SB 217

<TARGET><BILL>SB 217</BILL><SUBJECT>SB 217</SUBJECT><COMM>SFIN27</COMM></TARGET>

SENATE FINANCE COMMITTEE REPORT

DATE: 3/14/12

FURTHER:

DATE TURNED
IN TO OFFICE: _____

Finance Committee considered SENATE BILL NO. 217

SB 217-PHARMACY AUDITS

"An Act establishing procedures and guidelines for auditing pharmacy records; and providing for an effective date."

and recommends:

[X] be **replaced** with **CS** SB 217 (FIN) [X] *Same Title* [ ] *New Title*

[ ] adopt **previous CS** _____ (_____) [ ] *Same Title* [ ] *New Title*

[ ] attached amendment(s)

[ ] adopt _____ Letter of Intent

[ ] further referral to _____ Committee

Dept Abbr.	
ADM	LEG
CED	LAW
COR	LWF
CRT	MVA
EED	DNR
DEC	DPS
DFG	REV
GOV	DOT
DHS	UA

NEW FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #

PREVIOUS FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #
CED			X	2
ADM			X	1

[ ] **APPROPRIATION - no fiscal note**

SIGNATURES AND RECOMMENDATIONS:	PRINTED LAST NAME	DO PASS	DO NOT PASS	NO REC	AMEND
	Thomas	✓			
	Egan	✓			
	Olson			✓	
	Ellis	X			
CO-CHAIR:	Hoffman	✓			
CO-CHAIR:	Sfedman			✓	

FISCAL NOTE

STATE OF ALASKA
2012 LEGISLATIVE SESSION

Bill Version: **CSSB 217(L&C)**
Fiscal Note Number: 2
(S) Publish Date: 3/14/12

Identifier (file name): SB217-DCCED-CBPL-03-09-12
Title: Pharmacy Audits
Sponsor: Senate Labor & Commerce
Requester: Senate Labor & Commerce

Dept. Affected: DCCED
Appropriation: Corps, Bus & Professional Licensing
Allocation: Corps, Bus & Professional Licensing
OMB Component Number: 2360

Expenditures/Revenues (Thousands of Dollars)

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

	FY13 Appropriation Requested	Included in Governor's FY13 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY13**	**FY13**	**FY14**	**FY15**	**FY16**	**FY17**	**FY18**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants, Benefits							
Miscellaneous							
TOTAL OPERATING	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

FUND SOURCE		(Thousands of Dollars)						
1002	Federal Receipts							
1003	GF Match							
1004	GF							
1005	GF/Prgm (DGF)							
1037	GF/MH (UGF)							
1156	Rcpt Svcs (DGF)							
TOTAL		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

POSITIONS							
Full-time							
Part-time							
Temporary							

CHANGE IN REVENUES	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimated SUPPLEMENTAL (FY12) operating costs 0.0 *(separate supplemental appropriation required,*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY13) costs 0.0 *(separate capital appropriation required;*
(discuss reasons and fund source(s) in analysis section)

Why this fiscal note differs from previous version (If initial version, please note as such)

This version updates the sponsor and requestor.

Prepared by: Don Habeger, Director — Phone: 465-2536
Division: Corporations, Business and Professional Licensing — Date/Time: 2/24/2012 10:00am
Approved by: JoEllen Hanrahan, Director Administrative Services — Date: 3/9/2012
Commerce, Community and Economic Development

Revised 1/17/2012 (MB)

FISCAL NOTE #2

STATE OF ALASKA
2012 LEGISLATIVE SESSION

BILL NO. CSSB 217(L&C)

Analysis

SB 217 establishes standards and guidelines for an audit of a licensed pharmacy in the state of Alaska performed by an insurer, managed care company, a third-party payor, pharmacy manager or any entity that represents such companies.

This bill will have no fiscal impact to the Division of Corporation, Business and Professional Licensing.

FISCAL NOTE

STATE OF ALASKA
2012 LEGISLATIVE SESSION

Bill Version	**CSSB 217(L&C)**
Fiscal Note Number	1
(S) Publish Date	3/14/12

Identifier (file name)	SB217-DOA-DRB-2-27-12	Dept. Affected	Administration
Title	Pharmacy Audits	Appropriation	Centralized Administrative Services
		Allocation	Health Plan Administration
Sponsor	Labor & Commerce		
Requester	Senate Labor & Commerce	OMB Component Number	2152

Expenditures/Revenues (Thousands of Dollars)

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

	FY13 Appropriation Requested	Included in Governor's FY13 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY13**	**FY13**	**FY14**	**FY15**	**FY16**	**FY17**	**FY18**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants, Benefits							
Miscellaneous							
TOTAL OPERATING	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

FUND SOURCE		(Thousands of Dollars)						
1002	Federal Receipts							
1003	GF Match							
1004	GF							
1005	GF/Prgm (DGF)							
1037	GF/MH (UGF)							
1178	temp code (UGF)							
TOTAL		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

POSITIONS							
Full-time							
Part-time							
Temporary							

CHANGE IN REVENUES							

Estimated SUPPLEMENTAL (FY12) operating costs _____ *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY13) costs _____ *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Why this fiscal note differs from previous version (if initial version, please note as such)

Not applicable, initial version

Prepared by	Jim Puckett, Director	Phone	465-4471
Division	Division of Retirement & Benefits	Date/Time	2/27/12 1:15 PM
Approved by	John Cramer, Deputy Commissioner	Date	2/27/2012
	Department of Administration		

FISCAL NOTE #1

STATE OF ALASKA **BILL NO.** CSSB 217(L&C)
2012 LEGISLATIVE SESSION

Analysis

The intent of this bill is to establish standards for an audit of pharmacy records carried out by an insurer, a managed care company, a third-party payor, a pharmacy benefits manager, a health plan administered by the state, or any entity that represents such companies.

The division of Retirement and Benefits actuarial (Buck Consulting) does not anticipate there will be any financial impact on the AlaskaCare health plans.

CS FOR SENATE BILL NO. 217(FIN)

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-SEVENTH LEGISLATURE - SECOND SESSION

BY THE SENATE FINANCE COMMITTEE

Offered:
Referred:

Sponsor(s): SENATE LABOR AND COMMERCE COMMITTEE

A BILL

FOR AN ACT ENTITLED

"An Act establishing procedures and guidelines for auditing pharmacy records; and providing for an effective date."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

*** Section 1.** The uncodified law of the State of Alaska is amended by adding a new section to read:

INTENT. This Act is intended to establish standards for an audit of pharmacy records carried out by an insurer, a managed care company, a third-party payor, a pharmacy benefits manager, a health plan administered by the state, or any entity that represents such companies.

*** Sec. 2.** AS 08.80 is amended by adding a new section to read:

Sec. 08.80.477. Pharmacy audits. (a) When an audit of the records of a pharmacy licensed in this state is conducted by an insurer, managed care company, hospital or medical service corporation, third-party payor, or pharmacy benefits manager,

(1) for each audit cycle, the auditor shall provide the pharmacy or

pharmacist with notice of the audit at least two weeks before conducting the initial on-site audit;

(2) unless the pharmacy and the auditor agree otherwise, the audit may not be scheduled to occur during the first seven business days of a month because of the high volume of prescriptions that are filled during that time;

(3) an insurer, managed care company, hospital or medical service corporation, third-party payor, or pharmacy benefits manager may not conduct an audit within 90 days after an audit in which no errors were found; in this paragraph, "error" does not mean a clerical error, record keeping error, or typographical error;

(4) the audit of a claim shall occur within two years after the date the claim was submitted;

(5) if the audit involves clinical or professional judgment, the audit must be conducted by or in consultation with a pharmacist licensed in this or another state;

(6) each pharmacy shall be audited using the same standards and parameters as other similarly situated pharmacies;

(7) an auditor may not use the accounting practice of extrapolation to establish an overpayment or underpayment or for calculating recoupment or penalties;

(8) a finding of overpayment or underpayment by the auditor must be based on an actual overpayment or underpayment and may not be based on a projection based on the number of patients served who have a similar diagnosis or on the number of similar orders or refills for similar drugs;

(9) calculations of overpayment by an auditor may not include dispensing fees unless a prescription was not dispensed, a physician denied authorization to dispense the prescription, or the dispensing violated a term of a contract;

(10) an auditor may not assess a charge-back, recoupment, or other penalty against a pharmacy solely because a prescription is mailed or delivered at the request of a patient as part of a routine business practice of the pharmacy;

(11) to the extent that an audit finds clerical or record keeping errors in a required document or record, the pharmacy may not be subject to recoupment unless

the clerical or record keeping error results in actual financial harm to an insurer, managed care company, hospital or medical services corporation, third-party payor, pharmacy benefits manager, or a customer;

(12) the preliminary audit report must be delivered to the pharmacy within 120 days after the completion of the audit;

(13) interest may not accrue from the date of completion of the audit to the delivery date of the preliminary audit report, unless an auditor finds proof of intent to commit fraud;

(14) a pharmacy shall be allowed at least 30 days following receipt of a preliminary audit report to produce documentation to address a discrepancy found during the audit; a pharmacy may use any record, including the records of a hospital, physician, or other health care provider, or other written or electronic record to validate a pharmacy record;

(15) the insurer, managed care company, hospital or medical service corporation, third-party payor, or pharmacy benefits manager shall establish a written appeal process by which a pharmacy may appeal an unfavorable preliminary or final audit report;

(16) the final audit report must be delivered to the pharmacy within 90 days after receipt of the preliminary audit report or final appeal;

(17) the auditor may not receive compensation based on the percentage of the amount recovered by the auditor;

(18) the auditor shall provide a copy of the final report to a health benefit plan sponsor affected by the audit;

(19) patient information accessed in the course of an audit is confidential and may not be used for marketing purposes.

(b) This section does not apply to

(1) a criminal investigation; or

(2) state Medicaid programs.

(c) In this section, "health benefit plan" has the meaning given in AS 21.54.500.

* **Sec. 3.** The uncodified law of the State of Alaska is amended by adding a new section to

read:

APPLICABILITY. This Act applies to pharmacy audits conducted after the effective date of this Act.

* **Sec. 4.** This Act takes effect January 1, 2013.

ADOPTED 4/13/12 AM

27-LS1411\I
Martin
4/10/12

CS FOR SENATE BILL NO. 217( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-SEVENTH LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): SENATE LABOR AND COMMERCE COMMITTEE

A BILL

FOR AN ACT ENTITLED

"An Act establishing procedures and guidelines for auditing pharmacy records; and providing for an effective date."

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(1) for each audit cycle, the auditor shall provide the pharmacy or

pharmacist with notice of the audit at least two weeks before conducting the initial on-site audit;

(2) unless the pharmacy and the auditor agree otherwise, the audit may not be scheduled to occur during the first seven business days of a month because of the high volume of prescriptions that are filled during that time;

(3) an insurer, managed care company, hospital or medical service corporation, third-party payor, or pharmacy benefits manager may not conduct an audit within 90 days after an audit in which no errors were found; in this paragraph, "error" does not mean a clerical error, record keeping error, or typographical error unless the auditor finds proof of intent to commit fraud;

(4) the audit of a claim shall occur within two years after the date the claim was submitted;

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(10) an auditor may not assess a charge-back, recoupment, or other penalty against a pharmacy solely because a prescription is mailed or delivered at the request of a patient as part of a routine business practice of the pharmacy;

(11) to the extent that an audit finds clerical or record keeping errors in

a required document or record, the pharmacy may not be subject to recoupment unless there is proof of intent to commit fraud or the clerical or record keeping error results in actual financial harm to an insurer, managed care company, hospital or medical services corporation, third-party payor, pharmacy benefits manager, or a customer;

(12) the preliminary audit report must be delivered to the pharmacy within 120 days after the completion of the audit;

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(18) the auditor shall provide a copy of the final report to a health benefit plan sponsor affected by the audit;

(19) patient information accessed in the course of an audit is confidential and may not be used for marketing purposes.

(b) This section does not apply to

(1) a criminal investigation; or

(2) an investigation or audit by a governmental agency, including state Medicaid programs.

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ADOPTED 4/13/12 FM

27-LS1411\E
Martin
4/13/12

CS FOR SENATE BILL NO. 217( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-SEVENTH LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): SENATE LABOR AND COMMERCE COMMITTEE

A BILL

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the clerical or record keeping error results in actual financial harm to an insurer, managed care company, hospital or medical services corporation, third-party payor, pharmacy benefits manager, or a customer;

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*** Sec. 3.** The uncodified law of the State of Alaska is amended by adding a new section to

read:

APPLICABILITY. This Act applies to pharmacy audits conducted after the effective date of this Act.

*** Sec. 4.** This Act takes effect January 1, 2013.

HCCMCA
HEALTHCARE COST MANAGEMENT
CORPORATION

April 13, 2012

Senate Finance Committee
Honorable Bert Stedman, Chair
120 4th Street State Capitol, Rm. 516
Juneau, AK 99801-1182

Dear Senator Stedman,

HCCMCA is a coalition of over 35 Alaska and Northwest based self-funded and employer-sponsored health benefit plans. These funds represent over 65,000 covered lives in Alaska.

I was prepared to testify this morning via teleconference regarding SB 217, with concerns this bill does not do enough to protect the legal and fiduciary integrity of trustees and administrators of our Taft-Hartley and other trust funds. Many of our concerns are similar to those Director Jim Puckett described in his testimony.

Unfortunately, a copy of the most recent CS being considered by the committee was not available here at the Fairbanks LIO. Nevertheless, based on the testimony and description given, HCCMCA's position is that the proposed CS changes do not go far enough. For example, we think the provision limiting the number of scripts that can be audited to 75 during a single audit is overly restrictive and burdensome for auditors contracted by our health plans.

Regarding overall policy questions, in Section 2, we submit Alaska boroughs, municipalities and school districts should be included in the definition of governmental agencies (entities?) which are exempted from coverage by the bill. We also believe the committee should evaluate whether ERISA preempts application of this statute to Taft-Hartley trust funds.

In sum, we prefer SB 217 be held in committee and a work group formed allowing interested parties to better evaluate and understand the issues during the interim.

Feel free to contact me if you have any questions.

Sincerely,

Fred G. Brown
Executive Director

Cc: Senator Dennis Egan

Keeping health care affordable for workers and their families

1469 Holy Cross Drive, Fairbanks, AK 99709
(907) 474-4226 ▪ Toll-free (888) 474-4226 ▪ www.hccmca.org

Alaska State Legislature

State Capitol, Room 510
Juneau, Alaska 99801
Phone: (907) 465-4947
Fax: (907) 465-2108

Committee Members:
Senator Dennis Egan, Chair
Senator Joe Paskvan, V. Chair
Senator Bettye Davis
Senator Linda Menard
Senator Cathy Giessel

Senate Labor and Commerce Committee

Senate Bill 217 Pharmacy Audits

Sponsor Statement

Passage of Senate Bill 217 will establish procedures and guidelines for auditing pharmacy records so that all pharmacies are held to the same standards. It has been introduced by request of the Alaska Pharmacists Association.

The legislation would help assure all pharmacies in the state face reasonable audits, but it would especially help small-business pharmacies who, because of their smaller pool of assets, may face dire consequences due to an unreasonable audit.

Senate Bill 217 would set requirements for auditing pharmacy records by an insurer, a managed care company, a third-party payor, or a pharmacy benefits manager. Where there are disagreements between an auditor and a pharmacy, the measure would allow for an appeal in the case.

Pharmacists acknowledge that audits are a good tool to protect the public and detect fraud or abuse, but they say that, sometimes, audits may be unreasonable and used in a way to deprive them of fair reimbursement for their services. There may be times when pharmacists may give someone the right drug in the right dose, but because of a clerical or typographical error in billing, they may not get paid what they are due.

Senate Bill 217 is aimed at protecting the public from potential abuse, while at the same time assuring that pharmacists face fair, reasonable and consistent audits.

Supporters of this measure include the Alaska Pharmacists Association, the National Community Pharmacists Association, and the National Association of Chain Drug Stores.

Alaska State Legislature

State Capitol, Room 510
Juneau, Alaska 99801
Phone: (907) 465-4947
Fax: (907) 465-2108

Committee Members:
Senator Dennis Egan, Chair
Senator Joe Paskvan, V. Chair
Senator Bettye Davis
Senator Linda Menard
Senator Cathy Giessel

Senate Labor and Commerce Committee

CSSB 217 Pharmacy Audits

Sectional Analysis

Section 1. States the intent of the bill is to set standards for auditing pharmacy records.

Section 2. Amends Chapter 08.80, Pharmacists and Pharmacies, by adding a new section, 08.80.477, that sets out requirements for auditing pharmacy records by an insurer, a managed care company, a third-party payor, a pharmacy benefits manager, a health plan administered by the state, or an entity that represents such companies.

Some of those procedures cover:

- Notice requirements for audits;
- Scheduling of audits;
- Retrospective limitations;
- Auditor qualifications;
- Audit standards;
- Errors;
- Access to previous reports;
- Limits on providing audit reports;
- Prohibitions against extrapolation and projections;
- Requiring findings of actual overpayment;
- Exclusion of dispensing fees;
- Time limits relating to reports;
- Documentation;
- Appeals;
- Regulating auditor compensation;
- Limiting accrual of interest;
- Excluding applicability to criminal investigations or investigations by a governmental agency.

Section 3. Applies the bill to audits that occur after the immediate effective date set in Section 4.

Section 4. Provides for an immediate effective date.

Alaska State Legislature

State Capitol, Room 510
Juneau, Alaska 99801
Phone: (907) 465-4947
Fax: (907) 465-2108

Committee Members:
Senator Dennis Egan, Chair
Senator Joe Paskvan, V. Chair
Senator Bettye Davis
Senator Linda Menard
Senator Cathy Giessel

Senate Labor and Commerce Committee

Senate Bill 217 Pharmacy Audits

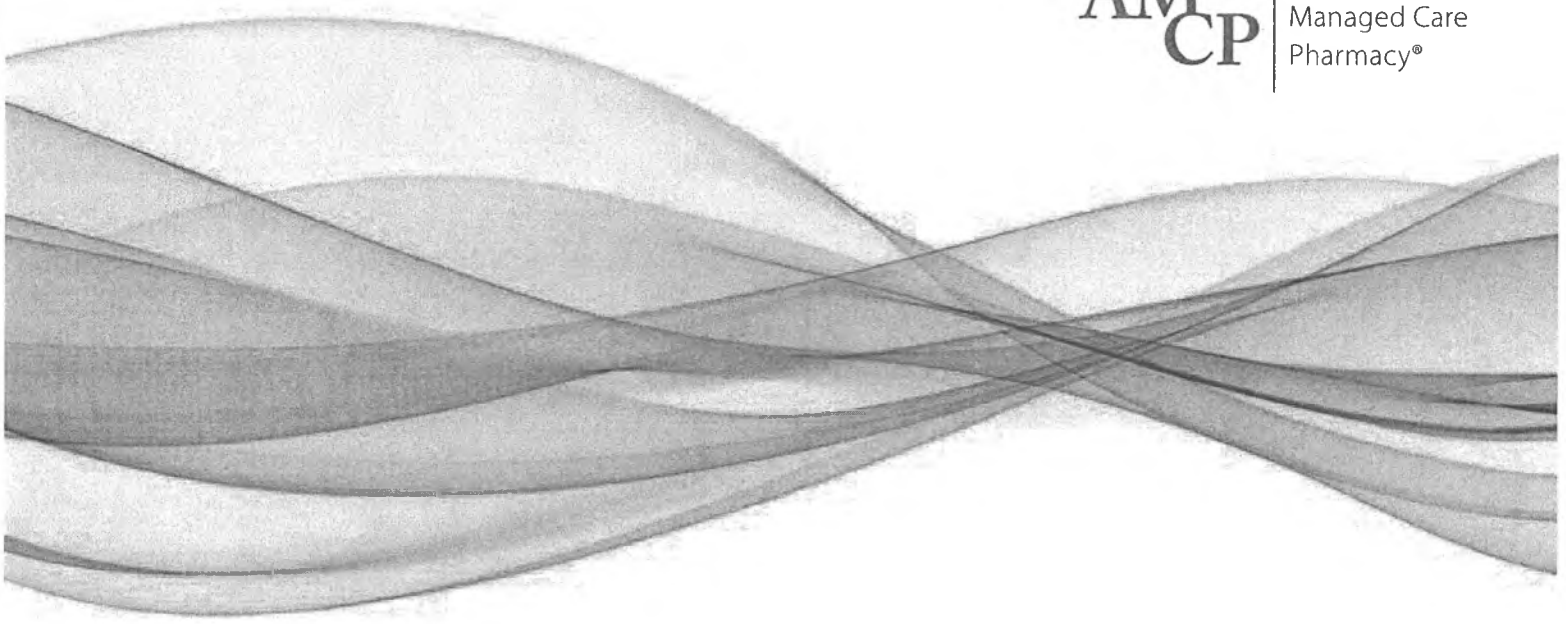
Summary of Changes
SB 217 \A to CSSB 217 (L&C) \B

Sec. 1.

- P.1, line 8. The word "such" is replaced by "those" for clarity.

Sec. 2.

- P.2, line 7. A new paragraph (3) is added limiting to 75 the number of prescriptions an auditor may audit in a single audit.
- P.2, line 15. A new paragraph (7) is added to limit the audit to requirements no stricter than state or federal law.
- P.2, line 18. The phrase "may not be the basis for finding of fraud" replaces "may not constitute fraud."
- P. 2, line 21. The phrase "provide information only" replaces "only provide information" for grammatical correctness and clarity.
- P.2, line 13. A new paragraph (13) is added to ensure that a prescription mailed or delivered at the request of a patient may not be the basis for a charge-back, recoupment or penalty.
- P. 3, line 7. Documented phone calls from a prescriber or prescriber's agent, is added to the list of items that can be used to validate a pharmacy record.
- P. 3, lines 25 – 27. Subsection (b) is rewritten to clarify that this bill does not apply to Medicaid audits.



AMCP Academy of Managed Care Pharmacy®

Model Audit Guidelines

for Pharmacy Claims

100 North Pitt Street | Suite 400
Alexandria, VA 22314

800 827 2627 | 703 683 8416
Fax 703 683 8417

www.amcp.org

ACKNOWLEDGEMENTS

The Academy of Managed Care Pharmacy wishes to thank the AMCP Community Pharmacy Outreach Council's Task Force on Model Audit Guidelines for providing their expertise in developing this document. AMCP also wishes to thank staff members from the American Pharmacists Association, the Food Marketing Institute and the National Community Pharmacists Association for their contributions to this project.

Members of the AMCP Community Pharmacy Outreach Advisory Council Task Force

Julie Lenhard, PharmD, RPh, Chair
Wegmans Food Markets
Member of the AMCP Community Pharmacy Outreach Advisory Council

Lowell Anderson, DSc
Center for Leading Healthcare Change, University of Minnesota
Appointed by the American Pharmacists Association

John Cronin, PharmD, JD
Fredrickson Mazeika & Grant LLP
Appointed by the American Society of Pharmacy Law

Leanne Kent, CPhT
The Kroger Co.
Appointed by the Food Marketing Institute

Brian J. Correia, CFE
CVS Caremark
Appointed by AMCP

Charlie Oltman, MBA, CHC
Target
Appointed by AMCP

G. William Strein, MSPH, RPh
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Michael Tocco, MEd, RPh
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NOTE: The *AMCP Model Guidelines for Pharmacy Claims* do not necessarily represent the views of the individual Task Force members or their organizations.

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INTRODUCTION

In 2009, the Academy of Managed Care Pharmacy (AMCP) established the Community Pharmacy Outreach Advisory Council to address issues that managed care pharmacy and community pharmacy share and that would lead to an enhanced relationship. The Council identified auditing of pharmacy claims as a high priority issue largely because of the friction it causes for both community and managed care pharmacy. The Council conducted a poll to learn about the issues that both practices had with auditing and determined that model guidelines for pharmacy claims auditing could serve as the foundation to address the issue.

The *AMCP Model Audit Guidelines for Pharmacy Claims* are the result of over a year-long effort by a Task Force comprised of pharmacists in managed care organizations[1] (MCOs), community practice and law; auditing administration; third party management; and, network administration.

It is important to note that while these *Guidelines* were developed for MCOs and community pharmacies as a way to improve the relationship between the parties, the contract between the MCO and the pharmacy should define the actual audit process. These *Guidelines* are offered to assist MCO's in developing a pharmacy claims audit program, and to help pharmacy providers to better understand the audit requirements and process.

THE ROLE OF AUDITS

Historically, health care services, including prescription medications, were paid by the patient as an out of pocket expense. These payments may then have been reimbursed by a third party or self-funded insurance plan. Over the twentieth century health care insurance evolved from indemnity pre-paid insurance, to managed care emerging as a major mechanism of coverage. The growth of plan design, administration and payment by third-party entities, coupled with increases in the total costs of care, have required oversight of plans and their financial services. Audits of claims made by pharmacies and payments made to pharmacies are included in the oversight process.

The auditing of pharmacy claims serves two main purposes: 1) detecting fraud, waste and abuse, and 2) validating data entry and documentation to ensure they meet regulatory and contractual requirements.

Fraud, Waste and Abuse

While a pharmacy may find audits unpleasant and disruptive as they are currently conducted, all providers need to recognize that audits remain the primary method presently available for MCOs to determine network pharmacy compliance and to identify fraud, waste and abuse (FWA) within the prescription drug benefit, as these contribute to the rising cost of health care.

With the launch of Medicare Part D in 2006 came an increase in federal funding of pharmacy benefits and a corresponding increase in the scrutiny of pharmacy claims and billing practices. Under the Centers for Medicare and Medicaid's (CMS) oversight of federally funded programs, plans and provider networks are subject to performance monitoring for compliance with and adherence to fraud, waste and abuse requirements that are well defined in federal law. The federal standards have led to an increasing level of oversight of pharmacy claims in commercial plans as well, and are reaching into the specialty pharmacy practices associated with long term care and home infusion pharmacies. Regardless of professional setting, an appreciation of the changing environment in which MCOs operate is essential for contemporary pharmacy practice and operation.

[1] Managed Care Organization (MCO) is used throughout the *Guidelines* and is defined as all types of MCOs including, but not limited to, health plans, PBMs, HMOs and contracted agents.

Data Entry and Documentation

Another purpose of audits is to validate the correct entry of required pharmacy claims information. These are the audits most commonly experienced by MCOs and pharmacies, and are among those that cause the most difficulties.

The misunderstandings that arise from data verification are often preventable. The MCO should supply the pharmacy provider with a document that defines the requirements on which it may base an audit. This document must be updated and communicated as changes occur. The actual audits should be conducted in a manner that leads to continuous quality improvement of the services of the provider, rather than as a source of revenue. Further, the provider must review and be comfortable with these documents before it agrees to a contract. Once a contract is entered into, it is incumbent on the provider to commit to review and comply with the requirements.

PHILOSOPHY and RESPONSIBILITIES

The audit is both a contract management essential and a public relations opportunity for the MCO. It is possible that the in-pharmacy audit is the only time the pharmacy provider and a representative of a MCO will ever meet in an official capacity. The way in which an audit is conducted can contribute substantially to the pharmacy staff's attitude about the MCO, and the MCO representative's attitude about the pharmacy's practice, and can affect the ongoing working relationship between the two parties and ultimately, patient care.

The audit experience, regardless of outcome, is often shared broadly with colleagues in the pharmacy practice community and back to the MCO. Experiences the pharmacy staff has with auditing, drug benefit design, benefit management, and help desk interaction can affect the attitude of the pharmacy staff towards the MCO. Therefore, the pharmacy staff is in a position to affect consumer perception of the health benefit broadly and the MCO's drug benefit specifically.

The audit provides an important opportunity for the MCO to market itself to the pharmacy staff by sharing the goals of the benefit design, discussing the importance of adherence to the contract, and gathering important market information from the pharmacy. The net result can be an improved relationship between the parties.

It is much easier for the pharmacy staff to understand the requirements of a MCO subject to audit if the goals of the drug benefit are shared. In many cases these goals are quite simple, e.g., target generic dispensing rates, adherence to formulary and compliance.

The audit process is a means of ensuring that pharmacy procedures and reimbursement mechanisms are consistent with regulatory and MCO contractual requirements. With increasing oversight of the cost of the many elements of health care, the frequency and nature of audits of pharmacy claims can only be expected to increase.

It is imperative that pharmacists-in-charge, and their staff, understand the dispensing and billing requirements and the implications of non-compliance. The pharmacy organization should consider appointing a "compliance officer" for the purpose of monitoring regulatory and MCO requirements and to ensure optimal performance of pharmacies.

A properly designed audit process should be transparent and have a fair design and implementation. Such a structure goes a long way towards fulfilling its purpose of assuring the performance of the pharmacy network. The auditors and the pharmacy staff must understand the elements of the audit process.

There are several considerations that will positively affect audit performance outcomes:

PHILOSOPHY and RESPONSIBILITIES

continued

Bilateral understanding and adherence to contract obligations: Both parties to the contract, and their representatives, should understand the obligations under the contract. This requires affirmative action of both parties.

Transparency of audit guidelines, dispensing requirements and process: It is important to the process that the MCO makes the audit elements and audit process available to the network in a clearly defined usable manner, and updates this information when changes are made. If included in the contract, it is helpful if these porocesses appear in a separate section labeled as "audit elements." Without this transparency, the pharmacy may be left with the assumption that the audit is merely a way for the MCO to make more money. In the interest of compliance with the requirements, the MCO should routinely offer audit tips to its pharmacy network.

Risk- or Incentive-based Auditing: Auditing of pharmacy claims that are paid for as a percentage of findings may lead to overzealous interpretation and frivolous recoupment of payment. It is strongly recommended that MCOs should avoid contracting pharmacy claims auditing based upon this practice.

State dispensing regulations and published MCO claim submission requirements must work in concert: Audit requirements should not require the pharmacy staff to act contrary to state regulations. However, the claim submission requirements regarding plan benefit design, and the audit of same, may be additive to state laws, rules and regulations to the extent that the MCO requires it to correctly administer its defined benefit.

Prescription Order Documentation: Pharmacy practice often requires modifications to the original prescription order after consultation with the prescriber or patient. These consultations must be documented by the pharmacist on the prescription order or electronic record. For example, a "use as directed" instruction on the prescription order needs further clarification to support appropriate billing of the claim.

Electronic documentation and records: With an ever increasing shift to electronic prescribing and record keeping, it is imperative that electronic documentation (e.g. prescription orders, transaction notes, etc.) become acceptable for audit purposes. It is, however, critical that electronic documentation and records are complete, secure and of high quality to ensure their readability and authenticity.

All participants to an audit need to be informed and professional: When an audit is seen as reasonable, transparent and fair in design and implementation, the entire process is raised to a professional and quality improvement level. On the part of the MCO this would include timely notice of pending audit and its purpose, timely arrival to conduct the audit, timely notification of results, and a reasonable appeals process, as well as professional demeanor by the auditors. On the part of the pharmacy it would be understanding of the contract, audit requirements and dispensing requirements, being prepared for the audit, providing a member of the pharmacy staff to assist the auditor, as well as a professional demeanor of the pharmacy staff. A bilateral professional level of performance can make the audit process run smoothly, be educational and improve quality.

THE AUDIT PROCESS

Over the years different types of audits have been developed to address changes in benefit and billing processes. Concurrent Daily Review Auditing was developed to attempt to make immediate changes to a claim before payment was made to the pharmacy. Another type, Retrospective Audits (desk, mail or in person) were designed to validate appropriate service by the pharmacy and help to detect FWA. And finally, an Investigative Audit is used after the normal audit processes have led to fraud.

Description of Audit Types

Concurrent Daily Review Audit is an audit of claims that may trigger the MCO to review them for various reasons (e.g. atypical quantities or excessive dosage). This type of audit focuses on the rationality of quantity and dosage form pairing. Once identified, typically a telephone call is made or an email is sent, usually immediately (generally within the same day but no later than 72 hours of claim submission), to the dispensing pharmacy to obtain an understanding of the claim submission. The claim concern is usually resolved at the time of notification by the pharmacy's electronic resubmission of the claim.

Retrospective Audit is a retrospective, usually quite detailed, analysis of the total volume of claims submitted by a pharmacy. Retrospective audits may be conducted using one of three different types of pharmacy claims audits:

- **Desk Top Audit** is conducted by contacting the pharmacy via fax, email, the U.S. mail or contracted mail services as defined in the contract between the parties. The pharmacy may be asked to provide photocopies of the specific prescription orders, signature logs, wholesaler invoices or other documentation within a date range of claims paid to the pharmacy. The pharmacy will be given a due date to submit the requested information. The requested information may be returned by fax, email or U.S. Mail.
- **In-Pharmacy Audit** is conducted by contacting the pharmacy via email, U.S. mail, or other channel as defined in the contract between the parties, prior to the scheduled on-site audit date. The notification may include the audit time frame and types of documents that will be reviewed during the on-site audit and optimally blinded prescription order number ranges that will be reviewed. These audits may be conducted during regular business hours and the auditor should make reasonable efforts to minimize disruptions to the pharmacy. The pharmacy may be expected to have the documentation to support the audit period readily retrievable and accessible. A member of the pharmacy staff should be dedicated to assist the auditor. When the audit is complete, the auditor should provide general feedback to the assigned pharmacy staff member.
- **Investigational Audit** differs from MCO to MCO, but typically it is broader than a pharmacy claims audit and may be initiated from a medical, dental or another type of claim. An investigational audit is usually a more extensive audit and can involve regulatory and law enforcement. Typically this type of audit commences when there is clear evidence based upon preliminary reviews or audits that reveal fraud or abuse by patient or provider. This type of audit will not be addressed by these Guidelines due to the individual nature of this type of audit.

Audit Process: Outline of Procedures

I. Concurrent Daily Review Audits

Concurrent Daily Review Audits are a great way for a MCO to monitor its network and work with pharmacy to identify claims that were submitted incorrectly so that these claims can be corrected prior to payment by the MCO. Pharmacy claims audits, with retroactive recovery of prior payments, may lead to friction between a pharmacy and MCO. The Concurrent Daily Review Audit process is a way to ease this friction by identifying claims immediately, and allowing for correction of the claims through a reversal and rebilling process. Pharmacy can appreciate this audit process as it avoids the notion that pharmacy claims audits are merely a revenue source for a MCO. This audit process creates more of a partnership between a MCO and pharmacy.

Documentation

When a relationship is established between a pharmacy and an MCO, there should be formal written documentation either included as contractually defined in the body of the contract or in the provider manual that includes specific information on the audit process. For Concurrent Daily Review Audits the following information[2] may be pertinent:

- Documentation of the audit process
- Documented list of items necessary to satisfy the audit which can include some or all of the following:
  - Prescription order copies
    - Original prescription orders or
    - Electronic scanned images

    Note: Regardless of the copy type, it is important that the prescription order copy must be able to be verified as a legitimate order with legible content and containing pertinent documentation on the prescription. For the electronic copies, documentation for the prescription may be in electronic transaction notes with a date and time stamp. It is important to be sure that all the necessary information related to the prescription order dispensing is provided. Usually, it is to the benefit of the community pharmacy to make sure its prescription copies are legible and all supporting documentation is presented.
  - Physician Notes
  - Additional Documentation
    - Electronic documentation on the dispensing of the prescription order with a date and time stamp of when the documentation occurred.
    - Written documentation on the dispensing of the prescription order that is dated as to when the documentation occurred.
- Timeframes should be outlined
  - Timeframe for a pharmacy to submit audit documentation for a concurrent audit. *Suggested timeframe:* At least 10 to 14 calendar days.
  - Timeframe of initial results to be sent to the pharmacy. *Suggested timeframe:* Within 24 to 48 hours after receiving initial documentation.
  - Timeframe for additional supporting documentation to be submitted. *Suggested timeframe:* Within 10 to 14 calendar days.
  - Timeframe to send final results to the pharmacy. *Suggested timeframe:* Within 24 to 48 hours after receiving any additional supporting documentation.

[2] There may be state laws regarding auditing pharmacy claims that differ from the Model Guidelines outlined.

Audit Process: Outline of Procedures

continued

- Types of discrepancies
  - Documentation on which discrepancies can be reviewed again if the pharmacy submits additional documentation
  - Each MCO may adopt its own unique policies regarding documents that are acceptable for additional review
- Documented appeals process
- Process for resolution of issues raised by the audit. This is typically handled through a reversal and rebilling process.

Procedures

1. The MCO identifies claims for audit.
   Guidance: The number of prescription orders to be audited typically ranges from 1 to 5. The prescription orders audited are typically no more than 7 to14 calendar days old and dependent on payment cycles.
2. The MCO can deliver the audit notification to the pharmacy via encrypted email or telephone call.
   Guidance: The audit notification should include the following information:
   a. Pharmacy response time
   b. Documentation needed to satisfy the audit request
   c. Contact within the auditing department at the MCO to answer any questions
   d. Expectation of when the pharmacy will receive initial results
3. The pharmacy is required to compile all audit documentation for submission to the MCO. The documentation should include everything necessary to satisfy the audit.
   Guidance: All documentation should be emailed or faxed back to the MCO within 14 calendar days. It may be to the benefit of the pharmacy if the pharmacy is able to provide the documentation right away. This may allow for prescription orders to be corrected prior to the prescription sale. Typically the pharmacy is given the opportunity to reverse the original claim and rebill the claim correctly. This process allows for corrections to be made prior to the payment of the claim which prevents any audit chargebacks from occurring.
4. The MCO then reviews all audit documentation submitted by the pharmacy, and creates an initial findings report for the pharmacy.
   Guidance: This report would typically be emailed to the pharmacy within 24 to 48 hours of receipt of the original documentation. The initial results should include a listing of all claims reviewed followed by the audit discrepancy, or indicate if there is no discrepancy.
5. The pharmacy will typically receive the initial audit results via email. At this time all claims should be reviewed to determine the following:
   a. No discrepancies are found.
   b. Pharmacy agrees with the audit discrepancy. The pharmacy may find that the prescription has not yet been dispensed to the customer and pharmacy can correct the prescription and prepare it for future fills. If the prescription has been dispensed, the pharmacy can make the correction in the system to prepare for future refills.

Audit Process: Outline of Procedures

continued

c. Pharmacy disagrees with the audit discrepancy and would like to submit additional documentation supporting the prescription order dispensing. The pharmacy is required to collect all additional documentation to be submitted to the MCO to support the original dispensing.
Guidance: Supporting documentation should be submitted within 14 calendar days of receiving the initial results.

6. The MCO will typically receive the supporting documentation via email or fax. At this time the MCO reviews the supporting documentation to determine the final audit results. The MCO will typically send final audit results to the pharmacy within 24 hours of receipt of supporting documentation. With the final audit results, the MCO should communicate the amount that the pharmacy is to expect on the next remittance advice as payment for the prescription order.
7. The pharmacy will then verify that the proper payment was received on the claim when the corresponding remittance advice is received.

II. Desktop Audits

Desktop Audits (a retrospective audit) are a method of auditing that MCOs use which many pharmacies prefer because they may be less disruptive to the day-to-day pharmacy operations when compared to an in-pharmacy audit. Typically these audits utilize a process where community pharmacy may provide copies of prescriptions along with additional documentation to satisfy the audit.

Documentation

When a relationship is established between a pharmacy and a MCO, there should be formal written documentation contractually defined either included in the body of the contract or in the provider manual that includes specific information on the process. It is strongly recommended that pharmacy staff responsible for approving contracts read the provider manual prior to signing any contracts. For desktop pharmacy audits the following information may be pertinent:

- Documentation of the audit process
- Documented list of items necessary to satisfy the audit which can include some or all of the following:
  - Prescription order copies — either original prescription orders or electronic scanned images
    Regardless of the copy type, it is important for the prescription copy to be legible and contain any pertinent documentation on the prescription. For the electronic copies, documentation for the prescription may be in electronic transaction notes with a date and time stamp. It is important that all necessary information related to the prescription order dispensing is provided.
  - Proof of pick up or delivery of the prescription. Pharmacy is most often allowed to provide one of the following:
    - Electronic date and time stamp in the pharmacy software system of the sold prescription
    - Electronic signature
    - Paper signature
  - Physician Notes
    - Notes should be on the written copy which is what will be reviewed in an audit.

Audit Process: Outline of Procedures

continued

- Additional Documentation
  - Electronic documentation on the dispensing of the prescription order with a date and time stamp of when the documentation occurred.
  - Written documentation on the dispensing of the prescription order that is dated as to when the documentation occurred.

- Timeframes should be outlined
  - Timeframe for a pharmacy to submit audit documentation for a desktop or mail audit. *Suggested timeframe:* At least 14 to 21 calendar days.
  - Timeframe of initial results to be sent to the pharmacy. *Suggested timeframe:* Within 30 to 45 calendar days of the audit.
  - Timeframe for additional supporting documentation to be submitted. *Suggested timeframe:* Within 14 to 21 calendar days after receipt of initial results.
  - Timeframe to send final results to the pharmacy. *Suggested timeframe:* Within 30 to 45 calendar days of receiving any follow up documentation.

- Types of discrepancies
  - Documentation on which discrepancies can be reviewed again if the pharmacy submits additional documentation
  - Each MCO may have different policies regarding documents that are acceptable for additional review

- Documented appeals process
- Process for chargebacks or recoupment of payment defined.

Procedures

1. The MCO identifies claims for audit.
   Guidance: The number of prescription orders audited typically ranges from 1 to 50 unique prescription claims and from 1 to 12 months old.
2. The MCO can deliver the audit notification to the pharmacy via mail or encrypted email.
   Guidance: The audit notification should include the following information:
   a. *Pharmacy response time*
   b. *Documentation needed to satisfy the audit request*
   c. *Contact within the auditing department at the MCO to answer any questions*
   d. *Expectation of when the pharmacy will receive initial results*
3. The pharmacy needs to compile all audit documentation for submission to the MCO. The documentation should include everything necessary to satisfy the audit.
   Guidance: All documentation should be faxed, emailed or mailed back to the MCO within the specified time which typically ranges from 14 to 21 calendar days.
4. The MCO will then review all audit documentation submitted by the pharmacy and create an initial findings report for the pharmacy.
   Guidance: This report is typically mailed or sent via secure email to the pharmacy within 30 to 45 calendar days after the receipt of the original documentation. The initial results typically include a listing of all claims reviewed followed by the audit discrepancy, or indicate if there is no discrepancy.

Audit Process: Outline of Procedures
continued

5. The pharmacy may receive the initial audit results via mail or secure email. At this time all claims should be reviewed to determine the following results:
   a. No discrepancies are found.
   b. Pharmacy agrees with the audit discrepancy.
   c. Pharmacy disagrees with the audit discrepancy and would like to submit additional documentation. The pharmacy will collect all additional documentation to be submitted to the MCO to support the original dispensing.
   Guidance: Supporting documentation is typically submitted 14 to 21 calendar days after reception of initial results.
6. The MCO will typically receive the additional documentation via fax, mail or email. At this time the MCO reviews the additional documentation to determine the final audit results.
   Guidance: The MCO will typically send final audit results to the pharmacy within 30 to 45 calendar days. With the final audit results, the MCO will typically give the pharmacy the choice to pay any chargeback amounts with a separate check or an automatic deduction from a future remittance to the pharmacy.
7. Once the pharmacy receives the final audit results, it can do the following:
   a. Appeal the audit results via the appeals process
   b. Agree with the results and select a payment method.
   Guidance: Alternatives include pharmacy submitting payment via check to the MCO within the period of time specified contractually, typically agreed to by the parties but generally within 30 calendar days of receipt of final audit results. The pharmacy may also opt to allow the MCO to complete an automatic deduction on a future remittance advice typically at least 30 calendar days from the date the pharmacy received the final audit results.

III. In-Pharmacy Audits

In-Pharmacy Audits (a retrospective audit) are used widely by MCOs because they provide the most comprehensive view of operational practices and procedures yet they are most intrusive to pharmacy practice as they can interrupt daily operations and patient care. MCOs should be sensitive to scheduling this type of audit to minimize disruption. It is also advisable for the pharmacy to provide dedicated pharmacy staff to the auditor to minimize exposure of health information and ascertain that the best effort is made to find all documentation. From a pharmacy perspective, Concurrent Daily Audits or Desktop Audits are typically preferred methods, but reality is that the In-Pharmacy Audit gives a MCO the opportunity to interact directly with members in the pharmacy network.

Documentation

When a relationship is established between a pharmacy and a MCO, there should be formal written documentation contractually defined either included in the body of the contract or in the provider manual that includes specific information on the process. It is strongly recommended that pharmacy staff responsible for approving contracts read the provider manual prior to signing any contracts.

For In-pharmacy audits the following information is pertinent:

- Documentation of the audit process
- Documented list of items and documentation necessary to satisfy the audit which can include some or all of the following:

Audit Process: Outline of Procedures

continued

- Prescription order copies — either original prescription orders or electronic scanned images

  Regardless of the copy type, it is important for the prescription copy to be legible and contain any pertinent documentation on the prescription. For the electronic copies, documentation for the prescription may be in electronic transaction notes with a date and time stamp. It is important that all necessary information related to the prescription order dispensing is provided.

- Proof of pick up or delivery of the prescription. Pharmacy may be allowed to provide as documentation, as defined in the pharmacy contract, one of the following:
  - Electronic date and time stamp in the pharmacy software system documenting the delivery of the sold prescription
  - Electronic signature
  - Paper signature
- Prescriber Notes
- Additional Documentation
  - Electronic documentation on the dispensing of the prescription order with a date and time stamp of when the documentation occurred.
  - Written documentation concerning the dispensing of the prescription order that is dated as to when the documentation occurred.

- Timeframes should be outlined
  - Timeframe of initial results to be sent to the pharmacy. *Suggested timeframe:* Within 30 to 45 calendar days of the audit.
  - Timeframe for additional supporting documentation to be submitted. *Suggested timeframe:* Within 14 to 21 calendar days after receipt of initial results.
  - Timeframe to send final results to the pharmacy. *Suggested timeframe:* Within 30 to 45 calendar days of receiving any follow up documentation.
- Types of discrepancies
  - Documentation on which discrepancies can be reviewed again if the pharmacy submits additional documentation
  - Each MCO may have different policies regarding documents that are acceptable for additional review
- Documented appeals process
- Process for chargebacks or recoupment of payment defined.

Procedures

1. The MCO identifies claims for audit.
   Guidance: The number of prescription orders audited typically ranges from 25 to 125 unique prescription claims and from 1 to 12 months old, however, Medicare Part D audits by the MCO or CMS (or its OIG) may require the review of claims substantially older than this general timeframe.
2. The MCO can deliver the audit notification to the pharmacy via mail or encrypted email.
   Guidance: The audit notification should include the following information:
   a. *Date and time of the In-Pharmacy audit. Guidance: The MCO would typically notify the pharmacy at least 14 to 21 calendar days prior to the audit date. In the event*

Audit Process: Outline of Procedures

continued

the pharmacy is not available for an In-Pharmacy audit on the date the MCO selected, there should be flexibility to reschedule the audit at a time when both parties are available. Effort should be made by the MCO to avoid the holiday timeframes, weekends, Mondays, or the first week of the month when pharmacies are experiencing high prescription volumes.

   b. *Documentation needed to satisfy the audit request along with the timeframe of the records to be audited. Guidance: All documentation should be within the rules and regulations of the State Board of Pharmacy, DEA, state regulatory/enforcement agencies, and HIPAA/HITECH.*
   c. *Contact within the auditing department at the MCO to answer any questions.*
   d. *Expectation of when the pharmacy will receive initial results after the In-Pharmacy audit is completed.*

3. The pharmacy must prepare for the In-Pharmacy audit. Preparation would include obtaining the appropriate records for review. Note: The MCO will typically provide a date range or masked prescription number for the community pharmacy to begin pulling appropriate records if they are in storage. Community pharmacy should also prepare from a staffing standpoint so that their day-to-day workflow is not impacted by the In-Pharmacy audit.

4. The MCO will then review all audit documentation submitted by the pharmacy and create an initial findings report for the pharmacy.
   Guidance: This report is typically mailed or emailed to the pharmacy within 30 to 45 calendar days after the receipt of the original documentation. The initial results typically include a listing of all claims reviewed followed by the audit discrepancy, or indicate if there is no discrepancy.

5. The pharmacy will receive the initial audit results via mail or email depending on agreement between MCO and pharmacy. At this time all audit reports detailed by claim should be reviewed to determine the following:
   a. No discrepancies were found
   b. Pharmacy agrees with the audit discrepancy
   c. Pharmacy disagrees with the audit discrepancy and would like to submit additional documentation. The pharmacy will collect all additional documentation to be submitted to the MCO to support the original dispensing.
      Guidance: The MCO may accept supporting documentation that is submitted by the pharmacy up to 21 calendar days after reception of initial results.

6. The MCO will typically accept the additional documentation via fax, mail, or email. At this time the MCO reviews the additional documentation to determine the final audit results.
   Guidance: The MCO will typically send final audit results to the pharmacy within 30 to 45 calendar days. With the final audit results, MCO will typically give the pharmacy the choice to pay any chargeback amounts with a separate check or an automatic deduction on a future remittance advice.

7. Once the pharmacy receives the final audit results, it can do the following:
   a. Appeal the audit results via the appeals process.
   b. Agree with the results and select a payment method.
      Guidance: The pharmacy typically would then send a check to the MCO within 30 calendar days of receipt of final audit results. The pharmacy may also opt to allow the MCO to complete an automatic deduction on a future remittance advice typically at least 30 calendar days from the date the pharmacy received the final audit results.

THE APPEAL PROCESS

Once the pharmacy receives the audit results, it is recommended that the pharmacy be given the opportunity to submit a formal appeal to the MCO. This is typically completed and received by the MCO no later than 30 calendar days from the date that the final audit report is communicated to the pharmacy.

If the pharmacy files an appeal, it should be filed according to the procedures and timeline as detailed in the contract between the parties. Many MCOs require the pharmacy to complete a formal appeal form and send it with the required documentation.

The pharmacy should provide appropriate additional documentation to substantiate the appeal of the final audit results. The MCO should provide a written determination of the appeal within 30 calendar days of the expiration of its specified review period.

Guidance:

1. *Reasonable documentation from a prescriber or a patient to substantiate the dispensing of a prescription should be accepted by the MCO.*
2. *The type of acceptable documentation should be outlined in the contract between the pharmacy and the MCO.*
3. *Regardless of what is required in the contract, the pharmacy should always submit the appeal by a secure mail service.*

COMPOUNDED MEDICATION: GENERAL DISCUSSION AND GUIDANCE

A compounded prescription order is a unique, nonstandard order for the preparation of a medication or medications in a form that is not commercially available; therefore, not standardized with a single specific NDC number describing the product dispensed. For this reason, billing for compounded medications is often confusing and inconsistent for MCOs and pharmacies. Most MCOs have their own specific process for pharmacies to submit a compounded prescription order claim. Pharmacies may be in many different MCO networks and not familiar with all the different processes. The pharmacy will choose one process and use it to bill all MCOs for compounded prescription orders resulting in an inappropriately billed claim because it is not the proper process.

There are pharmacies that prepare compounded prescription orders as a small percentage of the practice, and because they are members of MCO networks, they will direct bill to the MCO. However, there are others that specialize in compounding prescription orders. These pharmacies are commonly referred to as compounding pharmacies. Many of these compounding pharmacies do not participate in MCO networks, which will require patients to seek reimbursement by submitting a claim directly to the MCO.

It is important for pharmacy and MCOs to come together to develop model guidelines that specifically address billing for compounded prescription medications. Due to the lack of model guidelines addressing compounded prescription orders, there are inconsistencies in the way compounded prescription orders are submitted. The number that are inaccurately billed may result in auditors targeting compounded prescription claims disproportionately and more frequently than other types of claims. To a pharmacy submitting a high percentage of compounded prescription claims, this targeting appears unfair.

NCPDP recognized this and developed a new telecommunication standard (v D.0) that was adopted and its use will be required on January 1, 2012. Once MCOs and pharmacies adopt and implement the new standard, there will be a more accurate means of billing c ompounded prescription claims.

Guidance: Pharmacy and MCOs should develop model audit guidelines based on the implementation of the new vD.0 telecommunication standard for compounded prescription billing.

LONG TERM CARE: GENERAL DISCUSSION AND GUIDANCE

Auditing of Long Term Care (LTC) pharmacies is one of the more challenging areas of pharmacy practice for auditing. The volume of claims by the LTC pharmacy, the issue of medical orders versus prescription orders, state-by-state regulatory differences in the storage of prescription order documentation and physical accessibility of stored documents are just some of the underlying factors that make it so challenging. These Model Guidelines can provide only limited help in resolving the existing problems for LTC pharmacy audit processes. It is recommended that pharmacy and MCOs seek to develop a model audit process specific to LTC pharmacy. Further, it is recommended that the National Association of State Boards of Pharmacy (NABP) and state boards of pharmacy develop a national standard for the retention and storage requirements for LTC prescription orders.

The demographics of patients, the prescribers and the LTC facility make it difficult for pharmacies to get, verify and store what MCOs view as the appropriate documentation to validate appropriate filling and billing of a prescription order. It is recommended that the audit process should allow an extended period of time, perhaps 30 calendar days, for LTC pharmacies to locate and present the appropriate documentation; however, often the expected documents are simply not available. This is due primarily to physicians writing medication orders in a patient chart rather than writing prescription orders as is typical for ambulatory care patients. The lack of appropriate documentation onsite often leads to what auditors and MCOs today view as inappropriate documentation (such as a "bar code scan" for a reorder) as proof of a prescription order. The result is often a citation for recoupment of the claim payment which can frustrate the pharmacy. The LTC pharmacy may view this as a legitimately dispensed prescription order. The recoupment of the claim may result in the patient/beneficiary being denied the value of the benefit to which they are entitled. In turn, the MCO may then become frustrated by its inability to properly conduct its drug utilization review process and validation of a paid claim to meet the requirements of government and private payor programs. Each believes they are following best practices and regulations; however, the documentation requirements to fill a prescription order and to bill a prescription order are inconsistent. It is recommended that further discussion by the profession is needed to bridge this documentation gap.

Guidance: Pharmacies, MCOs and government regulatory entities should develop audit processes specific to LTC pharmacy practice. The processes should consider:

1. *The types of documentation that are legally accepted to support medication orders in the LTC pharmacy. Audit findings should be consistent with legal requirements under state laws, and until documentation requirements are standardized and clarified, pharmacies should ensure that documentation properly supports the dispensing and billing of prescription orders;*
2. *Proper execution of MCO DUR programs, which are an integral part of drug benefit management and utilization controls;*
3. *Government program documentation requirements that impose obligations on both MCOs and pharmacies; and,*
4. *Preservation of the drug benefit to which the patient/beneficiary is entitled.*

PRIVACY CONCERNS

Pharmacies are considered to be Covered Entities under the Federal HIPAA law as well as under state privacy laws. Amendments to HIPAA contained in the HITECH law passed in 2009 included expansion of several requirements to Business Associates, which include the MCO and audit contractors. In addition, there may be state privacy laws that place similar or separate privacy requirements on pharmacies, MCOs, and audit contractors. Audit procedures should incorporate any requirements contained in these laws to ensure that the audit does not place the MCO, audit contractor and pharmacy being audited in violation of these laws.

Guidance: Audit Procedures should include provisions to ensure that privacy protections required by federal and state law are met. Procedures should also include provisions to assist audited pharmacies in complying with their obligations under these laws.

In developing audit procedures, the MCO should analyze Federal and State laws to:

1. *Identify privacy issues and responsibilities of the MCO*
2. *Identify privacy issues and responsibilities of Pharmacy*
3. *Identify privacy issues and responsibilities of the Audit Contractor (if outside of the MCO)*
4. *Address compliance issues of all parties*
   a. *Patient Consent and Auditor authority regarding personal health information (PHI)*
   b. *Authorized disclosures*
   c. *Unauthorized disclosures*
   d. *Accounting of all disclosures*
   e. *Allowed exclusion of PHI*

STATE and FEDERAL OVERSIGHT

State and Federal Pharmacy Laws and Regulations

State and federal laws reflect a wide variety of requirements and regulatory oversight that apply to the practice of pharmacy, the distribution of federal legend drugs, the operation of pharmacies and the sale and administration of health benefit plans inclusive of prescription drug benefit coverage in each state and throughout the country. The pharmacy and pharmacist are required to comply with the law that applies to the location of the pharmacy, or, on occasion, the pharmacy law of the locale where the patient resides. In general, interpretation of, and compliance with, the applicable law is a matter that is left to a Board of Pharmacy, Department of Insurance, CMS or another regulatory agency with jurisdiction over the issue. Auditors are often asked to evaluate the legitimacy and legality of prescription drug orders as part of their auditing procedure. There have been wide complaints from audited pharmacies that auditors are not qualified to interpret the state laws, or that they make interpretations that are inconsistent with those of the state board of pharmacy.

Audit and appeal procedures should include provisions that prevent claim recoupment based on interpretations of law that are inconsistent with the law under which the pharmacy filled the prescription order.

In developing audit procedures and training for auditors, the MCO should outline the following federal and/or state laws and regulations:

- Related to Health Plans
  - General ERISA and non-ERISA
  - Medicare
  - Medicaid

State and Federal Pharmacy Laws and Regulations *continued*

- Related to Pharmacies
  - Dispensing
  - Controlled Substances
  - Compounding
  - Other Drug Laws
- Specific laws related to insurance other plans and/or audit standards
- Laws related to Pharmacy Practice
  - Board of Pharmacy
    - General Practice
    - Practice Site Specific (LTC, assisted living, home infusion, etc.)
    - Compounding
  - Other
- Laws related to Health Plans
- General laws related to contracts

Guidance

1. *Audit procedures should acknowledge that differences exist between:*
   a) *Contractual requirements of network participation in a variety of plans with defined benefits as one component of audit evaluation, and*
   b) *Various federal and state laws and regulations that govern the practice of pharmacy and the operation of pharmacies.*
2. *It is recommended that auditors be pharmacists or certified pharmacy technicians that have had experience in community pharmacy practice.*

PHARMACY AUDIT TRANSACTION STANDARDS

In 2009, NCPDP[3] sponsored audit focus groups including representatives from pharmacies, MCOs, and audit companies to develop the scope of a project on pharmacy audit transaction standards. With participants from all segments of the industry within and outside of the NCPDP membership, focus groups were conducted which resulted in the three goals of the project:

- Create an electronic audit transaction file with requests, responses, and final outcome transmissions for both Desk Top claim audits and for In-Pharmacy audit notices.
- Create a forum to discuss and resolve audit issues with government programs and state regulation
- Create a forum to discuss and resolve common prescription conflict/dispensing events that may be non-compliant with the plan coverage criteria.

An NCPDP Task Group within the Telecom Workgroup was assigned this project and the Implementation Guide was approved by NCPDP as a standard in May 2011.

The new NCPDP Pharmacy Audit Transaction Standard was developed to help guide those involved with the community pharmacy claims audit process and was intended to meet two needs:

- To provide practical guidelines for software developers throughout the industry as they implement the Audit Transaction Standard, and
- To ensure a consistent implementation of the Audit Transaction Standard.

[3] NCPDP (National Council of Prescription Drug Programs) is a not-for-profit ANSI-Accredited Standards Development Organization representing virtually every sector of the pharmacy services industry.

PHARMACY AUDIT TRANSACTION STANDARDS

continued

This Standard should facilitate a specific type of business communication among diverse parties within the audit process. However, the use of this standard may be too burdensome on both pharmacies and MCOs because a process to upload documentation that is so critical in the audit process has not been selected and HIPAA standards for this type of information exchange have not yet been released. These factors may slow its adoption.

Guidance

1. *The adoption of this new transaction standard should remain voluntary.*
2. *A mechanism to upload documentation needs to be determined to assist in the adoption of this new transaction standard.*

CONCLUSION

Pharmacy claims auditing has been a source of contention in pharmacy, and, to some degree, MCOs and pharmacies have been positioned as adversaries. It became necessary for the profession to develop a stakeholder-based process to address the pharmacy claims audit process.

The *AMCP Model Audit Guidelines for Pharmacy Claims* will assist stakeholders in taking the first steps in understanding the perspectives of the MCO and pharmacy to ensure the audit process policies and procedures are sensitive to all stakeholders.

It is encouraged that all stakeholders review the presented *Model Guidelines* and use them when developing or reviewing current audit processes to ensure that they are fair and balanced. If both MCOs and pharmacies objectively review and embrace these Model Guidelines, the result will be a transparent audit process, a better understanding of the audit process and a more cooperative relationship between the parties.

APPENDIX: GLOSSARY

Appeal: As it relates to pharmacy claims audits, a formal request by the pharmacy for reconsideration on the audit findings.

Audit Notification: A communication via US mail or electronic means that is sent by the MCO to notify the pharmacy of an audit.

Audit Process: A means of ensuring that pharmacy procedures and reimbursement mechanisms are consistent with regulatory and MCO contractual requirements.

Audit Types: There are different types of audits that apply to pharmacy claims or conducted by an MCO:

- **Concurrent Daily Review:** An audit that is conducted by telephone or email usually immediately (within the same day but no longer than 72 hours of claim submission). The claim concern is usually resolved at the time of notification by the pharmacy's electronic resubmission of the claim.
- **Retrospective Audit** is a retrospective detailed analysis of the total volume of claims submitted by a pharmacy. A retrospective audit can be conducted using one of three types of pharmacy claims auditing:
  - **Desk Top Audit** is conducted after notification by the MCO to the contracting pharmacy as defined in the contract between the parties. The audit is conducted electronically. See *Guidelines* for process.
  - **In Pharmacy Audit** is conducted after notification by the MCO to the contacting pharmacy via email, U.S. mail, or other channel as defined in the contract between the parties. This audit is conducted onsite in the pharmacy. See *Guidelines* for process.
  - **Investigational Audit** differs from MCO to MCO, but typically it is broader than a pharmacy claims audit and may be initiated from a medical, dental or another type of claim. An investigational audit is usually a more extensive audit and can involve regulatory and law enforcement. Typically this type of audit commences when there is clear evidence based upon preliminary reviews or audits that reveal fraud or abuse by patient or provider.

Adjudication: The process of completing all validity, process and file edits necessary to prepare a claim for final payment or denial.

Claim: A submission by the pharmacy to the MCO for payment of prescription dispensed to an MCO plan member.

Documentation: Items (i.e., prescription order, signature logs, purchasing invoices, etc) required to satisfy an audit and/or appeal process. These items should be listed in the provider manual under the audit process.

Employee Retirement Income Security Act of 1974 (ERISA): A federal law that regulates employer-sponsored benefit plans and restricts state government from regulating these plans. The law mandates reporting and disclosure requirements for group life and health plans with relevant guidance on the sponsorship, administration, minimum records retention period, servicing of plans, some claims processing, appeals regulations and minimum mandatory clinical benefits.

APPENDIX: GLOSSARY

continued

Fraud, Waste and Abuse (FWA)

- **Fraud:** It is the illegal acquisition of prescription drugs for personal use or profit. This definition excludes theft, burglary, backdoor pharmacies and illegal importation or distribution of prescription drugs (i.e., purposeful billing for non-existent prescriptions (phantom claims), billing for brand drugs when generics are dispensed)
- **Waste:** To consume, spend, or employ uselessly or without adequate return; use to no avail or profit (i.e., prescription medications ordered when not needed (auto fill or hoarding), filled after patient death or discontinuation of treatment, large day supplies filled when drug has not been shown effective for patient and medications automatically given because patient says they've been taken in the past yet there is no demonstrated need.
- **Abuse:** The use of a prescription medication in a way not intended by the prescriber.

HIPAA: The Health Insurance Portability and Accountability Act of 1996, a Federal law and subsequent regulations that include protection of personally identifiable health information and gives HHS the authority to mandate the use of electronic standards for the electronic exchange of health care data.

HITECH: The Health Information Technology for Economic and Clinical Health (HITECH) Act, was enacted as part of the American Recovery and Reinvestment Act of 2009 to promote the adoption and meaningful use of health information technology. It also addresses the privacy and security concerns associated with the electronic transmission of health information that strengthen the civil and criminal enforcement of the HIPAA regulations.

Incentive-based Auditing: Auditors are paid for their services based on a percentage of incorrectly or inappropriately submitted pharmacy claims.

Long Term Care (LTC) Pharmacy: Long term care typically refers to individuals who require health care either in an institutional facility on a long-term basis, but can also refer to those requiring services at home. Pharmacy services may be provided by the institutional facility or through an offsite pharmacy providing services to the facility.

Managed Care Organization (MCO): For the purposes of this document this term is used generically to include all types of MCOs including health plans, pharmacy benefit managers (PBM), health maintenance organizations (HMO), contracted agents, etc.

NDC Number (National Drug Code): A unique 11 digit code given to drugs that identifies the labeler, product and package size.

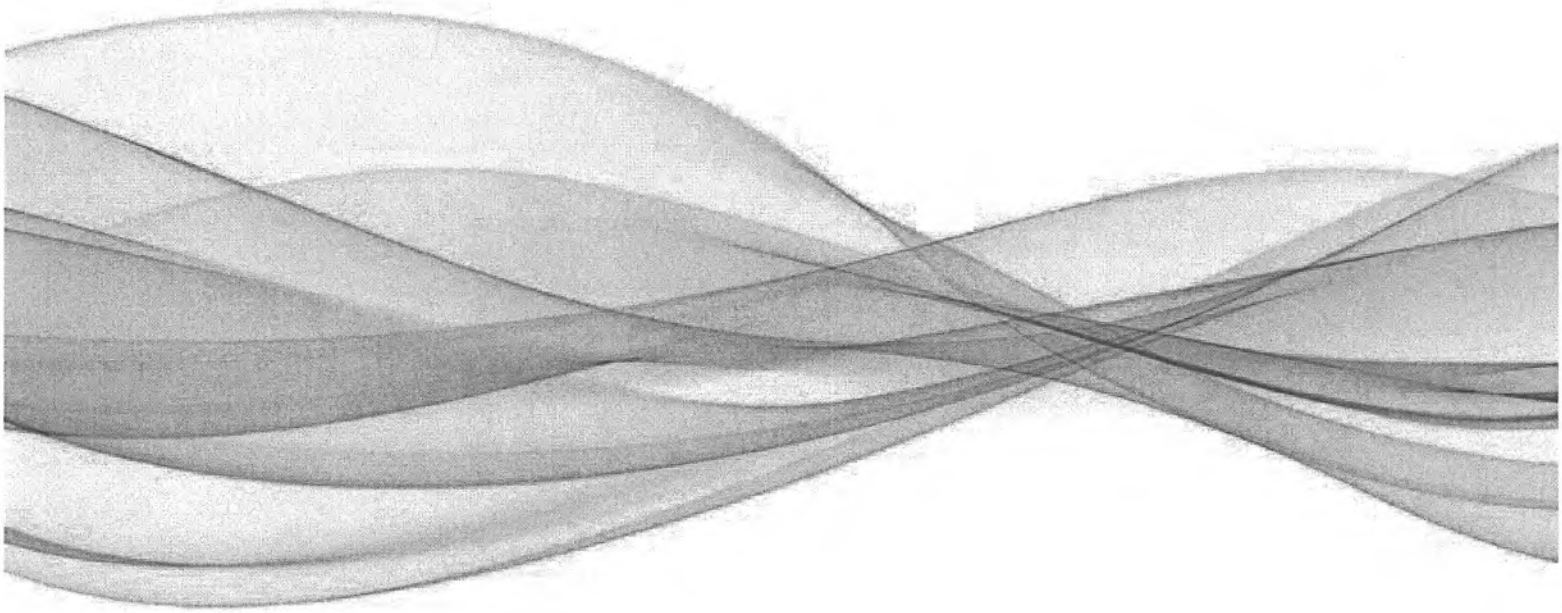
National Council of Prescription Drug Programs (NCPDP): National Council of Prescription Drug Programs is a not-for-profit ANSI-Accredited Standards Development Organization representing virtually every sector of the pharmacy services industry.

Pharmacy Benefits Manager (PBM): PBMs are hired by the health plan, employer, or PDP to orchestrate the development of the pharmacy network and adjudicate claims for the health plan.

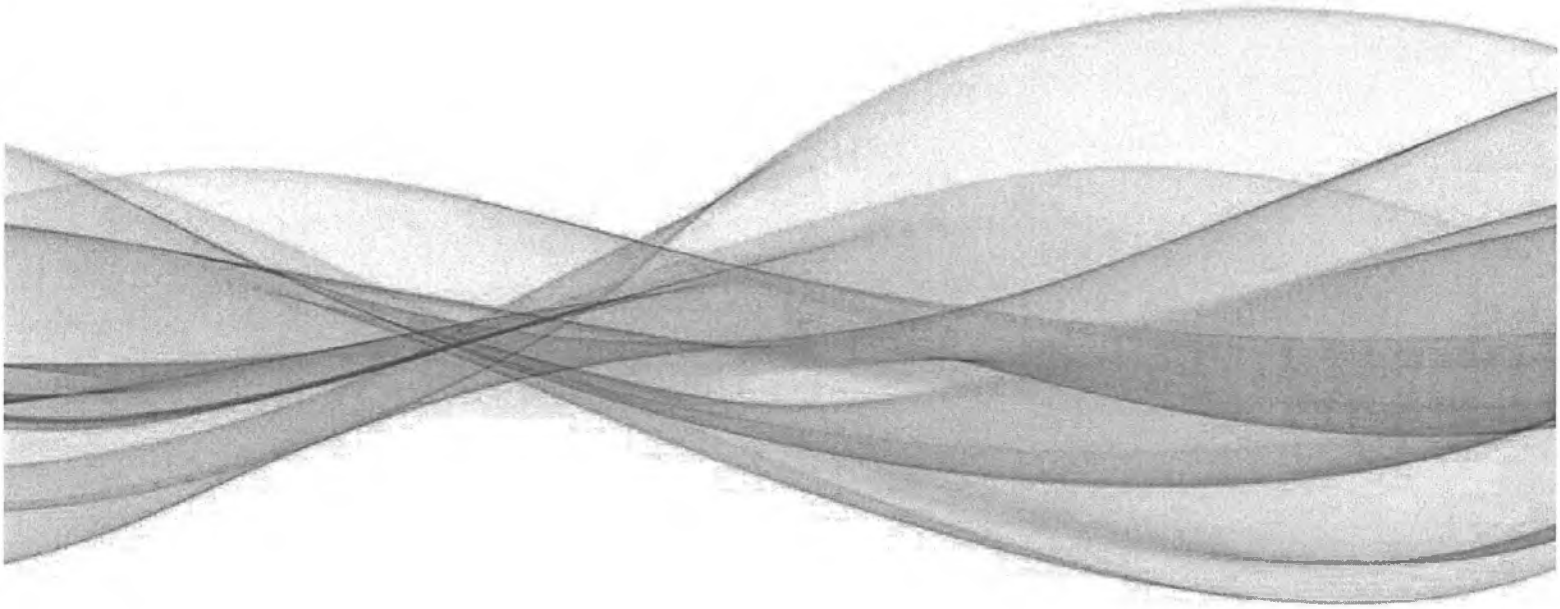
Pharmacy Network: Pharmacies that are contracted by a MCO in order to service the members of the health plan by providing convenient sites to fill their prescriptions.

Provider: An entity who has contracted with an MCO to deliver care to a covered person. In the case of pharmacy services, it is typically the pharmacy, rather than the pharmacist, that contracts with the MCO.

Provider Manual: A manual issued by the MCO and distributed to the pharmacy that outlines its processes, procedures, etc., as it relates to drug benefit and pharmacy claims.



This document is available electronically at
www.amcp.org/audit



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Survey of Community Pharmacies
Impact of Pharmacy Benefit Manager (PBM) Contracting and Auditing Practices on Patient Care

National

The Patient Choice and Pharmacy Competition Act of 2011 (H.R. 1971/S. 1058) would make several reforms to the unregulated Pharmacy Benefit Management (PBM) marketplace. These reforms would help community pharmacies serve patients and assure that there is a strong, accessible community pharmacy network.

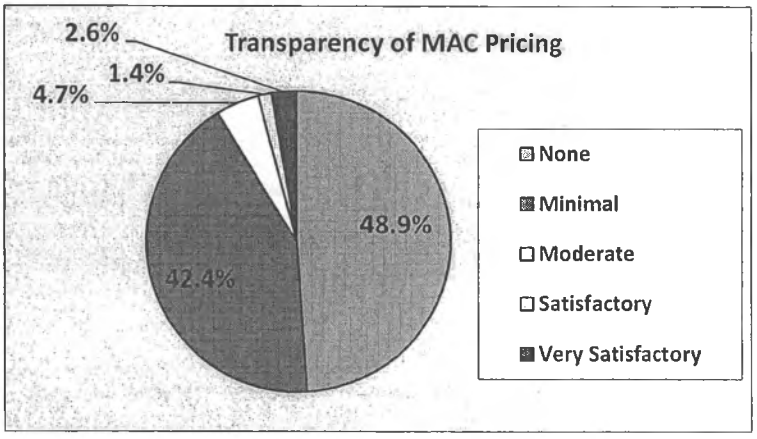
Among other provisions, the bill would require a minimum level of reimbursement transparency in the contracts that PBMs have with pharmacies for Part D and commercial insurance plans. For generic drugs, pharmacies generally don't know how much they will be reimbursed or when it will change. The bill would also make PBM auditing practices more focused on fraud rather than administrative and technical issues and make these audits more consistent among PBMs.

This survey provides important information to policymakers regarding the challenges that over 1,800 pharmacies report having with PBMs. This survey was conducted between June and July 2011.

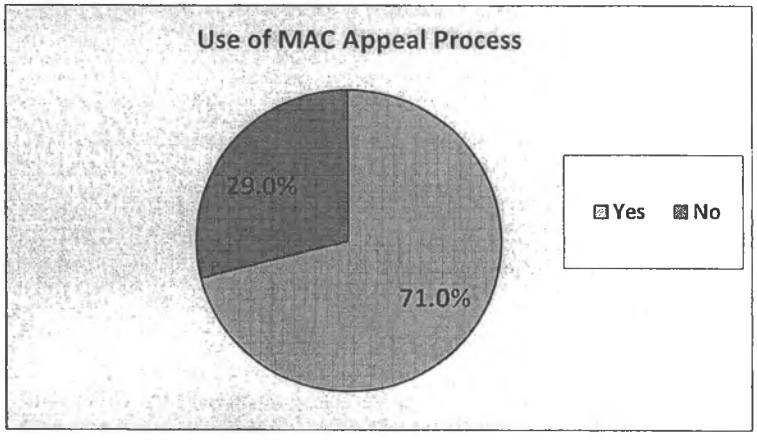
100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

Part I – Transparency of Generic Drug Reimbursement in PBM Contracts

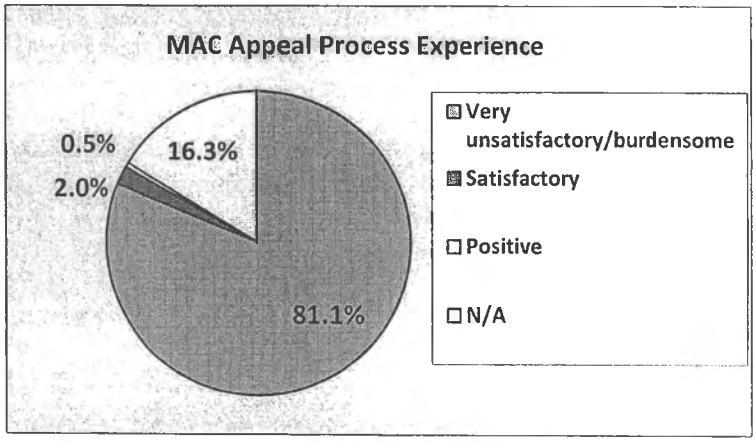
I - A provision of H.R. 1971 would require PBMs to disclose greater information to pharmacies in contracts regarding MAC reimbursement for generics. In a typical PBM/pharmacy contract, how much information or specificity is usually given regarding either how MAC pricing for generics is determined (methodology) or how often these prices will be updated?



II - Have you ever used or tried to use a PBM's MAC appeal process?

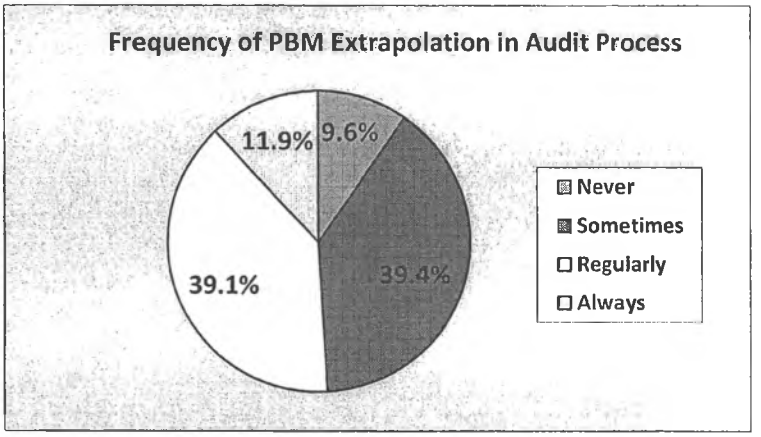


III - If you answered yes, did you find the process or overall experience to be:

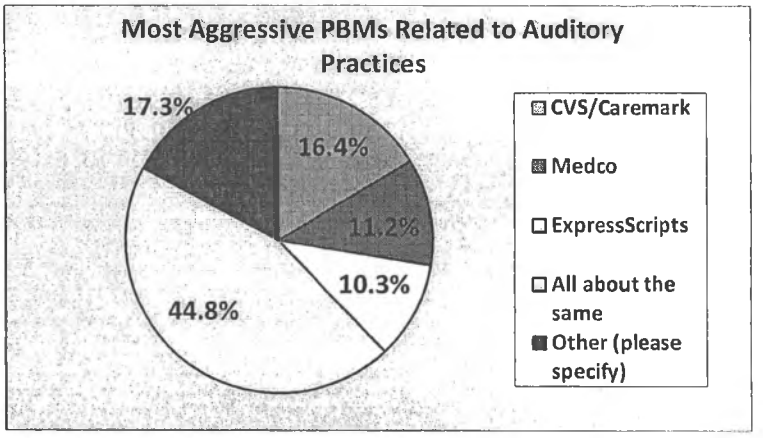


Part II – PBM Auditing Practices of Community Pharmacies

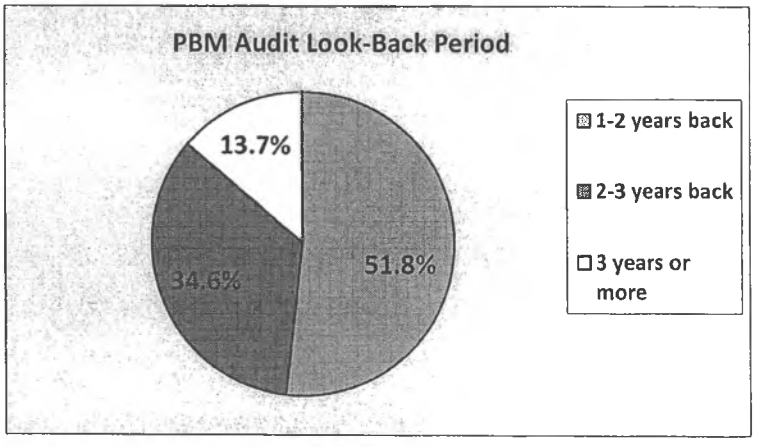
IV - Several provisions of H.R. 1971 would reform the manner in which PBMs could conduct audits. How often is extrapolation used in a PBM pharmacy audit?



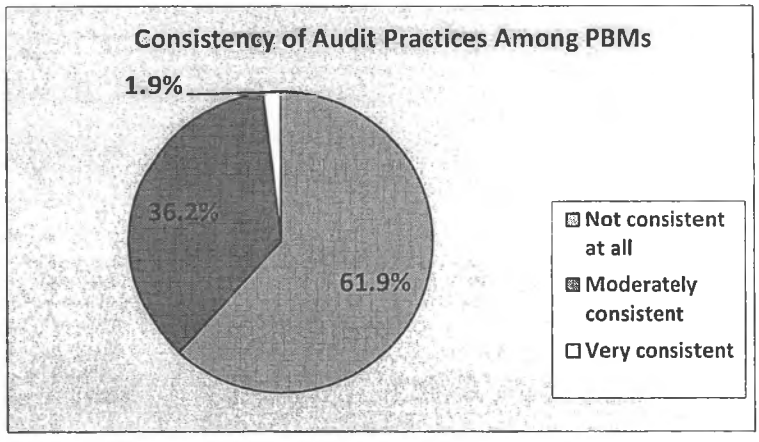
V - Which PBM typically conducts the most aggressive audits?



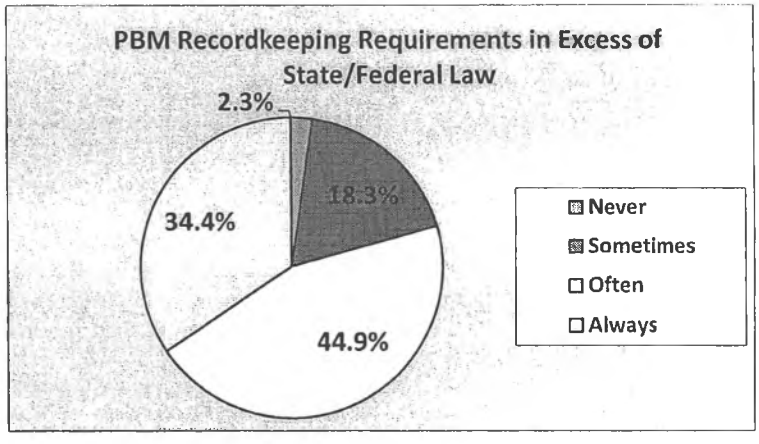
VI - In general, how many years back does a PBM go when auditing your pharmacy's claim data?



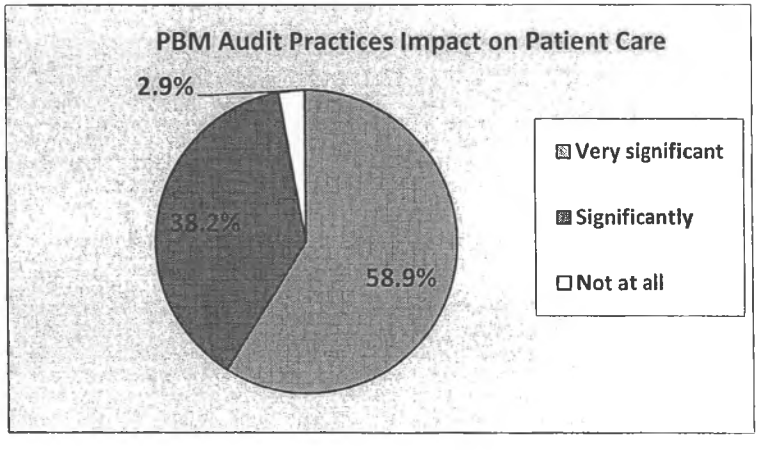
VII - How consistent are the auditing requirements across PBMs?



VIII - How often do PBM auditors require (and accordingly harshly penalize pharmacies for even minor noncompliance) recordkeeping requirements that go above and beyond what is required under state or federal law?



IX - How significantly are PBMs reimbursement and auditing practices affecting your ability to provide patient care and remain in business?



PBM Audits Steal Money From Pharmacies, Take Time Away from Patients

- The auditor disallowed a handwritten prescription for a high dollar medication and attempted to recoup the payments from every refill because "in his opinion, the prescription was written out by someone other than the practitioner who signed it." The script had been written (documented) by the physician's nurse due to his poor penmanship and signed by the physician. Despite thorough follow up documentation of the legitimacy and accuracy of the prescription, the payments were recouped in full.

- A physician once stamped his DEA number on a prescription for a $1000 med that the patient received. The PBM took the money back even though the patient got the meds, because they wanted the doctor to preprint the DEA# on the prescription pad. However, this was a new doctor at that group practice and the office manager did not have enough time to preprint thousands of pads at the print press.

- Doctor spelled the patient name incorrectly, and they refuse to pay the prescription and all refills

- Audited 4 months ago by ACS for Humana patients. They Found only one mistake and that was [that the] clinic NPI was used on physician name. Two years ago NPI was not available online, so we called the doctor's office to get his NPI. They gave us the clinic NPI. We do not have a way to find how many NPI's do not match with our physician profile. So we were using the same NPI for one doctor for [the] last 2 years. Humana or ACS never corrected us either. Unfortunately it was all AIDS medication (very expensive). Now they want $16,000 back for using wrong NPI. To appeal we went to [the] doctor's office and they filled out [a] form that [the] insurance required us to get from [the] doctor's office to make sure that they were legitimate prescriptions and sent it to ACS for further clarification. ACS denied our appeal twice and wants to recoup money now. I called Humana and left messages several times and never heard anything back. I can not go to court because it would cost me too much and I do not have this amount that I can pay them easily. Very discouraging.

- Doctor wrote prescription for 1 bottle of a liquid maintenance medication, we dispensed 1 month's supply. They claimed we should've only given 14 days worth and took all the money from the claim back, even though the patient received the whole prescription. They took all the money back for the life of the prescription (11 refills, or 12 months).

Alaska Pharmacists Association

Examples of Abusive Auditing Practices in Alaska

Audit Abuse Example:

1) Our pharmacy had filled a prescription for patient who had been having chronic hives (itching) from auto-immune type disease. The patient had seen a specialist who had prescribed a high dose antihistamine at a dose of two tablets three times per day to dispense a 3 month supply with refills. The patient refilled the prescription approximately 5 months after the first fill.

We received a desk audit from the Insurance Company (Aetna) about a year after that and sent them a copy of the prescription. We later received notice from Aetna that they would be recouping the total cost of the prescription (including the dispensing fee) since the patient didn't refill the prescription until 5 months after the first date of the fill (i.e. patient wasn't always using six tablets per day). We received no electronic notification of concern from Aetna at the time we dispensed the prescription (which is done in real time). We spent considerable time with the doctor's office getting a letter to document the patient's ongoing need for the medication in order to fight the recoupment.

We shouldn't have needed to do this since we filled the prescription as written and verified the need and dose at the original time of dispensing.

2) CareMart called our pharmacy and requested audit on 21 prescriptions; they would only give me the numbers over the phone and would not fax because they want deniability. It took a lot of time to comply with their audit.

3) One issue I remember was from a pharmacy in Alaska by Express Scripts. They were taking back our payment because of a transferred Rx. They were not accepting a prescription copy because at the time of transfer the prescription image was not sent correctly between the two Kroger Pharmacies. The pharmacist transcribed the information on an Rx blank with all the information. They were not accepting this, even though state law says this is good enough. I did appeal and win this.

4) In February, 2011 our pharmacy received notice of a large desk audit to be performed. The audit was for prescriptions from 2008 and over 100 prescriptions were involved. All of these prescriptions had to be copied, printed, signature logs, etc. - so it was very time consuming, especially since all of the records were from over 3 years ago. This was completed and sent to the auditors. Then we were notified that they were going to also do an on-site audit of these and other prescriptions.

In August of this year - 2 auditors arrived at our store and I spent the entire day answering their questions, pulling files, and finding documentation. They were not very well knowledgeable in pharmacy as many of their questions were not good questions. So, we made it through that and I was told we would be receiving a final report in a few weeks.

That report arrived and I was very pleased when I read the first few pages. Out of over $103,000 in claims reviewed - we had $89 in errors according to the auditors. However, when I got to the last page - through their "one-sided confidence extrapolation method" (their name for this) - they said I owed over $7,300! I called the auditors to no avail.

Since this - I have just hired a lawyer to help in disputing this claim. Most companies only use extrapolation when the error rate is over 5%. Ours was less than 0.1%! The last audit we had a few years ago - we had a zero repay. Being told to repay over $7000 is just not right!

5) Our pharmacy received a desk audit from ACS Audit and Compliance Solutions who was contracted by the Pharmacy Benefit Manager Healthspring. The letter was dated November 9, 2011 and we received the letter on November 14, 2011. All requested documentation had to be postmarked by 12/9/2011. On the 12/9/11 we mailed all documentation to ACS. On January 24, 2012 we received the results of the audit via UPS in a letter dated 1/17/12. The report indicated that "the signature documenting receipt of pharmacy services cannot be found in the signature logs" for one prescription. Because of this missing signature, the plan was going to deduct the entire amount of that prescription from a future remittance. This prescription was correctly filled for a legitimate purpose and mailed to the patient in Haines Alaska. To prevent this recoupment by the audit company, our pharmacy has had to send an affidavit to the patients daughter (the patient has since passed away from cancer) so she can sign to verify that they did indeed receive the medication. All supporting documentation was due back to ACS by 2/6/12. This pharmacy had to request and was granted a one week extension to this deadline. As of today, 2/9/12 the pharmacy has not received the affidavit, and has called for another extension but has not heard back from ACS. This pharmacy has already dispensed the medication correctly, the patient has taken the medication as prescribed, but because of a procedural error, the plan is attempting to recoup the entire amount of the prescription from the pharmacy.

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

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

- Pharmacy Audit Bill of Rights 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

Arkansas
Arkansas Code Title 9 Chapter 88 Sec. 801-804
Fair Disclosure of State Funded Payments for Pharmacists' Services Act

- Requires PBMs to itemize by individual claim the amount actually paid to the pharmacy or pharmacist, the identity of the pharmacy, and an identifier of the pharmacist services

Signed into law: 4/2/2009

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

- PBM must obtain a certificate of registration from the Insurance Department.
- PBM must complete an application form which must 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

FLORIDA
Florida Statutes Chapter 465
465.188dicaid audits of pharmacies

• Agency conducting the audit must give 1 week prior notice
• Audit must be conducted by a pharmacist licensed in this state
• Any clerical error, typographical error, scrivener's error or computer error regarding a document or record required under Medicaid program does not constitute a willful violation and is not subject to criminal penalties without proof of intent to commit fraud
• A pharmacist may use the physicians record or other order for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug
• Each pharmacy must be audited under same standards, parameters
• Pharmacist must be allowed at least 10 days to produce documentation to address any discrepancies
• Period covered by an audit may not exceed 1 calendar year
• Audit may not be scheduled during the first 5 days of any month due to high volume of prescriptions filled during that time
• Audit report must be delivered to pharmacist within 90 days after conclusion of audit.
• Entity conducting the audit may not use the accounting practice of extrapolation in calculating penalties for Medicaid audits
• Provisions do not apply to investigative audits conducted by Medicaid Fraud Control Unit of the Department of Legal Affairs

• Provisions do not apply when Florida Agency for Health Care Administration has reliable evidence that claim that is the subject of the audit involved fraud under the Medicaid program.

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 of 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).
• Pharmacy must be given notice at least one week prior to the conducting of 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 in which 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 seven calendar days of any month without the consent of the pharmacy.
• The preliminary report must be delivered to the pharmacy within120 days after the 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)

Official Code of GA Ann. Title 33 Chapter 64

- Provides for license requirements and filing fees for PBMs

- Requires a surety bond
- Provides that a pharmacy benefit manager shall not engage in the practice of medicine
- Makes certain audit requirements applicable to pharmacy benefit managers
- To provide that a pharmacy benefits managers shall not have no be licensed as an administrator

Effective: 06/02/10 (Senate Date Signed by Governor)

Indiana
Indiana Code 25-26-22

- Provides pharmacists procedural protections against audits initiated by PBMs
- PBM must provide description of audit procedures in audit contract
- Pharmacy must be given at least two weeks written notice in advance of an onsite audit
- Auditor may not interfere with pharmacist-delivered services to patients and must minimize disruption of pharmacy operations
- 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 health practitioners to validate a prescription for a legend drug
- Period covered by audit cannot exceed 24 months from the date the claim was submitted to or adjudicated by PBM
- PBM must permit pharmacy to electronically resubmit claims disputed by the audit
- Unless consented to by the pharmacy, the audit cannot take place during the first 5 days of the month
- On-site auditor may not be paid based on percentage of amount recovered, resulting from the audit
- Preliminary audit report must be delivered within 90 days after the conclusion of the audit
- Final report must be delivered within120 days after the preliminary audit is received by the pharmacy or if a final appeal is filed, after a determination is made
- Recoupment of claims must be based on actual overpayment or underpayment, not extrapolation –final audit report must be distributed prior to recoupment

Effective: 7/1/2009

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 three 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 pharmacy benefit managers 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 case of 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
(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

Kentucky
KRS Chapter 304, Subtitle 17A, Sections 1-5
An Act Relating to Pharmacy Audits

- Creates pharmacy audit protections
- Pharmacy must be given at least thirty days written 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 must be based on actual overpayment unless it is part of a settlement with the pharmacy
- Period covered by audit cannot exceed two years from the date the claim was submitted unless federal law allows a longer period or there is evidence of fraud
- Unless consented to by the pharmacy, the audit cannot take place during the first 7 days of the month
- Preliminary audit report must be delivered within 120 days after the conclusion of the audit – final report must be delivered in 6 months
- Following receipt of preliminary audit report, the pharmacy may take 30 days to produce documentation in response to discrepancies
- Final audit report must provide claim-level detail of amounts and reasons for each claim recovery
- Auditor may not be paid based on percentage of amount recovered, resulting from the audit
- Exit interview to provide pharmacy an opportunity to respond to questions, comment and clarify findings must be done at end of audit – time of interview must be agreed to by pharmacy
- Pharmacy must be provided written instruction of appeals process for final audit report
- If unsubstantiated audits discovered following appeal, they are dismissed without further proceeding.
- Auditor may not collect disputed funds until audit process, including appeals, is completed

Signed into Law: 3/24/2009

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 the 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 the PBM to transfer in full to the covered entity any benefit or payment received as a result of a substitution.
• Requires the 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 United States 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 that state law. This ruling ended any further legal challenges by PCMA to the law.)

MARYLAND
Subtitle 16, Sections 15-1601 et seq
Pharmacy Benefits Managers

• Prior to entering into a contract, the PBM must inform the purchaser that the PBM may solicit and received manufacturer payments, pas 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 a pharmacy and therapeutics (P&T) committee established by a PBM.
• 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 state 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 or noncompliance.
Effective: 06/30/06

MISSOURI
Revised Statutes
Chapter 338 Pharmacists and Pharmacies
Section 338.600

• Sets forth standards for pharmacy audits by a managed care company, insurance company, third party payor or any entity that represents such groups
• The entity conducting the audit must provide pharmacy with one-week notice prior to audit
• If clinical or professional judgment is required, must by conducted by or in consultation with licensed pharmacist
• Any clerical error, record-keeping error, typographical error, or scrivener's error shall not constitute fraud or grounds for recoupment, so long as the prescription was legally dispensed. No claim arising under this provision shall be subject to criminal penalties without proof of intent to commit fraud
• A pharmacy may use the records of a hospital, physician or other authorized practitioner of the healing arts for purposes of validating the pharmacy record. Electronically stored images of prescriptions, electronically created annotations shall be considered valid prescription records.
• Each pharmacy shall be audited under same standards/parameters
• Period covered by audit shall not exceed two-year period unless previous finding of fraud
• Audit shall not be conducted during first three business days of any month due to high volume of prescriptions filled during such time
• Entity conducting the audit shall not use extrapolation

• Recoupment shall only occur after final internal disposition of audit, including appeals process
• Each entity conducting audit shall establish an appeals process, lasting no longer than six months
• Entity conducting audit shall provide copy of final audit report (after appeals) to plan sponsor
• Section does not apply to investigative audit that involved probably fraud or willful misrepresentation or conducted by law enforcement agency
EFFECTIVE August 2009

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 two 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 five 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 five 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.
• Legislative Council was directed to study the PBM industry and make a report and recommendations, together with legislation required to implement the recommendations to the next assembly.
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.
- Not consider as fraud any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record; however, such claims may be subject to recoupment. No such claim shall be subject to criminal penalties without proof of intent to commit fraud;

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 and thus requires filing of an annual report
• Annual report filed by third-party administrators with the department of business regulation shall 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 a 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 this Chapter.
• 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 certain standards for audits of pharmacies conducted by PBMs
• At least two 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 with 6 months after receipt of the preliminary audit report or final appeal, whichever is later.
• Period covered by an audit cannot exceed two 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.
• Any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record may not, in and of itself, constitute fraud; however, such claims may be subject to recoupment. Notwithstanding any other provision of law to the contrary, no such claim shall be subject to criminal penalties without proof of intent to commit fraud;

Effective: 07/01/07

Tenn. Code Ann. Title 56, Chap. 7 Sec. 3201-3205

- Specifies that when PBMs provide patients information regarding out-of-pocket costs, such as co-pay, for a prescription or service, they must provide the patient the actual reimbursement
- Prohibits PBMs from restricting pharmacies from disclosing to patients the actual reimbursement for a particular prescription or covered service

Effective: 1/1/2010

TEXAS
Texas Insurance Code Chapter 1369, Subchapter B Sect. 1369

- Provides for a study to evaluate how PBMs use prescription drug information to manage therapeutic drug interchange programs and other drug substitution recommendations

Effective: 9/1/2009

Texas Gov. Code Chap. 2158, Subchapter H
An Act Relating to the Regulation of PBMs and Mail Order Pharmacies

- Requires state agencies to disclose information relating to amounts charged by PBMs for PBM services provided under prescription drug programs –information must be provided within 30 days of request
- Provides for a study to evaluate how PBMs use prescription drug information to manage therapeutic drug interchange programs and other drug substitution recommendations
- Provides that in awarding contracts to provide PBM services the board of trustees of the Employee Retirement System of Texas is not required to select the lowest bid but must meet certain criteria – includes, contract that must state board of trustees ability to audit PBM, entitlement to access PBM cost and service information during audit, define information PBM must provide related to pharmacy audits, and required independent auditing of mail order pharmacies owned by the PBM
- Prohibits mail order requirement for prescription drug coverage
- Requires PBMs to allow enrollees to obtain a multiple-month supply of any prescription drug from a community pharmacy under same terms and conditions as when purchased through a mail-order pharmacy – community pharmacy must accept same reimbursement that applies to a mail-order pharmacy
- PBMs must reimburse pharmacies for both brand and generic drugs using reimbursement rates based on current and nationally recognized benchmark indices that include AWP and MAC.

Effective: 9/1/2009

VERMONT
18 V.S.A. Chapter 221, Sections 9421, 9471 – 9473
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 contract with the PBM:

(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) notify the insurer 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) disclose 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 executive 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 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 remains the subject of litigation by PCMA.)

State of Alaska
Senate Labor and Commerce Committee
Hearing on Pharmacy Audits
Testimony of the National Community Pharmacists Association
March 1, 2012

Chairman Egan and honorable members of the committee:

On behalf of the National Community Pharmacists Association (NCPA) I wish to thank you for conducting this hearing. NCPA testifies today in strong support of S.B.217 as legislation that provides fair and common sense protections for pharmacies against what are currently abusive audit practices by PBMs. Let me first be clear, this legislation does not prevent audits from occurring for their intended purpose of preventing fraud, waste and abuse. In fact, this legislation specifically states that the standards within S.B.217 do not apply when pertaining to criminal investigation or an investigation by a government agency. NCPA members understand that audits must occur to catch fraud and abuse within the system. However, current PBM audits of pharmacy are in many cases simply being used as a lucrative revenue source

NCPA represents America's independent community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains. Together, they employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescription medicines. In Alaska alone there are over 39 community pharmacies, which employee a projected 413 residents. The average independent community pharmacy generates $4 million in annual revenue and employs 10.6 full-time individuals. Alaska's independent community pharmacies generate $157 million in annual revenue. Also, those community pharmacies support additional revenues to other state businesses in the amount of $141.2 million annually and support additional full-time employment to other businesses equal to 165 employees.

NCPA has long championed the need for greater oversight of pharmacy benefit managers (PBMs) and many of their questionable business practices due to the problems our members and their patients continue to face. One of the largest problems that NCPA pharmacist members face in today's pharmacy marketplace, is the issue of abusive audit practices. This issue occurs nationwide and many states are taking steps to protect their pharmacists and small business owners. Today about 15 states have implemented some level of fair audit protections. It is not uncommon for these audits to penalize an independent pharmacy tens of thousands or even hundreds of thousands of dollars for nothing more than a clerical or administrative mishap, many of which are not the fault of the pharmacy. Let me be clear, the so called errors I am referring to are instances in which the correct medication was dispensed to the correct person and the correct fee was charged to the patient and plan.

Let me provide you with a recent example of a "minor" audit that an NCPA member went through. This member was penalized $14,000 for not using a physician's number in their computer system. The catch was that in this case, it was a Certified Nurse Practitioner (CRNP) that wrote the order so there was no physician's number to log in. The prescriber was not a physician! The pharmacist took measures to ensure he was properly compliant and contacted the insurance company who indicated this was not a problem and he should use the CRNP License number. He did this. In addition, he also attached a copy of the CRNP's actual license just so it was clear what he was doing. He then logged the phone call to further protect himself. Even so, when he was audited, the PBM demanded $14,000 back. After all the steps this pharmacist took to ensure he was acting

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properly, he ultimately settled this issue for $12,000. The pharmacist was doing exactly what he was told to do by the insurance company and even took additional steps to make sure everything was properly documented. Even so, this pharmacist small business owner took a loss of $12,000. These stories occur on a regular basis. Similar stories have resulted in pharmacists being fined $250,000 or even more.

Rather than legitimately using the audit process to guard and protect against fraud, many PBMs now view the process as a profitable revenue stream for the company. In fact, many auditors are incentivized by receiving payment based on a percentage of the money reclaimed. PBMs now go well beyond the basic intent of an audit, to catch fraud and abuse, and instead focus on typographical or administrative errors, or loopholes in the rules and regulations such as the above story as a basis to recoup money from the pharmacy. In many cases, if a PBM auditor identifies an administrative error, he or she will "take back" 100% of the value of that prescription and even all its refills—a severe financial penalty that is out of proportion to the gravity of the offense.

Another egregious practice many PBMs employ in order to "ensure" that discrepancies will be found is to establish elaborate record keeping requirements well in excess of what is required under state or federal law or other PBMs. Pharmacies typically maintain contracts with multiple PBMs. The result is a myriad of conflicting documentation requirements that can make operating a busy pharmacy and providing patient care an even greater challenge.

NCPA is confident that once members review S.B.217 they will see the measures spelled out are reasonable standards to ensure that abuses do not occur. In circumstances where fraud or legitimate errors occur, independent pharmacists understand that steps must be taken to correct these errors and recoup a reasonable sum of money. As business owners, independent pharmacists realize that there are individuals in every profession that may try to work the system. In those cases, we fully support the recoupment of money. These instances are not what is being referred to today.

In conclusion, NCPA urges your support of S.B.217—legislation that will provide pharmacies an understandably needed degree of protection against the overaggressive and far reaching PBM audit practices. Community pharmacists understand that in business there must be audits to identify those instances where true fraud occurs. However, these audits should not be utilized to only increase PBMs profit margins. I thank you for taking NCPA's concerns into consideration.

I welcome your questions at this time.

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

February 29, 2012

The Honorable Dennis Egan
State Capitol Room 510
Juneau AK, 99801

Dear Senator Egan:

I am writing today on behalf of the National Community Pharmacists Association (NCPA) in strong support of S.B.217. This legislation would provide some fair and common sense protections for pharmacies against abusive pharmacy audit practices. NCPA represents America's independent community pharmacists, including the owners of more than 23,000 community pharmacies, pharmacy franchises and chains. Together, they employ over 300,000 full-time employees and dispense nearly half of the nation's retail prescription medicines. In Alaska alone there are over 39 community pharmacies which employee a projected 413 residents.

NCPA has long championed the need for greater oversight of pharmacy benefit managers (PBMs) and many of their questionable business practices due to the problems our members and their patients continue to face. PBMs have been allowed to operate virtually unchecked since their inception—slowed only by the increasing amount of litigation alleging fraudulent and deceptive business practices filed against the PBMs each year and some extremely limited regulation. One of the largest problems that NCPA pharmacist members face in today's pharmacy marketplace, is the issue of abusive audit practices.

Rather than legitimately using the audit process to guard and protect against fraud, many PBMs now view the pharmacy audit process as a profitable revenue stream for the company. These audits can claim hundreds of thousands of dollars for nothing more than basic administrative or typographical mistakes, many not even occurring at the fault of the pharmacist or pharmacy staff. Many PBMs now go well beyond the basic intent of an audit, to catch fraud and abuse, and instead focus on these typographical or administrative errors as a basis to recoup money from the pharmacy. In many cases, if a PBM auditor identifies an administrative error, he or she will "take back" 100% of the value of the prescription and all refills—a severe financial penalty that is out of proportion to the gravity of the offense.

Another egregious practice many PBMs employ in order to "ensure" that discrepancies will be found is to establish elaborate record keeping requirements well in excess of what is required under state or federal law or other PBMs. Pharmacies typically maintain contracts with multiple PBMs. The result is a myriad of conflicting documentation requirements that can make operating a busy pharmacy and providing patient care an even greater challenge.

In conclusion, NCPA urges the support of S.B.217—legislation that will provide pharmacies an understandably needed degree of protection against the overaggressive and far reaching PBM audit practices. Community pharmacists understand that in business there must be audits to identify those instances where true fraud occurs. NCPA is confident that once you review S.B.217 you will find it simply sets reasonable standards to insure that audits continue to be useful for their true intent yet cannot be utilized to only increase PBMs profit margins. If you have any questions about the information contained in this letter or wish to discuss in greater detail, please do not hesitate to contact me at matt.diloreto@ncpanet.org or at (703) 600-1223.

Sincerely,

Matthew J. DiLoreto
Director, State Government Affairs

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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

February 2, 2012

The Honorable Cathy Munoz
The Honorable Peggy Wilson
Alaska State House of Representatives
Alaska State Capitol
Juneau, AK 99801-1182

RE: House Bill 259 – Pharmacy Audits

Dear Representatives Munoz and Wilson,

On behalf of the members of the National Association of Chain Drug Stores (NACDS) operating in the State of Alaska, I ask for your support of House Bill 259. NACDS members operating in Alaska include Costco, Health Mart Systems, Safeway/Carrs, Target, Walgreen and Wal-Mart.

Auditing practices and their lack of standardization have long been the bane of pharmacies. House Bill 259 would set the standard by which pharmacies are audited and allow for appeal in the case of disagreement.

Pharmacies are not opposed to audits based on suspicion of fraud, unlawful billing practices and abuse. However, most audits are preformed based on a "hunting" expedition where the entity contracting for the audit is looking for additional revenue on the basis of overpayments based on technical errors.

Technical errors are ones in which the right person, got the right drug, in the right dose at the right time, but there is some type of clerical, record-keeping or typographical error.

We applaud your sponsorship of this legislation and the parameters it establishes for auditing practices.

Provisions of the Bill

- Two weeks notice would be very helpful due to the personnel and time needed to compile the records for auditing;
- Eliminating the first seven days of the month would be tremendously helpful to pharmacies due to the large influx of prescriptions during that time period;
- Limiting the "look back" to a period of two years allows the pharmacies to go back and bill a different third-party payer that they may have been unaware of at the time of original billing;
- Disallowing the use of extrapolation is a huge issue for pharmacies as they are an extremely inaccurate methodology for determining over or underpayment;
- Disallowing an overpayment to include dispensing fees is fair based on the fact overpayments are calculated on the cost of the drug; and
- Providing for a mechanism by which the pharmacy can appeal the findings allows for fairness in the process.

We appreciate your sponsorship of the legislation and stand ready to answer questions as they may arise to keep this bill moving through the legislative process.

Sincerely,

Lis Houchen

Lis Houchen
130 18th Avenue SE
Olympia, WA 98501
Lhouchen@nacds.org
360.480.6990

STATE OF ALASKA
DEPARTMENT OF
COMMERCE
COMMUNITY AND
ECONOMIC DEVELOPMENT
Board of Pharmacy

March 1, 2012

Senator Dennis Eagan
State Capitol Room 510
Juneau AK 99801-1182

RE: SB 217: Auditing Pharmacy Records

Dear Senator Eagan,

The Alaska Board of Pharmacy, at its February meeting in Anchorage, voted unanimously in favor of supporting House Bill 259 (An Act establishing procedures and guidelines for auditing pharmacy records, and providing for an effective date). The Board feels the time for such statutory oversight is overdue. This industry has operated far too long without oversight, and the need is great to protect not only our pharmacies, but the patients they serve. Our hope is to see this bill enacted without delay. Thank you.

Sincerely,

Richard Holm, R. Ph.
per MK Vellucci

Richard Holm, R.Ph.
Chair-Alaska Board of Pharmacy

cc: House Labor & Commerce Committee Members
Representative Dennis Eagan

PO Box 110806, Juneau, AK 99811-0806
Telephone: (907) 465-2589 Fax: (907) 465-2974 Text Tel: (907) 465-5437
Website: http://www.commerce.alaska.gov/occ/ppha.htm

Alaska Pharmacists Association

February 3, 2012

The Honorable Cathy Munoz
The Honorable Peggy Wilson
Alaska State House of Representatives
Alaska State Capitol
Juneau AK 99801-1182

RE: House Bill 259 – Pharmacy Audits

Dear Representatives Munoz and Wilson,

On behalf of the members of the Alaska Pharmacists Association, I ask for your support of this important bill for the benefit of all pharmacies in the State of Alaska. Our membership includes pharmacists, pharmacy technicians, pharmacies and others interested in the practice of pharmacy throughout the state.

This bill will standardize the manner in which pharmacies may be audited and will allow for appeal in the case of disagreement. Pharmacies realized that audits may be a way to detect fraud, unlawful billing practices, and abuse, but sometimes they are done as a way of looking for additional revenue on the basis of overpayment for technical errors. These technical errors are ones where the right person got the right drug in the right dose but there was some sort of clerical or typographical error in the billing.

Some provisions of the bill that we think are especially important are:

- Two weeks notice to allow pharmacies to gather the needed information with less disruption to their daily routine
- Eliminating the first 7 days of the month from a potential audit would be very helpful because pharmacies see a greater number of prescriptions in the first part of the month
- Limiting the audit period to two years
- Disallowing the use of extrapolation when auditors determine over or underpayment
- Disallowing an overpayment to include the dispensing fee since overpayments are based on the cost of the drug and dispensing fees are for the service rendered
- Providing for a method of appeal

The Alaska Pharmacists Association appreciates your sponsorship of this important piece of legislation.

Sincerely,

Margaret D. Soden, RPh, President

E-mail: akphrmcy@alaska.net

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PREMERA | BLUE CROSS BLUE SHIELD OF ALASKA

Jack C. McRae
Senior Vice President

March 6, 2012

Senator Dennis Egan
State Capitol Room 510
Juneau, Alaska 99801

Re: SB 217, Pharmacy Audits

Dear Senator Egan,

On behalf of Premera Blue Cross Blue Shield of Alaska, I am writing to you to express our concerns with SB 217, pertaining to pharmacy audits.

The purpose of pharmacy auditing is similar to other types of audits – it is a process for verifying compliance with requirements and regulations and to ensure appropriate quality standards are met. Typically, the language of the contract between the Pharmacy Benefits Manager (PBM) and a pharmacy specify the components and conditions of the auditing process.

In this case, Premera's Pharmacy Benefits Manager, Medco, conducts audits on a regular basis, as specified in the contract, to ensure pharmacies are providing services and billing in compliance with the contract that they hold with Medco. Medco has effective, appropriate pharmacy auditing processes already in place.

Therefore, we oppose SB 217, as it would interfere with the contractual agreement between these parties.

Thank you for considering our concerns on this issue. I would be happy to answer any questions that you may have.

Sincerely,

Jack C. McRae

Jack C. McRae
Senior Vice President

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April 4, 2012

Senator Dennis Egan
Alaska State Senate
State Capitol Room 510
Juneau AK, 99801

RE: Senate Bill 217 – Pharmacy Audits

Dear Senator Egan:

As one of Alaska's largest private employers (2900 employees in 11 stores in Alaska), I am writing to express Fred Meyer Stores' support of this important bill.

This bill will standardize the manner in which pharmacies may be audited and will allow for appeal in the case of disagreement. As Pharmacists, we recognize that audits are vital to detecting fraud, unlawful billing practices, and abuse. However, there are times when penalties are assessed for truly innocent technical errors. These technical errors are ones where the right person got the right drug in the right dose but there was some sort of clerical or typographical error in the billing. Penalties based on these situations fall outside the spirit and purpose of auditing.

Some provisions of the bill that we think are especially important are:

- Two weeks' notice to allow pharmacies to gather the needed information with less disruption to their daily routine (Pharmacies run a VERY tight ship in order to help do our part in preventing more increases in health care costs.)
- Eliminating the first 7 days of the month from a potential audit would be very helpful because pharmacies see a greater number of prescriptions in the first part of the month
- Limiting the audit period to two years
- Disallowing the use of extrapolation when auditors determine over or underpayment
- Disallowing an overpayment to include the dispensing fee since overpayments are based on the cost of the drug and dispensing fees are for the service rendered
- Providing for a method of appeal

These are reasonable provisions that still provide for the oversight needed in an industry such as Pharmacy, where the safety of our customers is our top priority, just as it is for the State.

Thank you for your sponsorship of this legislation. If I can answer any questions, please call me at 907-267-6786.

Sincerely,

Mark Bohrer

Mark Bohrer
Alaska Coordinator, Pharmacy

Alaska Pharmacists Association

To: Senate Labor and Commerce Committee

From: Barry Christensen, RPh
Co-Chair Legislative Committee Alaska Pharmacists Association
Date: March 25, 2012

Re: SB 217 Letter of Opposition from Alaska Teamsters on HB 259

The Alaska Pharmacists Association respectfully disagrees with the Teamsters that HB259 is not well defined and is not revenue neutral.

This bill is based on model legislation that has passed in approximately 20 states and legislative legal counsel has had adequate time to review and modify any Alaska specific language. The bill does not set forth any commissions or mandate any state specific agency oversight.

Regarding claims in the letter that certain portions of the bill are "vague and not well written" we again respectfully disagree. Our association is willing to sit down with teamster representatives anytime to explain the specific line items and why it's important to have fair audit standards for Alaskan Pharmacists.

I will address specific items that were addressed in the letter:

Subparagraph 3 requires the audit of a claim within two years. This is consistent with State of Alaska Pharmacy practice statutes that mandates pharmacies keep prescription records for only **two years.**

Subparagraph 6 merely says a clerical error doesn't constitute fraud. The "marking up the price of a prescription by a dollar" example isn't relevant in today's world. Even if a pharmacy submitted a price of a prescription for a dollar more than the contracted rate the pharmacy would still only get the contracted rate. Not a penny more or less.

Subparagraphs 8 & 9 sets forth when and how extrapolations can be used. Legislation addressing this issue has been enacted in at 11 other states. Extrapolation is a serious issue for pharmacy that must be corrected.

Subparagraph 11 the claim that "there is a lot of revenue built into the dispensing fee" is misleading. I am sure if you look at the total plan expenditures the dispensing fees, at an average of $2-$3 per prescription, are a small portion of the overall drug plan expenditures. However, these are the dollars necessary to provide pharmacy services and it is unfair to take them back when a service is provided.

Subparagraph 12 -16 covers delivery of the final audit and appeal process. The letter notes for example that most pharmacy contracts already allow 90 days for the audit results to be delivered to pharmacy. However in a Teamsters Healthtrans PBM contract example, submitted by one Alaskan pharmacy, no date was given for an audit finding results back to the pharmacy. In fact the contract only contained two reference lines regarding audits. This is exactly the problem pharmacies in Alaska face in dealing with multiple PBM contracts that do not allow for negotiating such language. HB 259 standardizes and gives structure to the auditing process.

E-mail: akphrmcy@alaska.net

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CVS CAREMARK

Testimony in Opposition to Senate Bill No. 217

Submitted by

Eric P. Douglas
Director, Government Affairs
CVS Caremark Corporation

To

Alaska State Senate
Senate Labor and Commerce Committee

March 1, 2012

Committee Chair Eagan, Vice Chair Paskvan, Honorable members of the Alaska Senate Labor and Commerce Committee; my name is Eric Douglas and I am the Director of Government Affairs for CVS Caremark over the Western United States. Thank you for providing me with an opportunity to testify before you today. CVS Caremark respectfully submits this testimony in opposition to Senate Bill 217 ("SB217"). This bill consists of four Sections covering numerous audit practices and procedures, many of which are overly prescriptive and would hinder our ability to perform audit functions on behalf of our clients. Therefore, we ask that you reject SB217.

Background and Information Regarding Fraud and Use of Audits

CVS Caremark is the leading pharmacy health care provider in the country. Through our integrated offerings across the entire spectrum of pharmacy care, we are uniquely positioned to provide greater access to care, engage plan members in behaviors that improve their health, and lower overall health care costs for health plans and their members. As one of the country's top PBMs, we also provide access to a network of more than 65,000 pharmacies, including over 7,300 CVS pharmacies. Our relationship with our network pharmacies is a critical component to the value we bring to our clients and their beneficiaries. To deter fraud and ensure contract pharmacies comply with CVS Caremark quality assurance requirements, we audit a minimum of five-percent (5%) of contracted pharmacies annually. CVS Caremark audits network pharmacies based on statistical analysis of claims data or as a result of state regulatory authorities and clients informing us about potential violations. PBMs look for errors, irregularities and

suspicious patterns over time and claims are compared with historical information as well as claims submitted by similarly situated pharmacies, e.g. geographically, by volume, etc. Substantial changes in the volume of claims submitted or the dollar amount of claims form particular pharmacies can also be in indication of fraudulent activity.

Following an audit, CVS Caremark allows a pharmacy 30 days to submit additional documentation on claim discrepancies. This is especially important to a pharmacy that has itself been a victim of fraudulent activity by one or more of its employees. Unacceptable findings discovered by an audit may include the submission of a fraudulent claim or a pharmacy consistently demonstrating a failure to follow the claims submissions policies clearly outlined in their Provider Manual. However, the more common type of fraud discovered is a "phantom" billing where a claim is submitted by a pharmacy but cannot be supported by a valid prescription on audit.

For pharmacies that have unacceptable audits or have submitted fraudulent claims, our Management Review Committee meets quarterly to review unacceptable and fraudulent activity to determine if continued membership in our network places our clients and their beneficiaries at risk. The Committee is made up of CVS Caremark employees from various cross-functional departments. Additionally, when we find irrefutable evidence of fraud we report it to the appropriate authorities and state agencies. CVS Caremark is active in both the National Association of Drug Diversion Investigators ("NADDI") and the National Health Care Anti-Fraud Association ("NHCAA"). These two organizations and their members make it their mission to assist in investigating and prosecuting pharmaceutical drug diversion.

"Health care fraud is a pervasive and costly drain on the U.S. health care system. In 2008, Americans spent $2.34 Trillion dollars on health care. Of these trillions of dollars spent, the Federal Bureau of Investigation ("FBI") estimates that between 3 and 10 percent (3%-10%) was lost to health care fraud." [i]

In 2010 alone, a joint health care fraud and prevention effort between the U.S. Department of Justice and the Department of Health and Human Services resulted in the recovery of more than $4 Billion in taxpayer dollars. A not insignificant portion of the recovered money came from uncovering pharmacy fraud schemes that included fraudulent billing practices and illegal dispensing of medications.[ii]

CVS Caremark recommends that the government not impose onerous pharmacy audit restrictions that will lessen PBM's ability to detect and recover monies resulting from fraudulent activity, abuse and wasteful spending in our healthcare system.

Conclusion

CVS Caremark sincerely appreciates the opportunity to submit our testimony regarding this legislation. SB217 unfortunately would create unreasonable restrictions on legitimate and necessary audits of prescription drug claims submitted for payment by pharmacies in Alaska. SB217 would weaken the ability of an insurer, MCO or PBM to protect its clients, detect fraud, reject invalid claims and recoup a clients' money when they have been improperly billed. For these reasons, CVS Caremark respectfully asks for your "NO" vote, rejecting SB217.

I will be pleased to answer any questions the Committee members may have and again, thank you for the opportunity to testify before you today.

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[i] National Heath Care Anti-Fraud Association, "Combating Health Care Fraud in a Post-Reform World: Seven Guiding Principles for Policymakers", October 2010, available online at: http://www.nhcaa.org/eweb/docs/nhcaa/PDFs/Member%20Services/WhitePaper_Oct10.pdf

[ii] U.S. Department of Health and Human Services & U.S. Department of Justice, "Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2010," January 2011, available online at: http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2010.pdf

From: NACDS News Release

Date sent 03/21/2012 01:03:41 pm

Subject: NACDS Applauds Enactment of Indiana Bill to Counter Unfair PBM Audit Practices

Print This

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

NewsRelease

FOR IMMEDIATE RELEASE
March 21, 2012

Contact: Chrissy Kopple
(703) 837-4266

NACDS Applauds Enactment of Indiana Bill to Counter Unfair PBM Audit Practices

Legislation reflects growing nationwide recognition of need to protect patients and community pharmacies from predatory PBM policies

Alexandria, Va. – The National Association of Chain Drug Stores (NACDS) today lauded the enactment of legislation in Indiana to prevent unfair pharmacy benefit manager (PBM) audit practices that could hinder patient access to community pharmacy-provided services, which help advance patient health and reduce costs to the health system.

Among other provisions, the legislation specifies PBM audit requirements of pharmacies – including reasonable time frames and procedures – and strengthens standards that help prohibit PBMs from acting in a belligerent manner to use their enormous leverage when conducting these audits.

Governor Mitch Daniels (R) signed Senate Bill 407 after the Indiana legislature approved the measure last week. NACDS sent a letter to Governor Daniels urging him to sign the bill, underscoring the importance of protecting community pharmacies from the virtually unregulated PBM industry.

"Ensuring PBM compliance with reasonable and appropriate business practices will increase transparency on the opaque PBM industry and benefit patients in making their healthcare choices," said NACDS President & Chief Executive Officer Steven C. Anderson, IOM, CAE. "We applaud Governor Daniels and Indiana policymakers for enacting this vital legislation that will help prevent PBMs from dictating unreasonable contract terms to pharmacies and employing anti-competitive practices."

Indiana now joins several other states that have either enacted or are considering legislation to rein in one-sided PBM tactics, audit requirements and reimbursement procedures. For example, Utah lawmakers recently passed legislation that also would require PBM audits of pharmacies to use fair and rational standards, while also addressing other concerns with reimbursement.

Unfair PBM audit, transparency and reimbursement practices have also generated attention on the federal level. Just this week, U.S. Representative Cathy McMorris Rodgers (R-WA) introduced legislation that would establish Medicare standards for pharmacy audits and reimbursement by PBMs. Representative McMorris Rodgers has also introduced, along with U.S. Senator Mark Pryor (D-AR), the Pharmacy Competition and Consumer Choice Act (H.R. 1971 and S. 1058), which address concerns with forcing beneficiaries to use a PBM's own mail order pharmacy, the frequency of updating maximum

allowable cost (MAC) pricing, data usage, and other issues identified by Members of Congress.

"From the U.S. Capitol to state legislatures, policymakers are sending a clear message that PBMs must use fair practices and cease the utilization of auditing gimmicks to attack community pharmacies," Anderson said. "NACDS will continue advocating on the federal, state and local levels to preserve patient access to neighborhood pharmacies, which have demonstrated a proven track record of gaining patients' trust and offering services to improve health while reducing costs."

For more information on NACDS efforts to highlight detrimental PBM practices and oppose the proposed mega-merger of PBMs Express Scripts and Medco, which would likely exacerbate existing PBM problems, please visit www.TooBigToPlayFair.com.

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The National Association of Chain Drug Stores (NACDS) represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chains operate more than 40,000 pharmacies and employ more than 3.5 million employees, including 130,000 pharmacists. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States. The total economic impact of all retail stores with pharmacies transcends their $900 billion in annual sales. Every $1 spent in these stores creates a ripple effect of $1.81 in other industries, for a total economic impact of $1.76 trillion, equal to 12 percent of GDP. For more information about NACDS, visit www.NACDS.org.

Pharmacies. The face of neighborhood healthcare.