SB

38

SENATE COMMITTEE REPORT
First Committee of Referral

DATE: 1/21/09

FURTHER: Labor and Commerce
Finance

Date of 5-Day Notice: _____
(in accordance with Uniform Rule 23)

DATE TURNED
IN TO OFFICE: 4/3/09

Health and Social Services Committee considered SENATE BILL NO. 38

SB 38 PHARMACY BENEFITS MANAGERS; MANAGED CARE

"An Act relating to insurance; removing references, definitions, and confidentiality of information provisions relating to managed care entities, substituting health care insurers in the former role of managed care entities, and amending the definitions of 'covered person,' 'managed care plan,' and 'utilization review,' as those terms relate to the administration of managed care insurance plans; authorizing persons to act as pharmacy benefits managers subject to oversight by the division of insurance; and amending the definition of 'health care insurer' as it relates to health care insurance."

and recommends:

[ ] be **replaced** with [ ] **SCS** or [ ] **CS** _____ (_____)

[ ] adopt **previous** [ ] **SCS** or [ ] **CS** _____ (_____)

[ ] attached amendment(s)

[ ] adopt _____Letter of Intent

[ ] further referral to _____Committee

SENATE BILL:
[ ] Same Title
[ ] New Title

HOUSE BILL:
[ ] Same Title
[ ] Technical Title Change
[ ] New Title w/ SCR #_____

NEW FISCAL NOTE(S):

Department	Date	Fiscal	Indet	Zero	FN#
CED	4/1			✓	

PREVIOUS FISCAL NOTE(S):

Department	Date	Fiscal	Indet	Zero	FN#

[ ] **APPROPRIATION - no fiscal note**

SIGNATURES AND RECOMMENDATIONS:	PRINTED LAST NAME	DO PASS	DO NOT PASS	NO REC	AMEND
	ELLIS	✓			
	DYSON				✓
	PARKINSON	X			
CHAIR:	DAVIS	✓			

FISCAL NOTE

STATE OF ALASKA
2009 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: SB 38
() Publish Date:

Identifier (file name): SB038-DOA-DRB-03-31-09
Dept. Affected: Administration
Title: An Act relating to insurance...and amending the definition of health care insurer' as it relates to health care insurance."
RDU: Centralized Administrative Services
Component: Group Health Insurance
Sponsor: SENATOR(S) ELTON, French
Requester: (S)HSS
Component Number: 2152

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

	Appropriation Required	Information					
OPERATING EXPENDITURES	**FY 2010**	**FY 2010**	**FY 2011**	**FY 2012**	**FY 2013**	**FY 2014**	**FY 2015**
Personal Services	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Travel	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Contractual	60.0	0.0	65.0	70.0	76.0	82.0	89.0
Supplies	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Equipment	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Land & Structures	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Grants & Claims	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Miscellaneous	0.0	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL OPERATING	60.0	0.0	65.0	70.0	76.0	82.0	89.0
CAPITAL EXPENDITURES							
CHANGE IN REVENUES ( )							

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts	0.0	0.0	0.0	0.0	0.0	0.0	0.0
1003 GF Match	0.0	0.0	0.0	0.0	0.0	0.0	0.0
1004 GF	0.0	0.0	0.0	0.0	0.0	0.0	0.0
1005 GF/Program Receipts	0.0	0.0	0.0	0.0	0.0	0.0	0.0
1037 GF/Mental Health	0.0	0.0	0.0	0.0	0.0	0.0	0.0
1017 Group Benefits	60.0	0.0	65.0	70.0	76.0	82.0	89.0
TOTAL	**60.0**	**0.0**	**65.0**	**70.0**	**76.0**	**82.0**	**89.0**

Estimate of any current year (FY2009) cost: 0.0

POSITIONS

Full-time	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Part-time	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Temporary	0.0	0.0	0.0	0.0	0.0	0.0	0.0

ANALYSIS: *(Attach a separate page if necessary)*

This legislation acts to remove references, definitions, and confidentiality of information provisions relating to managed care entities, and substitute health care insurers in the former role of managed care entities. It also amends the definitions of 'covered person,' 'managed care plan,' and 'utilization review,' as those terms relate to the administration of managed care insurance plans. The bill authorizes persons to act as pharmacy benefits managers subject to oversight by the division of insurance and amends the definition of 'health care insurer' as it relates to health care insurance.

Attached to this fiscal note is a letter from Buck Consultants upon which the estimates within this note are based. It is difficult to estimate the costs of the proposed changes in this bill because there is no experience with this arrangement in Alaska. The studies used to create these estimates are cited in the attached letter from Buck Consultants. Increased drug claim spend may exceed $77 million from FY10 through FY15. The increased drug claim spend would be paid through increased personal services costs in all State agencies and SB 125 payments to the retirement health trusts in FY11.

Prepared by: Patrick Shier, Director — Phone 465-4817
Division: Retirement and Benefits — Date/Time 3/31/09 3:02 PM
Approved by: Rachael Petro, Deputy — Date 3/31/2009
Department of Administration

(Revised 03/30/08 OMB)

buckconsultants
an ACS company

March 30, 2009

VIA EMAIL

Ms. Kathy Lea
Retirement Manager
Division of Retirement and Benefits
State of Alaska
333 Willoughby Avenue
6th Floor State Office Building
Juneau, AK 99811-0208

RE: Fiscal Note for SB 38 – PBM Portion

Dear Kathy:

As requested, we are providing you the information for a Fiscal Note on SB 38 regarding the pharmacy benefit manager (PBM) contracting portion of the bill. This bill defines allowable contract provisions to be overseen by the Division of Insurance. The following table includes brief comments on various sections of the bill and indicates if any cost estimate for each item is included below or instead if there is not yet a reasonable estimate of potential costs for such item:

Section Number	Description	Fiscal Impact
21.07.100(a)	Subjects PBM contracts to DOI oversight.	Potential cost increase to DRB attributable to assimilation of contract provisions not determined by the DRB (as with remainder of DRB contracting). Cost not estimated.
21.07.100(b)	Specified list of services PBMs are allowed to provide.	Potential cost increase to DRB as new cost-saving services are developed but excluded from allowed services, or through delay of inclusion of such cost-saving services. Specialty pharmacy services may already be in this category. Cost not estimated.
21.07.100(c)	Prohibited PBM contract provisions.	Potential cost increase to DRB to the extent current or newly developed cost-saving contract provisions are developed. Cost not estimated.

Tabor Center, 1200 17th Street, Suite 1200 • Denver, CO 80202
720.359.7700 • 720.359.7701 (fax)

21.07.100(d)	Requirement that uniform patient out-of-pocket features apply to prescriptions filled by contracted retail and mail-order pharmacies.	Cost increase to DRB through removal of patient incentives to use mail-order services; cost estimate included below. Potential cost increase to DRB to the extent all prescriptions under a given plan are required to have the same out-of-pocket feature(s). For example, if a plan uses a fixed-dollar copay approach and this copay may not be varied by formulary, brand, generic or specialty pharmacy category, the DRB will experience significant cost increases; cost for this potential impact not estimated.
21.07.100(e)	PBM fiduciary requirement.	Potential cost increase to DRB if PBMs charge a fee for fiduciary liability and/or additional administrative services attributable to this provision. Cost estimate included in general TPA admin cost increase estimate.
21.07.105	Prohibited practices.	Potential cost increase to DRB to the extent practices listed interfere with or inhibit application of disease management programs. Cost not estimated.
21.07.115	Basis of PBM reimbursement to contracted pharmacies.	Cost increase to DRB to the extent allowable bases for reimbursement lag industry developments. This is likely already the case for First DataBank and Facts and Comparisons databases as products of both firms are part of pending class action settlements regarding overpricing. Cost increases to DRB will be significant to the extent allowable reimbursements exceed any ingredient-cost based contracting the DRB may be otherwise able to develop in the future. Cost not estimated.
21.07.125	Requirements regarding PBM payments to and audits of pharmacies.	Potential cost increase to DRB to the extent additional compliance costs are passed through and to the extent that costs currently recoverable through prohibited retroactive adjustments and audits are forgone in future. Cost estimate included in general TPA admin cost increase estimate.
21.07.130 – 140	Drug substitution, complaint process and pharmacy compensation	Potential cost increase to DRB to the extent additional compliance costs are passed through. Cost estimate included in general TPA admin cost increase estimate.
21.07.145	Required pricing disclosures	Potential "loss of competition" cost increase to DRB to the extent PBMs anticipate disclosure of proprietary data (despite confidentiality provisions) and decide not to do business in Alaska. Cost not estimated.

The table below shows the cost of the bill for Fiscal Years 2010 through 2015. Dollars are in thousands.

AlaskaCare	FY10	FY11	FY12	FY13	FY14	FY15
Increase in third-party administrative cost	$60	$65	$70	$76	$82	$89
Increase in prescription claims cost	$10,759	$11,657	$12,485	$13,221	$14,000	$14,823
Total	$10,819	$11,722	$12,555	$13,297	$14,082	$14,912

Summary for Analysis Continuation Section of Fiscal Note

Cost estimates are based on AlaskaCare claims information used for setting 2009 (retiree) and FY2010 (active) premiums, health care cost trend assumptions used for the June 30, 2008 retiree health care valuations, and the following research:

- 2004 Rhode Island press release referencing "data from studies in the impact of any willing provider laws in other states point to a related increase in health insurance premiums." http://www.rilin.state.ri.us/News/pr1.asp?prid=1050
- 2003 Academy of Managed Care Pharmacy posting indicating that any willing pharmacy laws "*result in increased costs to the health care system" through loss of* "economies of scale, "*laws that do not require the pharmacy to meet the terms and conditions of the health plan's contract undermine managed care's ability to control the quality of clinical services provided," and that* "the Federal Trade Commission has held that any willing provider laws discourage competition in the health care marketplace for both pharmaceutical services and managed care programs, restricting consumer access to affordable health care." http://www.amcp.org/amcp.ark?p=AA21D611
- 2002 Journal of Health Politics, Policy and Law study *Any-Willing-Provider Laws: Their Financial Effects on HMOs* that indicates "Our results show that 'all-provider' AWP (any willing provider) laws have a very limited effect on the financial performance measures we examine. 'Pharmacy' AWP laws have a more significant effect." This study indicates that HMO administrative costs are 5.6% higher in states with any willing pharmacy laws (result is significant at the 5% level). http://www.oregonmentalhealth.info/Any-Willing-Provider%20Laws%20Carrol.pdf
- 2001 Ohio fiscal note indicating "potential negligible (cost) increase" for any willing pharmacy legislation that did NOT impact any PBM contracting provisions (i.e., some costs will increase even if PBMs continue to contract per usual but open such contracts to any pharmacy willing to accept terms) http://www.lbo.state.oh.us/fiscal/fiscalnotes/124ga/HB0053IN.HTM

We estimate a 0.5% increase in TPA fees. Prescription claim cost increases are estimated using calendar 2008 average retail and mail-order ingredient costs and duration, current employee and retiree copays and by assuming that if any copay-based incentive to use mail-order is eliminated, 50% of the current lower average duration-adjusted mail-order costs will be lost. This 50% factor accounts for the fact that some members will still use mail-order due to lack of local retail options, and conservatively understates lost savings due to the underlying difference in the type of prescriptions currently dispensed by mail-order versus retail.

Kathy, please let us know if you need any further information.

Sincerely,

Christopher R. Hulla
Principal, Health and Productivity

Aaron P. Jurgaitis, A.S.A.
Consultant, Health and Productivity

CRH:mw

c: Mr. Pat Shier, State of Alaska
Mr. Kevin Worley, State of Alaska
Ms. Michelle DeLange, Buck Consultants
Mr. Dave Slishinsky, Buck Consultants
Ms. Monica DeGraff, Buck Consultants

FISCAL NOTE

STATE OF ALASKA
2009 LEGISLATIVE SESSION

Fiscal Note Number:
Bill Version: SB 38
() Publish Date:

Identifier (file name): SB38-CED-INS-03-27-09
Dept. Affected: DCCED
Title: Pharmacy Benefits Managers; Managed Care
RDU: Insurance (116)
Component: Insurance
Sponsor: Senator Elton, French
Requester: Senate Health and Social Services Committee
Component Number: 354

Expenditures/Revenues (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

	Appropriation Required	Information					
OPERATING EXPENDITURES	**FY 2010**	**FY 2010**	**FY 2011**	**FY 2012**	**FY 2013**	**FY 2014**	**FY 2015**
Personal Services							
Travel							
Contractual							
Supplies							
Equipment							
Land & Structures							
Grants & Claims							
Miscellaneous							
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CAPITAL EXPENDITURES							
CHANGE IN REVENUES ( )							

FUND SOURCE (Thousands of Dollars)

1002 Federal Receipts							
1003 GF Match							
1004 GF							
1005 GF/Program Receipts							
1037 GF/Mental Health							
Other Interagency Receipts							
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Estimate of any current year (FY2009) cost:

POSITIONS

Full-time							
Part-time							
Temporary							

ANALYSIS: *(Attach a separate page if necessary)*

SB 38 provides for regulation of pharmacy benefit managers by the Division of Insurance. It updates the terminology to be consistent throughout Title 21 with the use of "health care insurer". It also proposes to require registration of pharmacy benefit managers as third-party administrators, details the functions that can be performed, describes prohibited practices, requires disclosures and regulates medication reimbursement rates. These changes should have no fiscal impact to the Division of Insurance.

Prepared by: Linda S. Hall, Director
Phone 907-269-7900
Division: Insurance
Date/Time 3/27/09 1:28 PM
Approved by: Emil R. Notti, Commissioner
Date 4/1/2009
Commerce, Community, and Economic Development

(Revised 9/10/2008 OMB)

SENATE DISTRICT B

MEMORANDUM

TO: Senator Bettye Davis, Health & Social Services Chair

FROM: Senate District B Kristen Bressette

SUBJECT: SB 38 Hearing Request

DATE: 3/25/2009

I respectfully request a hearing on SB 38, "An Act relating to insurance; removing references, definitions, and confidentiality of information provisions relating to managed care entities, substituting health care insurers in the former role of managed care entities, and amending the definitions of 'covered person,' 'managed care plan,' and 'utilization review,' as those terms relate to the administration of managed care insurance plans; authorizing persons to act as pharmacy benefits managers subject to oversight by the division of insurance; and amending the definition of 'health care insurer' as it relates to health care insurance."

SB 38 would regulate and bring transparency to the business practices of pharmacy benefit mangers in Alaska. Pharmacy benefit managers are the largely unregulated drug middlemen that administer the prescription drug benefit portion of health insurance plans for governments, private companies, and unions. The three major pharmacy benefit managers are Medco, CVS Caremark, and Express Scripts. Premera Blue Cross Blue Shield, the State of Alaska's health insurance provider, has a contract with Medco to administer prescription drug benefits for state employees.

Sixteen states as well as the District of Columbia have enacted laws that regulate the business practices of pharmacy benefit managers. In addition, the federal government and many states have sued pharmacy benefit managers and won. Other states have led the way with legislation regulating the business practices of pharmacy benefit managers and it is time for the Alaska Legislature to do the same.

Thank you for considering a hearing on SB 38. Please feel free to contact Kristen Bressette at 465-4790 if you have any questions.

ALASKA SENATE
STATE CAPITOL • JUNEAU, ALASKA 99801-1182 • (907) 465-4947 • FAX (907) 465-2108

SENATE DISTRICT B

SB 38 - PHARMACY BENEFITS MANAGERS; MANAGED CARE

"An Act relating to insurance; removing references, definitions, and confidentiality of information provisions relating to managed care entities, substituting health care insurers in the former role of managed care entities, and amending the definitions of 'covered person,' 'managed care plan,' and 'utilization review,' as those terms relate to the administration of managed care insurance plans; authorizing persons to act as pharmacy benefits managers subject to oversight by the division of insurance; and amending the definition of 'health care insurer' as it relates to health care insurance."

Sponsor Statement

SB 38 would regulate and bring transparency to the business practices of pharmacy benefit mangers in Alaska. Pharmacy benefit managers are the largely unregulated drug middlemen that administer the prescription drug benefit portion of health insurance plans for governments, private companies, and unions. The three major pharmacy benefit managers are Medco, CVS Caremark, and Express Scripts. Premera Blue Cross Blue Shield, the State of Alaska's health insurance provider, has a contract with Medco to administer prescription drug benefits for state employees.

Pharmacy benefit managers negotiate with drug manufacturers and pharmacies on behalf of health insurance plans. These negotiations include cash rebates that drug manufacturers pay for drugs placed on lists of approved drugs. The confidential and proprietary nature of these contracts and financial arrangements with drug manufacturers and pharmacies creates the opportunity for pharmacy benefit managers to engage in unfair business practices. Pharmacy benefit managers increase profits by accepting incentives from drug manufacturers that are not shared with health plan sponsors, such as the State of Alaska. SB 38 would prohibit pharmacy benefit managers from intervening in the delivery or transmission of prescriptions.

Twenty-nine states and the District of Columbia have sued Express Scripts and won, resulting in a settlement of $9.3 million to states and up to $200,000 to affected patients in May of 2008. Twenty-eight states and the District of Columbia have sued CVS Caremark and won, resulting in a settlement of $41 million in February of 2008. The federal government and twenty states have sued Medco and won, resulting in a settlement of $184.1 million in 2006. The lawsuits were filed under the federal False Claims Act and/or state False Claims Acts and/or statutes.

In addition to lawsuits against pharmacy benefit managers, sixteen states as well as the District of Columbia have enacted laws that regulate the business practices of pharmacy benefit managers. Other states have led the way with legislation regulating the business practices of pharmacy benefit managers and it is time for the Alaska Legislature to do the same.

ALASKA SENATE
STATE CAPITOL • JUNEAU, ALASKA 99801-1182 • (907) 465-4947 • FAX (907) 465-2108

LEGAL SERVICES

DIVISION OF LEGAL AND RESEARCH SERVICES
LEGISLATIVE AFFAIRS AGENCY
STATE OF ALASKA

(907) 465-3867 or 465-2450
FAX (907) 465-2029
Mail Stop 3101

State Capitol
Juneau, Alaska 99801-1182
Deliveries to: 129 6th St., Rm. 329

MEMORANDUM January 7, 2009

SUBJECT: Managed care insurance, pharmacy benefits manager; sectional summary (Work Order No. 26-LS0244\A)

TO: Senator Kim Elton
Attn: Kristen Bressette

FROM: Dennis C. Bailey
Legislative Counsel

You have requested a sectional summary of the above-described bill. As a preliminary matter, note that a sectional summary of a bill should not be considered an authoritative interpretation of the bill and the bill itself is the best statement of its contents. In this summary, for ease of reading, instead of using the phrase "pharmacist and pharmacy," I have used only the term "pharmacy" to refer to both. Also, please be aware that in previous correspondence I have identified issues with the draft summarized in this memorandum that have not been resolved.

Sections 1 - 16. Replaces statutory references to a "managed care entity" with a "health care insurer" with regard to the regulation of managed care insurance plans.

Section 17. Sec. 21.07.100 requires a pharmacy benefits manager to operate under the terms of a written agreement approved by the director; defines what benefits may be managed by a pharmacy benefits manager; defines what matters may not be included in an agreement between a health care insurer and a pharmacy benefits manager; and, requires that a pharmacy benefits manager that receives payment for the services of a pharmacy acts as a fiduciary of the pharmacy that provided the services.

Sec. 21.07.105 prohibits certain activities by a pharmacy benefits manager.

Sec. 21.07.110 limits the terms under which an agreement between a pharmacy benefits manager and a pharmacy may be terminated; requires notice of termination before a pharmacy is excluded from a network, allows immediate termination of the agreement if the pharmacy loses a license or is convicted of fraud; and prohibits discrimination against a pharmacy acting within the scope of a license or certification with respect to participation in a network or reimbursement plan.

Sec. 21.07.115 designates the method for determining reimbursement payments to pharmacies, including reimbursement for equivalent and interchangeable products.

Sec. 21.07.120 establishes time limits for electronic or non-electronic payments; requires price adjustment within 24 hours of notice of a price increase from a supplier; prohibits retroactive denial of certain claims; prohibits an extrapolation audit as a condition of participating in a contract, network, or program; and prohibits disputed setoff payments to the pharmacy benefits manager or health care insurer until review by the director.

Sec. 21.07.125 requires a health care insurer using the services of a pharmacy benefits manager to notify a covered person of the relationships among the pharmacy benefits manager, the health care insurer, and the covered person.

Sec. 21.07.130 authorizes a pharmacy benefits manager to substitute a lower priced generic or equivalent drugs if approved by the health professional; requires that the substitute of a higher cost drug must be made for a medical reason; requires a pharmacy benefits manager to disclose information to the covered person related to the substitution; and requires a pharmacy benefits manager to compensate a health care insurer for a benefit received by the pharmacy benefits manager as a result of a substitution.

Sec. 21.07.135 requires the director of the division of insurance to adopt regulations for the investigation of complaints concerning the activity of a pharmacy benefits manager.

Sec. 21.07.140 prohibits certain compensation to a pharmacy benefits manager based on claims experience, but does not prohibit payment based on the total number of claims paid or processed.

Sec. 21.07.145 requires a pharmacy benefits manager to provide financial and use information requested by a heath care insurer; allows a pharmacy benefits manager to designate the information as confidential and prohibits disclosure of the information by a covered entity without the consent of the pharmacy benefits manager or when required by a court; requires a pharmacy benefits manager to disclose to a health insurer the financial arrangement between the pharmacy benefits manager and a drug manufacturer or labeler; requires a pharmacy benefits manager to disclose whether there is a difference between the price paid to a retail pharmacy and the amount billed to the health care insurer; and allows a health care insurer to audit a pharmacy benefits manager's records.

Sec. 21.07.150 requires a pharmacy benefits manager to register as a third-party administrator.

Sec. 21.07.155 allows the division of insurance to regulate fees from a pharmacy benefits manager for costs of administration and prescribes penalties for failure to pay fees and for failure to register.

Sec. 21.07.160 applies the regulation of pharmacy benefits managers to the state when it provides group insurance by means of self insurance for eligible state employees or under a collective bargaining agreement, and for certain others receiving benefits; and applies

the regulation of pharmacy benefits managers to certain collective bargaining units

Section 18. Amends the definition of a "managed care plan" to remove a reference to a "managed care entity."

Section 19. Amends the definition of a "participating health care provider" substituting a "health care insurer" in place of a "managed care entity."

Section 20. Rewrites the definition of a "utilization review."

Section 21. Adds definitions to AS 21.07 for "Board of Pharmacy" or "board," "covered person," "health care insurer," "pharmacist," and "pharmacy."

Section 22. Amends the definition of a "health care insurer" to include a person subject to Title 21 (the Insurance Code) who provides coverage for the cost of medical care and to remove references in the definition relating to a church plan, a governmental plan, and an exception related to nonfederal governmental plans.

Section 23. Defines a "pharmacy benefits manager" for purposes of Title 21.

Section 24. Repeals AS 21.07.040, relating to confidentiality medical and financial information in the care of a managed care entity; and repeals AS 21.07.250(8) - 21.07.250(10), removing definitions for "managed care," a "managed care contractor," and a "managed care entity."

If I may be of further assistance, please advise.

DCB:plm
09-004.plm

LAWS THAT PROVIDE REGULATION OF THE BUSINESS PRACTICES OF PHARMACY BENEFIT MANAGERS

ARKANSAS
Title 17, Chapter 92
Section 17-92-1201, et.seq.

- Sets forth standards for audits by a managed care company, an insurance company, a third-party payor or any entity that represents such companies or groups.
- Pharmacy must be given at least one week advance notice of an audit.
- If clinical or professional judgment is required audit must be conducted by or in consultation with a pharmacist.
- Pharmacy may use records of a hospital, physician or other authorized practitioner to validate the pharmacy record.
- Recoupment of claims has to be based on actual overpayment unless it is part of a settlement with the pharmacy.
- Period covered by audit cannot exceed 24 months from the date the claim was submitted to or adjudicated by the entity.
- Unless consented to by the pharmacy, the audit cannot take place during the first 7 days of the month due to high volume of prescriptions filled during that time.
- Preliminary audit report must be delivered within 120 days after the conclusion of the audit - final report must be delivered within 6 months.
- Use of extrapolation audits for calculation of recoupments or penalties is prohibited.
- Copy of the final audit report to be provided to the plan sponsor.
- Applies to audits of claims submitted after January 1, 2008.
- Effective: 04.03.07

CONNECTICUT
Public Act No. 07-200
Registration of Pharmacy Benefit Managers

- PBM must obtain a certificate of registration from the Insurance Department.
- PBM must complete an application form and include the name and address for an agent for service of process, pay a fee and provide evidence of a surety bond.
- PBM operating as a line of business or affiliate of a health insurer or other entity does not have to obtain a certificate of registration but must provide annual notification to the Commissioner of its status.
- Registration may be denied and a hearing process is provided for an appeal.
- Commissioner has the authority to suspend, revoke or refuse to issue or renew for conduct of a character likely to mislead, deceive or defraud the public or the commissioner, unfair or deceptive business practices or nonpayment of renewal fee.
- Effective: 01.01.08

GEORGIA
Title 26, Chapter 26-4.110.1

- Requires a PBM to be licensed as a pharmacy, with a few exceptions, if it provides the services or benefits that constitute the practice of pharmacy.
- If the PBM is licensed then the Board can inspect its premises whether they are located within or outside the state.
- Effective: 05.22.02

Title 26, Chapter 4 – 26-4-118
The Pharmacy Audit Bill of Rights

- Requires certain procedures when an audit of pharmacy records is undertaken by a managed care company, insurance company, third-party payor or any entity that represents such companies (which would include PBMs).

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

- Pharmacy must be given notice at least one week prior to conducting the audit.
- Any audit that requires clinical or professional judgment must be conducted by or in consultation with a pharmacist.
- A finding of an overpayment or underpayment may be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs; however recoupment of claims must be based on the actual overpayment or underpayment unless the pharmacy agrees as part of a settlement.
- Pharmacy must be allowed at least 30 days following the receipt of the audit report to produce documentation to address any discrepancy found during the audit.
- Period covered by the audit may not exceed two years from the date that the claim was submitted to or adjudicated by the entity.
- An audit may not be scheduled during the first 7 calendar days of any month without the consent of the pharmacy.
- The preliminary report must be delivered to the pharmacy within120 days after conclusion of the audit.
- Extrapolation is prohibited in calculating recoupments or penalties for audits.
- Each entity conducting an audit shall establish an appeals process.
- Plan sponsor must be provided with a copy of the audit report.
- Effective: 04.19.06 (applies to audits to claims submitted for payment after 07.01.06)

IOWA
Title XIII Commerce
Subtitle 1 Insurance and Related Regulation
Chapter 510B.1 – 510B.9

- PBM must obtain a certificate as a third party administrator.
- PBM must perform its duties exercising good faith and fair dealing.
- PBM must notify the covered entity in writing of any conflicts.
- PBM cannot contact a covered individual without permission of the covered entity.
- PBM cannot require more stringent record keeping than that required by state or federal law or regulation.
- PBM must notify the pharmacy when it receives notice from a covered entity of a contract cancellation within 10 working days.
- Within 3 business days of a price increase notification by a manufacturer or supplier the PBM must adjust its payment to the pharmacy consistent with the price increase.
- Commissioner must enforce the provisions and adopt rules concerning timely payment of pharmacy claims and a process for adjudication of complaints and settlement of disputes between a PBM and a pharmacy related to auditing practices and termination of pharmacy agreements.
- Legislative Council is directed to establish an interim committee on PBMs to review transparency, disclosure, confidentiality protections, ability of covered entities to audit PBMs and appropriate remedies for covered entities to enforce the provisions in the Act.
- Effective: 01.01.08

KANSAS
Chapter 154
Pharmacy Benefits Manager Registration Act

- Requires PBMs to obtain a valid certificate of registration issued by the insurance commissioner in order to operate in the state.
- PBM must file an application form which includes:
  (a) Name, address, official position and professional qualification of each individual who is responsible for the conduct of the affairs of the PBM, 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 PBM.

(b) Name and address of the applicant's agent for service of process in the state and
(c) A nonrefundable application fee of $140.

- Registration expires on March 31st of each year and the renewal fee is $140.
- If the fee is not paid the registration may be revoked or suspended.
- PBMs must register within 90 days after the effective date of the act.
- Insurance commissioner may adopt rules.
- If a PBM acts without registering, it will be subject to a fine of $500 per violation.
- Effective: 04.28.06

LOUISIANA
Title 22: Sections 250:51 – 61

- Provides that nonelectronic "clean" claims submitted must be paid within 45 days and not more than 60 days after a corrected claim is submitted.
- Provisions must be made for late payment adjustments equal to one percent of the unpaid balance due for each month or partial month that such claim remains unpaid. An additional one percent will be added for those payments more than 25 days after the due date.
- Provides for electronic "clean" claims to be paid within 15 days after receipt, if not late payment adjustments are applicable.
- Reimbursement must be calculated according to a nationally recognized reference and the most current price or amount must be used based on the date of service shown on the claim.
- Recoupment of amounts owed to a pharmacy must begin with a notice to the pharmacy and a 30 day period for the pharmacy to respond.
- Effective: 01.01.2005

MAINE
Title 22, Chapter 603, Subchapter 4, Section 2699
Prescription drug practices

- Provides that a PBM owes a fiduciary duty to a covered entity and must discharge that duty in accordance with the provisions of state and federal law.
- Requires PBM to perform its duties with care, skill, prudence and diligence in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.
- Requires PBM to notify the covered entity in writing of any practice that is a conflict of interest.
- Upon request by the covered entity, the PBM must provide all financial and utilization information relating to services to that covered entity.
- The PBM may designate any information provided to the covered entity as confidential and the information may not be disclosed without the permission of the PBM except that disclosure may be ordered by a court. Also this provision does not limit the Attorney General's use of its investigative authority.
- Requires PBM to transfer in full to the covered entity any benefit or payment received as a result of a substitution.
- Requires PBM to disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the PBM and any drug manufacturer or labeler, including formulary management, drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees. The PBM may designate the information as confidential. However disclosure may be ordered by a court and this provision does not limit the Attorney General's use of its investigative authority.
- Provides that a violation of the Act is a violation of the Maine Unfair Trade Practices Act and subject to a fine of not more than $10,000.
- Applies to contracts executed or renewed on or after September 13, 2003.
- Effective: 04.13.05 (On 06.05.06, the U. S. Supreme Court denied the Petition for a Writ of Certiorari filed by PCMA seeking to overturn the Maine law on the grounds that ERISA preempted it. The Supreme Court ruling ended PCMA's legal challenges to the law.)

- Prior to entering into a contract, the PBM must inform the purchaser that the PBM may solicit and received manufacturer payments, pass through or retain those payments depending on the contract terms, sell aggregate utilization information and share aggregate utilization information with other entities.
- PBM must offer to provide to the purchaser a report that contains net revenue and manufacturer payments.
- If a purchaser has a rebate sharing agreement, the PBM must offer to provide a repot fore each fiscal quarter and each fiscal year that contains information on the net revenues, prescription drug expenditures, manufacturer payments and rebates.
- PBM may require purchaser to sign a nondisclosure agreement prior to releasing information.
- Ability of Attorney General or Insurance Commissioner to obtain information and use the information in any proceedings not affected by this section.
- PBM must disclose at the time of contracting with a pharmacist and at least 30 days before any contract change: the terms of reimbursement, process for verifying benefits and beneficiary eligibility, dispute resolution and audit appeals process and procedures for verifying drugs included on the formularies used by the PBM.
- PBM may not schedule an onsite audit to begin during the first 5 calendar days of a month unless requested by the pharmacist.
- PBM must use a pharmacist if the audit requires clinical or professional judgment.
- All pharmacies in the network must be audited under the same standards and parameters.
- Audit limited to claims submitted or adjudicated within the 2 year period immediately preceding the audit.
- Extrapolation audits are prohibited unless the pharmacist agrees to projected overpayments or denials as part of a settlement agreement.
- PBM must establish an internal appeals process for disputed audit claims.
- PBM must follow certain procedures for the timing of audit reports and payment of amounts due as a result of the audit,
- PBM may not request a therapeutic interchange unless certain criteria are met unless the proposed interchange is for medical reasons that benefit the beneficiary or it will result in financial savings and benefits to the purchaser or the beneficiary.
- PBM must follow disclose certain information to the prescriber when the PBM solicits the prescriber to make an interchange.
- If PBM receives payment from a manufacturer for making the interchange that payment must be disclosed to the prescriber at the time of the solicitation.
- If an interchange occurs, the PBM must provide certain information to the beneficiary.
- PBM must maintain a toll free number for prescribers, pharmacists and beneficiaries.
- PBM must register with the Insurance Commissioner and renew registration every 2 years.
- Commissioner may suspend, deny, revoke or refuse to renew a registration, PBM subject to administrative penalties.
- PBM may not ship, mail or deliver drugs through a non-resident pharmacy unless it holds a pharmacy permit from the Board of Pharmacy.
- Establishes requirements for the PBM's pharmacy and therapeutics (P&T) committee
- Members of a P&T committee must sign a conflict of interest statement.
- A majority of the P&T committee members must be practicing physicians or pharmacist.
- PBM must have policies and procedures including disclosure requirements to address potential conflicts of interest and a process to evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs.
- PBM may not require a pharmacist to participate on the P&T committee.
- Effective: 10.01.08

Title 15, Subtitle 10B, Section 15-10B-20
Private Review Agents

- Requires the Insurance Department to conduct an examination of any PBM registered as a private review agent at least once every three years.
- Requires the Commissioner to issue a report based on the examinations.
- Effective: 05.13.03

MISSISSIPPI
Pharmacy Audit Integrity Act

- Establishes minimum and uniform standards and criteria for the audit of pharmacy records.
- Pharmacy contract must identify and describe in detail the audit procedures.
- Entity conducting an onsite audit must give the pharmacy at least 2 weeks prior written notice before conducting an initial audit.
- An audit that involves clinical and professional judgment must be conducted by or in consultation with a pharmacist.
- Entity conducting the onsite audit may not interfere with the delivery of pharmacy services.
- Pharmacy may use records of a hospital, physician or other authorized practitioner to validate the pharmacy record
- Recoupment of claims has to be based on actual overpayment.
- A finding of an overpayment shall include the dispensing fee amount unless the prescription was not dispensed.
- Period covered by the audit may not exceed two years from the date that the claim was submitted to or adjudicated by the entity.
- Audit cannot take place during the first 5 days of the month.
- Preliminary audit report must be delivered within 120 days after the conclusion of the audit - final report must be delivered within 180 days. Pharmacy has at least 30 days to review preliminary report. Audit report must be written.
- Recoupments of disputed funds or repayment of funds must occur after final internal disposition of the audit including the appeal, if any, process. If identified discrepancy exceeds $25,000 future amounts in excess of that amount may be withheld pending finalization of the audit.
- Interest may not accrue during the audit period.
- Entity conducting the audit must establish a written appeals process and if either party is not satisfied with the appeal, that party may seek mediation.
- Plan sponsor must receive a copy of the final report.

Effective: 07.01.08

Title 73 – Professions and Vocations
Chapter 21 – Pharmacists
Sections 73- 21-151 – 73-21-159
Pharmacy Benefit Prompt Pay Act

- Requires PBMs to file financial statements with the Insurance Department.
- PBMs must use a nationally recognized reference in pricing calculations when reimbursing pharmacies and must update that reference no less than every three business days.
- Clean claims filed electronically must be paid within 15 days (not later than 35 days if filed as a paper claim).
- The Board of Pharmacy shall monitor PBMs for compliance with the law and is authorized to subject PBMs to administrative penalties for non-compliance.
- Effective: 06.30.06

NEW MEXICO
Chapter 61 – Article 11
61-11-18.2

- Requires a managed care company, insurance company, third-party payor or representative of the managed care company, insurance company or third-party payor to conduct audits according to certain criteria.
- Must give pharmacy at least 2 weeks notice prior to conducting an initial on-site audit.
- An audit that requires clinical or professional judgment must be conducted by or in consultation with a pharmacist.
- Pharmacy can use the records of a hospital, physician or other authorized practitioner for the purposes of validating the pharmacy record.
- A finding of overpayment or underpayment cannot be based on a projection and recoupment of claims must be based on actual overpayment or underpayment unless a statistically justifiable method of projection is part of an agreed settlement.
- Pharmacy must be allowed at least 21 days, with reasonable extensions, to produce documentation to address any discrepancies.
- Audit period cannot exceed 2 years, unless agreed by contract, from the date that the claim was submitted or adjudicated.
- Audit may not be initiated or scheduled during the first 5 calendar days of a month unless consented to by the pharmacy.
- Preliminary audit report must be delivered within 120 days, with reasonable extensions allowed, after the conclusion of the audit.
- Final report must be delivered within 6 months after receipt of the preliminary audit report or final appeal, whichever is later.
- Audit criteria apply to all audits of claims submitted after July 1, 2007.
- Extrapolation audits are prohibited in calculating recoupments or penalties.
- Each entity conducting an audit must have an appeals process. If the discrepancy exceeds $25,000 future payments to the pharmacy may be withheld pending finalization of the audit.
- Law does not apply to any investigative audit that involves fraud or willful misrepresentation.
- Effective: 07.01.07

NORTH DAKOTA
Chapter 26.1-27

- Defines a PBM as an administrator and requires PBM to be registered as an administrator.
- Requires disclosure of ownership interest in the PBM by an insurer or a pharmaceutical manufacturer.
- Requires the PBM to notify the Commissioner in writing within 5 business days of any material change in the PBM's ownership.
- Requires PBM to comply with statutory provisions concerning substitution of one drug for another.
- PBM may not exclude an otherwise qualified pharmacy from its network if the pharmacy accepts the terms, conditions and reimbursement rates of the PBM's contract.
- PBM may not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract.
- PBM must offer to the covered entity contracting options that must include: a transaction fee without a sharing of a payment received by the PBM, a combination of transaction fee and a sharing of the payment received by the PBM or a transaction fee based on the covered entity receiving all of the benefits of payments received by the PBM.
- Agreement between the PBM and the covered entity must include a provision allowing the covered entity to audit the PBM's books, accounts and records as necessary to confirm that the benefit of a payment received by the PBM is being shared as required by the contract.
- During an examination of a covered entity, the Commissioner may examine any contracts between the covered entity and the PBM in order to determine whether payments received from the PBM are being applied to reduce the covered entity's rates or have been distributed to covered individuals.

- Covered entity must disclose annually the benefits of the payments received and describe how the benefits received were applied towards reducing rates or distributed to covered individuals.
- Any information disclosed to the Commissioner is considered a trade secret.
- Commissioner may adopt rules as necessary.
- Effective: 08.01.05

OKLAHOMA
Title 59, Section 356
Pharmacy Audit Integrity Act

- Establishes minimum and uniform standards and criteria for the audit of pharmacy records.
- Pharmacy contract must identify and describe the audit procedures.
- Entity conducting an onsite audit must give the pharmacy at least 2 weeks prior written notice before conducting an initial audit.
- An audit that involves clinical and professional judgment must be conducted by or in consultation with a licensed pharmacist.
- Entity conducting the onsite audit may not interfere with the delivery of pharmacy services.
- Pharmacy may use records of a hospital, physician or other authorized practitioner to validate the pharmacy record
- Recoupment of claims has to be based on actual overpayment or underpayment; however a projection may be used as part of a settlement as agreed to by the pharmacy.
- A finding of an overpayment shall include the dispensing fee amount unless the prescription was not dispensed or a physician denied authorization.
- Each pharmacy must be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity.
- Period covered by the audit may not exceed two years from the date that the claim was submitted to or adjudicated by the entity.
- Audit cannot take place during the first 5 days of the month.
- Must disclose to the plan sponsor any money recouped in the audit.
- Preliminary audit report must be delivered within 120 days after the conclusion of the audit - final report must be delivered within 6 months after receipt of the preliminary report or final appeal. Pharmacy has at least 60 days to review preliminary report. Audit report must be written.
- Recoupments of disputed funds or repayment of funds must occur after final internal disposition of the audit including the appeal, if any, process. If identified discrepancy exceeds $25,000 future amounts in excess of that amount may be withheld pending finalization of the audit.
- Interest may not accrue during the audit period.
- Entity conducting the audit must establish a written appeals process.
- Plan sponsor must receive a copy of the final report.
- Act does not apply to any audit which involves fraud, abuse or willful misrepresentation.

Effective: 11.01.08

RHODE ISLAND
Title 27 – Insurance
Chapter 27-29.1

- Includes PBMs in the definition of third-party administrator under Chapter 20.7 which requires filing an annual report with the Department of Business Regulation.
- Annual report must include: contractual language that provides a complete description of the financial arrangements between the third-party administrator and each of the insurers covering benefit contracts delivered in Rhode Island.
- If the third-party administrator is owned by or affiliated with another entity or entities, it shall include an organization chart and brief description which shows the relationships among all affiliates within a holding company or otherwise affiliated.
- Report must be in a format required by the director and filed with the department as a public record.
- Effective: 07.05.04

SOUTH DAKOTA
Chapter 58-29E -- Pharmacy Benefits Management

- Requires PBMs to be licensed as a third party administrator.
- Requires PBM to perform its duties by exercising good faith and fair dealing toward the covered entity.
- Gives the covered entity the option to request information from the PBM on rebate revenues and retrospective utilization discounts.
- Gives the covered entity the option to request information on the nature, type and amount of all other revenue received from a pharmaceutical manufacturer or labeler for programs that the covered entity offers to its enrollees.
- Prohibits PBM from contacting a covered individual without express written permission of the covered entity.
- Provides that information disclosed to the covered entity shall be confidential and proprietary information; however insurance department may request information but it will be considered confidential and privileged and not open to public inspection or disclosure.
- Provides that the covered entity may audit the PBM's records as they relate to rebates and other information described in the law.
- Prescription may be substituted if it is a lower priced generic or if the substitution is for medical reasons but PBM must obtain prior approval from the prescriber.
- Allows the Division of Insurance to promulgate rules.
- Applies to contracts entered into or renewed after June 30, 2004.
- Effective: 03.09.04

TENNESSEE
Titles 56 and 63

- Establishes standards for audits of pharmacies conducted by PBMs.
- At least 2 weeks prior written notice must be given to the pharmacy before conducting the initial on-site audit.
- If clinical or professional judgment is required audit must be conducted in consultation with a pharmacist who has knowledge of the Tennessee Pharmacy Practice Act.
- Pharmacy may use records of a hospital, physician or other authorized practitioner to validate the pharmacy record.
- Unless consented to by the pharmacy, the audit cannot take place during the first 7 days of the month due to high volume of prescriptions filled during that time.
- Pharmacist must be given no less than 30 days following receipt of the audit report to produce documentation to address any discrepancy.
- PBM must establish an appeals process and provide the pharmacist a written explanation of the process.
- Use of extrapolation audits for calculation of recoupments or penalties is prohibited.
- Preliminary audit report must be delivered within 120 days and the final report must be delivered within 6 months after receipt of the preliminary audit report or final appeal, whichever is later.
- Period covered by an audit cannot exceed 2 years from the date the claim was submitted or adjudicated.
- Recoupment of any disputed funds cannot take place until after the final internal disposition of the audit including any appeal process.
- If PBM uses a nationally recognized reference to calculate reimbursement then the PBM must use the most current reference price or amount.
- Requires PBMs to provide timely updates to pharmacy product pricing files used to calculate prescription prices and reimburse pharmacies. Files must be updated no less than every 3 business days.
- Effective: 07.01.07

VERMONT
18 V[illegible]. Chapter 221, Sections 9421, 947[illegible]473
Pharmacy Benefit Managers

- PBM must discharge its duties with reasonable care and diligence and be fair and truthful.
- PBM must provide notice to a health insurer that the following terms may be included in its PBM contract:
  (1) all financial and utilization information requested by the insurer relating to the provision of benefits to beneficiaries through that insurer's health plan (information may be designated as confidential);
  (2) notification of any proposed or ongoing activity that, directly or indirectly, poses a conflict of interest;
  (3) if a substitute drug is to be dispensed which costs more than the prescribed drug and the PBM receives a payment or benefit then the cost of both drugs and the benefit or payment must be disclosed;
  (4) if PBM derives any benefit based on volume of sales for certain drugs or classes or brands of drugs, that payment or benefit must be passed on in full to the health insurer; and
  (5) disclosure of all financial terms and arrangement for remuneration of any kind that apply between the PBM and the drug manufacturer including formulary management and drug-switch programs, educational support, claims process and pharmacy network fees charged from retail pharmacies and data sales fees(information may be designated as confidential).
- PBM must register before doing business in the state.
- PBM must notify health insurers that they are entitled to a quote for an administrative-services-only (ASO) contract with full pass through of negotiated prices, rebates and other such financial benefits which would identify to the insurer external sources of revenue and profit generally available and whether the PBM offers that type of arrangement.
- In order to verify the pricing arrangements of ASO contracts, the PBM must allow access to the Commissioner to conduct an audit.
- Department's expenses in conducting the audit must be paid by the PBM.
- Applies to all contracts executed or renewed on or after September 1, 2007.
- Effective: 07.01.07

DISTRICT OF COLUMBIA
Title 48, Subtitle II, Chapter 8A, Subchapter II.
Transparent Business Practices Among Pharmacy Benefit Managers

- Requires a PBM to act as a fiduciary.
- PBM must perform its duties with care, skill, prudence and diligence.
- Requires the PBM to notify the covered entity in writing of any practice that is a conflict of interest.
- Requires any payments/benefits that a PBM receives from a drug manufacturer or labeler based on volume of sales or market share must be paid in full to the covered entity; however covered entity can agree to return a portion of the benefit or payment to the PBM.
- Upon request by the covered entity, the PBM must provide information on all rebates, discounts and other similar payments.
- Upon request by the covered entity, the PBM must disclose all financial terms and arrangements for remuneration of any kind between the PBM and a drug manufacturer or labeler including formulary management, drug substitution programs, educational support, claims processing and data sales fees.
- PBM may designate the information provided as confidential.
- If a PBM substitutes another prescription drug for a prescribed drug and if the substitute drug costs more than the prescribed drug, the PBM must disclose the costs of both drugs and any benefit or payment directly or indirectly that accrues to the PBM as a result of the substitution. Any benefit or payment received as a result of the substitution must be transferred in full to the covered entity.
- Violations are subject to a fine of not more than $10,000.
- Effective: 09.16.06 (This law is still the subject of a legal challenge by PCMA)

Federal and State Litigation Regarding Pharmacy Benefit Managers

David A. Balto
January 2009

From 2004 – 2008, the three major PBMs (Medco, CVS Caremark, and Express Scripts) faced six major federal or multidistrict cases over allegations of fraud; misrepresentation to plans, patients, and providers; unjust enrichment through secret kickback schemes; and failure to meet ethical and safety standards. These cases resulted in over $371.9 million in damages to states, plans, and patients so far. Below is a summary of these six cases. Note that the regulatory provisions of many of these settlements will expire within 2-10 years.

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1. *United States v. Merck & Co., Inc., et. al* (also cited as *United States of America v. Merck-Medco Managed Care L.L.C., et al.)* (E.D. Pa.)

Settled: October 23, 2006
Damages: $184.1 million

States participating: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

Claims:

Whistleblower lawsuits, filed under the federal False Claims Act and state False Claims Acts against Medco Health Solutions, Inc., alleged that Medco:

- systematically defrauded government-funded health insurance by accepting kickbacks from manufacturers in exchange for steering patients to certain products;
- secretly accepted rebates from drug manufacturers;
- secretly increased long term drug costs by switching patients away from cheaper drugs; and
- failed to comply with state-mandated quality of care standards.

Settlement:

- A preliminary settlement in April of 2004:
  - Required Medco to pay $29.1 million to participating states and affected patients;
  - Placed restrictions on the company's ability to switch drugs;

- Imposed measures to increase transparency; and
- Required Medco to adopt the American Pharmacists Association code of ethics for employees.

- The final settlement, brokered in October 2006 required Medco to:
  - Pay an additional $155 million;
  - Enter into a consent degree regulating drugs switching and mandating greater transparency; and
  - Enter into a Corporate Integrity Agreement (CIA) as a condition of Medco's continued participation in government health programs.

The Corporate Integrity Agreement will expire in 2011.

2. *United States of America, et al. v. AdvancePCS, Inc. (Case No. 02-cv-09236)(E.D. Pa.)*

Filed: 2002
Settled: September 8, 2005
Damages: $137.5 million

Claims:

Whistleblower lawsuit, filed under the Federal False Claims Act, alleging that Advance PCS (now part of CVS Caremark):

- Knowingly solicited and received kickbacks from drug manufacturers in exchange for favorable treatment of those companies' products;
- Paid improper kickbacks to existing and potential customers to induce them to sign contracts with the PBM;
- Submitted false claims in connection with excess fees paid for fee-for-service agreements; and
- Received flat fee rebates for inclusion of certain heavily utilized drugs.

Settlement:

A settlement in September, 2005 required Advance PCS, Inc., to:

- Pay a $137.5 million settlement and face a five-year injunction;
- Submit to regulations designed to promote transparency and restrict drug interchange programs;
- Enter into a five-year Corporate Integrity Agreement; and
- Develop procedures to ensure that any payments between them and pharmaceutical manufacturers, clients, and others do not violate the Anti-Kickback Statute of Stark Law.

3. ***United States of America, et al v. Caremark, Inc. (Case No. 99-cv-00914)(W.D. Tex.)***

Filed: 1999
Pending as of January 2009

States participating: Arkansas, California, DC, Florida, Hawaii, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Mexico, North Carolina, Tennessee, Texas, Utah and Virginia.

Claims:

Filed by an ex-employee, this case was prosecuted under the Federal False Claims Act and numerous state False Claims Statutes. It alleges that Caremark (now part of CVS Caremark):

- Submitted reverse false claims to the Government in order to avoid, decrease or conceal their obligation to pay the government under several federal health insurance programs including Medicaid, Indian Health Services, and Veterans Affairs/Military Treatment Facilities.

4. ***States Attorneys General v. Caremark, Inc.***

Filed: February 14, 2008
Settled: February 14, 2008
Damages: $41 million

States participating: Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Illinois, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia and Washington.

Claims:

Complaint decrees and consent orders against Caremark issued by 29 Attorneys General on February 14, 2008 allege that Caremark:

- Engaged in deceptive trade practices by encouraging doctors to switch patients from originally prescribed brand drugs to different brand name drugs.
- Did not inform clients that Caremark retained all the profits reaped from these drug switches; and
- Restocked and re-shipped previously dispensed drugs that had been returned to Caremark's mail order pharmacies.

Settlement:

In conjunction with the complaints, states issued a consent decree/final judgment that required Caremark to:

- Pay a collective settlement of $41 million;
- Significantly change its business practices by imposing restrictions on drug switches and creating greater transparency;
- Apply a code of ethics and professional standards; and
- Refrain from restocking and re-shipping returned drugs unless permitted by law.

5. *State Attorneys General v. Express Scripts*

Settled: May 27, 2008
Damages: $9.3 million to states, plus up to $200,000 to affected patients

States participating: Arizona, Arkansas, California, Connecticut, Delaware, District of Columbia, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachussetts, Michigan, Mississippi, Missouri, Montana, Nevada, New Mexico, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, and Washington.

Claims:

State Attorneys general settled consumer protection claims alleging that Express Scripts:

- Engaged in deceptive business practices by illegally encouraging doctors to switch their patients to different brand name drugs; and
- Illegally increased their spreads and rebates from manufacturers without passing the savings on to the plans.

Settlement:

The settlement required Express Scripts to:

- pay $9.3 million to the states, plus up to $200,000 in reimbursements to affected patients.
- Accept restrictions on drug switching practices;
- Increase transparency for plans, patients and providers; and
- Adopt a certain code of professional standards.

6. *Local 153 Health Fund v. Express Scripts (In re Express Scripts, Inc. Pharmacy Benefits Management Litigation)* (Case No. 4:05-md-01672-SNL)

Case consolidated: April 29, 2005
Pending as of January 2009

Claims:

This case, filed in the Eastern District of Missouri, alleges that Express Scripts:

- Retained undisclosed rebates from manufacturers;
- Enriched itself by creating a differential in fees;
- Failed to pass on or disclose discounted drug rates and dispensing fees;
- Gained kickbacks from drug manufacturers in exchange for favoring certain drugs on the formulary;
- Circumvented "Best Pricing" rules to artificially inflate AWP; and
- Enriched itself with bulk purchase discounts that it failed to pass on to the plaintiffs.

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Senator Bettye Davis
Chairwoman
Senate Health & Social Services Committee
Alaska State Capitol Building
Juneau, Alaska 99801

RE: SB 38 - Pharmacy Benefits Managers

Dear Chairwoman Davis and Committee Members:

I am writing to express my concerns with S.B. 38, a bill to regulate and restrict the use of pharmacy benefit services.

Express Scripts, Inc. is one of the largest pharmacy benefit management (PBM) companies in North America, providing PBM services to millions of consumers. PBMs manage prescription drug benefits for thousands of client groups, including managed-care organizations, insurance carriers, third-party administrators, employers and union-sponsored benefit plans.

Pharmacy Benefit Managers employ a variety of management tools to deliver an affordable and quality drug benefit to beneficiaries. PBMs provide purchasers a variety of tools and techniques that promote quality, improve outcomes and help drive down the cost of prescription drugs. PBMs also provide clients with clinically based services that reduce medication errors, increase compliance with drug therapies and improve health outcomes. According to a study by PricewaterhouseCoopers, pharmacy management by PBMs results in savings of 29 percent of retail prices.[1]

S.B. 38 would mandate that a PBM owe a fiduciary duty to a covered entity and require public disclosure of proprietary contract terms and conditions. (Section 21.07.100 (e); Section 21.07.125; Section 21.07.145). A study of PBM management tools shows that fiduciary mandates coupled with disclosure increases pharmacy costs by 7.1 percent.[2] PBMs simply do not fit the definition of fiduciaries under the Employee Retirement Income Security Act of 1974 (ERISA) law. PBMs perform claims processing and other ministerial tasks that do not involve discretionary control of plan assets, an essential threshold requirement for fiduciary status under ERISA. In addition, the Federal Trade Commission (FTC) has warned several states that legislation requiring PBM contract disclosure could increase costs and undermine the ability of some consumers to obtain drugs at a price they can afford. [3]

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[1] PricewaterhouseCoopers Pharmacy Benefit Management Savings in Medicare and the Commercial Marketplace & the Cost of Proposed PBM Legislation 2008-2017; March 2007.
[2] IBID
[3] FTC letter to Assemblyman Greg Aghazarian, California State Assembly (Sept. 3, 2004); FTC Letter to Delegate Terry Kilgore, Commonwealth of Virginia House of Delegates (Oct. 2, 2006).

This legislation restricts many of the tools and techniques that help manage costs and assure the appropriateness and suitability of prescribed medications, including prior authorization, drug utilization review, generic substitution, negotiated rebates and the option to use mail order. (Section21.07.100; Section 21.07.105). These tools all respect the physician's prescribing authority; PBMs do not "switch" prescriptions. Only a licensed pharmacy or pharmacist with a valid physician order can change an individual's prescription. Contrary to the assertions of some, these techniques reduce quality, recent research shows that employing behavior-centric clinical programs — strategies that help manage out waste and lower costs — can simultaneously achieve better patient compliance and improve overall beneficial use of prescription drugs. [4]

S.B. 38 mandates certain pricing terms that may look favorable in the short run, but could lead to higher long-term drug costs. (Section 21.07.130; Section 21.07.145). Specifically, the bill bans certain pricing models used by plan sponsors to align PBM financial incentives with that of the plan sponsor to lower overall costs. Plan sponsors are sophisticated purchasers and currently utilize several pricing methods with full knowledge of the financial incentives built in for PBMs. They should be able to choose the pricing model that best meets their needs.

Forty-one states and the District of Columbia currently require payment between 30-60 days. Alaska requires payment of clean claims within 30 days. S.B. 38 reduces this to 7 days (Section 21.07.120). This would significantly reduce the PBMs ability to proactively monitor for fraud and abuse and interfere with the PBM's ability to perform certain drug management techniques that are essential for consumer safety.

Finally, the bill prohibits PBMs from selectively contracting with only those providers necessary to enable the organization to provide patients with adequate access to pharmacy services, and quality, cost-effective health care (Section 21.07.100). PBMs go to great lengths to assure they have enough qualified providers in their networks so patients have adequate access to needed medical services. Any willing pharmacy laws increase costs to enrollees by disallowing efficiencies based on economies of scale and undermine PBM's ability to control the quality of clinical services provided to its members.

Now more than ever, the current state of the economy requires us to look for ways to ensure patients have access to affordable quality drug coverage. S.B. 38 would drive up overall drug expenditures and risk patient safety without any evidence of clinical benefit to the consumer.

Sincerely,

Michael Harrold
Senior Director, State Government Affairs

[4] Behavioral Economics on Medication Compliance; Emily Cox; American Journal of Managed Care, December 2008.

SB 38

Senate Health & Social Services Committee

Friday, April 3, 2009

Testifiers

Calling in (1-888-295-4546):

- Gerry Purcell, Pharmacy Partners
- David Balto, American Progress

In Person:

- Dirk White, Pharmacist/Board of Pharmacy

Calling in:

- Ron Miller, Pharmacist, Carrs-Safeway
- Kim West, Pharmacist, Fred Meyer
- Jerry Brown, Pharmacist
- Barry Christensen, Pharmacist/Chair, Alaska Pharmacists Association

Bio

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Gerry Purcell
Managing Partner

Since 1998, Gerry Purcell has become a nationally recognized heath care reformer, speaker and thought leader calling for full disclosure and transparency in health care spending. His primary focus has been in the fast growing area of Pharmacy Benefit Manager (PBM) revenues. He advocates on behalf of commercial, union and public sector plans, assisting them in managing their pharmacy programs and expenditures. He has led the charge in requiring PBMs to properly disclose, manage and account for plan assets where a fiduciary and/or a good faith duty exists.

Gerry ignited a national discussion with his 1998 article, "A Cost Effective Guide To Pharmacy Benefits", about the hidden practices PBMs have utilized for years to inflate pharmacy costs and derive excessive profits. Gerry authored the article with an insider's vantage point while serving as a sales manager for a leading public sector PBM. The article quickly gained national attention and was published in *Employee Benefit News, Benefit Solutions* and nine other health related publications.

Gerry is frequently interviewed by national news organizations to include being featured in the August 12, 2002 issue of *US News & World Report*, which exposed questionable PBM practices. He has served as a panelist in town hall debates moderated by Fox News' Chris Wallace and NBC's Forrest Sawyer.

In addition to work in the private sector, Gerry is frequently asked to offer insight to state executive and legislative entities and to testify before both federal and state legislative bodies, most recently in Georgia, New York, Oklahoma, Texas and Virginia. He has briefed Department of Justice attorneys and given confidential executive briefings to more than a dozen State Attorneys Generals on the subject of pharmacy benefits, and evaluated their respective state programs. He has worked extensively, on retainer, in support of the multi-state Attorneys Generals litigation against a major PBM regarding reimbursement of Medicaid claims; with estimated damages reported at potentially $500 million.

Gerry assists states, cities and private plans in selecting and contracting the best PBM, negotiating optimal contracts with pharmacies and drug manufacturers, selecting benefit designs, evaluating formularies, maximizing drug manufacturer rebate strategies and rebate migration, auditing, and litigation strategies. He is actively involved in assessing PBM business practices and the potential financial damages and overcharges as a result of their practices. He has evaluated hundreds of plan sponsor agreements, thousands of pages of PBM documents to include agreements with drug manufacturers and network pharmacies, and collaborated with the top PBM consultants and auditors in the United States for the purpose of developing a baseline model to determine potential overcharges, and ultimately the optimal contracting terms.

Gerry's efforts, along with other full disclosure advocates, are yielding substantial savings and recoveries for clients and are beginning to change PBM practices nationally.

Prior to working in the PBM industry and forming Pharmacy Partners, Gerry worked in the managed care industry with Kaiser Permanente. Prior to Kaiser, he served in several supervisory positions with multi-million dollar profit and loss responsibility to include Mobil Oil Corporation and six years as an Army intelligence officer. In 1980, he served as National President of the 300,000 member Vocational Industrial Clubs of America (VICA). In this capacity, he worked closely with corporate and union leaders and educators to prepare young people to enter trade and industrial industries.

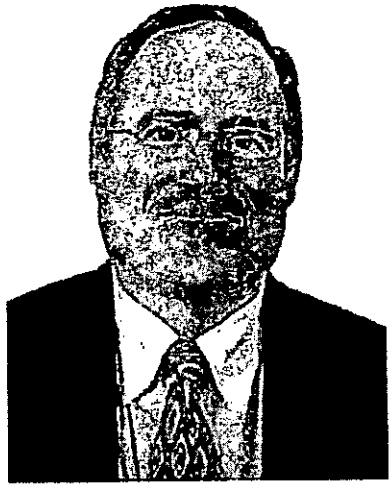
Gerry graduated with honors from the U.S. Army Intelligence Center and School and is a Distinguished Military Graduate of Chaminade University of Honolulu.

Gerry can be reached in his Atlanta office at 404.783.2020 or via email at gerrypurcell@mac.com.

Center for American Progress

David Balto

Senior Fellow



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David Balto is a Senior Fellow at American Progress focusing on competition policy, intellectual property law, and health care. He has over 20 years of experience as an antitrust attorney in the private sector, the Antitrust Division of the Department of Justice, and the Federal Trade Commission. He is nationally known for his expertise in competition policy in high tech industries, semiconductors, health care, pharmaceuticals, medical devices, media, and financial services. He regularly provides advice on mergers, strategic alliances, and joint ventures.

From 1995-2001 he was the policy director of the Bureau of Competition of the Federal Trade Commission and attorney advisor to Chairman Robert Pitofsky. In these leadership roles Mr. Balto was a senior advisor in developing competition policy and identifying key enforcement initiatives. He helped draft guidelines involving intellectual property, joint ventures, and health care. He played a key role in several litigated cases, including the challenges to the Staples/Office Depot and Heinz/Beechnut mergers, the Intel monopolization case, and the challenges to anticompetitive conduct by several pharmaceutical companies. He is the only person to twice win the FTC's award for outstanding scholarship and won the FTC's award for distinguished service, the highest award given a staff attorney.

Mr. Balto has authored more than 60 articles about competition policy focusing on intellectual property, health care, pharmaceuticals, financial services, and mergers. He regularly testifies before Congress, state legislatures, the FTC, and DOJ. He has authored numerous amicus briefs for consumer groups in seminal antitrust cases.

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Articles by David Balto

- Live Nation Ticketmaster Merger Is Too Good To Be True, March 16, 2009
- A Progressive Agenda for Antitrust Enforcement at the Antitrust Division, March 10, 2009
- Processor Wars Speed into Court, February 25, 2009
- The Ticketmaster-Live Nation Merger: What Does It Mean for Consumers and the Future of the Concert Business?, February 24, 2009
- An Open Letter to the Next Federal Trade Commission Chairman, February 23, 2009
- Bringing Back Antitrust Law, February 16, 2009
- A Perfect Storm, January 16, 2009
- What Bank Mergers Mean for Credit Cards, December 16, 2008
- Merge Not: A Highmark-IBC merger would handcuff health-care reform, December 10, 2008
- Reject Pennsylvania Insurance Merger, November 26, 2008
- Reject Pa. insurance merger, November 26, 2008
- Reviving Competition in Health Care Markets, October 17, 2008

TESTIMONY OF DAVID BALTO,
ANTITRUST ATTORNEY
SENIOR FELLOW
CENTER FOR AMERICAN PROGRESS ACTION FUND
FORMER POLICY DIRECTOR, FEDERAL TRADE COMMISSION

Hearing on Senate Bill No. 38: On Health Care Provider and Patient Protection
Senate Health & Social Services Committee
Alaska Senate
April 3, 2009

Distinguished members of the Alaska Senate, thank you for this opportunity to testify today regarding the use, and misuse of Pharmaceutical Benefit Managers ("PBMs") and the need to enact legislation to protect patients and providers. My testimony today presents a brief overview based on my over 25 years as an antitrust attorney and enforcer. I conclude that: (1) there is a significant problem involving PBMs, due to the concentration in the market, deceptive practices and lack of transparency; (2) because of the market power of PBMs pharmacies are compelled to participate in pharmacy benefit networks at extremely low reimbursement rates, leading to a reduction in pharmacy services for consumers; (3) market forces alone will not correct these problems; (4) litigation will not adequately address the issues; (5) the FTC report on PBM self-dealing is critically flawed; and (6) legislation is the appropriate solution for the competitive and deceptive practices in the market. I strongly believe that Senate Bill No. 38 is an appropriate response to these competitive and consumer protection problems.

I have practiced antitrust law for over 25 years both in the government and in private practice. Prior to entering private practice, I was at the Federal Trade Commission for almost a decade in several senior positions. I was the Assistant Director of the Office of Policy and Evaluation for the Bureau of Competition of the Federal Trade Commission and attorney advisor to Chairman Robert Pitofsky. In these positions, I was a senior advisor in the FTC's merger and non-merger enforcement program. I was involved in the drafting and issuance of the FTC and

DOJ Statements of Antitrust Enforcement Policy in Healthcare. I also assisted in the litigation of numerous monopolization cases as well as challenges to anticompetitive and exclusionary conduct by several health care companies. I am also a Senior Fellow at the Center for American Progress, where my work focuses on competition and health care reform.

During my tenure at the FTC PBMs began to arise and become a more significant competitive force. PBMs offered the potential for significant cost savings and other benefits. However, this depended upon whether market forces could function in an unimpeded fashion. In order for a market to function competitively two factors are crucial: choice and information. If either is lacking then government enforcement or regulation may be necessary. That is why the FTC acted in the 1990s to require restructuring of the Merck's acquisition of the Medco PBM, and Lilly's acquisition of the PCS PBM.

I have been in private practice for the past several years working extensively on healthcare antitrust issues. I counsel a wide variety of firms on pharmaceutical regulatory and antitrust issues. My clients include all types of participants in the PBM market including chain and independent pharmacies, plan sponsors, insurance companies and Pharmacy Benefit Managers.[1]

State legislatures around the country – as well as the U.S. Congress itself – have been searching for ways to stem dramatically rising healthcare costs. In recent years this has grown from a serious concern to a pressing crisis. Many proposals involve Pharmaceutical Benefit Managers as a promising way to increase efficiency and lower costs. PBMs provide a number of valuable services, including managing formularies and negotiating lower prices with pharmaceutical companies.

Although PBMs offer a great deal of promise in terms of controlling pharmaceutical costs, there is a pattern of conflicts of interest, self-dealing and anticompetitive conduct, which ultimately means that Alaska consumers pay far more for drugs than necessary. The dominant

[1] My views today reflect my own views and not those of any client.

PBMs have been plagued with opaque business practices, limited market competition and widespread allegations of fraud. Senator Montigny, Chair of the Board of The National Legislative Association on Prescription Drug Prices (NLARx), says "we know of no other market in which there has been such a significant number of prominent enforcement actions and investigations, *especially a market with such a significant impact on taxpayers.*"[2] The facts are clear: while PBMs may well prove a necessary expedient in lowering the cost of healthcare, measures must be taken to ensure that they operate as they are supposed to.

PBMs in their current form pose a serious financial problem for the state of Alaska and its consumers. While PBMs are in a position to negotiate low prices from pharmaceutical manufacturers, a lack of transparency makes this a dubious proposition. Even if PBMs receive significant revenue from pharmaceutical manufacturers; it is increasingly unclear the degree that these rebates reduce costs for the PBM's clients. Therefore, the very same aspect of the PBM that should create savings also contains an inherent conflict of interest. A review of the considerable federal and state litigation against PBMs reveals several recurring issues:

(1) conflicts of interest because PBMs both manage drug benefits and dispense drugs;

(2) the exercise of monopsony power harming pharmacies and reducing pharmacy services for consumers;

(3) improper prescription drug switching to a higher priced drug without medical justification and without the authorization of the prescribing physician;

(4) failing to disclose and pass on the full extent of rebates and other incentives received from drug manufacturers, and failing to pass through such discounts to pharmacies and consumers; and,

(5) price fixing.

The tremendous amount of litigation by employers, insurers, consumer groups and others against PBMs demonstrates the extent of the financial problem, fundamentally stemming from the lack of transparency. Regulation to create some sort of market transparency is crucial to the proper

[2] Letter from Senator Mark Montigny, on behalf of NLARx, to Deborah Platt Majoras, FTC Chair, May 11, 2005.

functioning of this market. The First Circuit Court of Appeals that upheld Maine's regulatory statute noted that PBMs "introduce a layer of fog to the market that prevents benefits providers from fully understanding how to best minimize their net prescription drug costs." Over the past four years, more than twenty states either have passed or are considering regulation of PBMs to address these problems. The State of Alaska should seriously consider legislation to alleviate the same opaque conditions that have already cost so much to so many.

PBMs harm consumers by using their market power to reduce compensation to pharmacies. As noted below the PBM market is highly concentrated and that enables them to exercise "monopsony" or buyer power to reduce compensation to the pharmacies that provide dispensing services. Although a reduction in compensation may appear attractive from the perspective of a buyer of PBM services, that attraction is misleading. The savings from reducing compensation is not passed on to buyers in lower prices because of the market power of PBMs. Moreover, ultimately the consumer of drugs is harmed because there are fewer pharmacies available or other forms of pharmacy services diminish.[3]

This is a particularly severe problem in largely rural states such as Alaska. Consumers value convenience and the ability to visit community pharmacies for face to face service. The interest of PBMs is to lower compensation to the minimal level (or even less) to drive pharmacies out of the market. PBMs have an inherent conflict of interest because they dispense drugs through their own mail order operations.

In Alaska, there is a chronic problem with PBMs either paying pharmacies late or manipulating the PBM claims process. Senate Bill No. 38 addresses this problem by requiring the timely payment of claims and limiting the ability of PBMs to manipulate claims processing.

Market forces and litigation are not the solution to this problem. PBMs consistently claim that market forces have taken or will take care of any problems. Clients are sophisticated, and can sufficiently ensure that their plans save money. The PBMs therefore contend that no

[3] 3] This monopsony power that PBMs enjoy is similar to that of health insurers, which have the ability to impose take-it-or-leave it contracts on physicians.

supervision is needed. Furthermore, they pretend, the litigation that has already occurred has been sufficient to iron out any difficulties with the current structure. Both of these arguments are critically flawed.

Market forces are not a complete solution. First of all, the PBM market is highly concentrated. The three largest PBMs (Caremark, Express Scripts, and Medco) control over 80% of insured prescriptions and 90% of insured mail order prescriptions... Furthermore, high barriers to entry insulate the market from potential competition. Meanwhile, the PBMs dismiss the issue by saying that clients are competent enough not to lose money. Indeed, those who have the resources for monitoring the PBMs have in some cases done so, and prosecution has been the frequent result.

Indeed, there have been market-driven reforms, such as contract negotiations which involve a degree of transparency similar to that of proposed legislation. This again relies on clients, however, to have sufficient resources for researching and sufficient leverage for negotiating such a contract. Clearly, PBMs are willing to accept transparency when necessary; though they will fight tooth and nail to avoid it whenever possible.

Litigation is not a complete solution. Proponents of PBMs may argue that if there are competitive problems or deceptive practices they will be cured by litigation. Certainly there are numerous antitrust, fraud and consumer protection cases ongoing. But as the Senate knows all too well, litigation is expensive and time-consuming. Some of these cases have been pending for several years. And the ultimate resolution of these cases will cure a single problem in the past. Litigation is too episodic, slow and expensive to be a cure all

Each of the major PBMs has been the subject of a major enforcement action brought by a coalition of state attorneys generals and in some cases by the Department of Justice. These cases have secured over $370 million of penalties and damages. And numerous settlement agreements involving varying degrees of information disclosure strongly recommend transparency as a reasonable solution to the problem. (A list of the respective cases is attached.)

For example, in September 2005, AdvancePCS (acquired by Caremark) agreed to a $137.5 million fine and a five-year injunction and settlement agreement with the United States Department of Justice. The allegations against AdvancePCS included receiving kickbacks from pharmaceutical manufacturers, improper therapeutic substitutions, as well as making false claims to the government. One key provisions of the settlement agreement was – unsurprisingly – disclosure to client plans of all information reasonably necessary to audit contract compliance.

Perhaps most importantly, recent litigation upheld a Maine law addressing these issues. In *PCMA v. Maine*, PBMs attempted to strike down a Maine statute that required them to disclose information regarding rebates from pharmaceutical manufacturers. The federal district court granted summary judgment in favor of Maine on all claims.[4] Furthermore, the First Circuit Court of Appeals upheld this decision unanimously. Judge Torruella of the First Circuit wrote, "If PBMs truly assumed that they would be free from disclosure requirements of the sort set forth in the Maine law here, this would be more wishful thinking than reasonable expectation. Whether or not the law strikes the right economic balance between competing producer and consumer interests, it is no more a taking than the requirement that public corporations disclose private corporate information about financial prospects to the public through regular SEC filings." In this context, it is easy to understand why so many states are considering saving themselves millions of dollars by demanding PBM transparency from the outset.

Senate Bill No. 38 attempts to address two problems identified in the past government enforcement actions. First, the Bill attempts to protect patients from unwarranted so-called "therapeutic substitutions." The government enforcement actions found that PBMs often compel patients to switch drugs, not because a drug is preferable or less costly, but because the PBM receives a greater rebate for the new drug. Senate Bill No. 38 requires the PBM to secure the approval of the prescriber to substitute the drug and informed the patient of the substitution and the reason for the substitution. (Section 21.07.130).

[4] Pharmaceutical Care Management Association (PCMA) v. Rowe, Civil No. 03-153-B-H (April 2005)(at 4-5)

Second, PBMs are often reluctant to provide information to covered entities on the sources and amounts of compensation and rebates they receive from pharmaceutical manufacturers. This lack of information allows the PBMs to secure new sources of revenue by failing to disclose the amount of revenue they secure or engaging in spread pricing. Transparency is essential for covered entities to make sure they receive the best price from their PBM and the provisions in the Bill will result in greater competition and cost savings.

Greater efficiency and ability to control costs are within reach. American healthcare is changing rapidly, and PBMs have become an important element in healthcare management. Legislation is absolutely necessary to ensure that this arrangement turns out to be a blessing and not a curse. If transparency and a fiduciary duty are mandated for PBMs, there will be little chance for them to defraud their clients and the state of Alaska with conflicts of interest or cryptic closed-door financial dealings. With careful legislation that actually allows market forces to work, the rising costs of pharmaceuticals can be at least in some considerable measure abated.

I appreciate the opportunity to provide this testimony and would be pleased to answer any questions.

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