SB 819

Department of Legislative Services

Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 819 (Senators Hayes and Hershey)
Finance

Health Insurance - Pharmaceutical Manufacturers - Transparency and Reporting

This bill requires "carriers" to disclose (1) specified information about the carrier's current prescription drug formularies; (2) whether members may be subject to excess cost sharing; and (3) specified notice of any change in pharmaceutical benefits. Carriers must also report to the Insurance Commissioner specified information on reconsideration requests, grievances, and appeals related to denials of prior authorization. A pharmacy benefits manager (PBM) must provide the Commissioner specified information about pharmaceutical benefits provided in the State and publish specified information on a public website. The Secretary of Health must identify specified prescription drugs on which the State spends significant health care dollars and require the manufacturers to report specified information on the prescription drugs. The Commissioner and the Secretary of Health must develop standard forms for reporting.

Fiscal Summary

State Effect: General fund expenditures increase by *at least* $90,000 annually beginning in FY 2020 for staff costs, as discussed below. Future years reflect annualization. Minimal increase in special fund expenditures for the Maryland Insurance Administration (MIA) beginning in FY 2020 for contractual support. No effect on the State Employee and Retiree Health and Welfare Benefits Program (State plan). Revenues are not affected.

(in dollars)	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Revenues	$0	$0	$0	$0	$0
GF Expenditure	90,000	113,200	116,900	120,800	124,800
SF Expenditure	-	-	-	-	-
Net Effect	($90,000)	($113,200)	($116,900)	($120,800)	($124,800)

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

Local Effect: The bill is not anticipated to materially affect local governmental finances or operations.

Small Business Effect: None.

Analysis

Bill Summary: "Rebates" means all rebates, discounts, or other price concessions that the State or another payer receives or expects to receive, directly or indirectly, from a pharmaceutical manufacturer related to the use of prescription drugs produced by the pharmaceutical manufacturer.

Carrier Provision of Information about Prescription Drug Formularies

A health insurer, nonprofit health service plan, health maintenance organization, Medicaid managed care organization, or any other person that provides health benefit plans (collectively known as carriers) must make specified information about the carrier's current prescription drug formulary available on the carrier's website in an easily accessible manner. A carrier may not require an account, a plan, or a policy number in order to access this information.

Carrier Reporting on Reconsideration Requests, Grievances, and Appeals

By March 1, 2020, and annually thereafter, each carrier must report to the Insurance Commissioner for each health benefit plan the following: (1) the number of reconsideration requests, grievances, and appeals that the carrier received in response to denials of prior authorization requests during the immediately preceding calendar year; and (2) the average number of hours that passed between the time that the carrier received a reconsideration request, grievance, or appeal in response to a denial of a prior authorization request, and the time that the carrier issued the carrier's final decision during the immediately preceding calendar year.

Carrier Notice of Changes in Pharmaceutical Benefits

Each carrier must provide each member with written notice at least 30 days before the effective date of any changes in the member's pharmaceutical benefit, including an exclusion of coverage for classes of drugs or a change in prior authorization procedures or requirements. The written notice provided must be consistent with written notice that the carrier provides to all in-network pharmacies.

Carrier Disclosure of Excess Cost Sharing

Beginning January 1, 2020, a carrier that charges members cost sharing amounts that may result in excess cost sharing for covered prescriptions must disclose that members may be subject to excess cost sharing. The disclosure must be included in specified health benefit plan documents.

In making this required disclosure, a carrier may not publish or otherwise reveal information regarding the amount of rebates the carrier receives. A carrier must impose confidentiality protections on any vendor, third party that performs health care or administrative service acting on behalf of the carrier that may receive or have access to rebate information. A county or municipality may not enact a law that regulates carrier disclosures.

Reports Required from Pharmacy Benefits Managers

Beginning January 1, 2020, and annually thereafter, each PBM must provide the Commissioner with a report with specified information about pharmacy benefits provided to enrollees in the State. The Commissioner must publish the information in a timely manner on the MIA website. The information must be made available in a form that does not disclose the identity of a specific purchaser, the prices charged for specific drugs or classes of drugs, or the amount of any manufacturer payments provided for specific drugs or classes of drugs. The PBM and the Commissioner may not publish or otherwise disclose any information that would reveal such information.

By March 1, 2020, and annually thereafter, for each of the PBM's contracts or other relationships with a purchaser, the PBM must publish on a publicly accessible website the purchaser's formulary and notification of formulary changes or product exclusions within 60 days before the effective date of the change. The Commissioner, in consultation with stakeholders, must establish a standardized form for reporting the information. A county or municipality may not enact a law that regulates these PBM disclosures.

Prescription Drugs on which the State Spends Significant Health Care Dollars

By March 1, 2020, and annually thereafter, the Secretary of Health must identify up to 10 prescription drugs on which the State spends significant health care dollars, after accounting for rebates, and for which the wholesale acquisition cost (WAC) has increased by a total of 50% or more during the immediately preceding calendar year. The drugs identified must represent different drug classes and include generic drugs.

For each prescription drug identified, the Secretary must require the manufacturer to report (1) a schedule of the drug's WAC increases during the immediately preceding calendar

year; (2) the manufacturer's aggregate, company-level research and development expenditures and other relevant capital expenditures for the most recent year for which final audited data are available; and (3) a written description of factors that contributed to the reported increases in WAC. Information reported by a manufacturer must be consistent with the manufacturer's Form 10-K filings with the U.S. Securities and Exchange Commission or other publicly available data sources.

The Secretary, in consultation with stakeholders, must establish a standardized form for manufacturer reporting. By June 1, 2020, and annually thereafter, the Secretary must publish a report on the department's website based on the manufacturer reporting.

Information provided to the Secretary must be considered a trade secret and confidential commercial information, is not subject to public inspection, and may not be disclosed in a manner that would allow for the identification of an individual drug, therapeutic class of drugs, or manufacturer, or in a manner that is likely to compromise the financial, competitive, or proprietary nature of the information. A county or municipality may not enact a law that regulates pharmaceutical manufacturers' disclosures of revenue-related, expense-related, and drug pricing-related information subject to these requirements.

Current Law: Carriers that limit coverage of prescription drugs and devices to a specified formulary must provide a procedure for coverage for a prescription drug or device that is not in the carrier's formulary if, in the judgment of the authorized prescriber, a contraceptive prescription drug or device that is not on the formulary is medically necessary for the member to adhere to the appropriate use of the prescription drug or device.

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 Commissioner is authorized to examine the affairs, transactions, accounts, and records of a registered PBM at the PBM's expense.

State Expenditures:

Maryland Department of Health

Under the bill, the Secretary of Health must annually identify up to 10 prescription drugs on which the State spends significant health care dollars. For each identified drug, the manufacturer must report specified information on a standardized form established by the Secretary. The Secretary must also annually publish a report on the Maryland Department of Health (MDH) website based on the manufacturer reporting.

To accomplish these requirements, MDH general fund expenditures increase by a minimum of $89,966 in fiscal 2020, which accounts for the bill's October 1, 2019 effective date. This reflects the cost to hire one full-time grade 24 pharmacist to identify the prescription drugs, develop a standardized form for manufacturer reporting, collect manufacturer reports, and publish the required report. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

Position	1.0
Salary and Fringe Benefits	$82,732
One-time Start-up Expenses	4,890
Ongoing Operating Expenses	2,344
FY 2020 General Fund Expenditures	**$89,966**

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

Maryland Insurance Administration

Under the bill, the Commissioner must receive new reports from carriers regarding reconsideration requests, grievances, and appeals relating to denials of prior authorization requests, as well as reports from PBMs regarding specified information about pharmacy benefits provided to enrollees in the State. The Commissioner must publish the PBM information on the MIA website and develop a standardized form for PBMs to publish certain information on a publicly available website. MIA advises that, while development of a standardized form and publishing of PBM information on the MIA website can be handled with existing resources, contractual support is likely needed to review the additional reports from carriers and PBMs annually at the time of submission. Any such special fund expenditures are anticipated to be minimal.

State Employee and Retiree Health and Welfare Benefits Program

The State plan is largely self-insured for its medical contracts and, as such, with the exception of one fully insured integrated health model medical plan (Kaiser, which does not include prescription coverage), is not subject to this bill. Prescription drug coverage under the State plan is provided through a separate PBM contract.

Additional Information

Prior Introductions: None.

Cross File: HB 920 (Delegate Kipke, *et al.*) - Health and Government Operations.

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

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