State of California **Department of Consumer Affairs**

Memorandum

To: **Ad Hoc Committee on PBM Regulation** **Date: September 5, 2003**

From: **Patty Harris** PH
Executive Officer
Board of Pharmacy

Subject: **Sunrise Criteria and Questions**

For the September 11th meeting, the committee requested that all interested parties, which included the proponents and opponents of PBM regulation, to complete the Sunrise questionnaire and submit it by September 1, 2003. This questionnaire is designed to assist proponents of new state boards or new categories of licensed professionals to collect and organize information that is necessary for an objective evaluation. The questionnaire is required pursuant to Government Code Sections 9148.4 and 9148.10.

The Sunrise Questionnaire is typically used for proposed licensure of a new occupational or professional group. The questionnaire is intended to determine the merits of the governmental regulation and the demonstrated need that licensure and regulation is necessary to protect the public. The questions in the following areas should guide the committee in making its recommendation regarding regulation.

- Unregulated practice of this occupation will harm or endanger the public health safety and welfare
- Existing protections available to the consumer are insufficient
- No alternatives to regulation will adequately protect the public
- Regulation will mitigate existing problems

Attached is the one completed questionnaire that was received. The Pharmaceutical Care Management Association (PCMA) prepared it. I have also attached a letter from the Academy of Managed Care Pharmacy (AMCP) and information from the National Community Pharmacists Association (NCPA). NCPA also provided a brief overview of PBM legislation introduced in the 2003 state legislative session.

cc: Board Members

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BOARD OF PHARMACY
2003 SEP -2 PM 5:01

August 29, 2003

Patricia Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814-6237

RE: Sunrise Criteria and Questions
Ad-Hoc Committee on Pharmaceutical Benefit Manager(PBM) Regulation

Dear Ms. Harris:

The undersigned organizations appreciate the opportunity to complete the Sunrise Criteria and Questions regarding regulation of PBMs by the Board of Pharmacy. As you know from earlier communications, we are opposed to additional regulation of PBMs by the Board of Pharmacy. The attached questionnaire goes into great detail. In summary, our concerns are as follows:

- There is no significant public demand to further regulate PBMs.
- PBM activities are already extensively regulated, directly and indirectly, at both the state and federal levels.
- The California State Board of Pharmacy is being asked to consider regulation of PBM business activity that is outside the scope of its authority and expertise.

PBMs provide tremendous advantages to consumers by holding down the costs of prescriptions, helping pharmacists to monitor potential adverse drug events, and providing consumers with wide access to medicines and pharmacies without the need to file paper claims.

Legislation to add duplicative new regulation of PBM activities through the Board of Pharmacy is unnecessary and will ultimately increase costs to consumers.

The undersigned organizations thank you for consideration of our concerns, and look forward to discussing them with you at the Ad Hoc Committee on PBM Regulation meeting on September 11, 2003.

Sincerely,

Advance PCS
Aetna
American Association of Health Plans
Blue Cross of California
Caremark Rx, Inc.
CIGNA HealthCare
Express Scripts, Inc.
Health Insurance Association of America
Medco Health Solutions, Inc.
MedImpact Healthcare System
PacifiCare Health Systems
Pharmaceutical Care Management Association
Wellpoint Pharmacy Management

California State Board of Pharmacy

Part C1 – Sunrise Criteria and Questions

I. CONTINUED PRACTICE OF THIS OCCUPATION WITHOUT ADDITIONAL REGULATION WILL NOT HARM OR ENDANGER THE PUBLIC HEALTH SAFETY AND WELFARE

12. Is there or has there been significant public demand for a regulatory standard? Document. If not, what is the basis for this application?

- **There is no significant public demand to further regulate Pharmacy Benefit Managers (PBMs).** As PBMs have sought to hold down prescription drug prices, some segments of the retail pharmacy community have sought legislation to regulate PBMs to protect their own economic interest. Cloaking themselves in the rhetoric of consumer protection, the retail pharmacy lobby wishes to limit consumer incentives to use more cost-efficient mail service pharmacies, undermine retail pharmacy networks, and minimize the ability of PBMs to negotiate prescription discounts on behalf of plan sponsors and their enrollees.

- **PBM activities are already extensively regulated, directly and indirectly, at both the state and federal levels.** Requiring additional licensure by the BOP would not increase consumer protection but would increase costs for consumers and would be redundant, time-intensive and create compliance complications. PBMs would be forced to comply with varying and potentially conflicting state and federal laws and regulations. As a result, additional licensure requirements would unnecessarily raise operating costs for PBMs and diminish their ability to pass on cost-savings to their clients, and ultimately the consumer.

- **The California Board of Pharmacy (BOP) is being asked to consider regulation PBM business activity that is outside the scope of the BOP's authority and expertise.** As noted in its Strategic Plan for 2002/2003, the programs administered by the BOP focus entirely on the individuals and firms that ship, store, and dispense prescription drugs and devices. To the extent PBMs perform these activities through their mail service pharmacies they are already appropriately regulated as a domestic pharmacy in their home state and as a non-resident pharmacy in the 44 states (including California) that have such requirements.

13. What is the nature and severity of the harm? Document the physical, social, intellectual, financial or other consequences to the consumer resulting from incompetent practice.

PBMs provide tremendous advantages to consumers by holding down the cost of prescriptions, helping pharmacists to monitor potential adverse drug events, and providing consumers with wide access to medicines and pharmacies without the need to file paper claims.

Access to Medications

- The assertion made by California Pharmacists Association (CPhA) and the National Community Pharmacists Association (NCPA) that PBMs delay consumers receiving medications is not supported by the facts. **PBMs have pioneered electronic claims adjudication that allows beneficiary eligibility, formulary status, and cost sharing requirements to be determined instantly, greatly expediting consumers receiving medications.** Moreover, within the few seconds it takes for these processes to occur, important safety checks are also being done, ensuring the consumer does not receive a medication that could have a dangerous interaction with other medications the consumer is taking. Again, this is all done within seconds, making the process seamless, quick and safe.
- Under California law, a patient cannot be put at risk because of a delay in receiving an essential medication. For refills requiring prior approval, the pharmacist can dispense a reasonable supply pending resolution of coverage questions. The California Business and Professions Code Section 4064 states *(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well being.* Therefore, if a patient's safety is at issue, the patient can receive his/her medication from the pharmacist even in the event of a delay due to prior approval or some other issue.

Safety Advantage

- PBMs enhance consumer safety by employing hundreds of pharmacists who use technology to ensure the safety and quality of pharmaceutical care. Before any prescription is dispensed, PBMs electronically screen the consumer's comprehensive prescription profile to detect and alert pharmacies about potentially harmful drug reactions and interactions—even when the consumer has used several pharmacies.
- Pharmacists at PBM-owned mail service pharmacies further enhance safety by using automation to achieve unprecedented accuracy in dispensing prescriptions.

- To enhance the quality of care, PBMs also educate and inform consumers, pharmacists, physicians, and other prescribers about safe, appropriate, and cost-effective drug use.
- **PBMs put consumer safety first.**

Financial Advantage

- **The financial "consequence" to the consumer resulting from the practice of PBMs is that they save money.**
- PBMs support the use of generic drugs and clinically appropriate, lower-cost brand name drugs, by actively encouraging the selection and use of cost-effective therapeutic drug alternatives. PBMs also negotiate the lowest possible price from manufacturers and retail pharmacies.
- A recent GAO study found that PBMs negotiated prices that were 18 percent below the average cash price consumers would have had to pay, and generic drugs cost 47 percent below the cash price consumers would have to pay. **GAO concluded that consumers benefited from these savings in the form of lower health plan premiums.**

14. How likely is it that harm will occur? Cite cases or instances of consumer injury? If none, how is harm currently avoided?

- **Proponents have failed to offer any evidence of harm to consumers resulting from PBM practices. On the contrary, PBMs protect consumers. Duplicative and unnecessary new regulation of PBMs will not enhance consumer protection. At the state level,** the BOP already appropriately regulates the activities of PBM-owned pharmacies involving the dispensing, storing and shipping of prescription drugs, *i.e.*, the practice of pharmacy. Current state and federal laws and regulations already appropriately govern non-pharmacy PBM operations.

- Through their contracts with health plans and insurers, PBMs comply with the same consumer protection laws and regulations governing utilization review and prior approval, timely claims payment, and dispute resolution systems, among others. Additionally, as part of their benefit design which a PBM may administer, health plans are required to provide coverage for all medically necessary prescription drugs. (See Attachment 1 for a complete list of health plan laws.)

- At the federal level, the Department of Labor enforces the Employee Retirement Income Security Act of 1974, as amended (ERISA). ERISA sets standards for employer group health plan activities, such as claims payment, appeals and grievances and coverage decisions. The relevant standards applicable to the employer group are applied to the PBM when it engages in those activities on behalf of the employer.

15. What provisions of the proposed regulation would preclude consumer injury?

None. The regulations are duplicative of existing state law and regulation and, therefore, offer no additional protections.

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE SUFFICIENT.

16. To what extent do consumers currently control their exposure to risk? How do clients locate and select practitioners?
17. Are clients frequently referred to practitioners for services? Give examples of referral patterns.
18. Are clients frequently referred elsewhere by practitioners? Give examples of referral patterns.

The existing protections to the consumer, under California law and federal law, are sufficient to protect California consumers.

- **PBMs are held accountable for consumer protections—including grievance and appeals processes—through their contractual obligations with their clients.** PBM clients include the majority of U.S. health plans and self-funded employer groups, including Fortune 500 companies. PBM clients are among the most sophisticated purchasers of health care in the world. Many use expert consultants to help them design and implement plans designs and to guide them through the PBM selection and negotiation process. The clients are able to monitor their PBM's activities and ensure its competence and quality, and, as the marketplace is highly competitive, those are two important criteria that clients use when choosing a PBM.

- While PBMs may make recommendations as to what drugs or drug categories ought to be covered, the client always chooses and approves its plan design, including the drugs that are covered and the cost-sharing arrangements, such as co-payments. **Plan sponsors—the PBM client—must ensure that its drug benefit coverage meets the minimum criteria established by regulatory entities and includes any mandated benefits. PBMs administer the health benefit plan's benefit design which must be in compliance with California and federal laws and regulations.**

- PBMs rely on independent panels called Pharmacy and Therapeutics (P&T) Committees comprised of doctors, pharmacists and other medical experts that recommend which medications will be included on formularies based on the highest standards of safety and efficacy. Cost is only considered after the safety and efficacy decisions are made. **The Department of Managed Health Care, the Insurance Department and the U.S. Department of Labor have all specified appeals procedures that must be in place for the coverage of non-formulary drugs.**

- **PBMs do not make referrals to specific pharmacies**. Rather, PBMs establish a network of retail pharmacies with a broad geographic range. Nationwide, more than 90 percent of retail pharmacies are in networks managed by PBMs. In establishing their networks, PBMs recruit and credential pharmacies, negotiate discounted prices for drug ingredient costs and dispensing services, monitor quality and customer service, audit pharmacy records, and provide technical support to pharmacists.

19. What sources exist to inform consumers of the risk inherent in incompetent practice and of what practitioners behaviors constitute competent performance?

The public is protected from incompetent practice on the part of PBM-owned pharmacies in the same manner as other pharmacies licensed by the BOP—existing BOP laws and regulations.

Other activities conducted by PBMs are not performed by pharmacy practitioners and are already governed by both federal and state laws and regulations as appropriate.

Consumer information on PBMs—including grievance and appeals processes—are normally supplied to consumers by their insurer, health plan, or employer. PBMs often help their clients answer consumer queries as part of their contractual agreement to manage their pharmacy benefit.

Consumers are further protected from incompetent practice by the usual practice of plan sponsors using sophisticated consulting firms to guide the selection and contract negation process with PBMs. Clients monitor and audit PBM activities to ensure compliance with contractual agreements, including quality standards. The California Health Care Foundation recently published two reports prepared by such a consulting firm, Mercer Human Resource Consulting:

- Prescription Drug Benefit Plans: A Buyer's Guide
- Navigating the Pharmacy Benefits Marketplace

These reports help plan sponsors located in California to not only guard against incompetent practice, but also receive maximum value from their PBM.

20. What administrative or legal remedies are currently available to redress consumer injury and abuse in this field?

PBM activities are subject to oversight by the Department of Managed Health Care and the Department of Insurance—agencies charged with the regulation and oversight of health plans and insurers, including the provision of pharmacy benefits through contracts with PBMs. Additionally, the Board of Pharmacy has jurisdiction over PBM activities as they relate to the provisions of the non-resident pharmacy act.

At the federal level, the Department of Labor has detailed rules governing how employer health plans handle appeals and grievances. The relevant standards applicable to the employer plan are applied to the PBM when it engages in activities on behalf of the plan.

21. *Are the currently available remedies insufficient or ineffective? If so, why?*

Current remedies are sufficient and effective. In the state of California, HMOs are already regulated by the Department of Managed Health Care. This department has enacted regulations related to the pharmacy benefit covering:

- Appropriate use of formularies
- Appeals for non-covered drugs
- Proper application of co-payments

As the administrator of benefits for an HMO, a PBM must support these obligations to ensure that their clients maintain regulatory compliance.Insurance companies are regulated by the Insurance Commissioner, which has adopted similar rules related to drug benefits. Self-funded employer group (ERISA) plans fall under the jurisdiction of the U.S. Department of Labor which regulates activities such as claims payment, member appeals and coverage decisions. Again, PBM activities related to such plans are governed by our clients' need to comply with such standards.

The BOP regulates pharmacies, both resident and non-resident. Many PBMs own and operate mail service/home delivery pharmacies. **Each of these pharmacies is licensed in its home state and may be registered as a nonresident pharmacy in other states. Approximately 44 states, including California, license nonresident pharmacies. There is no dispute over the BOP's authority when it comes to matters of pharmacy licensure or to the protection of public health and safety with regard to the practice of pharmacy.**

Matters related to benefit design and to financial regulation more rightly belong in the departments created to regulate insurance, managed care, and employer-provided health care benefits.

III. NO ALTERNATIVES TO REGULATION WILL ADEQUATELY PROTECT THE PUBLIC

22. *Explain why marketplace factors will not be as effective as governmental regulation in ensuring public welfare. Document specific instances in which market controls have broken down or proven ineffective in assuring consumer protection.*

- **Marketplace factors are, in fact, more effective than the addition of more governmental regulation in ensuring the public welfare.** In this fiercely competitive marketplace, PBM clients are sophisticated purchasers, including insurers, health plans, large self-funded employer groups, including Fortune 500

companies, and public purchasers. Many are guided through the process of selecting a PBM by expert consultants. Final selections are made through a highly competitive RFP and contract negotiation process. The clients closely monitor their PBM's activities and ensure its competence and quality. PBMs that don't meet the clients' expectations in terms of quality and cost will find themselves without clients and out of business.

- **PBM activities are already heavily regulated, by state and federal authorities.** The current regulations are sufficient in protecting the consumer and for keeping the cost down for the consumer. The outcome for the public if PBMs are more heavily regulated will be higher drug costs and less accessibility to important prescription drugs.

23. *Are there other states in which this occupation is regulated? If so, identify the states and indicate the manner in which consumer protection is ensured in those states. Provide, as an appendix, copies of the regulatory provision from these states.*

- **No state has passed comprehensive PBM licensure legislation that gives regulatory authority to the BOP.** Similar to California, other states govern PBMs by the same complex system that ensures appropriate and substantial safeguards for consumers.

- Proponents of PBM licensure legislation include certain segments within the retail pharmacy that have a clear economic interest in undermining the ability of PBMs to negotiate lower pharmacy benefit costs. Faced with a $38 billion budget deficit, California can ill afford to take on duplicative, inappropriate, and costly regulatory burdens.

Proponents of additional PBM regulation may say that Georgia and Maine have passed laws that regulate PBMs. Both of those laws can be distinguished from the type of licensure the BOP is currently considering.

- Georgia HB 585 (2002 session) only requires that "*Every pharmacy benefit manager providing services or benefits in this state which constitutes the practice of pharmacy ...shall be licensed in this state...*" In the present matter, there is no dispute over the authority of the CA BOP to regulate the practice of pharmacy by any entity.

- **Maine LD 554 signed into law in June does NOT require BOP regulation or licensure.** The law will make PBMs "fiduciaries" to their clients and impose certain other obligations on PBMs. It provides for enforcement by the Attorney General. The PBM industry, as well as other payers in Maine, including health plans and large employers, have very specific concerns about the law which requires unprecedented disclosures that would effectively eliminate the ability of PBMs to negotiate price concessions from pharmaceutical manufactures and would interfere with PBMsability to use proven private sector tools to help their clients provide high quality, cost effective drug benefits to their employees and

members. For example, in its analysis of similar disclosure language in the U.S. Senate's Medicare drug benefit legislation, the Congressional Budget Office concluded that these disclosure requirements would increase the cost to the federal government of providing a Medicare benefit by 10%, and it would also lead to higher premiums and out-of-pocket costs for Medicare beneficiaries. For these reasons, Maine LD 554 would greatly drive up the costs of prescription drug coverage, making it more difficult for employers to continue to offer voluntary prescription drug benefits. Following Maine's example is not the correct course for any state to take.

24. *What means other than governmental regulation has been employed in California to ensure consumer health and safety. Show why the following would be inadequate:*

a. code of ethics
b. codes of practice enforced by professional associations
c. dispute resolution mechanisms such as mediation or arbitration
d. recourse to current law
e. regulation of those that employ or supervise practitioners
f. other measures attempted

A number of important mechanisms other than governmental regulation help ensure that services provided by PBMs protect consumer health and safety:

- Through the insurance code, the regulation of health plans under the Knox-Keene Act and ERISA, dispute resolution mechanism, both internal and external, already exist.
- PBMs are often subject to the standards of private accreditation organizations through the clients that they serve. HMOs or other insurers frequently seek or maintain accreditation from the Utilization Review Accreditation Committee (URAC), the Joint Commission on Accreditation of HealthCare Organizations (JCAHO), or the National Committee for Quality Assurance (NCQA).
- Accreditation organizations subject PBMs to a range of requirements including those concerning the conduct of utilization review and member appeals, maintenance of a provider network and the privacy of health-care information.

25. *If a "grandfather" clause (in which current practitioners are exempted from compliance with proposed entry standards) has been included in the regulation proposed by the applicant group, how is that clause justified? What safeguards will be provided consumers regarding this group?*

Not applicable.

IV. REGULATION WILL MITIGATE EXISTING PROBLEMS

26. *What specific benefits will the public realize if this occupation is regulated? Indicate clearly how the proposed regulation will correct or preclude consumer injury. Do these benefits go beyond freedom from harm? If so, in what way?*

The public will not realize benefits from unnecessary new regulation. The only beneficiaries of PBM regulation are the proponents themselves—independent pharmacies seeking to limit, or eliminate altogether, marketplace competition that helps to hold down pharmacy benefit costs for the consumer. New and duplicative regulation of PBMs amounts to red tape which could well make obtaining a prescription a lengthier and more expensive proposition for consumers.

27. *Which consumers of practitioner services are most in need of protection? Which require least protection? Which consumers will benefit most and least from regulation?*

28. *Provide evidence of "net" benefit when the following possible effects of regulation are considered:*

a. restriction of opportunity to practice
b. restricted supply of practitioners
c. increased costs of service to consumers
d. increased governmental intervention in the marketplace.

Legislation to add duplicative new regulation of PBM activities through the BOP is unnecessary and will ultimately increase costs to consumers.

ATTACHMENT 1
Sunrise Criteria and Questions

In California, health plans are regulated by the Department of Managed Health Care under the Knox-Keene Act. Below is an overview of provisions of the Knox-Keene Act, applicable to health plans, which are generally as well as specifically applicable to prescription drug benefits. Through their contracts with health plans, PBMs comply with these same consumer protection laws and regulations.

General Consumer Protection Statutes

1348.6	Prohibits certain types of incentive plans between plans and providers that would serve as an inducement to deny, reduce, limit or delay medically necessary services.
1363.5	Requires health plan utilization review procedures to meet certain criteria and that any clinical guidelines used meet certain criteria.
1367.01	Requires health plan utilization review processes to meet specific requirements and timeframes for responding to requests by providers. Also sets requirements regarding communication of decisions to providers and enrollees.
1368	Along with sections 1368.01, 1368.015, 1368.02, 1368.03, establishes extensive requirements and procedural standards for receiving, processing, reviewing and responding to consumer grievances.
1370	Along with section 1370.1, requires all health plans to have quality assurance programs in place.
1371	Along with 1371.1, 1371.2, 1371.35, 1371.36, 1371.37 and 1371.38, establishes a comprehensive scheme for regulating the claims processing of health plans to ensure timely payment of claims to providers, dispute resolution mechanisms for providers and enforcement against unfair claims payment practices.
1374.30	Section 1374.30 through section 1374.36 establish an independent medical review process that provides independent clinical review of plan denials of coverage—for all medical services, including prescription drugs.

Prescription Drug-Specific Statutes

1342.7	Establishes DMHC authority to regulate the provision of medically necessary prescription drug benefits to the extent a plan covers

prescription drugs (which are not a mandated benefit under the Act.) Provides the DMHC with the authority to adopt regulations setting standards for copayments, deductibles, exclusions and limitations.

1363.01	Requires plans to disclose to enrollees the existing of a formulary and requires plans to provide any member of the public information upon request as to whether a drug is covered on the formulary.
1363.02	Requires plans that issue ID cards for claims purposes to include uniform prescription drug information.
1367.51	Requires plans to cover certain items, including prescription medications, for the treatment of diabetes.
1367.20	Requires health plans that have formularies to provide the most current list of drugs on the formulary to members of the public upon request. The list must include drugs by major therapeutic category and indicate whether any drugs are preferred.
1367.21	Prohibits health plans from excluding or limiting off-label use of drugs that meet certain criteria when they are prescribed for a life-threatening or chronic and seriously debilitating condition.
1367.215	Requires health plans that cover prescription drugs to cover appropriately prescribed pain management medications for the terminally ill.
1367.22	Provides for continuity of care on a drug that may have been dropped from the plan formulary if the enrollee's provider continues to prescribe the drug and the drug is considered safe and effective for treating the enrollee's condition.
1367.24	Requires health plans that cover prescription drugs to have an expeditious process by which providers can obtain authorization for medically necessary drugs that are not on the plan formulary and to disclose this process in evidence of coverage and disclosure forms. Also requires plans that cover prescription drugs to maintain certain information for review by the Department, including records of the Pharmacy & Therapeutics committee.
1367.25	Requires health plans that cover outpatient prescription drugs to include coverage for a variety of contraceptives.
1368.5	Permits health plans to reimburse pharmacies for the cost of services performed by a pharmacist, provided the services meet certain requirements.

Currently, the Department of Managed Health Care is working on regulations to implement Section 1342.7, which was passed by the Legislature in 2002. These regulations will deal with whether and how a health plan can have exclusions, limitations, copayments and deductibles in the prescription drug benefit package.

AMCP Academy of Managed Care Pharmacy

September 3, 2003

Patricia Harris
Executive Director
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814-6237

RE: Sunrise Criteria and Questions
Ad-Hoc Committee on Pharmaceutical Benefit Managers Regulation

Dear Ms. Harris:

Thank you for providing the Academy of Managed Care Pharmacy the opportunity to comment on the potential regulation of pharmacy benefit management companies (PBMs) in California. The Academy was pleased to present testimony (Deborah Stern, a member of our Board of Directors from California and William Hermelin, AMCP's General Counsel) during the March 4, 2003 meeting of the Ad-Hoc Committee on PBMs of the California Board of Pharmacy's Licensing Committee. We are confident you are receiving detailed responses to the "Sunrise Criteria and Questions" from organizations and individuals from California. The Academy therefore will limit its comments to restate its general view on the regulation of PBMs.

The Academy of Managed Care Pharmacy is the national professional society dedicated to the concept and practice of pharmaceutical care in managed health care environments. AMCP's mission is to promote the development and application of pharmaceutical care in order to ensure appropriate health care outcomes for all individuals. Its sole purpose is to represent the views and interest of managed care pharmacy. The Academy has more than 4,800 members nationally that provide comprehensive coverage to the more than 200 million Americans served by managed care.

The Academy opposes statutory and regulatory proposals that unduly restrict the ability of pharmacists working within managed care organizations such as PBMs from utilizing managed care tools and services that are essential for operating a prescription drug benefit. Examples of managed care tools that can both improve the delivery of pharmaceutical care and restrain the increases in the cost of prescription drugs are: formularies, disease state management and drug utilization review programs, mail service pharmacies and pharmacy provider networks.

Legislative or regulatory proposals that go beyond procedural protections and enter an arena traditionally within the purview, expertise, and experience of health care

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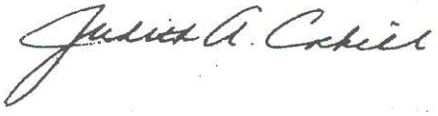
professionals could take away the flexibility that managed care pharmacists need to respond to a complex and continually changing health care delivery system. The imposition of unnecessary or overly burdensome regulatory restrictions potentially incapacitates managed care pharmacists from considering the range of clinical, legal, quality of life, safety and pharmacoeconomic factors which form the basis for the design and implementation of effective drug benefit strategies and programs.

The Academy believes that government should encourage an environment in which pharmacists working within managed care organizations including PBMs can continue to develop innovative and integrated strategies to manage prescription drug benefits for a given population. Proposals that limit the flexibility to use existing strategies and develop new ones could have unintended consequences such as compromising the quality, affordability, and availability of the prescription drug benefit. For additional information you may also refer to the Academy's position statement entitled "Regulation of Pharmacy Benefit Management Companies":
http://www.amcp.org/professional_res/position/017.asp

Once again, thank you for allowing the Academy to comment on the potential for regulation of PBMs in California. If you have any questions, please do not hesitate to contact me at 800-827-2627, ext. 313, or at jcahill@amcp.org.

Sincerely,



Judith A. Cahill
Executive Director

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National
COMMUNITY
PHARMACISTS
Association

Formerly NARD, the National Association of Retail Druggists

August 7, 2003

Patricia F. Harris, Executive Director
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814-6237

RE: The need for regulation of Pharmacy Benefit Managers

Dear Ms. Harris:

For your information and review, I have enclosed a copy of the following documents:

- Brief overview of PBM Legislation Introduced in the 2003 state legislative sessions (07/18/03)
- PBM$: What You Should Know
- Why States Should Adopt Laws to Regulate PBMs

I will be out of the office for a few days. When I return I will send you additional information. Thank you for keeping me on the interested parties list.

Cordially,

Reginia Grayson Benjamin
Associate Counsel and Director of State Government Affairs

Enclosures

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BRIEF OVERVIEW OF PBM LEGISLATION INTRODUCED IN THE 2003 STATE LEGISLATIVE SESSIONS

ALABAMA -- SBN 242/HBN 154

Regulation by the State Board of Pharmacy
Board must adopt rules to address qualifications, filing annual statements, co-payments issues, pricing, disclosures to consumers/enrollees, fees, fine and penalties.
*******Session adjourned 6/16/03. Bills did not pass.**

ARKANSAS -- SBN 313

PBM must obtain a license from the insurance department
Dual regulation (insurance and pharmacy)
Assessment provision
Contracts subject to approval
National benchmark required for reimbursements
No discrimination between pharmacies
Limits ability to deny claims retroactively
Extrapolation calculations in an audit prohibited
Cannot require participation in one contract in order to participate in another contract
*******Session adjourned 4/28/03. Bill did not pass.**

COLORADO – SBN 142

Requires a certificate of authority from the State Board of Pharmacy
Requires payment of an application fee
Requires copies of contracts to be filed
Specifies that the information obtained from an enrollee is confidential
Requires Board to promulgate rules regarding the form and content of contracts between the PBM and pharmacies or pharmacists
Rules must include: if a PBM and pharmacy/pharmacist do not agree on an audit that the Board will resolve the matter, Board can determine if a termination was wrongful, PBM may not switch a medication without approval from prescribing physician and the enrollee, participation by pharmacy in one network shall not affect participation in any other network offered by the PBM, extrapolation calculations in an audit are prohibited and no setoff without agreement by the pharmacist.
Nationally recognized benchmark must be used to calculate reimbursements.
PBM may only accept a rebate for "switching" if it is stipulated in the contract.
Limits placed on PBM's ability to terminate contracts.
*******Session adjourned 5/7/03. Bill did not pass.**

CONNECTICUT -- HBN 6606

Applies to PBMs doing business with a resident of the state
Requires annual statement
Dual regulation (insurance and pharmacy)
Must obtain a license to practice pharmacy
Fees collected to support regulation of PBMs
Contract approval required
Switching and rebate policies must be contained in the contract
No pharmacy/pharmaceutical manufacturer can own an entity that operates a PBM
Requires payments to pharmacists for each drug dispensed ($.10), a reasonable dispensing fee, transmittal costs and for any funds generated from the selling of patient information (50%)
Cannot discriminate when contracting with pharmacies on the basis of co-payments or days of supply
*******Session adjourned 6/4/03. Bill did not pass – however bill to be included in a study by an independent contractor on prescription drug costs and licensing issues over a two-year period.**

FLORIDA -- HBN 1599/SBN 2536

Dual regulation (insurance and pharmacy)
Provides for review/approval of contracts
Prohibits extrapolation audits
Requires use of nationally recognized benchmark to set reimbursement rates
Limits PBM's ability to retroactively deny claims
*******Session adjourned 5/2/03. Both died in Committee.**

HAWAII -- SBN 775/HBN 18

Requires PBMs to operate consistently with the standards of conduct applicable to a fiduciary under ERISA
*******Session adjourned 5/2/03. Bills did not pass. (HBN 18 passed House.)**

ILLINOIS – HBN 520

Requires certificate of authority from Director of Insurance and Pharmacy Board.
Provides for financial examinations of PBM.
Annual assessment on PBMs for cost of administering the act.
Contracts must be filed and approved. Board must develop criteria for approval/disapproval of contracts.
PBMs must give a notice to enrollees that complaints can be reported to the Board.
*******Re-referred to Rules Committee on 4/4/03.**

IOWA -- HF 496

Requires a certificate of authority to be issued by the Board of Pharmacy Examiners
Contains an assessment provision
Contracts must be approved
Extrapolation audits are prohibited
Claims cannot be retroactively denied after 7 days from adjudication except in limited circumstances
*******Session adjourned 5/1/03. Bill did not pass.**

KANSAS -- SBN 234

Requires a certificate of authority from the Insurance Department
Requires all incentive arrangements/programs to be disclosed
Establishes an enrollee grievance process.
*******Session adjourned 4/403. Bill did not pass.**

LOUISIANA – HB 1612

Requires a certificate of authority from the Insurance Department
Requires timely payments be made to pharmacies/pharmacists
Requires disclosure of ownership and affiliates
Limits ability to discriminate against pharmacies/pharmacists
Requires filing of information concerning incentive and rebate programs
*******Session adjourned 6/23. Bill did not pass.**

MAINE -- LD 554

Requires PBMs to act as a fiduciary for contracted entities and covered individuals
Requires all savings (rebates) to be passed to the covered entity or covered individual
Requires PBMs to disclose financial terms with a manufacturer or labeler
Provides that a violation of the act is an unfair trade practice.
*******Signed by the Governor - 6/3/03. P.L. 456**

MARYLAND -- HBN 410

Requires the Insurance Department to conduct an examination of any PBM registered as a private review agent.
*******Signed by Governor – 5/13/03.**

NEW JERSEY -- SBN 1619/A 2337

Requires a certificate from the Division of Consumer Affairs in the Department of Law and Public Safety
Exempts a PBM operated by an HMO solely for the benefit of its enrollees
The Department will forward the application to the Insurance Department for review
Contracts must be approved
PBMs may negotiate with pharmaceutical manufactures for rebates to be paid to the health plan
Prohibits the state from contracting with an hmo or a PBM to administer its Aged and Disabled program or the senior Gold Prescription Discount Program.
*******Referred to Senate Health Committee – 6/6/02**

NEW MEXICO -- SBN 871

Requires a certificate of authority to be issued by Superintendent of Insurance
Contains an assessment provision
PBM acts as a fiduciary for funds received for pharmacist services
Claims may only be retroactively denied under certain circumstances
*******Session adjourned on 3/22/03. Bill did not pass.**

OREGON -- SBN 629

Requires a certificate of authority
Dual regulation by the State Board of Pharmacy and Insurance Department
Includes an assessment provision
Requires that the PBM meet capital and surplus standards
Requires the Insurance Department to investigate and resolve complaints
*******Session adjourned on 6/30. Bill did not pass.**

PENNSYLVANIA

HBN 1067 (PN1247)

Requires a certificate of authority from the Insurance Department.
Requires a certificate issued by the Board of Pharmacy to indicate that the PBM's plan of operation is consistent with the Pharmacy Act.
Requires filing of all rebate, incentive arrangements and discount programs.
PBM subject to financial examination.
PBM cannot switch prescription without approval from prescribing physician and the covered person.
PBM cannot exclude a pharmacist from a network because the pharmacist declined to participate in another network managed by the PBM.
Limits termination of pharmacist to certain circumstances.

PBM must use nationally recognized benchmark for reimbursement determination.
PBM must transmit payment within 14 calendar days.
Limits retroactive denial of claims.
Prohibits extrapolation audits.
Board must review audit findings if there is a dispute prior to the PBM recouping payments.
*******Referred to Committee on Insurance -- 4/7/03**

SBN – 726 (PN846)

Includes basic requirements in HBN 1067.
Adds provision that PBM must adjust reimbursement within 24 hours of a price increase.
PBM must provide a written notice to consumer of their rights to file a complaint, grievance or appeal with the Insurance Department. Insurance Department will refer complaints to the Board of Pharmacy that involve a professional or patient health or safety issue.
Expenses of administering the Act are assessed against the PBM.
*******Referred to Banking and Insurance Committee -- 5/12/03**

TENNESSEE -- HBN 263/SBN 388

Requires PBMs to be licensed as a pharmacy
Requires PBMs to permit an inspection of their premises
*******Session adjourned 07/07/03. Bills did not pass.**

TEXAS

HB 3302/3320
SB 1746

Requires PBMs to receive a certificate of authority from the Insurance Department
The Commissioner must adopt rules to establish a standard contract form for use by the PBM and establishes a contract advisory committee to assist the Commissioner in adopting a standard form
Requires that the PBM file a description of all incentive and rebate programs
PBM cannot switch prescription without approval from prescribing physician and the covered person.
PBM cannot exclude a pharmacist from a network because the pharmacist declined to participate in another network managed by the PBM.
Limits termination of pharmacist to certain circumstances.
Requires Commissioner to develop a dispute resolution arbitration process
*******Session adjourned 6/02/03. Bills did not pass.**

VERMONT -- SBN 116

Requires a license from the Insurance Department
Requires prior approval of contracts
Fees paid by PBMs will be placed in an account to defray expenses of regulation
Holds PBMs to the standards of conduct applicable to a fiduciary under ERISA
Prohibits a PBM from substituting a higher priced generic drug for a lower priced prescribed drug
Requires that the annual statement to disclose any agreement to share revenue with a mail order or internet pharmacy and any agreement to share rebates.
*******Session adjourned 5/21/03. Bill did not pass.**

WYOMING -- HBN 208

Requires a certificate of authority from the Board of Pharmacy
Requires approval of the contracts
An annual statement must be filed
A financial examination is required
Includes an assessment provision
*******Session adjourned 3/6/03. Bill did not pass.**

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

PBM$: What You Should Know

A Pharmacy Benefit Manager, or PBM, is usually hired by the payor, often an employer, to administer the payor's prescription insurance benefits for its employees. PBMs are sometimes also referred to as "third-party payors."

What Is NCPA's Position On PBMs/Third-Party Payors?

NCPA believes that PBMs can play a role as a fiscal intermediary in the processing of prescription claims. As a claims processor, the PBM helps to facilitate the payment of the claim to the pharmacist, which offers convenience to the payor, patient, and to the pharmacist.

So What's NCPA's Problem With PBMs?

The number one complaint from NCPA's members is PBMs. PBMs have evolved from their original role of claim processors into the unauthorized practice of medicine and pharmacy.

1 PBMs often dictate medication formularies, in essence overruling the physician and pharmacist in choosing what medications patients receive. These medication selections are predicated on the best rebates the PBM can pressure the manufacturer to give, not on the patient's health status. Very little, if any, of the rebate dollars make their way back to the payor-especially those rebates from mail order pharmacy. We are unaware of any cases where any portion of these rebates has gone back to the patient or the pharmacist.

2 PBMs dictate how much medication the patient may have and how soon an authorized refill may be filled by the pharmacist. PBMs pay for a finite days' supply of medication and often allow little latitude for special circumstances. For example, a child spills his bottle of antibiotic medication. The PBM may not pay for a replacement prescription. If a patient takes an extended vacation, the PBM will not allow for an early refill.

3 PBMs force take-it-or-leave-it contracts on community pharmacists. PBMs claim the contracts are negotiated, but they are not. Community pharmacists have little option but to sign the one-sided, take-it-or-leave-it contracts dictated by PBMs. Because independent pharmacists by law cannot collectively negotiate insurance contracts, they fall prey to the PBMs threat of limiting the patient's access to the pharmacist's business. These contracts ratchet down the payment to pharmacies, but produce no savings to the health care system. Instead, those dollars go into the corporate profits and bonuses of PBM administrators and drive up the prescription drug costs of the health care system.

4 PBMs coerce patients into using unregulated mail order. Studies show that patients, especially seniors, would rather patronize their local independent pharmacy rather than mail order. Yet, PBMs economically coerce patients because the PBM receives rebates by pressuring patients to use "preferred" medications that the PBM mandates. They also charge different copayments and offer a 90-day supply. PBMs refuse to allow community pharmacists to offer a 90-day supply. Rarely are these rebates passed on or even known to the payor. The three largest PBMs own mail order businesses, so they have an increased economic incentive to leverage patients to mail order.

5 PBMs coerce patients into using mail order medications exposed to high doses of radiation. Following the anthrax threats, U.S. mail is exposed to anthrax-killing radiation. U.S. Postal Service officials have stated that they are unsure what effect this radiation may have on medication. Additionally, a study by the United States Pharmacopeia demonstrated that patients cannot count on receiving their mail order medications due to irregular delivery of the mail. The study also showed that mail order medications are exposed to extreme temperatures more than double the maximum manufacturer recommended temperature which can affect the medication's potency.

6 Despite PBM claims of saving money, the cost of medications increased more than 17 percent for 2001 (according to a GAO study). This increase came after a 19 percent increase in 2000. Despite the fictitious cost saving claims made by

PBMs, they actually contribute to increased medication costs. The average cost of a brand medication prescription approaches $70 while the average price of a generic prescription is $19.20. PBMs' generic substitution rate is half that of community pharmacy. Independent community pharmacists have a generic substitution rate of nearly 50 percent. IMS data shows PBMs only substitute generically on about 25 percent of prescriptions. One reason for the underperformance by PBMs may be that they receive significant rebates for not substituting equivalent cost-saving generics for higher priced brand name drugs.

7 Unscrupulous audits overcharge pharmacies. Although PBMs have limited regulatory oversight in three states, they are totally unregulated in 47 states. However, PBMs check the prescription claims by pharmacies often using extrapolation methods not recognized as accepted accounting procedures. The audits tend to be one sided and, since the PBMs reimburse the pharmacy for products the pharmacy has purchased, the pharmacy is extorted into paying exorbitant and unwarranted audit penalties. Ironically, because of the lack of regulatory oversight, there is no system of checks and balances used to audit the PBMs.

8 Stock prices for major PBMs continue to rise while pharmacy gross margins show little if any gains. PBMs are taking money from pharmacist small business owners to feed their multibillion dollar revenue streams. The CEOs of Express Scripts, Advance PCS, and Caremark all reported annual compensation exceeding $1 million with Express Scripts' CEO topping the list at $6.8 million. Each of the CEOs own stock in their company valued at $48 million, $29 million, and $49.5 million, respectively. The largest PBM, Merck-Medco, did not report the compensation or stock options owned by their CEO, Richard Clark. The gross margin in pharmacy small businesses average 23.6 percent, while pretax profits hover at 3.9 percent or less for most pharmacies.

9 PBMs are creating chaos in community pharmacies. PBMs do not allow the pharmacist to perform his/her function by forcing the pharmacist to:

- Act as their plan intermediary. The pharmacist is usually the person who, without payment, has to inform the patient of benefit plan changes-including changes in medication coverage and increases in copayments. They must also contend with inaccurate DUR messages generated by the PBM.
- The pharmacist must contend with a variety of inconsistently formatted prescription cards generated by PBMs. The lack of continuity between prescription cards causes logistical nightmares in the pharmacy. Often these problems can only be resolved by contacting the PBM's "help" desk, resulting in extended amounts of time on hold and interaction with PBM personnel who are often not trained satisfactorily to address typical problems. All these tasks consume the pharmacist's time slowing down pharmacy operations. Studies show that pharmacy personnel spend 20 percent of their workday dealing with these PBM interruptions. Model legislation has been offered to make prescription cards uniform and consumer friendly. Although this legislation has received support in several states, the PBMs have vigorously opposed the model legislation.

10 PBMs operate unregulated. While pharmacists and pharmacies are highly regulated by state laws, as are insurers. However, PBMs operate without regulation and oversight. NCPA has proposed model PBM Regulation legislation. Twenty states introduced legislation during the 2003 sessions, designed to address the fact that PBMs are not regulated.

Okay, a problem exists, what does NCPA plan to do?

There are several avenues NCPA will pursue. Two of those approaches are:

- Increase awareness and provide information to pharmacists. NCPA will provide the pharmacists with the tools they need to assess PBM contracts so the pharmacy owner can determine whether signing the contract is in his/her best financial interest.

THE MOST IMPORTANT and basic thing each pharmacist can do is to read the PBM's contract before signing it and determine if it is in your business's best interest to sign the contract. Also, write to your legislators.

- NCPA will also continue to pursue legislative remedies and encourage federal and state oversight, including audits of PBMs.

Urge your representatives and senators to support the bipartisan Bachus Conyers H.R.1120, which would allow independent pharmacists to negotiate with health plans and PBMs.

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Contact your state pharmacy association and state representatives to let them know that you support PBM oversight provided by the NCPA PBM model bill.

You can find a list of your state and national representatives at www.pharmacistelink.com.

Why States Should Adopt Laws to Regulate Prescription Benefit Managers (PBMs)

- PBMs now hold sway over more than 80% of the total prescription drug market (excluding Medicaid).

- There is no federal regulation of PBMs.

- PBMs are presently unregulated (except for three states-- Georgia, Maryland and Maine).

- At least 22 State Attorney Generals have initiated investigations into the practices of PBMs

- More than eleven class action lawsuits have been filed by consumers and plan sponsors (employers and insurance companies) alleging that various PBMs (those which control 47% of the total prescription drug market) have not exercised fiduciary responsibility in administering the prescription drug programs which they are supposed to manage.

  PBMs collect rebates from drug manufacturers to PUSH their drugs. In many cases the PBM pressures patients, physicians and pharmacists to utilize a more expensive medication (on which the PBM receives a rebate) even when the patients has already been stabilized on a lower cost generic drug. The result - higher drug costs for the plan sponsor. According to CNN Money Magazine Medco Health, the pharmacy benefits unit (PBM) of Merck & Co. Inc. was paid more than $3 billion in rebates in the late 1990s from drug makers seeking to promote their drugs.

- PBMs impose egregious terms in their "take-it-or-leave-it contracts" with pharmacies.

  One of the major PBMs recently mailed amended contracts which pharmacy owners were required to accept, sign and return to the PBM. The amended contract requires the pharmacy owner to provide liability insurance to indemnify the PBM in the event the PBM is held liable for violating any HIPPA regulations. Pharmacy owners who object cannot appeal to any entity within their state unless they happen to live in a state where the PBM is headquartered (in most cases, Arizona, New Jersey or Texas) because the contracts specify that all conflicts between the PBM and pharmacy owner must be adjudicated in the city where the home office of the PBM is located.