased co-payments or cost sharing, higher insurance premiums, or the loss of health care coverage altogether.

However, a July 2004, joint Federal Trade Commission (FTC) and U.S. Department of Justice (DOJ) study found that PBMs have saved money for their clients.[18] Furthermore, it is inaccurate to lay the blame for increased prescription drug costs at the feet of the PBMs alone. Drug manufacturers also bear some responsibility.

According to two separate reports issued by Families USA and the American Association of Retired Persons (AARP) in late spring 2004, brand name prescription drug prices rose between two and five times the rate of inflation between 2000 and 2004.[19] According to the AARP report, the prices of drugs in therapeutic classes with at least three brand name drugs have increased between 6 and 10 times the rate of inflation.

Families USA found that drugs for which there are no generic equivalents are the primary drivers of inflation in prescription drug costs.

[18] *Improving Health Care: A Dose of Competition*, a joint report by the Federal Trade Commission and the U.S. Department of Justice, July 24, 2004, Exec. Summ., p. 20.

[19] "Sticker Shock: Rising Prescription Drug Prices for Seniors," a report by Families USA, June 2004, p. 2. "Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 through 2003," by D. Gross, S. Schondelmeyer and S. Raetzman, AARP Pub. No. 2004-06, May 2004, p. 16.

This leads to another argument put forward by proponents of regulation: PBMs encourage the use of brand name drugs over generic drugs. Presumably, a PBM's motivation for doing this rests upon the fact that rebates are generally unavailable for generic drugs, so there is no financial incentive for the PBM to encourage their utilization.

Opponents of regulation dismiss such assertions. They claim that while this may have been true in the past -- when drug manufacturers owned PBMs, generics were not favored -- such is no longer the case because the cost-savings to be realized through the utilization of generic drugs far outweigh any rebate incentives. Every one percent increase in generic drug utilization generates more than $200 million in savings.[20] Additionally, PBMs can make as much as 1,000 percent profit on generic drugs, further increasing their incentive to encourage their utilization.[21]

Therefore, while many of the conclusions discussed above may seem logical, they cannot be substantiated. They are little more than speculation and are either incorrect or tenuous at best. As the sunrise criterion quoted at the beginning of this discussion clearly states, regulation is justified only in those situations where harm to the public is clear, not tenuous or remote.

These and other types of harm have been attributed to PBMs in various lawsuits filed in courts across the nation. In *U.S. v. Merck-Medco Managed Care, L.L.C.* (Case. No. 00-CV-737), the United States and the attorneys general of 20 states (excluding Colorado) alleged that Merck-Medco and its successor company, Medco Health Solutions, Inc. (Medco), through its mail order pharmacies, had, among other things:

- Cancelled and destroyed prescriptions;
- Switched drugs without patient knowledge or consent;
- Shipped medications and billed patients for drugs they never ordered;
- Created false records of contacts with physicians regarding drug switches; and
- Solicited and received rebates from drug manufacturers.

The harmfulness of several of these allegations are either self-evident or have already been discussed. One, however, merits further discussion: canceling and destroying prescriptions.

According to the complaint filed by the United States in September 2003, Medco's mail order pharmacies operate under tight deadlines, which are in part dictated by Medco's contracts with its clients. These contracts permit patients to obtain a three-month supply of medication for the price of two. The contracts also specify that prescription orders filled at mail order pharmacies must be filled and shipped within a certain number of days.

[20] "Medco Home Delivery Achieves 91% Generic Rate for Lisinopril," *Drug Cost Management Report*, Sept. 2002.
[21] "PBMs Push Generic Drugs to Save Clients' Money, but What's In It For Them?" *Drug Cost Management Report*, June 2003.

In order to fulfill these contractual obligations, the mail order pharmacies allegedly routinely destroy prescription orders that have been received but not filled within the required time frames. When patients call to complain that they have not received their medications, they are told that the prescription order was not received.

This forces the patient to contact the prescribing physician to obtain a duplicate prescription order and to submit it again. This is inconvenient for the patient, time consuming for the physician, and can lead to medical problems and physical harm for the patient by delaying the prescribed drug therapy.

Since Medco operates in Colorado, it is reasonable to conclude that similar problems exist for Colorado consumers, even though Colorado is not participating in this lawsuit against Medco. Although the parties to the Medco lawsuit entered into a consent decree in April 2004, whereby Medco agreed to change many of its practices, Medco did not admit to any wrongdoing. Therefore, legally, the allegations mentioned above remain only allegations.

More generically, proponents of regulation assert that drug switching is more prevalent in mail order pharmacies than at retail pharmacies. They attribute this to the fact that mail order pharmacies have several days in which to contact prescribing physicians, whereas retail pharmacies typically have only several hours. However, as discussed above, there is no direct evidence that drug switching causes significant harm.

Therefore, there are several types of harm that consumers allegedly suffer at the hands of PBMs. However, DORA was unable to definitively substantiate that any of them occur in Colorado.

Need for Regulation

Although DORA is unable to substantiate any harm caused by PBMs, the second sunrise criterion must be addressed. The second sunrise criterion asks:

> Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence.

One argument put forward by proponents of regulation posits that regulation is warranted because PBMs are the only part of the healthcare industry that is not regulated. However, this does not justify regulation.

Colorado has a proud history of imposing regulation only when necessary. The argument just articulated essentially boils down to regulation for regulation's sake. Without clear evidence of harm or a need for regulation, regulation should not be imposed.

During the course of this sunrise review, representatives of DORA interviewed representatives of various PBM clients, including self-insured employers and health insurance carriers. Without exception, each of these representatives opposed regulation of PBMs, maintaining that their contracts with PBMs provide sufficient protection for themselves and for their enrollees.

The FTC and DOJ reached a similar conclusion, finding:

> Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms. Vigorous competition is also more likely to help ensure that gains from cost savings are passed on to consumers of health care services, either as lower premiums for health insurance, lower out-of-pocket costs (for that portion of health care expenditures borne directly by consumers through deductible and co-payments), or improved services. Negotiated limitations on transparency are unlikely to be so severe that health plan sponsors cannot assess the price and quality of the services they are receiving. Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages disclosure of the information health plan sponsors require to decide on the PBM with which to contract.[22]

This is important because proponents of regulation maintain that PBM clients lack the sophistication to understand formulary design and lack the capacity to understand the harmful nature of the relationships between PBMs and drug manufacturers.

This argument fails on several levels. First, the sunrise criteria are designed so as to ensure regulation is imposed only when there is clear evidence that the public is being harmed absent regulation, not when businesses are being harmed.

Additionally, and perhaps more convincingly, PBM clients are some of the most sophisticated businesses around – large employers and employer groups, and health insurance companies. What expertise these entities may lack in-house, they are certainly able to secure through consulting agreements. When things go wrong, these entities can sue the PBM. The various lawsuits now pending against PBMs across the nation provide ample evidence that this system works.

Not all of these lawsuits have been filed by PBM clients, however. Recall that the case against Medco was brought by the United States and 20 state attorneys general. This case, which is still pending, involves alleged violations of state unfair practices laws. Even this illustrates the adequacy of existing laws to protect consumers. When those laws are broken, violating PBMs are taken to task.

[22] *Improving Health Care: A Dose of Competition* at Chp. 7, p. 17.

The Medco case is important for more practical reasons as well. Pursuant to a consent decree entered on April 24, 2004, Medco will:

- Disclose to physicians and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to physicians and patients, Medco's financial incentives for certain drug switches;
- Disclose to physicians, material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for out-of-pocket costs for drug switch-related health costs and notify patients and physicians that such reimbursement is available;
- Obtain express, verifiable authorization from physicians for all drug switches;
- Inform patients that they may decline drug switches and receive the originally prescribed drug;
- Monitor the effect of drug switches on the health of patients; and
- Adopt the American Pharmacists Association code of ethics and principles of practice for pharmaceutical care for employees at its mail order pharmacies.

Additionally, the consent decree prohibits Medco from soliciting drug switches when:

- The net drug cost of the proposed drug exceeds the cost of the originally prescribed drug;
- The originally prescribed drug has a generic equivalent and the proposed drug does not;
- The switch is made to avoid competition from generic drugs; or
- The switch is made more often than once in two years within a therapeutic class of drugs for any patient.

Recall that Colorado is not a party to the lawsuit that produced the consent decree, so the terms of the consent decree are not binding on Medco's operations in Colorado. However, it is reasonable to conclude that Medco will adopt the requirements of the consent decree for all of its operations, rather than just half because it would not be cost effective to maintain two systems. Since Medco operates in Colorado, Colorado consumers can expect to benefit from the consent decree.

The consent decree applies only to Medco; it does not apply to any other PBM. However, competition among PBMs is fierce. If the terms of the Medco consent decree are perceived by PBM clients to present value, those clients will consider entering into future contracts with Medco, rather than other PBMs. It is reasonable to conclude that this will, ultimately, force other PBMs to adopt similar business practices in order to remain competitive. Again, Colorado consumers benefit.

Additionally, at least one researcher has concluded that the PBM industry as a whole seems to have heard the calls for greater transparency and is trending away from secrecy. "To the extent that this trend continues," the researcher found, "it suggests that free market forces are a viable alternative to fiduciary laws that mandate full disclosure."[23]

This sentiment was confirmed in conversations between representatives of PBMs and DORA. Since competition among PBMs is so intense, PBMs are increasingly likely to grant client requests to examine rebate and other agreements with drug manufacturers, provided strict confidentially precautions are observed. Since drug switching has traditionally been attributed to the PBMs' financial interests, this greater transparency can be expected to reduce the frequency of drug switching, thus further eliminating the need for regulation.

Since the contract between PBMs and their clients seem to afford those clients sufficient protection, and since the Medco consent decree and the free market seem to be increasing transparency in the industry, regulation is not warranted.

Alternatives to Regulation

The third sunrise criterion asks:

> Whether the public can be adequately protected by other means in a more cost-effective manner.

One alternative to regulation is the *status quo*. Although PBMs are not currently regulated directly, many of their functions are. For example, if a PBM operates a mail order pharmacy, that pharmacy must be registered with the Colorado State Board of Pharmacy. Similarly, many of Colorado's existing insurance statutes apply to PBMs under certain circumstances.

Additionally, until June 2004 and the creation of Medicare's prescription drug discount cards, PBMs rarely contracted directly with individuals to provide services. Rather, PBMs have traditionally contracted with self-insured employers, managed care organizations and health insurance carriers. In all of these traditional scenarios, the contract between the PBM and its client outlines the rights and responsibilities of the parties.

[23] "The Role of PBMs in Formulary Design: Service Providers or Fiduciaries?" by L. Abrams, March 2004, p. 20.

In the traditional scenario, the consumer rarely, if ever, deals directly with the PBM. Rather, if the consumer has a complaint, that complaint is typically filed with the individual's medical coverage provider (i.e., insurance company), which then deals with the PBM. If there are enough quality issues, or if the anticipated cost savings fail to materialize, the contract with the PBM may not be renewed.

Thus, PBM contracts with clients offer a viable alternative to direct state regulation. The viability of this alternative is evidenced by the many lawsuits around the nation involving PBMs and their clients. When the PBM fails to deliver on a contract, the client brings legal action.

Even if Colorado were to directly regulate PBMs, as the Applicant requests, the state would not replace clients in such lawsuits because contracts would continue to govern the relationships between PBMs and their clients. State regulation would merely seek to ensure PBM solvency and fair business practices. Since solvency has not been, and is not expected to become a problem for PBMs and the Applicant could not provide specific instances of harm and DORA could not document harm, there is no direct evidence that PBM business practices warrant regulation.

Yet another alternative to regulation is based on the legal principal of "fiduciary duty." In very simplified terms, a fiduciary duty requires the holder of the duty to place the interests of the duty's beneficiary above the interests of the holder.

One of the primary accusations leveled against PBMs posits that rather than looking out for the best interests of patients, PBMs are more concerned with maximizing their own profits. Provisions in the handful of laws that other jurisdictions have implemented in their attempts to regulate PBMs have included the imposition of fiduciary duties on PBMs to the benefit of PBM clients, patients, or both.

PBMs, however, argue that the imposition of such duties is void, unnecessary and counterproductive. Healthcare benefits offered by self-insured employers are governed by the Employee Retirement Income Security Act of 1974 (ERISA), which imposes upon ERISA-governed health plans, a fiduciary duty to the benefit of the patient. ERISA's pre-emption provisions all but preclude any state regulation of ERISA-governed health plans. Thus, the PBMs assert, any attempt to impose a fiduciary duty on them to the benefit of ERISA-governed patients, is void.

It is also valid to point out that in the case of ERISA, the self-insured employer has a fiduciary duty to the benefit of the patient, meaning that the employer is legally required to put the patient's interests above its own interests. Thus, as far as ERISA-governed health plans are concerned, the imposition of a fiduciary duty upon PBMs to the benefit of patients is unnecessary because the patient is already the beneficiary of the duty held by the employer.

Additionally, PBMs argue that it is illogical to impose upon them a fiduciary duty because they do not exercise discretion. According to PBMs, they simply administer the plans developed by their clients. The PBMs do not decide whether a drug is included on a formulary, they simply administer the formulary designed by the client.

This proposition rests upon the premise that a fiduciary duty is viable only under those circumstances where the holder of the duty has the authority to make decisions that could adversely impact the beneficiary. Since, in very simple terms, a fiduciary duty requires the holder of the duty to put the interests of the beneficiary above the interests of the holder, it is only logical that there must be some necessity for the holder to make some kind of decision for the beneficiary in order to impose the duty in the first place. Without the necessity, or ability, to make decisions, a fiduciary duty is moot.

When discussing fiduciary duties, it is also important to clearly identify the beneficiary of the duty. When discussing PBMs, is the proper beneficiary the client or the patient? This is vitally important because the client and the patient can have adverse interests in that what may be best for the client may not be best for the patient.

Although research indicates many factors play roles in determining which particular drug in a given therapeutic class a physician will prescribe, the following example assumes that the purpose for prescribing Drug A is based on a clinical determination that Drug A is more ideal than Drug B. In this example scenario, a physician prescribes Drug A. However, Drug B is a therapeutic equivalent but is less expensive. While the patient's best interests, which are governed by clinical concerns, may require Drug A, the client's best interests, which are governed by economic concerns, may require Drug B. Their interests are diverse.

Finally, PBMs argue that imposing a fiduciary duty on PBMs would actually serve to harm consumers by defeating the PBM business model. This argument rests on the idea that the very lack of transparency that the Applicant criticizes, serves to protect consumers by allowing PBMs to negotiate better and better deals with drug manufacturers, which ultimately result in lower prescription drug costs. The argument assumes that fiduciary status would require disclosure of the agreements between drug manufacturers and PBMs.

In the end, most alternatives to regulation appear to already be in place, to one extent or another. All clients have contracts with their PBMs upon which they can sue on whatever grounds are appropriate. While PBMs may not hold a fiduciary duty to anyone, PBM clients often do hold such duties to the benefit of their enrollees, so the consumer is protected.

Regardless, accusations persist that PBMs influence formulary design and physician prescribing habits to their own benefit and to the possible detriment of the client, the patient or both.

Therefore, a viable alternative to regulation would impose an ERISA-like fiduciary duty on all ERISA-exempt PBMs in favor of patients whose drug benefits are administered by such PBMs. This duty would only apply to those PBMs that actually exercise discretionary authority, either by contract or in violation of a contract. Such a provision could be inserted into the Colorado Consumer Protection Act so that the Attorney General's Office (AGO) could receive and act on complaints. This structure would not violate pre-emption principles and would only apply to those PBMs that actually make decisions. The AGO would then have to establish 1) that the PBM is not subject to ERISA in a given case; 2) that the PBM made decisions; and 3) that such decisions breached the PBM's fiduciary duty to the consumer.

Conclusion

Given the clear lack of demonstrated harm, the regulation proposed by the Applicant is not only overly broad and unwarranted it is also protectionist with respect to pharmacies.

A simple review of the Applicant's proposed legislation, which can be found in Appendix A on page 32, demonstrates the Applicant's interest in protecting pharmacies and pharmacists, not necessarily consumers.

For example, only two of the seven prohibited acts described in section 12 clearly benefit consumers: prohibition against PBM interference in the transmission of prescriptions from a physician to a pharmacy and the prohibition against drug switching without first receiving authorization from the prescribing physician and the patient. Furthermore, it is arguable that two of the prohibited practices intended to protect pharmacies could actually harm consumers.

First, section 12(C) prohibits PBMs from discriminating with respect to inclusion in pharmacy networks. This type of provision is also referred to as an "any willing provider" provision, meaning that it restricts the ability of PBMs to refuse to contract with certain pharmacies and limits the ability of PBMs to negotiate with those pharmacies with which it does contract. Under this type of scenario, a PBM would develop a standard contract and offer it to all pharmacies. If a pharmacy chose to accept the terms of that contract, it could sign and join the network. If a pharmacy chose to reject the terms of that contract, it could refuse to sign and, thus, not become part of the network. In other words, any pharmacy willing to accept the contract could then provide pharmacy services to those patients.

PBMs offer three arguments against "any willing provider" provisions. Such provisions deny PBMs with a quality control mechanism. That is, if it is obvious that a particular pharmacy will be difficult to work with or that it will not abide by its contractual obligations, the "any willing provider" provision would deny the PBM the ability to refuse to contract with such a pharmacy. This is inefficient and violates the general principal of freedom of contract, a central tenet of contract law.

Such provisions also limit a PBM's ability to customize pharmacy networks for clients. While the goal of most clients is to provide a pharmacy network that is as convenient as possible for enrollees and that offers enrollees a considerable degree of choice, such is not always the case. There are clients that desire smaller, more restricted networks.

Generally, though not always, smaller networks cost the client less than larger networks. This is because when selecting pharmacies for a smaller network, the PBM is able to offer participating pharmacies a more solid revenue stream. For example, larger, open pharmacy networks allow patients to go to any one of a number of pharmacies. Thus, the amount of business that the PBM can guaranty to such pharmacies is limited because the patients decide which pharmacies to go to. As a result, the PBM's ability to negotiate reimbursement rates with the pharmacy is weaker.

With a smaller network, however, the PBM can guaranty participating pharmacies with more business, because the patients have a more limited selection of pharmacies. As a result, the PBM can extract better prices from the pharmacy and those savings are then, in theory, passed to the client, and ultimately the consumer, through either lower co-payments or lower premiums.

"Any willing provider" provisions, however, prohibit this ability and deny this cost-saving option to clients. Since those clients would be forced to pay more to the PBM, the patients involved would face higher co-payments or other cost sharing, higher premiums, or both. Thus, what would serve to protect pharmacies by ensuring their ability to participate in PBM networks would actually cost the consumer more without delivering any added benefit to the consumer.

Finally, the FTC and DOJ found that most PBMs contract with almost 90 percent of retail pharmacies in the areas the PBMs serve.[24] It is important to draw the distinction between mandatory "any willing provider" statutes and this finding. The fact that fewer than 100 percent of pharmacies are included in the networks lends credence to the arguments raised against "any willing provider" statutes. Clearly, PBMs have reasons for not contracting with 10 percent of the pharmacies in the regions they serve. Those reasons could be based on quality control, incompatible computer systems, restricted networks, or other issues.

Additionally, given the current environment, a pharmacy negotiating with a PBM is not guaranteed inclusion in the network, thus the pharmacy has an incentive to offer greater discounts to the PBM with which it is negotiating. This incentive evaporates if the pharmacy is guaranteed inclusion in the network by virtue of an "any willing provider" statute.

[24] *Improving Health Care: A Dose of Competition* at Chp. 7, p.12.

In an April 2004 letter, the FTC found:

> Any willing provider [statutes] have the unintended consequences of limiting competition, undermining freedom of choice, and increasing the costs of pharmaceutical services. Of course, to the extent that these prices rise, they would also have the effect of increasing health insurance prices and restricting the availability of insurance.[25]

States with "any willing provider" statutes typically spend two percent more on healthcare than states without such statutes.[26] Thus, not only are "any willing provider" provisions anti-competitive, they also increase the overall cost of healthcare, which ultimately harms the consumer.

Section 12(E) of the Applicant's proposed legislation would prohibit a PBM from offering discounted co-payments when patients utilize mail order pharmacies. Mail order pharmacies are generally used for medications that treat chronic conditions.

In a typical scenario, a patient may pay a local, retail pharmacy a $20-co-payment, for example, for a 30-day supply of medication. Alternatively, the patient could pay a mail order pharmacy a $40-co-payment for a 90-day supply of the same medication, realizing a savings of $20.

Opponents of mail order pharmacies raise several arguments in support of their efforts. First, they argue, PBMs attempt to coerce patients to use mail order pharmacies because PBMs realize greater profits when patients use the PBMs' own pharmacies. In this way, reimbursements that otherwise would have been paid to retail pharmacies are kept in-house. Additionally, PBMs are able to purchase drugs at better prices on the wholesale market than retail pharmacies because the PBMs purchase such drugs in greater numbers and mail order pharmacies are generally highly automated, making them more profitable than most brick and mortar retail pharmacies.

Second, opponents of mail order pharmacies allege that PBMs charge health plan sponsors more than is necessary because of repackaging. In this scenario, the PBM's mail order pharmacy repackages 30-day supply units into 90-day supply units and increases the cost of the 90-day packages disproportionately. Thus, the health plan sponsor realizes little or no cost savings.

[25] Letter dated April 8, 2004, from T. Zywicki, S. Creighton, L. Froeb and D. Hyman of the FTC to P. Lynch and J. Pichardo of the State of Rhode Island.

[26] "Regulatory Restrictions on Selective Contracting: An Empirical Analysis of 'Any Willing Provider' Regulations," *Journal of Health Economics*, 20 (2001), pp. 955-966.

Finally, opponents of mail order pharmacies point to the allegations contained in the lawsuit against Medco. It is alleged in that suit that Medco's mail order pharmacies switched drugs without obtaining prior approval from prescribing physicians and that in order to meet certain goals, prescription orders were destroyed. Most mail order pharmacies have goals regarding the amount of time that passes between when a prescription order is first received and when that order is shipped out. In the Medco case, if orders were not filled within allowable time frames, those orders were "lost" so that they would not be counted against the pharmacy's management team.

In such situations, the consumer is harmed because the consumer does not receive the prescribed medication in a timely manner and will very likely have to resubmit the order. The consumer may also have to visit the prescribing physician a second time, or at the very least, place a call to the physician's office, in order to obtain a replacement order.

While some of these points are valid, particularly with respect to drug switching and "lost" orders, mail order pharmacies also offer consumers a tremendous benefit. In addition to reduced co-payments, mail order pharmacies are, for the most part, more convenient. A patient who uses a mail order pharmacy need travel no further than the mailbox to submit an order and to retrieve it. Additionally, most mail order pharmacies maintain 24-hour call centers for consumer questions, something very few retail pharmacies offer.

The mail order pharmacy business is growing. In 1992, mail order pharmacies filled approximately 8.9 percent of prescription orders.[27] By 2003, that number reached 11 percent.[28]

Thus, while mail order pharmacies are less than perfect, they do offer consumers the advantage of convenience and lower co-payments.

Section 14 of the Applicant's proposed legislation would set the rate at which PBMs would be required to reimburse pharmacies by tying reimbursement rates to the average wholesale price (AWP) for single-source, brand name drugs, and to maximum allowable costs (MAC) for generic drugs. Since AWP is a drug's "sticker price" and is determined by the drug's manufacturer, not necessarily market forces, this would allow drug manufacturers, not the market, to establish reimbursement rates to pharmacies. In addition, this would prevent PBMs from negotiating with pharmacies to obtain lower rates. Instead, the Applicant proposes that all pharmacies be reimbursed at the same rate. Taken in conjunction with the proposed "any willing provider" provision discussed above, this would completely eviscerate a PBM's ability to negotiate with retail pharmacies because all contracts would necessarily be identical. It is reasonable to conclude that this would lead to an overall increase in what consumers pay for prescription drugs.

[27] "The Cost of PBM 'Self-Dealing' Under a Medicare Prescription Drug Benefit," by J. Langenfild and R. Maness, Sept. 9, 2003, p. 4.
[28] "PBMs Push Mail-Order Penetration Rates, but Employers Should be Wary of Incentives," *Managed Care Week*, Sept. 15, 2003.

Finally, the Applicant's proposed legislation provides for fairly onerous reporting and filing requirements for which the Applicant has provided no evidence of need. For example, section 6 would require a PBM to post a fidelity bond equal to 10 percent of funds handled by the PBM. Such bonds are typically used to pay obligations that are unmet. However, no evidence has been provided to suggest that solvency is an issue for PBMs or that PBMs refuse to pay their obligations. Thus, there is no justification for such an onerous requirement.

As this report has mentioned numerous times in numerous contexts, the Applicant was unable to provide DORA with specific instances of harm to Colorado consumers as a result of non-regulation of PBMs. This is critically important because there is no justification for regulation if there is no harm.

With this in mind, DORA surveyed Colorado-licensed physicians and pharmacists. Only five percent of respondents reported that consumers had been harmed by drug switching. While this is evidence of harm, it is insufficient to justify the level of regulation proposed by the Applicant.

Additionally, it is reasonable to assume that since Medco operates in Colorado, the harm alleged in the lawsuit against Medco also occurs in Colorado. However, since this is presumed evidence and not direct evidence of harm to Colorado consumers, it, too, is insufficient to justify the level of regulation proposed by the Applicant.

Nevertheless, harm to Colorado consumers is, at the very least, foreseeable. A viable alternative to the Applicant's proposal would impose an ERISA-like fiduciary duty on all ERISA-exempt PBMs in favor of patients whose drug benefits are administered by such PBMs. This duty would only apply to those PBMs that actually exercise discretionary authority, either by contract or in violation of a contract. Such a provision could be inserted into the Colorado Consumer Protection Act so that the AGO could receive and act on complaints. This structure would not violate pre-emption principles and would only apply to those PBMs that actually make decisions. The AGO would then have to establish 1) that the PBM is not subject to ERISA in a given case; 2) that the PBM made decisions; and 3) that such decisions breached the PBM's fiduciary duty to the consumer.

This proposal has several benefits. First, it would not actually regulate PBMs. Rather, this proposal would grant to the AGO the clear legal ability to bring action against PBMs that exercise discretionary authority, regardless of whether that authority is exercised by virtue of a contract or outside the scope of a contract. Since PBMs claim that they do not exercise such authority, this proposal should not adversely affect them. At whatever point they cross the line, however, Colorado law would hold them responsible for ensuring that any discretion that is exercised is exercised in the best interests of the patient, not the PBM.

Additionally, this proposal could help to address the lack of evidence of harm to consumers. By enabling the AGO to receive and act on complaints against PBMs, this proposal would create a repository of evidence of harm, if any occurs. If, at some future point, there is sufficient harm to warrant increased oversight or regulation, then the evidence would exist to support such an effort.

While the level of regulation proposed by the Applicant is not warranted, some legislative action seems appropriate in light of the fact that harm to Colorado consumers is, at the very least foreseeable, though not yet documented.

Recommendation - Impose an ERISA-like fiduciary duty on all ERISA-exempt PBMs in favor of patients whose drug benefits are administered by such PBMs. This duty should only apply to those PBMs that actually exercise discretionary authority, either by contract or in violation of a contract. This provision should be inserted into the Colorado Consumer Protection Act so that the AGO can receive and act on complaints.

Appendix A – NCPA Pharmacy Benefit Manager Licensure and Solvency Protection Model Act

NCPA

Pharmacy Benefit Manager Licensure and Solvency Protection Model Act

Table of Contents

Section 1. Title.

This Act shall be known and cited as the Pharmacy Benefit Manager Licensure and Solvency Protection Act.

Section 2. Purpose and Intent.

The purpose of this Act is to establish standards and criteria for the regulation and licensing of Pharmacy Benefit Managers. This Act is designed to promote, preserve, and protect the public health, safety, and welfare by and through effective regulation and licensing of Pharmacy Benefit Managers.

Section 3. Definitions.

For purposes of this Act:

A. "Board of Pharmacy" or "Board" means the State Board of Pharmacy.

B. "Commissioner" means the Commissioner of Insurance.

C. "Covered Person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan.

D. "Department" means Department of Insurance.

E. "Health Benefit Plan" means a policy, contract, certificate or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the cost of health care services including prescription drug benefits.

F. "Maintenance drug" means a drug prescribed by a practitioner who is licensed to prescribe drugs and used to treat a medical condition for a period greater than 30 days.

G. "Multi-source drug" means a drug that is stocked and is available from three or more suppliers.

H. "Pharmacist" means any individual properly licensed as a pharmacist by the State Board of Pharmacy.

I. "Pharmacist Services" includes drug therapy and other patient care services provided by a licensed pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the Rules of the Board.

DRAFTING NOTE: You may define it as "the practice of pharmacy as defined in (provide state code cite)."

J. "Pharmacy" means any appropriately licensed place within this state where drugs are dispensed and pharmacist services are provided.

DRAFTING NOTE: You may define it by referencing the appropriate cite in the state code.

K. "Pharmacy Benefit Management Plan" means an arrangement for the delivery of pharmacist services in which a Pharmacy Benefit Manager undertakes to, pay for, or reimburse any of the costs of pharmacist services for a covered person on a prepaid or insured basis which (i) contains one or more incentive arrangements intended to influence the cost or level of pharmacist services between the health benefit plan sponsor and one or more pharmacies with respect to the delivery of pharmacist services and (ii) requires or creates benefit payment differential incentives for covered persons to use under contract with the Pharmacy Benefit Manager.

L. "Pharmacy Benefits Manager" or "PBM" means a person, business or other entity and any wholly or partially owned or controlled subsidiary of such entity, that administers the prescription drug/device portion of health benefit plans on behalf of a third party including plan sponsors, insurance companies, unions, and health maintenance organizations in accordance with a pharmacy benefit management plan.

M. "Usual and Customary Price" means the price the pharmacist would have charged a cash paying (not a patient where reimbursement rates are set by a contract) patient for the same services on the same date inclusive of any discounts applicable.

Section 4. Applicability and Scope.

This Act shall apply to a Pharmacy Benefit Manager that provides claims processing services, other prescription drug or device services, or both to covered persons who are residents of this state.

Section 5. Certificate of Authority to act as a Pharmacy Benefit Manager.

A. No person or organization shall act or operate as a Pharmacy Benefit Manager in this state without a valid certificate of authority issued by the Department. The failure of any person to hold such a certificate while acting as a Pharmacy Benefit Manager shall subject such person to a fine of not less than $5,000 or more than $10,000 for each violation.

B. Each person seeking a certificate of authority to act as a Pharmacy Benefit Manager shall file with the Department an application for a certificate of authority upon a

form to be furnished by the Department, which application shall include or have attached the following information and documents:

(1) All basic organizational documents of the Pharmacy Benefit Manager, such as the articles of incorporation, articles of association, partnership agreement, trade name certificate, trust agreement, shareholder agreement and other applicable documents and all amendments to those documents.

(2) The bylaws, rules and regulations or similar documents regulating the conduct or the internal affairs of the Pharmacy Benefit Manager.

(3) The names, addresses, official positions and professional qualifications of the individuals who are responsible for the conduct of the affairs of the Pharmacy Benefit Manager, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association and any other person who exercises control or influence over the affairs of the Pharmacy Benefit Manager.

(4) A Certificate of Compliance issued by the State Board of Pharmacy indicating that the Pharmacy Benefit Manager's plan of operation is consistent with the Pharmacy Practice Act and any regulations promulgated thereunder.

(5) Annual statements or reports for the 3 most recent years, or such other information as the Department may require in order to review the current financial condition of the applicant.

(6) If the applicant is not currently acting as a Pharmacy Benefit Manager, a statement of the amounts and sources of funds available for organization expenses and the proposed arrangements for reimbursement and compensation of incorporators or other principals.

(7) The name and address of the agent for service of process in the state.

(8) A detailed description of the claims processing services, pharmacy services, insurance services, other prescription drug or device services, audit procedures for network pharmacies or other administrative services to be provided.

(9) All incentive arrangements or programs such as rebates, discounts, disbursements, or any other similar financial program or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical company, that relates to prescription drug or device services, including at a minimum information on the formula or other method for calculation and amount of the incentive arrangements, rebates or other disbursements, the identity of the associated drug or device and the dates and amounts of such disbursements.

(10) A copy of the Fidelity Bond required in Section 6.

(11) Such other information as the Commissioner may require.

(12) A filing fee of $5,000.

C. The applicant shall make available for inspection by the Department copies of all contracts with insurers or other persons utilizing the services of the Pharmacy Benefit Manager. Certain contracts are subject to prior approval as provided in Section 11.

D. The Department shall not issue a certificate of authority if it determines that the Pharmacy Benefit Manager or any principal thereof is not competent, trustworthy, financially responsible, or of good personal and business reputation or has had an insurance license or pharmacy license denied for cause by any state.

E. A certificate of authority issued under this section shall remain valid, unless suspended or revoked by the Department, so long as the Pharmacy Benefit Manager continues to do business in this state.

Section 6. Fidelity Bond.

A Pharmacy Benefit Manager shall have and keep in full force and effect a fidelity bond equal to at least 10 percent of the amount of the funds handled or managed annually by the Pharmacy Benefit Manager. However, the Department, after due notice to all interested parties and an opportunity for hearing and after consideration of the record, may require an amount in excess of $500,000 but not more than 10 percent of the amount of the funds handled or managed annually by the Pharmacy Benefit Manager.

Section 7. Certificate of Compliance issued by Board of Pharmacy.

A. Each Pharmacy Benefit Manager seeking to become licensed in the state must submit its plan of operation for review in a format to be furnished by the Board of Pharmacy.
B. The Board will review the submission in order to determine if it complies with the Pharmacy Practice Act. The Board shall promulgate rules and regulations concerning, but not limited to, the format required, the fee to accompany the filing, the requirements for annual filings for re-certification and any other information that it may require to complete its review.
C. If the Pharmacy Benefit Manager's filing meets with the Board 's approval, it shall be issued a Certificate of Compliance. Subsequent changes in the plan of operation must be filed with the Board.
D. The Pharmacy Benefit Manager must update its filing on an annual basis.
E. The fees collected shall be used solely for the purpose of regulating Pharmacy Benefit Managers.

Section 8. Disclosure of ownership or affiliation and certain agreements.

A. Each Pharmacy Benefit Manager shall identify to the Department any ownership interest or affiliation of any kind with:

1. Any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the Pharmacy Benefit Manager provides services; or

2. Any parent companies, subsidiaries and other entities or businesses relative to the provision of pharmacy services, other prescription drug or device services or a pharmaceutical manufacturer.

B. Every Pharmacy Benefit Manager shall disclose the following agreements:

1.any agreement with a pharmaceutical manufacturer to favor the manufacturer's products over a competitor's products or to place the manufacturer's drug on the Pharmacy Benefit Manager's preferred list or formulary, or to switch the drug prescribed by the patient's health care provider with a drug agreed to by the Pharmacy Benefit Manager and the manufacturer;

2.any agreement with a pharmaceutical manufacturer to share manufacturer rebates and discounts with the Pharmacy Benefit Manager or to pay money or other economic benefits to the Pharmacy Benefit Manager,

3.any agreement or practice to bill the health plan for prescription drugs at a cost higher than the Pharmacy Benefit Manager pays the pharmacy and

4. any agreement to share revenue with a mail order or internet pharmacy company.

5.any agreement to sell prescription drug data including data concerning the prescribing practices of the health care providers in the state.

Section 9. Maintenance of records by Pharmacy Benefit Manager; access; confidentiality; financial examination.

A. Every Pharmacy Benefit Manager shall maintain for the duration of the written agreement and for 2 years thereafter books and records of all transactions between the Pharmacy Benefit Manager, insurers, covered persons and pharmacies.

B. The Department shall have access to books and records maintained by the Pharmacy Benefit Manager for the purposes of examination, audit and inspection. The information contained in such books and records is confidential. However, the Department may use such information in any proceeding instituted against the Pharmacy Benefit Manager or insurer.

C. The Commissioner shall conduct periodic financial examinations of every Pharmacy Benefit Manager in this state to ensure an appropriate level of regulatory oversight. The Pharmacy Benefit Manager shall pay the cost of the examination. The cost of the examination shall be deposited in a special fund to provide all expenses for the regulation, supervision and examination of all entities subject to regulation under this Act.

Section 10. Annual financial statement and filing fee; notice of change of ownership.

A. Each authorized Pharmacy Benefit Manager shall file with the Department a full and true statement of its financial condition, transactions and affairs. The statement shall be filed annually on or before March 1 or within such extension of time therefore as the Department for cause may have granted. The statement shall be in such form and contain such matters as the Department prescribes and it must include the total number of persons subject to management by the Pharmacy Benefit Manager during the year, number of persons terminated during the year, the number of persons covered at the end of the year and the dollar value of claims processed.

B. The statement shall disclose all incentive arrangements or programs such as rebates, discounts, disbursements, or any other similar financial program or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical company, that relates to prescription drug or device services, including at a minimum information on the formula or other method for calculation and amount of the incentive arrangements, rebates or other disbursements, the identity of the associated drug or device and the dates and amounts of such disbursements.

C. The annual financial statement shall be verified by at least two officers of the Pharmacy Benefit Manager.

D. At the time of the filing its annual statement, the Pharmacy Benefit Manager shall pay a filing fee of $1000.00.

E. The Pharmacy Benefit Manager must notify the Department in writing within 5 calendar days of any material change in its ownership.

Section 11. Contracts; Agreements must be Approved; Prohibited Provisions.

A. No person may act as a Pharmacy Benefit Manager without a written agreement between such person and the Pharmacy Benefit Manager.

B. A Pharmacy Benefit Manager shall not require a pharmacist/pharmacy to participate in one contract in order to participate in another contract. The Pharmacy Benefit Manager shall not exclude an otherwise qualified pharmacist/pharmacy

from participation in a particular network solely because the pharmacist/pharmacy declined to participate in another plan or network managed by the Pharmacy Benefit Manager.

C. The Pharmacy Benefit Manager must file a copy with the Department of all contracts/agreements with pharmacies for approval not less than thirty (30) days before the execution of the contract/agreement. The contract shall be deemed approved unless the Department disapproves the contract/agreement within thirty (30) days after it is filed.

D. The written agreement between the insurer and the P harmacy Benefit Manager shall not provide that the pharmacist/pharmacy is responsible for the actions of the insurer or the Pharmacy Benefit Manager.

E. All agreements shall provide that when the Pharmacy Benefits Manager receives payment for the services of the pharmacist/pharmacy that the Pharmacy Benefit Manager shall act as a fiduciary of the pharmacy/pharmacist who provided the services. The Pharmacy Benefit Manager shall distribute said funds in accordance with the time frames provided in this Act.

F. In addition to the requirements set forth in this Section and Sections 12 and 13, the Department shall develop formal criteria for the approval and disapproval of such contracts/agreements.

G. Such written agreements shall be retained as part of the official records of both the Pharmacy Benefit Manager and the insurer for the duration of the agreement and for 2 years thereafter.

H. The Department shall consult with the Board on the criteria prior to promulgation.

Section 12. Pharmacy Benefit Manager Prohibited Practices

A. A Pharmacy Benefit Manager shall not intervene in the delivery or transmission of prescriptions from the prescriber to the pharmacist or pharmacy for the purpose of: influencing the prescriber's choice of therapy; influencing the patient's choice of pharmacist or pharmacy; or altering the prescription information, including but not limited to, switching the prescribed drug without the express written authorization of the prescriber.

B. No agreement shall mandate that a pharmacist/pharmacy change a covered person's prescription unless the prescribing physician and the covered person authorize the pharmacist to make the change.

C. The insurer and the Pharmacy Benefit Manager may not discriminate with

respect to participation in the network or reimbursement as to any pharmacist/pharmacy that is acting within the scope of his or her license or certification.

D. The Pharmacy Benefit Manager may not transfer a health benefit plan to another payment network unless it receives written authorization from the insurer.

E. No Pharmacy Benefit Manager may discriminate when contracting with pharmacies on the basis of co-payments or days of supply. A contract shall apply the same coinsurance, co-payment and deductible to covered drug prescriptions filled by any pharmacy or pharmacist who participates in the network.

F. No Pharmacy Benefit Manager may discriminate when advertising with pharmacies are participating pharmacies. Any list of participating pharmacies shall be complete and all inclusive.

G. No Pharmacy Benefits Manager may mandate basic record keeping by any pharmacist or pharmacy that is more stringent than required by state or federal laws or regulations.

Section 13. Termination of Agreements between Pharmacy Benefit Manager and the Pharmacist/Pharmacy.

A. A pharmacist/pharmacy may not be terminated or penalized by a Pharmacy Benefit Manager solely because of filing a complaint, grievance or appeal as permitted under this Act.

B. A pharmacist/pharmacy may not be terminated or penalized because it expresses disagreement with the Pharmacy Benefit Manager's decision to deny or limit benefits to a Covered Person or because the pharmacist/pharmacy assists such Covered Person to seek reconsideration of the Pharmacy Benefit Manager's decision or because the pharmacist/pharmacy discusses alternative medications.

C. Prior to the terminating a pharmacy from the network, the Pharmacy Benefit Manager must give the pharmacy/pharmacist a written explanation of the reason for the termination at least 30 days prior to the termination date unless the termination is based on the (i) loss of the pharmacy's license to practice pharmacy or cancellation of professional liability insurance or (ii) conviction of fraud.

D. Termination of a contract between a pharmacy benefits manager and a pharmacy or pharmacist, or termination of a pharmacy or pharmacist from a pharmacy benefits manager's provider network shall not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist's services rendered.

Section 14. Medication Reimbursement Costs; Use of Index Required.

Pharmacy Benefit Managers shall use a current and nationally recognized benchmark to base the reimbursement paid to network pharmacies for medications and products. The reimbursement must be determined as follows:

A. For brand (single source) products the Average Wholesale Price (AWP) as listed in First Data Bank (Hearst publications) or Facts & Comparisons (formerly Medispan) correct and current on the date of service provided shall be used as an index.

B. For generic drug (multi-source) products, Maximum Allowable Cost (MAC) shall be established by referencing First Data Bank/Facts & Comparisons Baseline Price (BLP). Only products that are compliant with pharmacy laws as equivalent and generically interchangeable with a Federal FDA Orange Book rating of "A-B" will be reimbursed from a MAC price methodology. If a multi-source product has no BLP price, then it shall be treated as a single source branded drug for the purpose of determining reimbursement.

Section 15. Timely Payments to Pharmacists/Pharmacies; Audits.

A. If a Pharmacy Benefit Manager processes claims via electronic review then it shall electronically transmit payment within seven calendar days of said claims transmission to the pharmacist/pharmacy. Specific time limits for the Pharmacy Benefit Manager to pay the pharmacist for all other services rendered must be set forth in the Agreement.

B. Within 24 hours of a price increase notification by a manufacturer or supplier, the PBM must adjust its payments to the pharmacist/pharmacy consistent with the price increase.

C. Claims paid by the PBM shall not be retroactively denied or adjusted after seven days from adjudication of such claims except as provided in paragraph D below. In no case shall acknowledgement of eligibility be retroactively reversed.

D. The PBM may retroactively deny or adjust in the event (i) the original claim was submitted fraudulently; (ii) the original claim payment was incorrect because the provider was already paid for services rendered, or (iii) the services were not rendered by the pharmacist/pharmacy.

E. The PBM may not require extrapolation audits as a condition of participating in the contract, network or program.

F. The PBM shall not recoup any monies that it believes are due as a result of the audit by set off until the pharmacist/pharmacy has the opportunity to review the PBM's findings and concurs with the results. If the parties cannot then the audit shall be subject to review by the Board.

Section 16. Notice to Covered Person.

A. When the services of a Pharmacy Benefit Manager are utilized, the Pharmacy Benefit Manager must provide a written notice approved by the insurer to covered persons advising them of the identity of, and relationship between, the Pharmacy Benefit Manager, the insured and the covered person.

B. The notice must contain a statement advising the covered person that the Pharmacy Benefit Manager is regulated by the Insurance Department and that the consumer has the right to file a complaint, appeal or grievance with the Insurance Department concerning the Pharmacy Benefit Manager. The notice shall provide the toll-free telephone number, mailing address and electronic mail address of the Insurance Department.

C. The notice must be written in plain English, using terms that will be generally understood by the prudent layperson.

D. A copy of the notice shall be provided to the Insurance Department and each pharmacist/pharmacy participating in the network.

Section 17. Complaint Process.

A. The Department and the Board shall each adopt procedures for formal investigation of complaints concerning the failure of a pharmacy benefits manager to comply with this Act.

B. The Department shall refer a complaint received under this Act to the Board if the complaint involves a professional or patient health or safety issue.

C. The Board shall refer a complaint received under this chapter to the Department if the complaint involves a business or financial issue.

Section 18. Adjustment or settlement of claims; compensation of Pharmacy Benefit Manager.

Compensation to a Pharmacy Benefit Manager for any claims that the Pharmacy Benefit Manager adjusts or settles on behalf of an insurer shall in no way be contingent on claims experience. This section does not prohibit the compensation of a Pharmacy Benefit Manager based on total number of claims paid or processed.

Section 19. Grounds for suspension or revocation of certificate of authority.

A. The certificate of authority of a Pharmacy Benefit Manager shall be suspended or revoked if the Department determines that the Pharmacy Benefit Manager:

1. Is in an unsound financial condition;

2. Has used or is using such methods or practices in the conduct of its business so as to render its further transaction of business in this state hazardous or injurious to insured persons or the public; or
3. Has failed to pay any judgment rendered against it in this state within 60 days after the judgment is final.

B. The Department may, in its discretion, suspend or revoke the certificate of authority of a Pharmacy Benefit Manager if it finds that the Pharmacy Benefit Manager:

1. Has violated any lawful rule or order of the Department or any provision of this chapter;
2. Has refused to be examined or to produce its accounts, records, and files for examination, or if any of its officers has refused to give information with, respect to its affairs or has refused to perform any other legal obligation as to such examination, when required by the Department;
3. Has, without just cause, refused to pay proper claims or perform services arising under its contracts or has, without just cause, compelled covered persons to accept less than the amount due them or to employ attorneys or bring suit against the Pharmacy Benefit Manager to secure full payment or settlement of such claims;
4. Has failed to reimburse pharmacists/pharmacies in a timely manner as required by this Act;
5. Has failed to pay any fees or other financial requirements levied by the Department;
6. Is or was affiliated with and under the same general management or interlocking directorate or ownership as another Pharmacy Benefit Manager which transacts business in this state without having a certificate of authority;
7. At any time fails to meet any qualification for which issuance of the certificate could have been refused had such failure then existed and had been known to the Department;
8. Has, or any person on its behalf, has advertised or merchandised its services in an untrue, misrepresentative, misleading, deceptive or unfair manner.
9. Has been convicted of, or has entered a plea of guilty or nolo contendere to, a felony relating to the business of insurance or insurance administration in this state or in any other state without regard to whether adjudication was withheld; or
10. Is under suspension or revocation in another state.

C. The Department may, in its discretion and without advance notice or hearing thereon, immediately suspend the certificate of any Pharmacy Benefit Manager. If it finds that one or more of the following circumstances exist:

1. The Pharmacy Benefit Manager is insolvent or impaired.
2. The fidelity bond required by Section 6 is not maintained.

3. A proceeding for receivership, conservatorship, rehabilitation, or other delinquency proceeding regarding the Pharmacy Benefit Manager has been commenced in any state
4. The financial condition or business practices of the Pharmacy Benefit Manager otherwise poses an imminent threat to the public health, safety, or welfare of the residents of this state.

Section 20. Order of suspension or revocation of certificate of authority; notice.

A. The suspension or revocation of a certificate of authority of a Pharmacy Benefit Manager shall be affected by order of the Department mailed to the Pharmacy Benefit Manager by registered, certified or overnight mail.

B. In its discretion, the Department may cause notice of any such revocation or suspension to be published in one or more newspapers of general circulation published in this state.

Section 21. Period of suspension; obligations during suspension; reinstatement.

A. A certificate of authority of a Pharmacy Benefit Manager shall be suspended for such period, not to exceed 1 year, as is fixed in the order of suspension, unless such suspension or the order upon which the suspension is based is modified, rescinded, or reversed.

B. During the period of suspension, the Pharmacy Benefit Manager shall file its annual statement and pay fees as required under this part as if the certificate had continued in full force.

C. Upon expiration of the suspension period, if within such period the certificate has not otherwise terminated, the certificate shall automatically be reinstated, unless the causes of the suspension have not been removed or the Pharmacy Benefit Manager is otherwise not in compliance with the requirements of this Act.

Section 22. Administrative fine in lieu of suspension or revocation.

A. If the Department finds that one or more grounds exist for the suspension or revocation of a certificate of authority issued under this part, the Department may, in lieu of such suspension or revocation, impose a fine upon the Pharmacy Benefit Manager.

B. With respect to any nonwillful violation, such fine may not exceed $1,000 per violation. In no event may such fine exceed an aggregate amount of $5,000 for all nonwillful violations arising out of the same action. When a Pharmacy Benefit Manager discovers a nonwillful violation, the Pharmacy Benefit Manager shall correct the violation and, if restitution is due, the restitution shall include interest at the rate of 12 percent per year from either the date of the violation or the date of inception of the policy of the affected person, at the option of the Pharmacy Benefit Manager.

C. With respect to any knowing and willful violation of a lawful order or rule of the Department or a provision of this part, the Department may impose a fine upon the Pharmacy Benefit Manager in an amount not to exceed $5,000 for each such violation. In no event may such fine exceed an aggregate amount of $25,000 for all knowing and willful violations arising out of the same action. In addition to such fine, the Pharmacy Benefit Manager shall make restitution when due in accordance with the provisions of subsection (b).

D. The failure of a Pharmacy Benefit Manager to make restitution when due as required under this section constitutes a willful violation of this Act. However, if a Pharmacy Benefit Manager in good faith is uncertain as to whether any restitution is due or as to the amount of restitution due, it shall promptly notify the Department of the circumstances; and the failure to make restitution pending a determination of whether restitution is due or the amount of restitution due will not constitute a violation of this Act.

Section 23. Regulations.

The Commissioner and the Board may promulgate regulations to carry out the provisions of this Act. The regulations shall be subject to review in accordance with general rules of administrative rulemaking and review of regulations.

Section 24. Applicability of other laws and regulations.

(Drafting Note: If the State has an unfair trade practices act and a privacy/confidentiality act then the Pharmacy Benefit Manager Act should be subject to those provisions. If not then this Act needs to be revised to include prohibitions against discrimination, false and misleading advertising and protections for privacy/confidentiality of covered person information.)

Section 25. Separability.

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of the Act, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

Section 26. Effective Date.

This Act shall be effective (insert date). In order to continue to do business in this state, a Pharmacy Benefit Manager must obtain a Certificate of Authority from the Insurance Department within ninety (90) days after the effective date of this Act.

Section __ Assessment; Creation of Pharmacy Benefit Managers Licensing Fund **(Optional)**

A. The expense of administering this Act, including the cost incurred by the Commissioner, shall be assessed annually by the Commissioner against all Pharmacy Benefit Managers operating in this state. The assessment shall be in proportion to the business done in this state.

B. All fees assessed under this Act and paid to the Commissioner shall be deposited in the Pharmacy Benefit Managers Licensing Fund that shall provide all expenses for the regulation, supervision and examination of all entities subject to regulation under this Act.

C. The Commissioner shall give each Pharmacy Benefit Manager notice of the assessment, which shall be paid to the Commissioner on or before April 1 of each year.

D. If an assessment is not paid by the prescribed date, the amount of any assessment, plus a penalty, the license of the defaulting pharmacy benefits manger may be revoked or suspended by the Commissioner until the assessment and any penalty has been paid.

Appendix B – Survey of Colorado Licensed Physicians and Pharmacists

In June 2004, the Department of Regulatory Agencies mailed surveys to ten percent of Colorado-licensed and domiciled physicians and five percent of Colorado-licensed and domiciled pharmacists. Of the 938 surveys mailed, 22 were returned as undeliverable by the U.S. Postal Service and 365 were returned completed, for a response rate of 39 percent.

The actual survey questions and responses are provided below. Not all percentages total 100 because many survey respondents did not answer questions consistent with the instructions.

Practitioner comments are provided following Question #6. Only comments that were responsive to this survey or that addressed issues involving PBMs are included.

2004 Sunrise Review of Pharmacy Benefit Managers
Survey of Colorado Physicians and Pharmacists

1. Please indicate which Colorado license you currently hold:

_*210*_ Physician _*156*_ Pharmacist _*0*_ Other (please specify _____)

210 (37%) physicians responded
156 (41%) pharmacists responded

2. Have you ever been contacted by a pharmacy or a pharmacy benefit manager (PBM) in an effort to change a prescription from one drug to another drug in the same therapeutic class (excluding generics)?

No _*156 (43%)*_ Yes _*204 (56%)*_

79 (38%) of physicians *130 (62%) of physicians*
77 (49%) of pharmacists *74 (47%) of pharmacists*

If "yes," how frequently does this occur? Approximately __*11.6*_ times per month

3.9 times per month for physicians
9.0 times per month for pharmacists

If "yes," on average, were the new drugs more or less expensive than the originally prescribed drugs?

Don't know _62 (17%)_ More expensive _14 (4%)_ Less expensive _114 (31%)_

39 (30%) of physicians *7 (5%) of physicians* *74 (57%) of physicians*
23 (31%) of pharmacists *7 (9%) of pharmacists* *40 (54%) of pharmacists*

3. If you are a physician, have any of the prescriptions that you have written been changed by a pharmacy or a PBM without your permission?

Don't know _98 (27%)_ No _76 (21%)_ Yes _39 (11%)_

If "yes," how frequently does this occur? Approximately _4_ times per month

4. If you are a pharmacist, have you ever, at the insistence of a PBM, changed a prescription from one drug to another (excluding generics) without the prescribing physician's permission?

No _148 (41%)_ Yes _5 (1%)_

If "yes," how frequently does this occur? Approximately _4_ times per month

5. If you answered "yes" to any of the questions in this survey, did the patients involved suffer any physical harm as a result of the drug change?

Don't know _87 (24%)_ No _87 (24%)_ Yes _17 (5%)_

62 (30%) of physicians *59 (28%) of physicians* *10 (5%) of physicians*
24 (15%) of pharmacists *28 (18%) of pharmacists* *7 (4%) of pharmacists*

6. If you answered "yes" to either question 3 or 4, did you file a complaint with the Board of Medical Examiners or the Board of Pharmacy?

No _47 (25%)_ Yes _1 (1%)_

34 (27%) of physicians *1 (0%) of physicians*
13 (22%) of pharmacists *0 (0%) of pharmacists*

If not, why not?

Not a serious enough problem and the time would have been excessive.

It wouldn't do any good.

Manager was supposed to handle it. I was told by my manager that they would report it.

I did not feel it would change behaviors and I did not have the time to invest.

Complained to the pharmacy - did not know I had other recourse

I am a hospitalist - medications are changed routinely for formulary purposes without my consent. If I have a specific reason for wanting a particular drug, I have to make a special request to change the drug back to what I originally ordered.

Talked with pharmacy involved, often the supervisors. Didn't know doing so was an option. Time constraints.

Didn't figure it would do any good.

Didn't know it was an infraction.

Didn't know I could.

Too passive.

Didn't want to take the time.

Changes were the result of decisions by the pharmacy and therapeutics committee of the hospital to use lower cost therapies. The committee has physicians representation. Once substitutions are decided by the committee, they become conditions of employment - unless there are other considerations such as allergies. Prescribers can request that orders be filled as written.

Did not know it was necessary.

Pharmacists are very threatened by PBMs - we are afraid of an audit or a denial of the "take it or leave it" contracts.

Takes too much time.

Didn't know I could.

Drug change was consistent with therapeutic desires - I called responsible person and warned - "don't ever do that again without calling me." Point was well made.

The process described above is a counter productive activity. Why compound the problem and take additional time away from patient care?

No injury or harm to patient. Also, unclear if someone else in my office was contacted about the substitution.

Did not know what the impact would be and/or what regulations apply to PBMs.

I did not know this warranted a complaint.

Work 10pm-8am shift . . .very quiet.

It didn't occur to me that this might be under your purview.

Too late to change outcome. Individual physicians do not have enough clout to change policy. Deal with it one on one with pharmacist.

I am not sure how to file a complaint.

I do not know what current boundaries are in existing regulations (or complete lack thereof).

I was unaware as to what action should be taken or even if this was allowed procedure.

Do not know which pharmacist or pharmacy the patient went to.

Neither will accept any responsibility and will disavow any authority.

Comments:

PBMs add substantial "hassles" to my practice. They are of NO benefit to me (as I treat patients).

As a physician, change should be ONLY with physician approval. There are times a specific, more expensive drug is chosen.

I would never change a prescription without contacting the physician, no matter the pressure from insurance company or PBM. A generic may be dispensed if the space on the Rx is checked ("may dispense generic").

I have found that some drugs in a therapeutic class are not covered. If not, a message is usually given on the rejection screen. Then I call the MD to get it changed.

I am afraid we are going from "health care" to "cost care" at the expense of the patient. Proper drug therapy usually shortens recovery.

Rx was changed back to the originally prescribed drug by MD. Most of the time, PBMs contact the physician about a change in drug. Then the patient brings us a "change order" signed by the MD that they have received by mail from PBM. LOTS of older people are very confused by this practice. Many times I think that drs' office staff take care of this for the Dr because many times the physicians seems unaware of the change in Rx even though they signed the form (some forms aren't signed).

Work for [managed care organization] - generic or drug substitutes used regularly with restricted formulary - no problems in 17 years.

The PBM formulary(ies) is good for 1970. If it is a new, and/or expensive medication, they automatically reject. Require a lot of phone calls to MD, patient and PBM to try to comply with their restrictions. The result is a lot of my time and delay in care for the patient.

Physical harm: but only minor problems like breakthrough bleeding on generic OCP.

Often the PBM requests a same (similar) drug in class, at no cost savings, because of a relationship with insurance company.

I think that insurance companies do not have the patients' best interest at heart. I frequently have to use a less effective medication because the insurance PBMs will not allow the use of the more effective one.

PBMs do not decrease the cost of health care - they increase it. They take up Rph & MDs time and do not pass along savings to patients that they get from manufacturers. Several instances of harm to patients have occurred from changing meds. Medication prescribing should be evaluated and done by physicians only - not insurance companies. The PBMs have created jobs for themselves, and use the money that should be for patient care and pocket it themselves.

Re more or less expensive after switching: some were less, but through pill splitting, generics, the Internet, Canada and Mexico, our patients can often do better.

Requests from the plans are a major pain and not without costs to me. Most of the requests are solely for the benefit of the companies running the plans (I.e., [PBM] requesting a change to a [PBM-parent company] product) and not to benefit the patient or the insurer.

Patients suffered more due to medication was not effective.

Many PBMs require failure with trials of less expensive therapeutic class alternatives before granting a prior authorization request. One could view drug trial and failure as "harm" in a sense. In all such cases, the patient can opt to pay out of pocket for the doctor's preferred treatment. The patient is always making a money decision in the last analysis.

Hospital pharmacy - not an issue

When costs are similar, insurance companies should not, but do get kickbacks from drug companies for using particular drugs. This practice should stop and formularies opened up.

Pharmacy costs are one of the reasons for rapidly increasing health care costs nationally.

Harm: poor pain control, re-occurrence of heart arrthymias, heart block. Comments: PBMs are out of control. They practice medicine with the best interest of the PBM no the patient, at heart.

Patients have received unsatisfactory clinical response. Several such instances and mandated return to my original prescription. The time (uncompensated) in each instance is unacceptable. I would prefer not to deal with these pharmacy issues. As the prescribing physician, my judgment, based on individual patient needs, prior therapy responses, and patient's compliance are some of the factors involved in deciding on a specific medication. PBMs are just another unnecessary paid cog in the wheel of medical care. We don't need them.

PBMs are very annoying.

As a practicing pharmacist, I feel full disclosure by all PBMs is in the best interest of the public. I also encourage overview of PBMs by an independent regulatory body.

As a pharmacist, many times daily we are prompted to call Dr to get drugs changed to something else in the same therapeutic class. This is very time consuming to the pharmacy and the doctor's office.

Loss of control of treatment is a serious problem.

This does not seem to be a problem for me.

They definitely need to be regulated. It is a mess out here. Some Rxs they don't cover our acq cost and we wind up dispensing a brand versus a generic. It costs the patient more co-pay, the insurance more $$.

Mail-in pharmacies often request Rx changes within a class (i.e., different PPI), implying less cost to patient. I am told by affected drug reps that the lower cost only applies to the pharmacy - and that savings are NOT passed on to the patient. Please tell me what is true about that situation . . .

Pharmacists, in general, do NOT change drugs without a physician's approval. On a daily basis, we get rejections by PBM asking for formulary alternatives. Our time explaining this process to patients and contacting physicians is not compensated. The PBMs are out of control. Regulation would be welcome.

PBMs make "discounts" and "supplementary discounts" from the pharmaceutical companies whose drugs they push. If physicians did this, they would be called "kickbacks," which are unethical.

This is occurring on an individual basis as well as in large groupings (I.e., an entire population covered by the PBM will be forced to change therapies/drugs, none of which were initiated by a physician or pharmacist).

Pharmacy perspective: we call the dr's office numerous times/day to get Rxs changed to a "formulary" drug. This usually occurs at the patient's request because they don't want to pay either the full price or a $50 or $60 co-pay. We always call the Dr./-and never take it upon ourselves to change a prescription. The process is lengthy and the patient usually has to wait 2-4 days.

As a hospital pharmacist, we routinely exchange class agents as therapeutic substitutions. PBM monitoring is not likely to be a positive use of CSBP time. Start policing pharmaceutical sales representatives for accuracy of claims, unethical promotional strategies, etc.

No physical harm done but inconvenience to patients and time commitment for physicians.

Reference question #5: after the requested PBM change was made a month later the patients return needing to go back on the original medication. Some of the time.

If generic substitution is not authorized, I do not want another pharmacy or PBM attempting to coerce a pharmacist into changing a prescribed medication without the authorizing practitioner's knowledge or permission. Therefore, I believe such activity as may occur via a PBM should be regulated to prevent non-generic substitution without the authorizing practitioner's approval.

This survey is not applicable to me because I work for a pharmaceutical company. I have been a clinical pharmacist in the past and as such, I commend you for doing this survey. I'd like to see some of the "power" of selecting medications swing back to the prescriber because, in many cases, drugs within the same therapeutic class ARE NOT equally efficacious. It's unfortunate that cost is not hidden when health plans decide which agent to add to their formularies.

The entire system of pharmacy benefits is very frustrating for patients and physicians. Every medicine I prescribe is chosen for a reason. Every time I'm asked to change a prescription, I am less comfortable with the new medicine than the one I initially chose. Rarely does the change save the patient money. Most changes are recommended to boost profits for the company administering the plan. For all these reasons, a fundamental change in this system is needed. I hope what you are proposing is going to fix this system.

License them. Control them. They are smart enough to not FORCE people to buy from their mail order pharmacies and get their drugs changed, but they are coerced by being charged more for their undesired brands by way of a higher co-pay. And they coerced their customer into their mail-order pharmacy by giving a deal on 3-month supplies, which we could do also if allowed. Why is that not called illegal?

I think regulation of PBMs is a good idea to prevent cost being the sole consideration in drug selection.

The doctors in our area have stated that any such request will have to be reviewed with an office call, etc. They do not appreciate this sort of thing! I do not appreciate it either!

Drug restrictive formularies especially regarding PPI have caused several patients harm in terms of their symptoms. They also forced the patient to go through procedures that could have been avoided and in the long run are more costly to Medicaid. I understand the effort to contain costs but stop trying to practice medicine without a license!

Has not happened in over 6 months.

Sometimes the brand is required when a generic is available. For any patient to pay a brand co-pay. Often a patient is given a different drug via mail order with no mention of a change.

The patients have to wait longer for their Rx in some cases since you have to discuss changing Rx with them. Specifically, [one PBM] has a program that has a hard halt where you need to ask the patient if they would like you to contact the MD to change the Rx. They have an incentive program to pay the pharmacy more if they can get the drug switched. I personally do no favor the incentive since it seems to be a conflict of interest.

As a pharmacist, we have seen Rxs sent by mail that the patient brings in and is confused because they got a different medication than what they expected due to a change by the PBM. In at least two cases, the MD did not know of the change.

We see changes from one SSRI to another, or antibiotic, proton pump inhibitor, Nasocort to Flonase, etc. We call MD office to request a change and sometimes and "office assistant" approves the change. I have doubts about if MD was really consulted.

I am in favor of PBMs. One must also estimate the benefit they provide by lower Rx expense.

My experience with PBMs has been positive.

Sometimes the PBMs do such idiotic and frustrating things that I suspect they simply want the doctor to cave in and prescribe something else. For example, Zoloft comes in 50mg and 100mg sizes. It is cheaper to give #15 100mg for a month at 50mg dose, than #30 50mg. If I prescribe 75mg/dy, I will have to call for special permission for the patient to get 50mg pills instead of 100mg, even though it is impossible to get 75mg/dy from 100mg pills.

Pharmacists occasionally try to substitute name-brand drugs in place of generics already prescribed by saying they are "out" of the generic.

Contact by pharmacist to change to an insurance approved drug in same class.

I believe it should be OK to change meds within a particular class, for example ACE-Inhibitor or Statins.

There is entirely "too much" emphasis placed on patient care with regard to "cost savings." The PBMs call this "pharmacoeconomics." In my opinion, "nothing" should be sacrificed for the betterment of a patient's health and welfare. Dollars are important but not as important as morbidity.

Never been a problem.

Harm = less beneficial.

Usually Rx change is to a generic but certainly not always!

Work in an inpatient hospital setting - work with a formulary - encourage formulary agents, however not due to PBM.

I don't like answering to insurance companies, however physicians usually are not aware of the cost of the drugs they prescribe. Many times a much less expensive drug that is equally effective for a certain condition can be prescribed.

Several meds were denied for which there were no specific substitutions available.

As a prescriber, this is another new "jungle out there" area as there seems to be NO policies-procedures or regulations or even a minimal core of ethical conduct guidelines as to what PBMs can and will do. It adds an awful and unwelcome load of phone calls/faxes and forms to fill out to my schedule so far. As it is currently, I constantly feel caught in the middle of the very frequent denial situations.

This practice of changing usually generates a lot of telephone calls between patient and doctor - a lot of extra work for all to get the same result. I hope the few dollars it saves is worth everyone's disgruntlement.

I think the practice of medicine should continue to be done by physicians and pharmacists who have the patient's best interest in mind, not PBMs or other 3rd parties.

It's all about insurance company profits. I don't believe that all generics are equivalent - hard to prove "harm" done.

I feel that many times a physician/provider will write for a new drug following the information from a pharmaceutical sales rep who only highlights certain aspects. The older drug in most cases has more history and more often is a more appropriate choice. Also, patients see something on TV and request it - with no basis for their request.

I am a hospital staff pharmacist, we do make therapeutic changes based on a P&T substitution policy.

Generics should be "included." Contracts are DICTATED not negotiated. Must have ability to negotiate and sign contracts through our professional associations. Eliminate differential co-pays, which force consumers to mail order firms owned by PBMs. Eliminate 30-day supply requirement, which now only impedes retail pharmacy. Require PBM to be bonded, insured, etc. to ensure payment and require payment on at least terms of drug wholesalers. Require PBM to disclose "kickbacks" on drugs and require full amount be passed on to consumer. Eliminate "juggling" formularies in favor of drugs with "rebates" (kickbacks). Require reimbursements by state or federal statutes thereby eliminating arbitrary reimbursements so low as to create economic hardships on pharmacy. Stiffer penalties for violating HIPAA by taking data from pharmacy claims to call patients to coerce them to mail order. Must provide 800 number directly to company rep to resolve disputes (NOT a call to a service center). Separate drug cost from pharmacy fee.

I support cost control in healthcare. As a physician, I am very leery of the info and marketing provided by "drug reps." They need to be CONTROLLED.