Department of Legislative Services

Maryland General Assembly
2004 Session

FISCAL AND POLICY NOTE

House Bill 840 (Delegate Rudolph)
Health and Government Operations

Pharmacy Benefits Managers

This bill imposes certain practice standards on Pharmacy Benefits Managers (PBMs).

Fiscal Summary

State Effect: Potential significant expenditure increases in the State Employee and Retiree Health and Welfare Benefit Plan, beginning in FY 2005. No effect on revenues.

Local Effect: Expenditures for local government employee health benefits could increase if carriers raise their premiums as a result of the bill's requirements. Revenues would not be affected.

Small Business Effect: Potential minimal. Expenditures for small business health benefits could increase if carriers raise their premiums as a result of the bill's requirements.

Analysis

Bill Summary: This bill requires a PBM to discharge its duties solely in the interests of health plan members and for the primary purpose of providing benefits to members and defraying reasonable costs of administering health benefit plans. A PBM must notify a member in writing of any practice that is a conflict of interest with the bill's provisions. It must provide to a carrier all financial and utilization information relating to the provision of benefits and services to members and the carrier.

The bill places limitations on when a PBM may substitute drugs for those prescribed. A PBM may substitute a lower-priced generic drug for a higher-priced prescribed drug, but

cannot substitute a higher-priced drug for a lower-priced drug. The PBM must consult with the prescriber with regard to the drug substitution and obtain the prescriber's approval for the drug substitution. The PBM must disclose the costs of both drugs to the member and the carrier and any benefit or payment accruing to the PBM from the substitution. The PBM must transfer to the carrier or member any benefit or payment received as a result of the drug substitution. If the PBM derived any benefit for dispensing prescription drugs based on volume of sales or drug classes or brands, it must give the benefit to the carrier or member. A PBM must disclose to the carrier all financial terms and arrangements for remuneration that apply between the PBM and a drug manufacturer or labeler.

A PBM may not accept or agree to an obligation in a contract with a carrier, drug manufacturer, or labeler that is inconsistent with the fiduciary duties imposed by State or federal law. Any agreement to waive the bill's provisions is against public policy and void. Any person who violates the bill's provisions may be subject to an injunction and a civil fine up to $10,000 per violation, plus legal fees.

The bill's provisions do not apply to PBMs that provide services to Medicaid managed care organizations (MCOs).

Current Law: Chapter 323 of 2000 established 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:

A PBM's Fiduciary Role: Currently, a variety of federal law suits against PBMs are claiming that PBMs are fiduciaries under the federal Employee Retirement Income Security Act of 1974 (ERISA). ERISA governs employee health benefit plans by imposing a variety of reporting and disclosure requirements on benefit plan administrators. In addition, it imposes certain fiduciary duties on plan administrators and provides appropriate remedies and sanctions in the federal courts when these responsibilities have been breached. In general, the employer is the fiduciary, regardless of whether another fiduciary has been appointed.

Generally, a fiduciary is a person or institution who manages money or property for another, such as a trustee, executor of estate, or guardian, and who must exercise a standard of care imposed by law or contract. A fiduciary has a duty to act primarily for another's benefit, while subordinating his or her personal interests to that of the other person. Under ERISA, a person who lacks the power to make any decisions about plan policy, interpretations, practices, or procedures and who performs only ministerial duties is not a fiduciary.

The core issue in ongoing litigation is whether PBMs are fiduciaries under ERISA, and if so, then whether PBMs have breached their fiduciary duty by accepting hidden revenues from drug manufacturers, substituting higher-priced drugs in order to obtain a higher share of negotiated rebates, and creating price spreads between what a PBM pays a pharmacy and what they charge the employer for a particular drug. To date, no court has ruled that a PBM is a fiduciary under ERISA.

PBM Industry: The first PBM, Pharmaceutical Card System (PCS), was created in 1969. From 1969 until the late 1980s, PBMs simply administered prescription claims payments. In the late 1980s, PBMs began providing online claims adjudication. Since the mid-1990s, PBMs have become involved in utilization review, formulary development, disease management programs, and a number of other practices that many perceive as practicing medicine, practicing pharmacy, or engaging in the business of insurance. They have done this without traditional state regulation imposed on pharmacists, doctors, and insurers in order to protect patients. Some PBM practices of concern are failing to return negotiated discounts to the consumers, failing to make prompt payment for claims, designing formularies based on manufacturer rebates rather than clinical effectiveness, restricting consumer access to only participating pharmacies, and requiring mail order prescriptions.

In 2003, Maine passed a law similar to this bill, imposing a fiduciary duty on PBMs to their clients; requiring disclosure of all discount, pricing, and rebate arrangements with manufacturers; limiting drug switching; and passing all discounts and rebates on to the covered entity.

More than 100 PBMs operate in the U.S., but the industry is dominated by four: AdvancePCS (75 million people covered); Medco (65 million); Express Scripts, Inc (40 million); and Caremark Rx, Inc. (20 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 on average 18% off brand-named drugs and 47% off generics.

PBMs save money for health plans by directing prescribers toward less-expensive brand-named medications and generic treatments through drug formularies. Drug manufacturers would offer PBMs discounts and rebates to have their drugs placed on the formularies, and PBMs would share the discounts with their clients. In the past few years, however, competition among PBMs has driven down the rates that they can charge

clients to process claims from about $1 per claim in 1992 to between 20 cents and 30 cents per claim in 2002. As a result, PBMs generate significant revenue from brand-named drug makers instead.

State Fiscal Effect:

State Employee and Retiree Health and Welfare Benefit Plan (State plan) Prescription Drug Expenditures: Prescription drug expenditures for the State plan could increase by a significant amount, beginning in fiscal 2005. The bill's various provisions could both increase and decrease prescription drug expenditures for health benefit plans. The bill requires a PBM to pass on to a health benefit plan in full all benefits or payments derived from drug substitutions and volume sales. These provisions would reduce prescription drug expenditures for the State plan, potentially by a significant amount.

However, other provisions in the bill could significantly increase costs, outweighing any initial savings. Most PBMs depend on price, discount, and rebate negotiations with drug manufacturers to both produce savings for covered entities and realize a profit for themselves. To the extent the bill's disclosure requirements erode a PBM's ability to keep its negotiated prices with drug manufacturers private, drug manufacturers could increase drug costs, which would then be passed onto covered entities such as the State. In addition, the bill's provisions imposing certain fiduciary duties and prohibiting certain price negotiations with manufacturers could substantially change the way PBMs must do business, either discouraging them from doing business with covered entities in the State, or requiring them to charge higher administrative fees to covered entities to fully cover costs for administrative services.

For illustrative purposes only, if the bill's provisions increased drug spending in the State plan by 5%, expenditures could increase by as much as $11.2 million total funds in fiscal 2005. Projected fiscal 2005 prescription drug expenditures are $223.7 million in the State plan.

State plan expenditures assume a fund mix of 60% general funds, 20% federal funds, and 20% special funds; and 20% of expenditures are reimbursable through employee contributions.

The civil penalty provisions of this bill are not expected to significantly affect State revenues.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): *Wall Street Journal* (August 12, 2002); *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* (January 10, 2003) U.S. General Accounting Office; *Daily Health Policy Report* (January 16, 2004); *BenefitNews.com* (November 2003); Kaiser Family Foundation; *Cost Estimate for H.R. 1, the Medicare Prescription Drug and Modernization Act of 2003* (July 22, 2003); U.S. Congressional Budget Office; Department of Health and Mental Hygiene (Medicaid, Boards and Commissions); Maryland Insurance Administration; Department of Legislative Services

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