HB 978

Department of Legislative Services
Maryland General Assembly
2020 Session

FISCAL AND POLICY NOTE
First Reader
House Bill 978 (Delegate Kelly)
Health and Government Operations

Maryland Insurance Administration - Pharmacy Services Administrative Organizations - Regulation

This bill requires a “pharmacy services administrative organization” (PSAO) to register with the Insurance Commissioner, beginning July 1, 2021, before providing services as a PSAO to independent pharmacies in the State. A PSAO that has not registered may not enter into an agreement or a contract with an independent pharmacy or a pharmacy benefits manager (PBM). The Commissioner may adopt implementing regulations.

Fiscal Summary

State Effect: Special fund revenues for the Maryland Insurance Administration (MIA) increase from registration fees beginning in FY 2022. MIA special fund expenditures increase by $37,000 in FY 2021 for staff. Future years reflect annualization and additional staff. General fund revenues increase, likely beginning in FY 2022, to the extent the Commissioner imposes civil fines or penalties on PSAOs, as discussed below.

<table>
<thead>
<tr>
<th>(in dollars)</th>
<th>FY 2021</th>
<th>FY 2022</th>
<th>FY 2023</th>
<th>FY 2024</th>
<th>FY 2025</th>
</tr>
</thead>
<tbody>
<tr>
<td>GF Revenue</td>
<td>$0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>SF Revenue</td>
<td>$0</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>SF Expenditure</td>
<td>$37,000</td>
<td>$134,800</td>
<td>$135,300</td>
<td>$139,800</td>
<td>$144,500</td>
</tr>
<tr>
<td>Net Effect</td>
<td>($37,000)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

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

Local Effect: The bill does not have a material impact on local finances or operations.

Small Business Effect: Potential meaningful.
Analysis

Bill Summary: PSAO means an entity operating within the State that contracts with independent pharmacies to conduct business on their behalf with third-party payers, provides administrative services to independent pharmacies, or negotiates and enters into contracts with third-party payers or PBMs on behalf of independent pharmacies. PSAO includes a person that performs one or more of the following administrative services for an independent pharmacy: claims assistance, audit assistance, centralized payment, special care programs certification, compliance support, flat fee setting for generic drugs, store layout assistance, inventory management, marketing support, payment and drug dispensing data management and analysis, or provision of resources for retail cash cards.

Application, Renewal, Recordkeeping, and Examination

An applicant for registration as a PSAO must file an application and pay a registration fee set by the Commissioner. A registration expires on the second September 30 after its effective date. A PSAO may renew its registration for an additional two-year term if the PSAO is otherwise entitled to be registered, files a renewal application, and pays a renewal fee set by the Commissioner. Subject to the applicable hearing provisions, the Commissioner may deny a registration or refuse to renew, suspend, or revoke the registration of a PSAO on specified grounds.

A PSAO must maintain adequate books and records regarding each independent pharmacy for which the PSAO provides services, as specified. The Commissioner may examine the affairs, transactions, accounts, and records of a registered PSAO.

Pharmacy Services Administrative Contract Requirements

A pharmacy services administrative contract (PSAC) or a contract between a PSAO, on behalf of an independent pharmacy, and a PBM or group purchasing organization (and related amendments to such contracts) may not become effective unless (1) the PSAO files the contract or amendment with the Commissioner at least 30 days before the contract or amendment is to become effective and (2) the Commissioner does not disapprove the filing within 30 days after the contract or amendment is filed. The Commissioner must adopt regulations to establish the circumstances under which a contract may be disapproved.

A PSAC must require the PSAO to provide to an independent pharmacy a copy of any contracts, amendments, payment schedules, or reimbursement rates within three calendar days after the execution of a contract, or an amendment to a contract, signed on behalf of the independent pharmacy by the PSAO.
A contract between a PBM and a PSAO that authorizes a PBM to conduct audits of independent pharmacies for which the PSAO provides services must contain specific language that authorizes the PBM to obtain information from the PSAO regarding the independent pharmacy for purposes of the audit.

A PSAC must (1) require all remittances for claims submitted by a PBM or third-party payer on behalf of an independent pharmacy to be passed by the PSAO to the independent pharmacy within a reasonable amount of time and (2) specify the reasonable amount of time in which the PSAO is required to pass the remittances received from the PBM or third-party payer to the independent pharmacy.

A PSAO that owns or is owned by, in whole or in part, an entity that manufactures, sells, or distributes prescription drugs, biologics, or medical devices may not require, as a condition of entering into a PSAC, that an independent pharmacy purchase any drugs, biologics, or medical devices from the entity and must disclose to the Commissioner any agreement with an independent pharmacy under which the independent pharmacy purchases prescription drugs, biologics, or medical devices from the entity.

Disclosure of Ownership or Control

Each PSAO must disclose to the Commissioner, an independent pharmacy, a third-party payer, or a PBM the extent of any ownership or control of the PSAO by any parent company, subsidiary, or other organization that provides pharmacy services, provides prescription drug or device services, or manufactures, sells, or distributes prescription drugs, biologics, or medical devices. Each PSAO must notify these entities within five calendar days after any material change in its ownership or control.

Miscellaneous Provisions

A PSAO that provides, accepts, or processes a discount, concession, or product voucher to reduce, directly or indirectly, an out-of-pocket expense for the order, dispensing, substitution, sale, or purchase of a prescription drug must submit to the Commissioner a specified annual report. The Commissioner must make the reports available to the public.

A PSAO may not (1) misrepresent pertinent facts or policy provisions that relate to an issue in a complaint or an appeal of a decision regarding a complaint; (2) refuse to pay or reimburse an independent pharmacy or a PBM for an arbitrary or capricious reason based on all available information; (3) fail to settle a dispute promptly whenever liability is reasonably clear under one part of a policy or contract, in order to influence settlements under other parts of the policy or contract; or (4) fail to act in good faith.
Violations and Penalties

If the Commissioner determines that a PSAO has violated any provision of the bill or related regulations, the Commissioner may issue an order that requires a PSAO to (1) cease and desist; (2) take specific affirmative action to correct the violation; (3) make restitution to a person that has suffered financial injury because of the violation; or (4) pay a fine determined by the Commissioner. In addition to any other enforcement action taken by the Commissioner, the Commissioner may impose a civil penalty of up to $10,000 for each violation of the bill.

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.

State Revenues: Special fund revenues for MIA increase from registration fees beginning in fiscal 2022, which reflects the bill’s requirement that PSAOs must register with the Commissioner on or after July 1, 2021. As the amount of PSAOs currently operating in Maryland is unknown, the amount of registration revenues cannot be reliably estimated at this time.

General fund revenues increase by an indeterminate amount, likely beginning in fiscal 2022, to the extent the Commissioner exercises the authority to impose a civil fine or civil penalty on a PSAO if the Commissioner determines that a PBM has violated any provision of law or regulations.

State Expenditures: MIA special fund expenditures increase by $37,015 in fiscal 2021, which accounts for the bill’s October 1, 2020 effective date. This estimate reflects the cost of hiring one company licensing analyst (beginning January 1, 2021) to establish the registration process, adopt any regulations, and begin registering PSAOs by July 1, 2021. It includes a salary, fringe benefits, one-time start-up costs, and ongoing operating expenses.

<table>
<thead>
<tr>
<th>Position</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salary and Fringe Benefits</td>
<td>$29,307</td>
</tr>
<tr>
<td>One-time Start-up Expenses</td>
<td>4,890</td>
</tr>
<tr>
<td>Ongoing Operating Expenses</td>
<td>2,818</td>
</tr>
<tr>
<td><strong>Total FY 2021 State Expenditures</strong></td>
<td><strong>$37,015</strong></td>
</tr>
</tbody>
</table>

In fiscal 2022, expenditures increase further to hire one full-time investigator (beginning July 1, 2021) to review PSAO contracts and contract amendments. Future year
expenditures reflect full salaries with annual increases and employee turnover and ongoing operating expenses.

**Small Business Effect:** PSAOs, some of which may be small businesses, must register with the Commissioner and comply with the bill’s requirements. Small business independent pharmacies may benefit.

---

**Additional Information**

**Prior Introductions:** None.

**Designated Cross File:** SB 915 (Senator Kramer) - Finance.

**Information Source(s):** Judiciary (Administrative Office of the Courts); Office of Administrative Hearings; Maryland Insurance Administration; Department of Legislative Services

**Fiscal Note History:** First Reader - February 26, 2020

rh/ljm

Analysis by: Jennifer B. Chasse

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