HB 1058

Department of Legislative Services

Maryland General Assembly
2005 Session

FISCAL AND POLICY NOTE
Revised

House Bill 1058 (Delegate Rudolph, *et al.*)
Health and Government Operations Finance

Pharmacy Benefits Managers Regulation Act of 2005

This bill establishes a regulatory scheme for, and imposes certain practice standards on, Pharmacy Benefits Managers (PBMs).

Fiscal Summary

State Effect: Maryland Insurance Administration (MIA) special fund expenditures could increase by $48,000 in FY 2006. MIA special fund revenues could increase by a minimal amount beginning in FY 2006. Board of Pharmacy special fund revenues and expenditures could each increase by a significant amount, beginning in FY 2006. Any effect on prescription drug prices cannot be reliably estimated at this time.

(in dollars)	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010
SF Revenue	-	-	-	-	-
SF Expenditure	48,000	58,800	62,300	66,100	70,100
Net Effect	($48,000)	($58,800)	($62,300)	($66,100)	($70,100)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate effect

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary: The bill's provisions do not apply to a health insurer, nonprofit health service plan, or HMO (carrier) if the carrier directly offers PBM services and these services are provided only to enrollees who are also covered by health benefits. The bill does not apply to Medicaid managed care organizations (MCOs).

Registration: The bill requires a person to register with the Insurance Commissioner before a person may act as or represent itself to be a PBM in the State. The person must submit an application and registration fee, and the Insurance Commissioner must requester each applicant that meets the requirements established by regulation. The registration is effective for two years. A carrier may not enter into an agreement with an unregistered PBM.

The bill specifies prohibited acts, such as violating the bill's provisions, any applicable regulations, or failing to meet registration requirements. The Insurance Commissioner may deny a registration or refuse to renew, suspend, or revoke a registration.

A PBM must register with the Insurance Commissioner as a third-party administrator (TPA) if the PBM processes prescription drug claims or administers payments related to claims. A PBM that conducts utilization review must be registered as a private review agent (PRA).

When considered advisable, the Insurance Commissioner may examine the affairs, transactions, accounts, records, and assets of each PBM. A PBM must maintain adequate books and records.

A PBM that is currently operating in the State must register with the Insurance Commissioner by September 1, 2006.

PBM Disclosure Requirements: A PBM must disclose to prospective purchasers: (1) the amount of all rebates, administrative fees, and other payments and discounts; (2) the nature, type, and amount of all other revenue the PBM would receive from manufacturers or labelers in connection with drug benefits provided to the purchasers; (3) any administrative or other fees charged to the purchaser; (4) any arrangements with prescribing providers, medical groups, and other persons to encourage formulary compliance; and (5) a list of any drugs the PBM repackaged and assigned new or different national drug code numbers. A PBM must disclose similar information at least quarterly to a purchaser. A PBM must also disclose a list of prescriptions for which there was a price differential between the retail price paid and the amount billed to the purchaser.

Other than utilization information, a PBM does not need to make these disclosures unless and until the prospective purchaser or purchaser agrees in writing to maintain as confidential any proprietary information disclosed by the PBM.

The bill specifies terms that must be included in contracts for PBM services.

Drug Substitutions: A PBM may not substitute another prescription drug for the drug originally prescribed unless: (1) the substitution is made for medical reasons that benefit the beneficiary; or (2) the substitution results in financial savings and benefits to the purchaser. If a substitution is made, the PBM must disclose to the purchaser any benefit or payment received in any form by the PBM. A PBM must obtain authorization from a prescriber to substitute a prescription drug and disclose to the prescriber specified cost and reimbursement information. The bill specifies membership for a PBM's pharmacy and therapeutics committee.

A PBM must permit a beneficiary to obtain covered pharmacy services from the pharmacy provider of choice within the PBM's network. It must permit a retail or institutional pharmacy to fill orders if it meets the same terms and conditions as a mail order pharmacy. It may not require a beneficiary to use a mail order service.

Penalties: The Insurance Commissioner may asses a civil penalty not exceeding $10,000 against any person that violates these provisions.

Nonresident Pharmacy: A PBM located within or outside the State that is regulated under the PBM registration requirements is considered a nonresident pharmacy if it ships, mails, or delivers drugs or devices to a person in the State pursuant to a prescription. A PBM employee or contractor must be licensed to practice pharmacy if the employee or contractor practices pharmacy for or on behalf of the nonresident pharmacy.

Current Law: Chapter 323 of 2000 provided for the regulation of HMO downstream risk arrangements. PBMs that conduct utilization review are required to be registered with the Maryland Insurance Administration as an administrative service provider.

Background: PBMs are businesses that administer and manage prescription drug benefit plans for a variety of organizations. More than 100 PBMs operate in the U.S., but the industry is dominated by three: Caremark (100 million people covered); Medco (65 million); and Express Scripts, Inc (40 million). PBMs manage an estimated 71% of the total volume of prescription drugs dispensed through retail pharmacies that are covered by private third-party payors.

One study indicates that using PBM services can decrease drug costs for a health plan by up to 30%. A 2003 U.S. General Accounting Office report indicated that PBMs in the federal employees' health plans saved the federal health plan an average of 18% on brand-named drugs and 47% on generics.

PBMs earn most of their revenues in three ways: (1) receiving a fee for the administrative tasks they perform; (2) negotiating discounts and rebates from drug manufacturers by including a company's drugs on a preferred drug list and obtaining a

greater market share for the company's drug; and (3) through the operation of mail-order prescription drug companies.

Concerns have been raised by several states regarding the business practices of PBMs nationwide. Specifically, demands for greater transparency in the financial relationships between PBMs and drug manufacturers have prompted several states to propose bills regulating PBM activities. Maine passed comprehensive legislation in 2003, and Washington, DC and South Dakota passed PBM regulatory laws in 2004.

State Expenditures: To the extent the bill erodes a PBM's ability to contain costs, expenditures for the State Employee and Retiree Health and Welfare Benefit Plan (State plan) could increase. Limitations on drug substitution and restrictions on the use of mail order pharmacy services could increase State plan expenditures. The extent of any increase cannot be reliably determined at this time.

Maryland Insurance Administration

MIA special fund expenditures would increase by $48,028 in fiscal 2006, which accounts for the bill's October 1, 2005 effective date This estimate reflects the cost of hiring one MIA analyst to process and review registration applications, issue registrations, and monitor PBM compliance with the bill's requirements. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Salary and Fringe Benefits	$42,622
Operating Expenses	5,406
Total FY 2006 State Expenditures	**$48,028**

Future year expenditures reflect: (1) full salary with 4.6% annual increases and 3% employee turnover; and (2) 1% annual increases in ongoing operating expenses.

Board of Pharmacy

Board of Pharmacy special fund expenditures could increase by a significant amount beginning in fiscal 2006. The board would be required to issue nonresident permits to PBMs and license specified PBM staff as pharmacists. Depending on the number of new permits and licenses required, the board could require additional staff to process applications. In addition, complaints submitted to the board are expected to increase significantly as the board receives complaints from pharmacies, pharmacists, and plan enrollees about PBM practices. Depending on the increase in complaint volume, the board could require additional compliance and investigative staff. There are insufficient data at this time to reliably estimate the increase.

State Revenues: MIA special fund revenues could increase by a minimal amount from registration fees, which are not specified in the bill. It is unknown how many PBMs would apply for certification; however, there are only three major PBMs operating in the nation. Any increase in revenues is assumed to be minimal.

Board of Pharmacy special fund revenues could increase by a significant amount from licensure and permit fees, beginning in fiscal 2006. PBMs must obtain pharmacy permits, as well as ensure specified employees or contractors are licensed as pharmacists. The board currently charges $100 for a pharmacist license, $300 for a pharmacy permit, and $500 for a distributor license. There are insufficient data at this time to reliably estimate how many and what type of licenses would be issued.

The civil penalty provisions of this bill are not expected to significantly affect State finances or operations.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): *Pharmacy Regulation in Connecticut* (September 15, 2004), Connecticut General Assembly; Department of Health and Mental Hygiene (Board of Pharmacy); Maryland Insurance Administration; Department of Legislative Services

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