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.)