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NCSL Background Brief - 2007

State Legislation Affecting Pharmaceutical Benefit Managers (PBMs)

Updated February 5, 2007

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Pharmaceutical Benefit Managers or "PBMs" have emerged as major forces in the selection, sale and delivery of prescription drugs in the United States. They exert wide influence on which drugs are utilized and what they cost. They negotiate with and pressure drug makers to provide significant discounts or rebates in return for access to tens of millions of patients. Increasingly, they also help governments, insurers and major employers design and administer pharmacy benefits, and directly operate mail-order pharmacy services. A 2004 industry report estimates that "200 million people, or about 68 percent of the U.S. population, are in private plans with pharmacy benefit management." By 2006, with Medicare benefits provided by private health insurance plans, those numbers increased to about 217 million, or about 76 percent of the population.¹

During the past four years, a growing number of state legislatures have debated or considered proposed new laws to define and regulate the operation of PBMs. From 2001, when just three states had bills, to 2003 when the number grew to at least 22 states, these measures have become a relatively high-visibility part of the larger policy debate on prescription drugs.

As of December 2006, nine states plus the District of Columbia had enacted some type of state PBM regulation. These recent laws vary substantially in their design and requirements. In addition, two of the laws, in Maine and D.C. have been subject to separate federal District Court actions, pending final rulings in the future. A 2005 law in Montana, listed separately below, affects all companies that offer pharmacy discount cards, including PBMs, but is not aimed at the other PBM practices. A California bill passed the legislature but was vetoed by the Governor in September 2005.

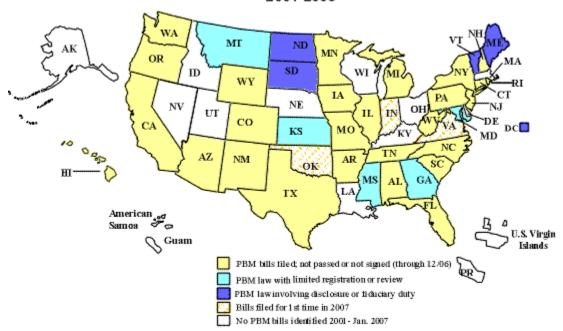
The tables below provide a snapshot and summary of the measures in law, and a few examples of non-enacted legislation from 2004-2006.

State Legislation for regulation of pharmaceutical benefit managers

YEAR	# Bills	States with PBM bills filed BOLD = Signed law; (//) = indirect regulation
2001	3	GA, NH, WV
2002:	8	AL, CA, <u>GA</u> , IL, IA, MD, MO, <u>VT</u>
2003:	22	AL, AR, CO, CT, FL, HI, IL, IA, KS, LA, <u>ME</u> , (<u>MD)</u> , MS, NJ, NM, OR, PA, TN, TX, VT, WA, WY
2004:	15	CA, CT, <u>DC</u> , FL, IL, IA, ME, MD, MI, MN, MS, NH, NY, <u>SD</u> , VT

2005:	13	AR, CA, CO, CT, FL, HI, IL, MN, (<u>MT)</u> , (<u>NM)</u> , NY, <u>ND</u> , PA, TX
2006:	28	AL, CA, CO, CT, DE, GA, HI, IL, IA, KS , MD, MN, (MS) , MO, NH, NJ, NM, NY, NC, OK, PA, RI, SC, TN, VT, VA, WA, WV
2007:		CT, IN, IA, MO, NH, OK, SC, VA, WA, WV (preliminary list as of 2/5/07)

State Legislation Regulating Pharmaceutical Benefit Managers (PBMs) 2001-2006



Data categories based on legislation filed 2001-2007, updated through February 6, 2007. C 2007 NCSL. Content of legislation varies widely; details available in NCSL's Annual "Prescription Drug State Legislation" reports.

SIGNED STATE LAWS REGULATING PBMs

SIGNED STATE LAWS REGULATING FEMILE		
State/District Bill# Sponsor	Description	
B15-569 Councilmember Catania	Enacts the Rx Access Act of 2003, requiring the Dept. of Health to run an AccessRx subsidy program. Also regulates PBMs, including establishing a legal "fiduciary duty" to any covered entity or customer, transparent business practices, pass through of payments and disclosure of rebates from manufacturers. (Filed 11/4/03; Passed City Council 3/24/04; signed by mayor as Act 15-410; passed the U.S. Congress 30-day review period; codified as D.C. Official Code Sec. 48-831.01] Update: On December 21, 2004, a preliminary injunction issued by the U.S. District Court blocked implementation; on 1/31/06 the D.C. Circuit Court returned the case to the District Court for reconsideration in light of the PCMA v. Rowe ruling favoring the Maine PBM law.)	
GA HB 585 Rep. Parham	Provides for the licensing and inspection of pharmacy benefit managers (PBMs), who would be "licensed to practice as a pharmacy." (Filed 2/14/01; passed House, 3/2/01; passed Senate 4/3/02; signed by governor, 5/22/02)	
KS SB 547 Fin. Inst. and Ins. Comm.	Requires all pharmacy benefits managers to obtain a valid certificate of registration, including a \$140 application fee, from the Commissioner of Insurance. A \$500 fine will be assessed to any PBM in violation of the registration requirement. Effective 4/27/06. (Filed 2/13/06; passed Senate 39y-1n, 2/28/06; passed House 122y-0n, 3/24/06; signed into law by governor 4/20/06)	
ME LD 554/ SP 194 Sen. Treat	Regulates the practices of pharmacy benefit mangers (PBMs) to ensure full disclosure of contracted activities including contractual financial terms that apply between a pharmacy benefit manger and a drug manufacturer. It also would require that benefits of special drug pricing deals negotiated by these companies would be passed through to consumers and not	

simply used to as company profits. It also clarifies that violations of law regarding these issues are violations of the Maine Unfair Trade Practices Act and are enforceable by private action or the attorney general. (Filed 2/6/03; passed Senate and House; signed by governor as Chapter 456, 6/13/03) **Update:** On March 9, 2004, a decision by the U.S. District Court in Maine temporarily blocked the implementation by issuing a preliminary injunction of LD 554. On Feb. 2, 2005 US District Magistrate Judge Kravchuk upheld the Maine law and lifted the injunction effective April 13, 2005. On July 6, 2005 the U.S. First Circuit denied PCMA's Motion for Stay Pending Appeal in this case; the District Court reaffirmed its ruling later in 2005. In 2006 the U.S. Supreme Court declined) MD Requires the MD Insurance Department to conduct an examination of any pharmaceutical HB 410 benefit manager (PBM) acting as a private review agent, conducting utilization reviews Del. Goldwater affecting enrollees of a health insurer, nonprofit health service plan, HMO or other provider or administrator of health care services. (Filed 2/5/03; passed House and Senate; signed by governor as Chapter 298, 5/13/03) MS Creates the "Pharmacy Benefit Prompt Pay Act," regulating claims paid by pharmacy benefits **HB 542** managers. Provides definitions to require the use of the most current nationally recognized reference price by pharmacy benefit managers; requiring PBMs to update such prices at least Rep. Warren every three business days; requiring payments by pharmacy benefit management plans to be made within 15 days if in electronic format and within 35 days if in paper format; providing for administrative penalties to be assessed by the state board of pharmacy against pharmacy benefit managers who fail to comply with prompt pay provisions; requiring financial statements to be made by PBMs with the commissioner of insurance and the state board of pharmacy. (Filed and referred to committee 1/9/06; passed House, 1/26/06; passed Senate, 3/8/06; signed into law by governor 3/27/06) Establishes regulation of pharmacy benefit managers (PBMs), including requiring a certificate ND HB 1332 of authority, and disclosure and transparency provisions including state examination of Rep. N. Johnson contracts and contract options allowing pass-through of rebates and discounts. (Filed 1/10/05; passed House 2/17/05; passed Senate 3/30/05; signed by governor 5/4/05) SD Provides for the regulation of pharmacy benefits management (PBMs), including licensing, HB 1311 "exercising good faith and fair dealing" toward covered entities including health plans. Governor employers, state agencies and others providing Rx coverage. Entities contracting with a PBM may request disclose to the covered entity, the amount of all rebates and other revenues received from pharmaceutical manufacturers, and may obtain an audit of PBM records regarding such transactions. PBMs must treat utilization information as confidential. (Filed and sent to committee 1/28/04; passed House 2/12/04; passed Senate 2/24/04; signed by governor 3/9/04)

INDIRECT REGULATION OF CERTAIN PBMs

FL HB 581, SB 1122 Rep. Proctor, Sen. Saunders	Requires third-party liability administrators and pharmacy benefits managers (PBMs) to provide records and information to the state agency relating to payments on behalf of Medicaid-eligible persons. (Filed 1/28/05; favorable reports; SB 1122 passed Senate 4/21/05; signed by governor as Chapter No. 2005-140, 6/3/05)
MT SB 380 Sen. Pres. Tester	Regulates medical care discount cards and pharmacy discount cards, including requiring registration and corporate financial disclosure by card sponsors, which include PBMs. (Filed 2/4/05; passed Senate 48y-2n, 2/22/05; passed House 98y-2n; signed by governor 4/28/05)
NM HJM 98 Rep. Trujillo	Non-binding resolution, requests creation of a task force to study the need for oversight and regulation of the PBM industry. (<u>Passed House</u> 33y-0n; <u>passed Senate</u> 29y-8n; <u>signed</u> 2005)
VT H.31 of 2002 Rep. Koch; Sen. Shumlin	Establishes a Healthy Vermont Prescription Discount and multi-faceted pharmaceutical requirements. Establishes detailed disclosure and financial reporting requirements for any PBMs that contract with the state. Requires annual report including: (1) a description of the activities of the pharmacy benefit manager; (2) an analysis of the success of the pharmacy benefit manager in achieving each of the department's public policy goals, together with the pharmacy benefit manager's report of its activities and achievements.

- (3) a fiscal report on the state fiscal costs and savings to Vermont of the pharmacy benefit manager contract, including an accounting of any payments, fees, offsets, savings and other financial transactions or accountings;
- (4) any recommendations for enhancing the benefits of the pharmacy benefit manager contract, and an identification of, and any recommendations for minimizing any problems with the contract

(H.31 <u>Passed House</u> 4/25/01; <u>Senate substituted & passed S.269</u> 2/21/02; <u>signed by governor</u> 6/13/02) |

EXAMPLES OF 2004-06 BILLS THAT PASSED ONE CHAMBER OR WERE VETOED

CA AB 1960 (2004) Assm. Pavley	Defines the term "pharmacy benefits management" (PBM) as negotiating the purchase of drugs on behalf of specified entities and administering or managing the prescription drug benefit programs. Requires disclosures of rebates, discounts and other revenue from manufacturers, to purchasers and prospective purchasers of services. Would also impose a fiduciary duty to the person employing or contracting with the PBM. Prohibits medication substitution by the PBM unless patient is given advance notification and consumer protection details. (Filed 2/12/04; passed Assembly 5/26/04; passed Senate 23y-19n, 8/25/04; vetoed by governor 9/29/04)
CA AB 78 Assm. Pavley (2005)	Would require a pharmacy benefits manager to disclose financial and contractual details to purchasers using the PBM services. Disclosure is required only upon written request from the purchaser; the PBM may include a provision requiring disclosed information to remain confidential and proprietary. Authorized disclosure requests include total amounts of rebates and other discounts that the PBM receives from each pharmaceutical manufacturer for drugs specified in contract; the "nature, type and amount of all revenues" the PBM receives from manufacturers for any other products or services; any aggregate drug utilization data for the purchaser's enrollees; any financial arrangements with prescribing providers, pharmacists or others associated with activities "to encourage formulary compliance." Exempts health insurers and state-run programs. (Deleted from original bill) Would require a PBM to make disclosures to its prospective purchasers, and to make specified disclosures to the public upon request. Would impose requirements on the membership of a pharmacy and therapeutics committee for a PBM, and require a pharmacy benefits manager to meet conditions before substituting a prescribed medication. (Filed 1/18/05; passed Assembly 44y-34n; passed Senate 23y-14n 9/6/05; vetoed by governor 9/29/05; consideration of governor's veto dropped, 2/23/06)
CO SB 06-164 Sen. Keller	Would require a pharmacy benefits manager to disclose any conflicts of interest to a covered entity; would prohibit a pharmacy benefits manager from requiring a pharmacist to participate in one contract as a requirement to participate in another contract; would require periodic audits; would make the information disclosed to a covered entity a trade secret. (Filed and referred to committee 1/30/06; passed Senate 21y-13n, 2/27/06; did not pass House committee by end of session 3/20/06)
CT SB 111	Would regulate pharmacy benefit management companies, requiring an annual license from the Insurance Commission, a license to practice pharmacy, financial statements, approval of contracts, and cannot discriminate when contracting with pharmacies on the basis of copayments or days of supply. (Filed 2/11/04; passed Senate 4/22/04; did not pass by end of regular session 5/5/04)
HI HB 31 Rep. Takumi	Would require transparency in pharmacy benefit managers (PBMs), including that purchasers "may request that any pharmacy benefits manager "disclose to the covered entity the amount of all rebate revenues and the nature, type, and amounts of all other revenues" the PBM receives from each pharmaceutical manufacturer, at least annually. Includes the right to obtain annual audits of the PBM, with the PBMs' "confidential and proprietary information" included but protected from further use or distribution. NOTE: Final versions delayed the effective date for 45 years, until 2050, but could be changed in a conference committee. (Filed 1/20/05; passed House; passed Senate 4/12/05; conferees appointed 4/18/05; did not pass Conference Comm. by end of regular session 5/5/05; carried-over to 2006 session)
MD HB 397 (2004) Del. Goldwater	Would require pharmacy benefits managers (PBMs) to register with the secretary of Health and Mental Hygiene; requires an applicant to file an application, submit required documents, and pay an application fee; authorizes the secretary to suspend or revoke a registration or deny an application under specified circumstances.

	(Filed 1/29/04; passed House 3/19/04; did not pass Senate 4/9/04)
MD HB 1058 (2005) Del. Rudolph	Would create the Pharmacy Benefits Managers (PBM) Regulation Act of 2005. Would prohibit PBMs from imposing a different reimbursement, co-payment, deductible, limit on quantity, or other conditions on retail than on mail order. (Filed 1/11/05; passed House 3/17/05; did not pass Senate committee by end of session 3/29/05)
TX HB 2145 Rep. Hupp	Would make it illegal for any pharmacy, pharmacist or PBM to change a drug dispensed without the approval of the prescribing health care practitioner, for any state-coordinated public employee benefit program, but would allow generic substitution. Senate amendments added: PBM audit language included in SB 1845; Amendment 2 by Van de Putte codified some of the lawsuit settlement language between Medco and Attorney General Abbott to make it apply to PBM contracts (involves drug-switching practices) (Filed 3/14/05; passed House 5/9/05; passed Senate 31y-0n, 5/25/05; final conference report did not pass by end of regular session 5/28/05)

¹ - "The Value of Pharmacy Benefit Management and the National Cost Impact of Proposed PBM Legislation. Prepared for PCMA by PriceWaterhouseCoopers, July 2004.

NOTE: For updates on bill status and live links, see complete 2005 and 2006 report sat http://www.ncsl.org/programs/health/drugdisc05.htm and http://www.ncsl.org/programs/health/drugdisc05.htm

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