Department of Legislative Services

Maryland General Assembly
2008 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 723 (Senator Klausmeier, *et al.*)

Finance Health and Government Operations

Pharmacy Benefits Managers - Therapeutic Interchanges

This bill prohibits a pharmacy benefits manager from requesting a "therapeutic interchange" except under specified circumstances. The bill establishes procedures for therapeutic interchanges by PBMs.

Fiscal Summary

State Effect: Potential minimal increase in special fund expenditures for the Maryland Insurance Administration beginning in FY 2009 to ensure compliance with the bill.

Local Effect: None.

Small Business Effect: Minimal to none.

Analysis

Bill Summary: The bill does not apply to Medicaid managed care organizations.

Therapeutic interchange means any change from one prescription drug to another, excluding specified circumstances.

A PBM may only request a therapeutic interchange if it is for medical reasons that benefit the beneficiary or will result in financial savings and benefits to the purchaser or the beneficiary.

Before making a therapeutic interchange, a PBM or its agent must obtain authorization from a prescriber or an individual authorized by the prescriber and make specified disclosures to the prescriber. When soliciting a therapeutic interchange from a prescriber, a PBM may not make a claim that the therapeutic interchange will save the purchaser money unless the claim can be substantiated. If the PBM receives payment for making a therapeutic interchange that is not reflected in cost savings to the purchaser, the payment must be communicated to the prescriber at the time of the therapeutic interchange solicitation.

If a therapeutic interchange occurs, the PBM must make specified disclosures to the beneficiary and include with the new prescription drug dispensed a patient package insert about potential side effects and a toll-free number to communicate with the PBM.

A PBM must cancel and reverse a therapeutic interchange on written or verbal instructions from a prescriber, the beneficiary, or the beneficiary's representative. If a therapeutic interchange is reversed, the PBM must obtain a prescription for and dispense the originally prescribed drug and charge the beneficiary no more than one copayment. A PBM may not be required to cancel and reverse a therapeutic interchange if the beneficiary is unwilling to pay a higher copayment or coinsurance.

Under specified circumstances regarding a therapeutic interchange through a mail order pharmacy, a PBM must provide an appropriate quantity of replacement prescription drugs at a local community pharmacy at no additional cost to the beneficiary.

A PBM must maintain a toll-free telephone number for prescribers, pharmacy providers, and beneficiaries and establish appropriate policies and procedures to implement the requirements of the bill.

All disclosures made under the bill must comply with the privacy standards of the federal Health Insurance Portability and Accountability Act.

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 United States, but the industry is dominated by three – CVS Caremark; Express Scripts; and Medco. Approximately 95% of all patients with prescription drug coverage receive benefits through a PBM. PBMs manage an estimated 70% of prescription drugs dispensed through retail pharmacies that are covered by private third-party payors.

PBMs earn most of their revenues in three ways: • receiving a fee for administrative tasks; • 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 • operating mail-order prescription drug companies.

Regulation of PBMs in Other States: Concerns have been raised by consumer organizations and several states regarding the business practices of PBMs. Specifically, demands for greater transparency in financial relationships between PBMs and drug manufacturers have prompted states to propose regulation of PBM activities.

Since 2003, 36 states and the District of Columbia have introduced legislation to regulate PBMs including transparency and financial disclosure requirements and licensure and certification requirements. Kansas requires registration of PBMs with the state insurance department. North Dakota requires licensure and financial disclosure. Maine, South Dakota, Vermont, and the District of Columbia require disclosure of financial relationships. California passed legislation requiring registration of PBMs and financial disclosure, but the bill was vetoed by the Governor in 2005.

State Expenditures: MIA special fund expenditures could increase beginning in fiscal 2009 to ensure that PBMs are in compliance with the bill's requirements and, to the extent that complaints about PBMs increase, for the Market Conduct Unit to investigate. The amount of any increase cannot be reliably estimated at this time but is expected to be minimal.

Additional Information

Prior Introductions: Similar provisions, in addition to other regulatory requirements relating to PBMs, were included in SB 677/HB 734 of 2007. No action was taken on either bill by the Senate Finance or House Health and Government Operations committees.

Cross File: HB 343 (Delegate Kipke, *et al.*) – Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene, Maryland Insurance Administration, Department of Budget and Management, Department of Legislative Services

Fiscal Note History: First Reader - March 6, 2008
ncs/ljm Revised - Senate Third Reader - April 1, 2008
Revised - Enrolled Bill - May 2, 2008

Analysis by: Jennifer B. Chasse

Direct Inquiries to:
(410) 946-5510
(301) 970-5510