Department of Legislative Services
Maryland General Assembly
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FISCAL AND POLICY NOTE

Senate Bill 677 (Senator Klausmeier, *et al.*)
Finance

Pharmacy Benefits Managers Regulation Act

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 beginning in FY 2008 to the extent additional resources are required to regulate PBMs. MIA special fund revenues could increase by a minimal amount beginning in FY 2008 from registration fees and rate and form filing fees. Board of Pharmacy special fund revenues and expenditures potentially could increase by a significant amount, beginning in FY 2008. Any effect on the State Employee and Retiree Health and Welfare Benefit Program (State plan) cannot be reliably estimated at this time.

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.

Registration: The bill requires a person to register with the Insurance Commissioner before the person may act as or represent itself to be a PBM in the State. The person

must submit an application and pay a registration fee, and the Insurance Commissioner must register 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 and any applicable regulations. 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 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.

When considered advisable, the Insurance Commissioner may examine the affairs, transactions, accounts, records, and assets of each PBM at the expense of the 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, 2008.

PBM Disclosure Requirements: A PBM must disclose to each "prospective purchaser": (1) the amount of all rebates, administrative fees, and other payments and discounts it would receive specific to the prospective purchaser; (2) the nature, type, and amount of all other revenues the PBM would receive from manufacturers or labelers specific to drug benefits provided to the purchaser; (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 detailed 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 price paid to a retail pharmacy 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.

Contracts and Pharmacy and Therapeutics Committee Membership: The bill specifies terms that must be included in contracts for PBM services and specifies membership for a PBM's pharmacy and therapeutics committee.

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 provides for an exception if the drug is no longer available or not covered by the beneficiary's formulary or plan. Upon written or verbal instructions from a prescriber, beneficiary, or a beneficiary's representative, a PBM must cancel and reverse a substitution, dispense the currently prescribed drug, and charge the beneficiary only one copayment. Exceptions are provided if the drug is no longer on the purchaser's formulary or the beneficiary is unwilling to pay a higher copayment or cost associated with the prescribed drug. A PBM must maintain a toll-free telephone number at all times for prescribers, pharmacy providers, and beneficiaries.

Retail, Institutional, and Mail-order Pharmacies: A PBM must allow a beneficiary to obtain covered pharmacy services from the pharmacy provider of choice within the PBM's network. If a retail or institutional pharmacy meets the same terms and conditions as a mail-order pharmacy, a PBM must allow a retail or institutional pharmacy to fill orders and may not require a beneficiary to use a mail-order service. A PBM is prohibited from using any disincentives or penalties to discourage use of retail or institutional pharmacies or limiting the quantity of drugs that a beneficiary can obtain at any one time unless the limitation is applied uniformly to all providers in the PBM's network.

Audits of Pharmacies: A PBM may only audit claims that have been requested for auditing and may not require extrapolation audits as a condition of participation in the PBM's network. A PBM is prohibited from recouping by setoff any moneys that the PBM contends are due as a result of an audit until the pharmacy has the opportunity to review and concur with the audit findings. The Insurance Commissioner must review any audits for which the PBM and a pharmacy cannot agree on the amount due.

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. Nonresident pharmacies must obtain a pharmacy permit from the Board of Pharmacy. A PBM employee or contractor must be licensed to practice pharmacy in Maryland if the employee or contractor practices pharmacy for or on behalf of the nonresident pharmacy.

Current Law: Chapter 323 of 2000 provides for the regulation of HMO downstream risk arrangements. PBMs that conduct utilization review are required to be registered with MIA as a private review agent.

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 Revenues: MIA special fund revenues could increase beginning in fiscal 2008 from registration fees, which are not specified in the bill. It is unknown how many PBMs would apply for certification. There are three major PBMs operating in the nation, although nine PBMs bid for the State plan prescription drug contract for fiscal 2007. MIA special fund revenues could also increase from the $125 rate and form filing fee in fiscal 2008 to the extent carriers amend contracts to comply with the requirements of the bill. Any increase in revenues is assumed to be minimal.

Board of Pharmacy special fund revenues could increase, perhaps significantly, from licensure and permit fees beginning in fiscal 2008. 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.

State Expenditures:

Maryland Insurance Administration

MIA special fund expenditures could increase beginning in fiscal 2008 to the extent additional resources are needed to regulate PBMs. MIA notes that while the regulation of PBMs in itself does not require an additional position, the compounding effect of multiple registration and enforcement requirements may impose additional workload requirements beyond what MIA can handle with existing resources. The amount of additional resources required cannot be reliably estimated at this time.

Board of Pharmacy

Board of Pharmacy special fund expenditures could increase by a significant amount beginning in fiscal 2007. 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 Plan

The bill's restrictions on and the additional steps required for prescription drug substitutions could result in increased costs to the State plan, the extent of which cannot be reliably estimated at this time.

The bill's prohibition against using disincentives or penalties to discourage use of retail or institutional pharmacies compared with mail-order pharmacies, if a retail or institutional pharmacy meets the same terms and conditions as a mail-order pharmacy, could increase or decrease State plan expenditures. Mail-order copayments for the State plan are capped at $20, thus, there is a financial incentive for State plan members to use mail-order pharmacies. If the State plan were required to reduce retail and institutional pharmacy copayments to a maximum of $20, State plan expenditures could increase significantly beginning in fiscal 2008. If the $20 cap on mail-order copayments were removed, State plan expenditures could decrease by a minimal amount, while State plan

members would experience higher copayments. DBM indicates that the most likely scenario is that institutional and retail pharmacies will not be able to meet the same terms and conditions as mail-order pharmacies and no change will be needed regarding copayments under the State plan. In this case, this provision of the bill would have no fiscal impact on the State plan.

Additional Information

Prior Introductions: Substantially similar bills were introduced in 2005 and 2006. HB 1058 of 2005 passed the House but no action was taken in the Senate. HB 493 of 2006 had a hearing in the House Health and Government Operations Committee but no further action was taken.

Cross File: HB 734 (Delegates Rudolph and Elliott) – Health and Government Operations.

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

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