

Department of Legislative Services
 Maryland General Assembly
 2018 Session

FISCAL AND POLICY NOTE
 Enrolled - Revised

House Bill 1349

(Delegate Anderton, *et al.*)

Health and Government Operations

Finance

Pharmacy Benefits Managers - Revisions

This bill imposes specified requirements and prohibitions on pharmacy benefits managers (PBMs) related to reimbursement for pharmacy services and maximum allowable cost (MAC) lists. The Insurance Commissioner is authorized to adopt regulations to govern PBMs and to establish a complaint process to address specified grievances and appeals. **The bill takes effect June 1, 2018, and applies to all contracts between a PBM and a pharmacy entered into or in effect on or after January 1, 2019.**

Fiscal Summary

State Effect: No effect in FY 2018. General fund revenues increase by an indeterminate amount beginning in FY 2019 to the extent the Insurance Commissioner imposes fines on PBMs, as discussed below. Special fund expenditures for the Maryland Insurance Administration (MIA) increase by \$58,100 in FY 2019 for staff. Future years reflect annualization. To the extent PBMs' increased costs are passed on to employers, expenditures increase for the State Employee and Retiree Health and Welfare Benefit Program by an indeterminate amount (not reflected below).

(in dollars)	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023
GF Revenue	-	-	-	-	-
SF Expenditure	\$58,100	\$71,300	\$73,500	\$76,100	\$78,900
Net Effect	(\$58,100)	(\$71,300)	(\$73,500)	(\$76,100)	(\$78,900)

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

Local Effect: To the extent PBMs' increased costs are passed on to employers, local government expenditures may increase. Revenues are not affected.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary:

Registration and Renewal Requirements

The Commissioner may require any additional information or submissions from a PBM to verify an initial or renewal application.

Reimbursement for Pharmacy Services

A PBM may not reimburse a pharmacy or pharmacist for a pharmaceutical product or pharmacist service in an amount less than the PBM reimburses itself or an affiliate for the same product or service. This provision does not apply to reimbursement for specialty drugs, for mail order drugs, or to a chain pharmacy with more than 15 stores or a pharmacist who is an employee of the chain pharmacy.

Maximum Allowable Cost Lists

“Drug shortage list” is defined as a list of drug products listed on the U.S. Food and Drug Administration’s drug shortages [website](#).

The bill specifies that “maximum allowable cost” does not include dispensing fees.

A PBM must (1) establish a reasonable process by which a contracted pharmacy has access to the current and applicable MAC price lists in an electronic format as updated in accordance with specified requirements and (2) immediately after a pricing update, use the updated pricing information in calculating the payments made to all contracted pharmacies.

A PBM must maintain a procedure to eliminate products from the list of drugs subject to MAC pricing *as necessary* to remove drugs that no longer meet specified requirements and reflect the current availability of drugs in the marketplace. A product on the MAC list must be eliminated from the list by the PBM within seven days after the PBM knows of a change in the availability of the product.

Before placing a prescription drug on a MAC list, a PBM must ensure its availability. Specifically, a PBM must ensure that, if a drug is manufactured by more than one manufacturer, the drug is generally available for purchase by contracted pharmacies, *including contracted retail pharmacies* from a wholesale distributor *with a permit in the State*. However, if a drug is manufactured by only one manufacturer, the drug must generally be available for purchase from at least two such wholesale distributors. In

addition, a PBM must ensure that the drug is not obsolete, temporarily unavailable, or listed on a drug shortage list as currently in shortage.

Appeals Related to Maximum Allowable Cost Pricing

The process available to a contracted pharmacy to appeal, investigate, and resolve disputes regarding MAC pricing must include a requirement that (1) an appeal be filed *by the contract pharmacy* no later than 21 days after the date of the initial *adjudicated* claim; (2) within 21 days after the date the appeal is filed, the PBM investigate and resolve the appeal and report to the contracted pharmacy on the PBM's determination; (3) the PBM make available on its website specified information about the appeals process; and (4) the PBM provide, in addition to a reason for any appeal denial, the national drug code of a drug and the name of the wholesale distributor from which the drug was available on the date the claim was adjudicated at a price at or below the MAC determined by the PBM.

The process must also include, if an appeal is upheld, a requirement that a PBM (1) for the appealing pharmacy, adjust the MAC in a specified manner and provide specified reimbursement for claims and (2) for a similarly situated contracted pharmacy in the State, adjust the MAC in a specified manner and provide specified notice of the contracted pharmacy's right to reverse and rebill specified claims.

A PBM may not retaliate against a contracted pharmacy for exercising its right to appeal a MAC price or filing a complaint with the Commissioner. A PBM may not charge a contracted pharmacy a fee related to the readjudication of a claim or claims resulting from an appeal related to MAC pricing.

If a PBM denies an appeal and a contracted pharmacy files a complaint with the Commissioner, the Commissioner must (1) review the compensation program of the PBM to ensure that the reimbursement paid to the pharmacist or pharmacy complies with specified law and the terms of the contract and (2) based on this determination, dismiss the appeal or uphold the appeal and order the PBM to pay the claim or claims in accordance with the Commissioner's findings. All pricing information and data collected by the Commissioner during such a review is confidential and proprietary and not subject to disclosure under the Public Information Act.

Additional Penalty Authority

If the Commissioner determines a PBM has violated specified provisions of law or regulations, the Commissioner may, in addition to existing remedies, issue an order requiring a PBM to pay a fine in an amount determined by the Commissioner.

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. A PBM is prohibited from shipping, mailing, or delivering prescription drugs or devices to a person in the State through a nonresident pharmacy unless the nonresident pharmacy holds a nonresident pharmacy permit from the State Board of Pharmacy.

Maximum Allowable Cost Lists

A PBM must include the sources used to determine MAC pricing in each contract with a contracted pharmacy. A PBM must update pricing information at least every seven days and provide a means for contracted pharmacies to promptly review pricing updates. A PBM must maintain a procedure to eliminate products from any MAC list. Before placing a prescription drug on a MAC list, a PBM must ensure that the drug meets specified criteria. Each contract between a PBM and a contracted pharmacy must include a process to appeal, investigate, and resolve disputes regarding MAC pricing.

Appeals Related to Maximum Allowable Cost Pricing

A process to appeal, investigate, and resolve disputes regarding MAC pricing must meet several requirements. An appeal must be (1) filed no later than 21 days after the date of the initial claim and (2) investigated and resolved within 21 days after the date the appeal is filed. A contracted pharmacy must be provided with a telephone number at which the pharmacy may speak to an individual responsible for processing appeals. A PBM must provide a reason for any appeal denial and the national drug code of any drug that may be purchased by the contracted pharmacy at a price at or below the benchmark price determined by the PBM. If an appeal is upheld, a PBM must make the change in the MAC no later than one business day after the date of determination on the appeal and permit the appealing contracting pharmacy to reverse and rebill the claim and any subsequent similar claims.

State Revenues: General fund revenues increase by an indeterminate amount beginning in fiscal 2019 to the extent the Commissioner exercises the authority to impose a fine (in an amount determined by the Commissioner) on a PBM if the Commissioner determines that a PBM has violated any provision of law or regulations.

State Expenditures: MIA special fund expenditures increase by \$58,081 in fiscal 2019, which accounts for a four-month start-up delay, during which time regulations are developed and a complaint process is established. This estimate reflects the cost to hire one full-time investigator (beginning October 1, 2018) to receive complaints about PBM

denials of appeals by a contracted pharmacy. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Position	1
Salary and Fringe Benefits	\$52,722
One-time Start-up Costs	4,890
Ongoing Operating Expenses	<u>469</u>
Total FY 2019 State Expenditures	\$58,081

Future year expenditures reflect a full salary with annual increases and employee turnover and ongoing operating expenses.

The Department of Budget and Management advises that the bill increases costs for PBMs that are likely to be passed on to employers and carriers in the form of increased administrative fees. This in turn increases costs for prescription benefits under the State Employee and Retiree Health and Welfare Benefits Program by an indeterminate amount.

Small Business Effect: Small business pharmacies benefit from additional transparency under the bill and gain the right to appeal a PBM's denial of an appeal to the Commissioner.

Additional Information

Prior Introductions: None.

Cross File: SB 1079 (Senator Mathias, *et al.*) - Finance.

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

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