

# HOUSE BILL REPORT

## 4ESSB 5857

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As of Second Reading

**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 Fourth Engrossed Substitute Bill**

- Transfers regulatory authority over pharmacy benefit managers from the Department of Revenue to the Office of the Insurance Commissioner.
- Changes requirements relating to maximum allowable cost lists maintained by pharmacy benefit managers.
- Changes the appeals process between pharmacies and pharmacy benefit managers and allows pharmacies to appeal adverse decisions in appeals to the Office of the Insurance Commissioner.
- Requires the Office of the Insurance Commissioner and the Department of Health to make recommendations regarding the use of independent review organizations in appeals of decisions by pharmacy benefit managers.
- Requires the Joint Select Committee on Health Care Oversight to convene a stakeholder work group to review the drug supply chain.

**Staff:** Jim Morishima (786-7191).

**Background:**

I. Regulation of Pharmacy Benefit Managers.

A pharmacy benefit manager (PBM) acts as an intermediary between the entities with which it contracts and pharmaceutical manufacturers to administer the drug benefit portion of a

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health plan. A PBM processes and pays prescription drug claims, develops and maintains the formulary, contracts with pharmacies, and negotiates discounts and rebates with manufacturers.

A PBM doing business in Washington must register with the Department of Revenue's Business Licensing Program. To register, a PBM must submit an application and a registration fee of \$200.

## II. Maximum Allowable Cost List.

Maximum allowable cost (MAC) is the maximum amount that a PBM will reimburse a pharmacy for the cost of a drug. Most PBMs develop lists of drugs that have MACs. A PBM may not place a drug on its MAC list unless there are at least two therapeutically equivalent drugs available from at least two manufacturers or at least one generic drug from one manufacturer. The PBM must ensure that all the drugs on the MAC list are generally available for purchase by pharmacies in Washington from national wholesalers.

## III. Appeals.

Each PBM must establish a process through which a network pharmacy may appeal reimbursements for drugs on the MAC list. A pharmacy may appeal a MAC if the reimbursement for the drug is less than the net amount that the pharmacy paid to the supplier of the drug. If the appeal is upheld, the PBM must make an adjustment for the pharmacy and all similarly situated network pharmacies in Washington. If the appeal is denied, the PBM must provide the reason for denial and the national drug code of a drug that may be purchased by similarly situated pharmacies at a price that is less than or equal to the MAC.

## IV. Independent Review Organizations.

An Independent Review Organization (IRO) is an entity that handles disputes between an enrollee and a health carrier. An enrollee may seek review by an IRO if: (1) a health carrier denies, modifies, reduces, or terminates coverage of, or payment for, a health care service; and (2) the enrollee has exhausted the carrier's grievance process or the carrier has exceeded timelines for grievances. The Office of the Insurance Commissioner (OIC) maintains a rotational registry system for assigning IROs and the Department of Health (DOH) certifies IROs.

## V. The Joint Select Committee on Health Care Oversight.

The Joint Select Committee on Health Care Oversight (JSCHCO) consists of the chairs of the health care committees of the Senate and the House of Representatives, who serve as co-chairs, and four members of the Senate and four members of the House of Representatives. The Governor may appoint a non-voting member as a liaison to the JSCHCO.

The JSCHCO provides oversight between the HCA, the HBE, the Commissioner, the DOH, and the DSHS. This oversight must include monitoring of each agency's activities to ensure they are not duplicating their efforts and are working toward a goal of increased quality of service, which will then lead to reduced costs to the health care consumer. The JSCHCO

coordinates with the Research and Analysis Division of the DSHS to monitor health care cost trends. The JSCHCO also, as necessary, proposes legislation and budget recommendations to the Legislature.

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## **Summary of Bill:**

### I. Regulation of Pharmacy Benefit Managers.

To conduct business in Washington, a PBM must register with the OIC, instead of the Department of Revenue. Registration and renewal fees for PBMs must be set by the OIC in rule and must allow the OIC's PBM registration and oversight activities to be self-sustaining.

The OIC has enforcement authority over PBMs and may render a binding decision in any dispute between a PBM, or third-party administrator of prescription drug benefits, and a pharmacy arising out of an appeal regarding drug pricing and reimbursement. A person, corporation, third-party administrator of prescription drug benefits, PBM, or business entity that violates laws relating to PBMs is subject to a civil penalty of \$1,000 per violation or \$5,000 per violation if the violation was knowing and willful.

### II. Maximum Allowable Cost List.

All drugs on the MAC list must be readily (instead of generally) available for purchase by network pharmacies in Washington. The national or regional wholesalers from whom MAC list drugs must be readily available must serve pharmacies in Washington.

### III. Appeals.

A PBM must uphold a pharmacy's appeal if pharmacy can demonstrate that it is unable to purchase a therapeutically equivalent interchangeable product from its Washington suppliers at the PBM's list price. If the appeal is upheld, the PBM must reimburse the pharmacy the amount that the pharmacy paid to the supplier of the drug. The requirement that an adjustment be made for all other similarly situated network pharmacies is removed.

If an appeal is not completed after 30 days, it is deemed denied. If the appeal is denied, the PBM must provide the drug code of a drug that has been purchased (rather than a drug that may be purchased) by other pharmacies. The requirement that the other pharmacies be similarly situated is removed. Instead, the other pharmacies must be in-network and located in Washington.

Beginning January 1, 2017, if the appeal is denied or the pharmacy is unsatisfied with the outcome, the pharmacy may appeal the decision to the OIC within 30 days. All relevant information from the parties must be presented to the OIC, and the OIC may enter an order directing the PBM 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. Appeals by the OIC are subject to

the Administrative Procedures Act. The Insurance Commissioner may authorize the Office of Administrative Hearings to conduct the appeals.

#### IV. Independent Review Organizations.

The OIC, in collaboration with the DOH, must review the potential to use IROs as an alternative to the appeal process for disputes between pharmacies and PBMs. By December 1, 2015, the agencies must submit recommendations for using IROs in this manner, including detailed suggestions for modifications to the process and possible transition of the process from the DOH to the OIC.

#### V. The Joint Select Committee on Health Care Oversight.

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.

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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 OIC, which takes effect January 1, 2016.

**Staff Summary of Public Testimony:**

*Public testimony on ESSB 5857 in House Health Care and Wellness Committee on March 24, 2015.*

(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:***

*Persons testifying on ESSB 5857 in House Health Care and Wellness Committee on March 24, 2015*

(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.