STATE REGULATIONS in Pharmacy Benefit Management

This informational tool provides employers with an overview of state regulations addressing Pharmacy Benefit Managers (PBMs), with a focus on PBM regulations affecting plan sponsors. The tool has four main sections beginning with a short background of PBMs, which includes current views to regulating PBMs. The next section provides a general overview of state regulations that address PBMs. Lastly, the remaining two sections focus on state regulations addressing PBMs and their conduct when contracting with plan sponsors.
I. BACKGROUND

PBMs are the third party administrators responsible for managing prescription plans for 95% of Americans with prescription drug coverage. While PBMs are subject to many federal laws governing businesses, such as the False Claims Act, the Federal Trade Commission Act, and the Anti-Kickback Act, no federal agency or law is responsible for regulating the PBM industry. Likewise, at the state level, the majority of states do not regulate PBMs. The states that do regulate PBMs vary as to the aspect of PBM activities they regulate and to the extent they impose regulations.

Proponents of regulation argue that regulation is necessary to curb anticompetitive activities by PBMs and to ensure that PBMs pass on cost savings to plan sponsors. These proponents point to recent litigation against PBMs to underlie their position. For instance, over the past decade, both Caremark and Express Scripts-Medco, which account for nearly 75% of the PBM market, have faced major lawsuits questioning PBM business practices. These claims involved allegations of fraud, misrepresentation to plan sponsors, and kickbacks. Meanwhile, opponents of regulating PBMs contend that more regulation of the PBM industry will lead to increased costs and maintain that competition is the best way to control the PBM market. Opponents point to a report from the Federal Trade Commission (FTC) that found "vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms."

Despite the controversy and the lack of federal oversight, states have continued to propose regulations in an attempt to regulate the PBM industry. Since 2002, twenty-five states and the District of Columbia have proposed PBM regulation. Additionally, seven new states are currently in the process of considering PBM legislation. These regulations vary from state to state and address different aspects of PBM activities.

II. OVERVIEW OF PBM REGULATIONS

At least twenty-one states currently regulate PBMs (see Table 1). Of these state regulations, most address fair auditing provisions of pharmacies. Fair auditing regulations impose restrictions and establish requirements on PBMs that audit pharmacies. States passed these regulations in response to concerns from pharmacists and pharmacy owners about PBM requirements for pharmacy audits. Concerns included PBMs structuring audits to be time-consuming, disallowing pharmacies to correct or appeal errors discovered in audits, and classifying minor clerical errors as acts of fraud. Additionally, pharmacists and pharmacy owners were concerned that the PBM practice of hiring auditors on a contingency fee basis incentivized auditors to find more errors and to recoup payment.

Most of these state regulations include a requirement that PBMs provide "notice" to pharmacies before conducting an audit, with notice ranging from seven to fourteen days. These regulations also require PBMs to allow pharmacies an opportunity to appeal audit results, generally within a thirty-day timeframe. States have also set limitations on what PBMs can audit. For example, states may limit the number of claims a PBM may audit or limit the period covered by a PBM audit to between one to two years. Some states, such as North Dakota, include additional protections specifying that PBMs may not consider clerical or recordkeeping errors as acts of fraud although they may recoup payment. Indiana's regulation further specifies that auditors may not be paid based on a percentage of the amount recovered.

Another prevalent type of state PBM regulation requires the PBM to register with the state. These regulations require PBMs to register through the state insurance department, to attain licensure as a third party administrator, or to register with the state board of pharmacy. Most of these regulations address the process for doing business in these states and include requiring PBMs to submit an application, to name board members and principle officers, and to pay a fee in order to do business in the state. However, some states impose additional registration requirements for PBMs. For example, Connecticut allows the Insurance Commissioner to "suspend, revoke or refuse to issue or renew any certificate of registration for:

1. [c]onduct of a character likely to mislead, deceive or defraud the public or the commissioner;
2. unfair or deceptive business practices . . . ."

Some states also require PBMs to provide financial reports, including its income statement and balance sheet, to the department that oversees them.

While these regulations increase a state's authority over PBMs and their conduct, these regulations are limited to addressing the relationship between pharmacies and PBMs, and do little to enhance agreements with plan sponsors. While some
states have passed regulations governing PBM-plan sponsor agreements, these regulations appear to be under increased scrutiny—particularly, regulations that impose a duty on the PBM to act in the best interest of a plan sponsor, referred to as a fiduciary duty. The following sections provide a summary of the common state regulations that address plan sponsor rights, beginning with an overview of regulations imposing a fiduciary duty on a PBM.

III. FIDUCIARY DUTIES: LEGISLATIVE AND LITIGATION HISTORY

In 2003, Maine passed the Unfair Prescription Drug Practices Act making it the first state to impose a fiduciary duty on PBMs. The Act required PBMs to "perform its duties with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims." The Act also required PBMs to inform plan sponsors of "all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs." In 2004, D.C. joined Maine in imposing a fiduciary duty on PBMs by passing a very similar bill, the Rx Access Act. While these regulations changed the landscape for PBM-plan sponsor relations, they were also subject to criticism and attack from the PBM industry.

Shortly after both Maine and D.C. passed their regulations, the Pharmaceutical Care Management Association (PCMA) filed suit to stop enforcement of these regulations. PCMA is trade organization representing the PBM industry with a strong national lobbying influence. After years of litigation, the cases resulted in contradicting decisions. While one court upheld the Maine regulation in 2006, the other court found that the Employee Retirement Income Security Act (ERISA) conflicted with the D.C. law, and thus struck it down in 2010. Although Maine's law requiring a fiduciary duty on PBMs survived PCMA litigation, the PBM industry successfully lobbied the Maine legislature to repeal the regulation in 2011.

PCMA's litigation against regulations imposing a fiduciary duty seems to have impacted other states and their decisions not to enact similar measures. Between 2004 and 2005 alone, eighteen states rejected or delayed legislation imposing a fiduciary duty or disclosure requirements on PBMs. Still, some states have continued to consider fiduciary duty regulations. Organizations such as the National Legislative Association on Prescription Drug Prices (NLARx) continue to encourage states to enact fiduciary duty regulations, recommending a model policy that mirrors Maine's PBM law. Over the years several state legislatures have considered enacting NLARx's model policy or similar regulations imposing a fiduciary duty.

In January 2013, Mississippi considered a law requiring PBMs to "operate to the best interest of the patient or citizen of Mississippi, including costs related to the patient or citizen." Likewise, New York is currently considering imposing heightened duties on PBMs, requiring PBMs to have a fiduciary relationship with a health plan, pass through all monies to a health plan other than fee or payment for services, account for all funds and provide access to all necessary information, disclose any relevant relationships, and not substitute or cause the substitution of prescription drugs.

Mississippi, however, rescinded its proposed fiduciary duty regulation after PCMA threatened a lawsuit, and it seems likely PCMA will oppose New York's proposal as well. Over thirty states have introduced bills imposing a fiduciary duty on PBMs over the past decade; however, no state has successfully passed such a regulation.

IV. PLAN SPONSORS: SELECT REGULATIONS

While no states currently have a law imposing a fiduciary duty on PBMs, some states have passed PBM regulations that benefit plan sponsors without reaching the level of a fiduciary duty. For example, several states require the PBM to perform its duties in good faith and fair dealing. Relatedly, some states require PBMs to disclose conflicts of interest to the plan sponsor. Select regulations benefiting plan sponsors are highlighted below. Note that this memorandum does not present an inclusive list of state regulations related to PBMs and plan sponsors. For example, in addition to the regulations listed below, some states have regulated the issue of mandatory mail order because of the increasing trend that members under a prescription plan use a mail order pharmacy. New York permits members under various types of health plans to fill their
prescriptions at either a mail order or retail pharmacy (within the plan’s network) as long as the retail pharmacy accepts a price comparable to the mail order pharmacy. 56

A. FORMULARY AND INTERCHANGE

Some state regulations include provisions addressing formulary and interchange requirements for PBMs contracting with plan sponsors. These regulations either place restrictions on establishing and making changes to the preferred list of drugs on a prescription plan, or set limitations on when and how PBMs can require drug substitutions. These regulations attempt to contain the costs of prescriptions and to prevent PBMs from failing to pass on drug savings to plan sponsors.

South Dakota’s regulation limits the ability of PBMs to require drug substitutions. 57 Under the regulation, PBMs may only request a drug substitution if the product is therapeutically equivalent and less expensive. Substitutions that are more expensive must only be for medical reasons. 58 Similarly, Maryland’s PBM regulation also requires therapeutic substitutions to be based on medical and scientific evidence. Maryland also requires members of the PBM’s formulary selection committee to disclose any conflicts of interests and requires a PBM to notify the plan sponsors of any formulary changes in a timely manner. 59 Vermont allows a PBM to substitute a drug with one that is more costly; however, requires the PBM to disclose to the plan sponsor the cost of both drugs, and to disclose any financial benefit the PBM received as a result of the substitution. 60 Additionally, Vermont requires PBMs to disclose to plan sponsors any arrangements for remuneration received from drug manufacturers relating to the formulary and drug-switch programs. 61

B. DRUG PRICING REQUIREMENTS

PBM drug pricing is another area that some states have regulated in response to concerns that PBMs were not passing all potential savings to plan sponsors. 62 Some of these state regulations are designed to help prevent “price spreading,” which allows PBMs to charge a plan sponsor for a drug, but pay a lower amount to the pharmacy that dispenses the drug and keep the difference. 63 In Maryland, PBMs must inform the plan sponsor that the terms agreed to in the PBM-plan sponsor contract determine whether the PBM passes through all drug savings to the plan sponsor or retains some or all of the drug savings. 64 Similarly in Vermont, PBMs must notify plan sponsors if they offer pass-through pricing. 65 North Dakota requires PBMs to give plan sponsors the option of deciding between paying the PBM under three different payment structures, including an option for payment with pass-through pricing. 66

Other state regulations focus on the reimbursement rates to pharmacies. Many different pricing formulas are available for PBMs to use when reimbursing pharmacies for drugs. The pricing standard the PBM uses may make it difficult for a plan sponsor to determine whether the calculated price accurately reflects the cost of the drug. 67 For plan sponsors with contracts requiring pass-through pricing, regulations that control pharmacy reimbursement rates can help plan sponsors understand drug pricing. For example, Alabama prohibits agreements between PBMs and pharmacies to establish reimbursement rates or procedures for members under a prescription plan that would be less than the “usual and customary rate” a non-member customer would pay for the same or similar service. 68 Mississippi requires PBMs to use a nationally recognized reference in calculating pricing when reimbursing pharmacies. 69 It also requires the PBM to update the reference every three days. 70 Although Tennessee does not require PBMs to use a nationally recognized reference, it requires the PBM to use the most current reference price. 71 And recently, Kentucky passed a law addressing contracts between a PBM and pharmacy. The law requires such contracts to include the sources that the PBM uses to calculate payment to the pharmacy. Moreover, contracts must include provisions requiring the PBM to identify the national drug pricing compendia or sources it uses to obtain drug pricing data for every drug the PBM establishes a maximum allowable cost. Contracts must also provide provisions allowing a pharmacy to appeal payments based on maximum allowable cost. 72

C. FEE ARRANGEMENT RIGHTS

PBMs utilize different fee arrangements based on whether the PBM passes through pricing to the plan sponsor. 73 Additionally, some PBMs stipulate a flat fee for all plan services, while others charge for different services individually. 74 Some states require a PBM to offer plan sponsors different options for the PBM’s payment structure. Regulations addressing payment structure are designed to ensure plan sponsors pay appropriate fees in relation to the agreed pricing arrangement. For example, in North Dakota, the payment options that PBMs provide plan sponsors specify whether payment will be primarily through transaction fees. 75 In Vermont, PBMs may only charge plan sponsors a reasonable fee, “which represents a competitive pharmacy benefit manager profit.” 76
D. AUDIT RIGHTS

A number of states give plan sponsors a right to information the PBM may otherwise deem proprietary. Historically, PBMs have claimed many critical components of a PBM contract, such as claims data or rebate information, as proprietary information and refused to share this information with the plan sponsor. These states give plan sponsors a statutory right to information that PBMs might not have granted to the plan sponsor under contract.

For example, in South Dakota, plan sponsors have a right to request information from the PBM. Under the law, plan sponsors may request information on all rebate revenues and other remuneration from pharmaceutical manufacturers. Additionally, plan sponsors are given a legal right to audit the PBM’s books with an independent auditor. Maryland also provides a higher level of transparency for plan sponsors. In Maryland, PBMs must inform the plan sponsor that it may receive manufacturer payments, and must offer a report outlining the amount of money that it receives from manufacturers. The PBM must also offer a report detailing its net revenue from all pharmacies within its network. Under the law, plan sponsors have a right to request this information prior to entering into a contract with the PBM.

North Dakota requires that PBM-plan sponsor contracts include a provision granting plan sponsors the right to audit “manager’s books, accounts, and records, including de-identified utilization information, as necessary . . .” to confirm the PBM is only retaining the money as entitled to under contract. Similarly in Vermont, PBMs must allow plan sponsors periodic access to any information necessary for plan sponsors to verify the plan’s pricing arrangement with an independent auditor. Vermont also allows plan sponsors to request all financial and utilization data relating to a prescription plan.

V. CONCLUSION

Less than half of the United States regulates PBMs, but states continue to propose new laws although they have faced barriers in successfully passing these regulations. Most of these regulations address fair auditing of pharmacies or require PBMs to register with the state. Several states have attempted to regulate PBMs to benefit plan sponsors, but regulations rising to the level of imposing a fiduciary duty have failed due to PBM intervention. While regulations not rising to the level of imposing a fiduciary duty have not faced the same legal challenges as the D.C. and Maine regulations, PBMs have been consistent in opposing attempts to regulate the PBM industry.

Although state regulations of PBMs exist, it is unclear whether these regulations are effective, particularly for plan sponsors. The question remains whether states actively enforce these regulations and to what degree. Also, there is a question of whether states with PBM regulations, but without a registration requirement, have the authority to enforce their regulations. Another area of uncertainty with existing state regulations is the extent of knowledge that plan sponsors have about their rights under their state laws. In particular, whether plan sponsors know what kind of information to request from PBMs or what information to look for to safeguard their interests.

Questions also remain with future state regulations of PBMs. For example, would more states pass PBM legislation if proposed regulations contained less stringent requirements? Most model regulations mirror Maine’s fiduciary duty law, however, states might be more successful in passing and upholding PBM regulations if regulations did not rise to the level of imposing a fiduciary duty. Similarly, determining the reasons why so many proposed regulations have failed, including any differences in statutory language or lobbying interventions by the PBM industry, may help future attempts to regulate PBMs. Further research in these areas can assist to clarify what types of state laws are effective in regulating PBMs and what types of regulations states may want to propose in regulating the PBM industry.
Table 1: States with PBM Regulations

[Map of the United States showing states with PBM regulations highlighted in blue.]
ENDNOTES


5 Garrett & Garis, supra note 3, at 62. See also Thomas O’Donnell & Mark Fendler, Prescription or Proscription? The General Failure of Attempts to Litigate and Legisl ate Against PBMs as “Fiduc iari es,” and the Role of Market Forces Allowing PBMs to Contain Private-Sector Prescription Drug Prices, 40 J. Health L. 205, 228, FN 112 (2007) (citing a letter from Senator Mark Montigny, Chair, Nat’l Legislative Ass’n on Prescription Drug Prices, to Deborah Platt Majoras, Chair, FTC (May 11, 2005)).

6 See generally Meador, supra note 2.


9 See, e.g., States Attorneys General v. Caremark, Inc., et al.; In re Pharmacy Benefit Managers Antitrust Litigation, 582 F.3d 432 (3d Cir. 2009).


15 See, e.g., O’Donnell & Fendler, supra note 5, at 224-25.

16 See NCPA, PBM Regulation, supra note 4.

17 Id.


19 Id.


27 Id.


32 See NCPA, PBM Regulation, supra note 4.


34 See O’Donnell & Fendler, supra note 5, at 229-30.


36 Id. at § 2699(2)(G) (repealed 2011).

37 D.C. Code § 48-832.01 (found to be preempted by Pharm. Care Mgmt. Ass’n v. Dist. of Columbia, 613 F.3d 179 (2010)).

38 D.C. Code §§ 48-831.01 to 42. See also O’Donnell & Fendler, supra note 5, at 231.

39 See, e.g., Pharm. Care Mgmt. Ass’n v. Rowe, 429 F.3d 294, 313 (1st Cir. 2005); Pharm. Care Mgmt Ass’n v. Dist. of Columbia, 613 F.3d 179, 184-90 (D.C. Cir. 2010). See also Letter from FTC Directors to Terry G. Kilgore, Va. H. D., Concerning PBM Regulation (Oct. 1, 2006) available at http://www.ftc.gov/bp/v060108.pdf (stating that a proposed Virginia bill imposing a fiduciary duty would likely increase PBM prices).

40 Id. at 230.

41 Id. at 226.

42 Pharm. Care Mgmt. Ass’n v. Rowe, 429 F.3d 294, 313 (1st Cir. 2005); Pharm. Care Mgmt Ass’n v. Dist. of Columbia, 613 F.3d 179, 184-90 (D.C. Cir. 2010).
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45 Id.

46 Shepherd, supra note 1, at 23 (noting Mississippi’s proposal in January 2013 requiring PBMs to act in the best interest of the patient).


49 See also Shepherd, supra note 1, at 23-24 (citing the Mississippi proposal).


53 See Shepherd, supra note 1, at 26.


56 These health plans include individual, group, and Medicaid managed care plans. See N.Y. Ins. Law §§ 4503 (c)(4) and (hh); §§ 5221 (k) (6)(D) and (l)(18); and N.Y. Soc. Serv. Law § 364-j(4) (u) (McKinney 2013).

57 S.D. Codified Laws § 58-29E-8 (West 2013).

58 Id.


61 Id.

62 See Clark, supra note 49, at 590.


68 Ala. Code § 34-23-115 (West 2013). Note that this statute does not apply to Alabama’s Medicaid program, the Public Education Employee’s Health Insurance Plan, and health plans organized under Title 10, Chapter 4, Article 6 (e.g., nonstock, nonprofit corporations). Ala. Code § 34-23-116 (West 2013).


70 Id. at § 73-21-155(2).


78 S.D. Codified Laws § 58-29E-4 (West 2013).

79 Id.

80 Id., § 58-29E-7.


82 Id.


85 Id. at § 9472(c)(1).


87 See Nat’l Cmty. Pharmacists Ass’n., Snapshot of State Regulation of PBMs, (last visited Apr. 18, 2013) available at http://www.ncpanet.org/pdf/leg/aug11/snapshot_pbm_state_reg.pdf (noting that many plan sponsors may not be familiar with what information to request, and also may not understand the information it receives).
