

# PBM WATCH

March 2016

## Pharmacy Benefit Manager Legislation

### Current Legislation:

**Alabama:** §34-23-180 through 187: This law sets out to establish minimum and uniform standards and criteria for the audit of pharmacy records by or on behalf of certain entities.

**Arkansas:** §17-92-1201: This law creates a Bill of Rights to be followed for any entity conducting an audit of a pharmacy.

§4-88-801 through 804: Requires PBMs to itemize by individual claim the amount actually paid to the pharmacy or pharmacist, and an identifier of the pharmacist services.

§Act 1007: This act preserves the professional independence of a pharmacist/pharmacy. Additionally this act limits the retaliatory actions that a PBM can engage in vis a vis a pharmacy.

Act 1194: Regulates how drugs can be put on the MAC list as well as requires the MAC lists be made available to pharmacies. The act also requires that necessary updates be performed on the MAC list every 7 days. It also creates an appeals process for pharmacies to dispute MAC price billing with PBMs. (Act signed into Law April 12, 2013)

**California:** BPC §9.5-4430 through §4439: This law dictates the procedures governing how entities may conduct audits of pharmacies, specifically the regulations governing the timing of the audit as well as an appeals process for the pharmacies being audited.

**Colorado:** §10-16-122: This law governs how PBM networks will be set up, and that any PBM or intermediary whose contract with a carrier includes an open network shall allow participation by each pharmacy provider in the contract service area. Additionally that no PBM or carrier offering a managed care plan shall transfer or request that a pharmacy provider transfer the prescriptions of a covered person to a different participating pharmacy provider unless certain conditions are met.

H.B. 13-1221: This law sets standards for a PBM or entity acting on behalf of a PBM to follow when auditing a pharmacy. The auditing entity shall give written notice prior to conducting an audit as well as conducting the audit with a licensed pharmacist when required. Further it set forbade certain techniques in calculating the amount of recoupment or penalty as well as established a process for Pharmacies to appeal or dispute a claim. (Signed into law by Governor April 8, 2013)

**Connecticut:** Act 07-200: This act governs the process that PBMs must engage in in order to receive a certificate of registration from the Connecticut Insurance Department. Also the act lays out what recourse the Insurance Commissioner has regarding PBMs who act contrary to the established rules.

**Florida:** Title XXXII §465.188: This law governs how entities may audit pharmacies participating in Florida Medicaid programs. Specifically, this act particularly governs the timing of the audits, as well as the time period for which an auditor may look at.

**Georgia:** §26-4-110.1: This law with a few exceptions requires PBMs to be licensed as pharmacies. As a function of being licensed as a pharmacy the PBM shall be obliged to permit inspections of their premises.

§26-4-118: This law governs the timing as well as the period of time under investigation for PBM audits of pharmacies. Additionally this law regulates the rights of pharmacies in responding to audits and establishes an appeals process to contest the PBMs conclusions.

**Hawaii:** H.B. 62: This law is to prohibit PBMs from using a patient's claim information to market or advertise to that patient the services of a preferred pharmacy network that is owned by the PBM. It goes on to say that a PBM company shall take no action that would restrict a patient's choice of pharmacy from which to receive prescription drug benefits. Signed into Law July 2, 2013.

**Indiana:** §25-26-22: This law governs the procedures that a PBM must abide by when drafting an audit contract as well as the processes for conducting an audit. Additionally, the law dictates the time allowances and constraints that must be followed by both the PBM and the pharmacy regarding the auditing.

**Iowa:** §510B.1 through §510B.7: This law requires that PBMs doing business in Iowa obtain a certificate as a third-party administrator and follow the rules outlined for third-party administrators that was previously set out. The law also regulates the process and procedures for the dispensing of substitute prescription drugs. Additionally the law provides a guide for the distribution of data while simultaneously forbidding the process of extrapolation.

HF 2297: This law regulates PBM management of Maximum Allowable Costs. Among the various provisions is a requirement for the PBM to include in its contract information regarding which of the national compendia is used to obtain pricing data used in the calculation of the maximum reimbursement amount pricing and a process to allow a pharmacy to comment on, contest, or appeal the maximum reimbursement amount rates or maximum reimbursement amount list. (Signed by the Governor March 14, 2014)

**Kansas:** H.B. 2182: This law regulates the the timing and procedures for audits, including who must be present as well as how much prior written notice is required to conduct an on-site initial audit. The law also regulates the appeals process should the pharmacy contest the audit.

§40-3821 through §40-3828: This law requires PBMs to obtain certificates of registration from the insurance commissioner in order to do business in Kansas. It also states that there is a fee for obtaining this registration and that the insurance commissioner can adjust or adopt new rules concerning the certification.

**Kentucky:** §304.17A-740 through §304.17A-747: This law governs the timing and procedures for the audits of pharmacies by PBMs. It dictates what access pharmacists have to records and information to

verify the pharmacy's records. Additionally the law discusses procedures as well as standards for how compensation for overpayments will be addressed.

**HB 349:** This law amended KRS 304.17A-741, to prohibit an auditing entity from requiring a pharmacy to keep records longer than two years, or longer than required by state or federal law. This law also prohibited an auditing entity from receiving payment based on the total amount recovered in an audit.

**SB 107:** This law requires PBMs to include the methodology used to calculate drug product reimbursements as well as sets certain requirements surrounding the Maximum Allowable Cost. A PBM must include information identifying the national drug compendia or source used to obtain the drug price. Additionally a PBM must review the list of drugs subject to the MAC and to update it and make changes at least once every seven days. Signed into Law March 22, 2013.

**Louisiana:** §22:1856.1: This law establishes rules concerning the timing and process that PBMs must abide by with regards to pharmacies. It spells out the regulations concerning recoupment of assets, as well as the appeals process that must be made available to pharmacists who wish to contest the audits findings.

**Maine:** L.D. 44: This law limits the total amount that may be recouped in pharmacy audits to dispensing fees, unless a misfill occurs. The Law also limits access by pharmacy auditors to certain records as well as requires auditors to give advance notice of an audit. The law also specified that to preserve the neutrality of an audit, the auditor must use a random sample of pharmacy transactions so as to not unduly influence the audit. Signed into Law by Governor May 7, 2013.

**Maryland:** §15-10B-20: This law requires the Insurance Commissioner to conduct an examination of any PBM registered as a private review agent to ascertain if the PBM is acting in compliance with Maryland law. This review is to take place at least once every 3 years.

§15-1601 through §15-1610: This law regulates how PBMs may negotiate their contracts with pharmacies, including what must be disclosed as well as the timing for specific actions like audits. Additionally the law outlines the process that must be followed during and after an audit as well as specifying the appeals process for pharmacies.

§15-16-1629: This law further specifies the requirements and processes regarding audits of pharmacies by Pharmacy Benefit Managers. For instance it outlines that an on-site audit of a pharmacy may not be conducted during the first five calendar days of a month unless requested by a pharmacy or pharmacist. The law also outlines the processes for validating the pharmacy records as well as who may have access to what.

**Massachusetts:** Title XXII-176D-3B: This law specifies how PBMs within Massachusetts may structure their restricted pharmacy networks as well as the requirements that may be imposed on pharmacies wishing to participate in the restricted network. To ensure that fair and competitive bidding ensue, the PBM must ensure that equal requirements are imposed on the prospective pharmacies and that equal information is dispersed.

**Minnesota:** §151.60 through §151.70: This law governs how PBMs may write their contracts with pharmacies. Specifically it addresses the notice period needed for changes in contracts or audit terms as

well as the scope of information that can be required. Additionally the law describes the standards and processes for over-payment recoupment as well as the appeal process for a pharmacy wanting to contest the PBMs conclusions.

**Mississippi:** §73-21-151 through §73-21-159: This law regulates the how PBMs must interact with the state Insurance Department as well as who will monitor the PBMs compliance with state laws. Additionally the law regulates the reference material that PBMs must use in making their pricing calculations. It should be noted that several sections of this law will be repealed as of July 1st, 2013.

§73-21-179 through §73-21-191: This law requires PBMs to clearly identify and describe the audit procedures that appear in their contracts with pharmacies. The law specified particular issues of timing and focus that the PBM must adhere to in conducting their audit. This includes the sample size under investigation, as well as policies involving overpayment and recoupment.

**Missouri:** Title XXII §338.600: This law outlines and establishes standards for audits of pharmacies by managed care companies, insurance companies, third party payors or any entity that represents such groups. It requires that when an entity audits a pharmacy, the entity will use the same standards and parameters consistently. Additionally, the law sets out standards for appeals processes for pharmacies that contest the auditor's conclusions.

**New Mexico:** H.B. 126: This legislation would provide a reasonable degree of transparency over how MAC pricing is determined and reported. The legislation also takes additional steps to reform PBM activities in New Mexico. This law will help preserve patient access to prescription drugs and better protect New Mexico's small business community pharmacies from being reimbursed at a financial loss. It will establish guidelines and notice provisions for Maximum Allowable Cost for drugs and a system for challenging the MAC pricing. (Signed into law by the Governor March 5th.)

§61-11-18.2: This law obligates managed care companies, insurance companies, third-party payors or their representatives to follow particular regulations and standards when conducting audits. The law gives pharmacies certain rights with respect to what must be provided to auditors as well as on what time frame. Among those rights include a guaranteed appeals process for the pharmacy to dispute the auditor's conclusions. It should be noted that some sections of this law will be repealed as of July 1st, 2016.

**New York:** A05502B: This law prohibits health insurers from requiring the insured purchase prescribed drugs from a mail order pharmacy or pay a co-payment fee when such purchases are not made from a mail order pharmacy if a similar fee is not charged for drugs from a mail order pharmacy.

**North Carolina:** §90-85.50 through 90-85.53: This law provides rights for pharmacies who would be audited by managed care companies, insurance companies, third-party payers or other entities. This includes a notice period prior to the start of the audit as well as an appeals process for the pharmacy. The law also describes the processes that must be followed for entities seeking recoupment of funds following an audit.

**North Dakota:** §26.1-27.1-01 through §26.1-27.1-07: This law requires that for PBMs to conduct business in the North Dakota they must obtain a certificate of registration as an administrator. Additionally PBMs must comply with the laws concerning drug substitution for prescriptions that will be filled. Further PBMs may not require a pharmacy to participate in one contract in order to participate in

another contract. It also states that a PBM may not exclude an otherwise qualified pharmacy from participation in a particular network if the pharmacy accepts the terms, conditions, and reimbursement rates of the PBM's contract.

**H.B. 1418:** This law regulates entities conducting audits of pharmacies by providing ground rules that must be followed. These regulations include the timing of notice given to the pharmacy by the auditing entity, as well what documents or records are to be made available to the auditor. The law also establishes the standards for seeking recoupment for overpayment as well as underpayment. Additionally, the law mandates that any entity conducting an audit shall establish a written appeals process.

**H.B. 1363:** Requires the PBMs to every year divulge the market-based source utilized to determine MAC and update the pricing information every seven calendar days. Also ensures that the MAC prices are not set below market-based sources available for purchases without limitations by pharmacy providers. (Signed into Law April 12, 2013) - See our letter in support of H.B. 1363.

**Oklahoma:** §59.356: This law necessitates that entities that would audit pharmacies clearly identify and describe the procedures of the audit within their contracts. The law goes on to define the process to be followed for entities seeking recoupment of disputed funds. Additionally, the law specifies that the entity conducting the audit must make available a written appeals process for pharmacies wishing to dispute the conclusions of the auditing entity.

**Oregon:** H.B. 2123:- Requires PBMs to disclose to pharmacies the sources used to determine the MAC pricing at the start of each contract and upon each subsequent renewal of the contract. PBMs also can no longer include the dispensing fee in the calculation of the MAC. (Signed into Law July 1, 2013)

**Rhode Island:** §27-29.1: This law identifies PBMs as third-party administrators who are obligated to fill out and submit annual reports with the department of business. Should a third-party administrator be owned or affiliated with another entity it would be required to provide an organizational chart and description demarcating all of the relationships among the affiliates within a holding company or otherwise affiliated.

**South Carolina:** §38-71-1810 through §38-7140: This law identifies the rights of pharmacies who would be audited by a managed care organization, insurer, third-party payor, or any entity that represents a responsible party. The pharmacy must have at least fourteen days advance notice of the initial audit for each audit cycle, with no audit to be initiated or scheduled during the first five days of any month without prior expressed consent from the pharmacy, which shall cooperate with the auditor to find an alternate date for the audit if the audit would fall within an excluded day. The law also outlines how the process of recoupment for overpayments must take place, and specifies that the pharmacy must have an access to an appeals period should they wish to dispute the auditors conclusions.

**South Dakota:** §59-29E: This law mandates that PBMs must obtain a valid license to operate as a third party administrator to conduct business in South Dakota. Additionally, the law requires disclosure of revenue received from pharmaceutical manufacturers or labelers under contract with the manager. The law allows for covered entities 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. With that information, the covered entity may audit the records of the PBM as it relates to rebates or other incentives.

**Tennessee:** §56-7-3103: This law regulates the manner and process through which a covered entity or PBM may audit a Pharmacy. It states that the PBM shall give at least two weeks prior written notice before conducting the initial on-site audit for each audit cycle. Additionally, the PBM conducting an audit is required to establish an appeals process under which a pharmacist or pharmacy may appeal an unfavorable report. The law also outlines the processes for recoupment of any disputed funds, specifically that it shall only occur after final internal disposition of the audit, including the appeal process set out within.

§56-7-3104: This law regulates the calculation of reimbursement used by pharmacy benefit managers. It states that reimbursement by a PBM to a pharmacy for prescription drugs or other products using a nationally recognized reference for pricing shall use the most current nationally recognized reference for the price amount. To that end, PBMs shall be required to update the nationally recognized reference prices used for calculation no less than every three business days.

§56-7-3201 through 3204: This law states that a PBM or other covered entity may not in any way restrict a pharmacy from disclosing to the patient or authorized representative the actual reimbursement for a particular prescription or covered service. The law also specifies that when PBMs provide patients with information regarding out-of-pocket costs, such as co-pay, for a prescription or service, they must provide the patient the actual reimbursement.

**Texas:** §1551.224: This law forbids a board of trustees or a health benefit plan for Texan Government workers to require participation in mail order programs for the purchase of prescription drugs.

§2158.401 & §2158.402: This law mandates that a state agency, upon request of another state agency will disclose information cataloging the charge for services rendered by a PBM no later than 30 days after the date the information is requested.

§843.339: This law regulates the deadlines for action on prescription claims. It states that for electronically submitted claims which have been affirmatively adjudicated, the PBMs must pay pharmacies through electronic fund transfer no later than the 18th day after the date on which the claim was affirmatively adjudicated. If the claim was not submitted electronically, the PBM shall pay the amount to the pharmacy no later than the 21st day after the date on which the claim was affirmatively adjudicated.

§843.3401: This law governs how PBMs may audit Pharmacies. It forbids the use of extrapolation to complete the audit of a pharmacy, as well as outlines how on-site audits will be conducted. PBMs must provide notice to a pharmacy, in writing, through certified mail no later than 15 days before the on-site audit is scheduled to occur.

S.B. 1106: This law regulates what drugs can be placed on the MAC cost list. Specifies information that must be given to pharmacies when entering or renewing contracts as well as creates an appeals process if the for pharmacies to contest MAC reimbursement rates. (Signed into Law June 14, 2013)

H.B 1358: This law regulates the procedures for conducting audits of Pharmacies by PBMs. The law lays out the specifications for notice that must be given to a pharmacy prior to it being audited. The law further goes on to describe the different kinds of audits that can take place as well as who must be present for one to take place. (Signed into Law June 14, 2013)

**Utah:** §49-20-501 through §49-20-503: This law establishes requirements for transparency for PBMs. When the Utah State Retirement Board solicits requests for proposals from PBMs to provide pharmacy benefits management services for the Public Employee's Benefit and Insurance Program, the PBMs must provide a billing option that requires the PBM to on a monthly basis submit to the board an invoice for all pharmacy services paid by the PBM on behalf of the program. That invoice will include the total amount due to the PBM for all pharmacy services and the total amount paid by the PBM for all the same pharmacy services.

§58-17b-622: This law governs how the audits of pharmacies may be conducted. Some of the guidelines include, mandating that audits that involve clinical or professional judgement are to be conducted by, or in consultation with a pharmacist who is licensed through a State agency. Some of the other guidelines specify the timing of the audits and how much notice prior notice must be given. Signed into Law March 28, 2013.

H.B. 113: This law regulates certain reimbursement practices of Pharmacy Benefits Managers including the Maximum Allowable Cost as well as appeal rights for Pharmacies. The MAC may be determined by using comparable and current data on drug prices obtained from multiple nationally recognized, comprehensive data sources, including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are available for purchase by pharmacies in the state. The PBM is however responsible for disclosing in their contract with a pharmacy the national drug pricing compendia and other sources used to obtain the drug prices, as well as review and make necessary changes to the MAC list once per week. (Signed into Law March 31, 2014)

**Vermont:** §18-221-9421: This law establishes the ground rules for conducting business for PBMs within the State of Vermont. First, a PBM is by law required to register with the commissioner to do business in the State. PBMs are obligated to alert health insurers that they are entitled to a quote for an administrative-services-only 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.

§18-221-9471 through 9473: This section of laws state that unless contractually obligated otherwise a PBM that provides pharmacy benefit management for a health plan shall: Provide all financial and utilization information requested by a health insurer relating to the provision of benefits to beneficiaries through that health insurer's health plan and all financial and utilization information relating to services to that health insurer. The PBM must also notify a health insurer in writing if any proposed or ongoing activity, policy or practice of the PBM presents, directly or indirectly, any conflict of interest with the stated requirements.

§18-79-3801 through 3805: This section of laws establishes the processes for conducting audits of pharmacies within Vermont as well as the accompanying rights of pharmacies. One such right is a requirement that audits which involve clinical or professional judgement must be conducted in part, or in consultation with a pharmacist who is both licensed by a state agency and is familiar with Vermont

pharmacy statutes and rules. It also provides that on-site audits must be conducted with at least 14 days' advance written notice as well as notice of the specific prescriptions to be included in the audit. The law also enshrines the appeals process that must be provided for pharmacies wishing to contest the auditing entities conclusions.

**Act No. 150:** This act updates and expands the rights of pharmacies that was established in 18-22-221 in several key ways, particularly as it applies to audit procedures and options available to pharmacists. PBM management of MAC, was signed into law by Gov. Terry Branstad (R) on March 14, 2014. Among the various provisions is a requirement for the PBM to include in its contract information regarding which of the national compendia is used to obtain pricing data used in the calculation of the maximum reimbursement amount pricing and a process to allow a pharmacy to comment on, contest, or appeal the maximum reimbursement amount rates or maximum reimbursement amount list.

**Virginia:** HB 108: This law regulates PBM audit procedures, among the various provisions are prohibitions of recoupment by extrapolation and recoupment for clerical errors, if the act or omission was not specifically prohibited in the contract, if the claim was more than 24 months old or if the pharmacist was not allowed to submit an electronic record to validate a claim. (Signed into law by Gov. Terry McAuliffe (D) on March 27, 2014.)

**Washington:** SB 6137: This law requires PBMs to register with the Department of Revenue, imposes limits on audits of pharmacies by PBMs and other entities, places restrictions on the use of MAC pricing and includes appeals processes for pharmacy audits and MAC pricing. Would regulate how Pharmacy Benefit Managers operate in the State broadly as well as outlines specifics including how audits are to be conducted and take place as well as details surrounding the application of a Maximum Allowable Cost list. A PBM would be required to make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the MAC pricing of the PBM. Additionally a PBM is mandated to update each list every seven business days and make said updated lists available to network pharmacies. (Signed into law by Gov. Jay Inslee (D) on April 3, 2014)

~ *Distributed by Sen. Cathy Giessel*