Title: An act relating to registration and regulation of pharmacy benefit managers.

Brief Description: Addressing registration and regulation of pharmacy benefit managers.

Sponsors: Senate Committee on Ways & Means (originally sponsored by Senators Parlette, Conway, Becker and Pearson).

Brief History:
Committee Activity:
Health Care & Wellness: 3/24/15, 3/26/15 [DPA].

Brief Summary of Engrossed Substitute Bill (As Amended by Committee)

- Grants the Office of the Insurance Commissioner (OIC) enforcement authority over pharmacy benefit managers, and permits the OIC to issue binding decisions in disputes between pharmacy benefit managers and pharmacies.

- Requires a pharmacy benefit manager to ensure that all drugs for which a maximum allowable cost has been established are readily available for purchase by community retail pharmacies.

- Requires that a pharmacy benefit manager reimburse a pharmacy for the amount it paid for a drug if it can demonstrate that it is unable to purchase a therapeutically equivalent interchangeable product from its supplier at the maximum allowable cost price.

- Requires the Joint Select Committee on Health Care Oversight to convene a stakeholder work group to review the drug supply chain.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: Do pass as amended. Signed by 13 members: Representatives Cody, Chair; Riccelli, Vice Chair; Schmick, Ranking Minority Member; Harris, Assistant Ranking

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.
Minority Member; Caldier, Cibborn, Jinkins, Johnson, Moeller, Robinson, Short, Tharinger and Van De Wege.

**Minority Report:** Without recommendation. Signed by 1 member: Representative Rodne.

**Staff:** Alexa Silver (786-7190).

**Background:**

Pharmacy benefit managers act as an intermediary between the entities with which they contract and pharmaceutical manufacturers to administer the drug benefit portion of a health plan. They process and pay prescription drug claims, develop and maintain the formulary, contract with pharmacies, and negotiate discounts and rebates with manufacturers.

Legislation enacted in 2014 requires pharmacy benefit managers to register with the Department of Revenue, establishes requirements related to audits of pharmacies, regulates actions related to lists of drugs for which a maximum allowable cost has been established, and requires pharmacy benefit managers to establish an appeals process.

With respect to a list of drugs for which a maximum allowable cost has been established, a pharmacy benefit manager must ensure that all drugs on the list are generally available for purchase by pharmacies in the state from national or regional wholesalers.

With respect to appeals, a pharmacy benefit manager is required to establish a process for a network pharmacy to appeal its reimbursement for a drug subject to maximum allowable cost pricing. A pharmacy may file an appeal if reimbursement is less than the net amount the pharmacy paid to the supplier for the drug. A pharmacy benefit manager must provide a final response to an appeal within seven business days. If the appeal is denied, the pharmacy benefit manager must provide a reason for the denial and the national drug code of a drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost. If the appeal is upheld, the pharmacy benefit manager must make an adjustment within one day of the determination, and the adjustment must be effective for all similarly situated network pharmacies in the state.

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**Summary of Amended Bill:**

**Regulation of Pharmacy Benefit Managers.**

To conduct business in Washington, pharmacy benefit managers are required to register with the Office of the Insurance Commissioner (OIC) instead of the Department of Revenue. The OIC must establish registration and renewal fees at a level that allows the registration, renewal, and oversight activities to be self-supporting, and the fees must be deposited into the OIC's regulatory account.

A pharmacy benefit manager must ensure that all drugs on a list establishing maximum allowable costs are readily available for purchase by community retail pharmacies in
Washington from national or regional wholesalers that service community retail pharmacies in Washington. If a pharmacy appeals its reimbursement, the pharmacy benefit manager must reimburse the pharmacy or pharmacist for the amount it paid to the supplier if the pharmacy or pharmacist can demonstrate that it was unable to purchase a therapeutically equivalent interchangeable product from its supplier at the maximum allowable cost.

The OIC has enforcement authority over the pharmacy benefit manager law and has authority to render a binding decision in a dispute between a pharmacy benefit manager or third-party administrator of prescription drug benefits and a pharmacy that arises out of an appeal regarding drug pricing and reimbursement. If a pharmacy appeal to a pharmacy benefit manager is denied, the pharmacy or pharmacist may dispute the denial and request review by the OIC. "Denial" of an appeal by a pharmacy benefit manager includes failing to reimburse a pharmacy or pharmacist and reimbursing a pharmacy or pharmacist for less than the amount the pharmacy or pharmacist paid to the supplier. All relevant information from the parties must be presented to the OIC, and the OIC may enter an order directing the pharmacy benefit manager to make an adjustment, deny the pharmacy appeal, or take other actions deemed fair and equitable. Upon resolution of the dispute, the OIC must provide a copy of the decision to both parties within seven calendar days.

A person, corporation, third-party administrator of prescription drug benefits, pharmacy benefit manager, or business entity that violates the pharmacy benefit manager law is subject to a civil penalty of $1,000 per violation or $5,000 per violation if the violation was knowing and willful.

The OIC may adopt rules to implement the pharmacy benefit manager law and establish registration and renewal fees.

**Stakeholder Work Group.**

The Joint Select Committee on Health Care Oversight (Joint Select Committee) must convene a stakeholder work group comprised of participants in the prescription drug delivery chain, including pharmacy benefit managers, drug manufacturers, wholesalers, pharmacy service administrative organizations, pharmacies, health plans, and other payors. The work group must provide periodic updates to the Joint Select Committee.

The work group assignments may include, but are not limited to:

- reviewing the entire drug supply chain, including plan and pharmacy benefit manager reimbursements to independent pharmacies, wholesaler or pharmacy service administrative organization prices to independent pharmacies, and drug manufacturer prices to independent pharmacies;
- discussing suggestions that recognize the unique nature of small retail pharmacies and possible options that support a viable business model without increasing the cost of pharmacy products;
- reviewing the availability of all drugs on a list establishing maximum allowable costs and list prices for community retail pharmacies;
- reviewing the phone contacts and standards for response times and availability; and
- reviewing the pharmacy acquisition cost from national or regional wholesalers that serve community retail pharmacies in Washington and considering when or whether
to make an adjustment and under what standards. The review may assess the timing of pharmacy purchases of products and the relative risk of list price changes related to the timing of dispensing the products.

**Amended Bill Compared to Engrossed Substitute Bill:**

The amended bill adds the provision requiring a pharmacy benefit manager to reimburse a pharmacy or pharmacist if it can demonstrate that it was unable to purchase a therapeutically equivalent interchangeable product from its supplier at the maximum allowable cost. It also adds the provision defining a "denial" of an appeal.

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**Appropriation:** None.

**Fiscal Note:** Available.

**Effective Date of Amended Bill:** This bill takes effect 90 days after adjournment of the session in which the bill is passed, except for section 1, relating to registration with the Office of the Insurance Commissioner, which takes effect January 1, 2016.

**Staff Summary of Public Testimony:**

(In support) Pharmacy benefit managers are the middle men that help employers manage prescription drug costs, but too often pharmacy benefit managers reimburse pharmacies below what it costs them to buy a drug, not including the pharmacies' cost to dispense. Pharmacies are doing all they can to obtain prescriptions at the lowest possible price. There has been a substantial increase in the cost of generic drugs. Wholesalers update their prices on a daily basis, and the technology is available to rapidly adjust prices, but it takes months for the price to be adjusted in the pharmacy benefit managers' systems. Pharmacy benefit managers assume stores can purchase from wholesalers that do not sell in this state. The pharmacy benefit managers' help desks transfer calls without any resolution. Pharmacists spend a significant amount of time trying to recoup underpayments by pharmacy benefit managers, but the process is largely unsuccessful. If Washington can solve this problem, it will benefit the rest of the nation. Pharmacies have an obligation to members of their communities, but have had to stop filling medications for patients who they have seen for years.

This bill fixes the problem by addressing the lack of regulatory enforcement in last year's legislation. Pharmacy benefit managers have not complied with the law. This bill is crucial to the survival of independent pharmacies in this state. Pharmacies have had to borrow from lenders to make payroll and pay the bills, but this is not sustainable. Owners of independent drug stores cannot afford to take a salary, and many pharmacists have taken on personal debt. Pharmacies cannot stockpile drugs to avoid taking a loss because they cannot predict future pricing trends, they do not have enough cash flow, and medications expire.

Pharmacy benefit managers are clearly part of the insurance system, and the Office of the Insurance Commissioner (OIC) is the right regulator for these companies. There is no other
entity in state government that would have the knowledge base and understanding. Registration with the Department of Revenue is not enough. The actions of large companies should not shift risk from insurers to independent businesses in an attempt to put them out of business.

(In support with amendment(s)) This bill allows stakeholders to provide important data to the Joint Select Committee on Health Care Oversight so there will be full appreciation of all the factors that go into the cash flow issues. All parties should be at the table to resolve this issue; independent pharmacies are an important part of the delivery system, especially in rural communities. Neither pharmacy benefit managers nor pharmacies are risk bearing entities, so the OIC is the wrong entity to regulate pharmacy benefit managers. There is no opposition to appropriate regulatory accountability or independent review of the internal appeals processes. Pharmacy benefit managers contract with plans and employers to provide services at a contractual rate. The carrier or self-insured employer bears the insurance risk. Sometimes the pharmacy benefit manager's client bears the risk of price fluctuations, but the contract may be structured so that the client has a defined cost per transaction.

(With concerns) There is support for the provisions related to a study, but concern with the provisions related to the OIC. The OIC is not the appropriate entity to perform this role because they do not have the scope of authority. The OIC regulates the commercial market; Tricare, Medicare, and self-insured employers are not under the purview of the OIC. There has been no conversation about the rise of generic drug costs. There is no intent to put anyone out of business.

(Opposed) There are significant problems with the OIC inserting itself in disputes between pharmacy benefit managers and pharmacies. Both are commercial entities rather than insurers, and they are not subject to the insurance code. The OIC lacks subject matter expertise on drug pricing issues. Other provider types will also want the OIC to insert itself into pricing issues in contract disputes.

Persons Testifying: (In support) Senator Parlette, prime sponsor; Ian Warren and Debra Torgeson, Costless Rx; Kirk Heinz, Kirk's Pharmacy; Kari VanderHouwen, Duvall Family Drugs; David Arnold, Cavallini's Pharmacy; and Carolyn Logue, Washington Food Industry Association.

(In support with amendment(s)) Mel Sorensen, Express Scripts and American Health Insurance Plans; and Carrie Tellefsen and Peter Harty, CVS Health.

(With concerns) Chris Bandoli, Regence.

(Opposed) Sydney Smith Zvara, Association of Washington Health Plans.

Persons Signed In To Testify But Not Testifying: None.