HB 374

Department of Legislative Services

Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
Enrolled - Revised

House Bill 374 (Delegate Kipke, *et al.*)

Health and Government Operations Finance

Health Insurance – Pharmacy Benefits Managers – Audits of Pharmacies and Pharmacists

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This bill establishes additional requirements and restrictions regarding the pharmacy audit process on pharmacy benefits managers (PBMs) that provide pharmacy benefits management services on behalf of carriers and authorizes those PBMs to conduct an audit through an auditing entity. The Secretary of Health must adopt regulations for PBMs that contract with Medicaid managed care organizations (MCOs) for conducting audits of pharmacies or pharmacists, as specified. **The bill takes effect January 1, 2024, and, except as specified, applies to an audit of a pharmacy or pharmacist under contract with a PBM performed on or after that date.**

Fiscal Summary

State Effect: To the extent that the regulations adopted by the Secretary increase the cost of PBM contracts for MCOs, Medicaid expenditures (and federal matching fund revenues) increase by an indeterminate amount, as discussed below. Expenditures (general, federal, and special funds) for the State Employee and Retiree Health and Welfare Benefits Program (State Plan) also increase if PBMs incur costs that are passed on to purchasers, as discussed below. Any additional workload on the Maryland Insurance Administration (MIA) can be handled with existing budgeted resources. MIA revenues are not affected.

Local Effect: To the extent health insurance costs increase as a result of the bill, health care expenditures for local governments that purchase fully insured health benefit plans may increase. Revenues are not affected.

Small Business Effect: Meaningful.

Analysis

Bill Summary/Current Law: A PBM is a business that administers and manages prescription drug benefit plans for purchasers. A PBM must register with MIA prior to providing pharmacy benefits management services. The Insurance Commissioner is authorized to examine the affairs, transactions, accounts, and records of a registered PBM at the PBM's expense.

Pharmacy Audits

When conducting an audit of a pharmacy or pharmacist under contract with the PBM, the PBM must follow specified procedures and requirements. These procedures and requirements apply only to a PBM that provides pharmacy benefits management services on behalf of a carrier. These provisions do not apply to PBMs providing services on behalf of plans subject to the federal Employee Retirement Income Security Act of 1974 (ERISA) or PBMs that contract with MCOs.

Under the bill, the Secretary must adopt regulations for PBMs that contract with MCOs that establish requirements for conducting audits of pharmacies or pharmacists that are (1) to the extent practicable, substantively similar to the audit provisions applicable to PBMs that provide pharmacy benefits management services on behalf of a carrier and (2) consistent with federal law.

While under current law an audit must be conducted by a PBM itself, the bill authorizes a PBM to conduct an audit through an auditing entity.

Audit Procedures

Under current law, when conducting an audit of a pharmacy or pharmacist, a PBM may only audit claims submitted or adjudicated within the two-year period immediately preceding the audit, unless a longer period is permitted under federal or State law. For an on-site audit, the PBM must provide written notice to a pharmacy or pharmacist at least two weeks before initiating the audit and may not schedule an audit to begin during the first five calendar days of a month, unless requested by the pharmacy. Under current law, a PBM must also:

- employ the services of a pharmacist if an audit requires the clinical or professional judgment of a pharmacist;
- permit its auditors to enter the prescription area of a pharmacy only when accompanied by or authorized by a pharmacy staff member;

- allow a pharmacist or pharmacy to use any prescription (or authorized change to a prescription) that meets specified requirements to validate claims submitted for reimbursement for dispensing of original and refill prescriptions;
- allow a pharmacy or pharmacist to use the written or electronically transmitted records of a hospital, physician, or authorized prescriber to validate the pharmacy record with respect to orders or refills of a drug;
- audit each pharmacy and pharmacist using the same standards and parameters as used for others similarly situated; and
- avoid disrupting a pharmacy's provision of services to customers.

In addition to meeting the audit procedures and requirements specified above, the bill requires a PBM to accept a completed cash register transaction as proof of delivery or pickup for a pharmacy customer, unless there is contradictory information. A PBM is prohibited from doing the following:

- auditing more than 125 prescriptions during a desk or site audit; or
- auditing claims that were reversed or for which there was no remuneration by the purchaser or cost to the pharmacy customer, except if necessary to evaluate compliance to a contract.

Telephone Hotline: The bill requires a PBM to provide a pharmacy or pharmacist being audited with a phone number and, if available, access to a secure portal that can be used to ask questions regarding the audit. An individual who is familiar with the audit must respond to any inquiry made by the pharmacy or pharmacist via telephone or the secure portal within three business days after the inquiry was made.

Email and Fax Communications: The bill requires a PBM to give a pharmacy or pharmacist the option to provide requested audit documentation by mail, email, or facsimile. If a PBM or auditing entity requests a document during an audit, the PBM must provide a secure facsimile number and a mechanism for receiving secure emails.

Secure Electronic Communications: The bill requires, by October 1, 2025, that a PBM provide a mechanism for secure electronic communication for pharmacies and pharmacists to communicate with and submit documents to the auditing entity.

Financial-related Restrictions on Pharmacy Benefits Managers: The bill prohibits a PBM from recouping any funds from or charging any fees to a pharmacy or pharmacist for a prescription with regard to an incorrect days of supply calculation if (1) the package size of the medication is unbreakable and (2) the PBM is unable to accept the correct mathematically calculable days' supply during prescription adjudication. Additionally, the bill prohibits a PBM from having or requesting access to a pharmacy's or pharmacist's bank, credit card, or depository statements or data as it relates to cost-sharing.

Applicability of New Audit Procedures

The bill takes effect January 1, 2024, and generally applies to any audit of a pharmacy or pharmacist that is under contract with a PBM performed on or after that date. However, for a PBM that contracts with the State, the bill applies only to audits that occur (1) on the first day of the first plan year beginning on or after January 1, 2024, or (2) the first time a contract between a PBM and the State is amended or renewed on or after January 1, 2024.

State Fiscal Effect: The Department of Budget and Management (DBM) and the Maryland Department of Health both advise that the bill's changes likely result in an indeterminate increase in expenditures for the State Plan and Medicaid MCOs, respectively.

According to DBM, the bill's audit provisions are generally less favorable to PBMs and any additional net costs are likely to be passed on to purchasers. However, DBM advises that it is not privy to all the audit procedures contained in existing agreements and, thus, cannot determine the magnitude of any cost difference between current audit procedures and those required under the bill as they apply to the State Plan. To the extent that PBMs pass along increased administrative expenses to purchasers, expenditures for the State Plan (general, federal, and special funds) increase under the bill.

The Secretary must adopt regulations for PBMs that contract with MCOs that establish requirements for conducting audits of pharmacies or pharmacists that are, to the extent practicable, substantively similar to the audit provisions applicable to carriers and consistent with federal law. The precise scope of these regulations is not known; however, to the extent the regulations increase administrative expenses for PBMs contracting with MCOs and PBMs pass along those costs to MCOs, Medicaid general and federal fund expenditures (and federal matching fund revenues) also increase. Expenditures are eligible for a 51% federal matching rate in fiscal 2024, decreasing to 50% in fiscal 2025 and beyond.

Small Business Effect: Independent and community pharmacies benefit from more accommodating audit procedures. Conversely, the additional requirements and restrictions placed on PBMs when conducting pharmacy audits may lead to a slight increase in premiums for small businesses that purchase fully insured health benefit plans.

Additional Information

Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: SB 565 (Senators Ready and Klausmeier) - Finance.

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

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