Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

5ESSB 5857

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 Summary of Fifth 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 to make recommendations regarding the use of independent review organizations of disputes between pharmacies and pharmacy benefit managers and other disputes between providers and carriers.
- Requires pharmacy benefit managers to make disclosures to plan sponsors.

Hearing Date: 2/23/16

Staff: Jim Morishima (786-7191).

Background:

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 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.

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.

I. Regulation of Pharmacy Benefit Managers.

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. An appeal must be completed within 30 days of the pharmacy making the claim. A final response to an appeal of a MAC must be provided within seven days.

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.

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-supporting.

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 or pharmacy services administrative organization 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.

Any list for which predetermined reimbursement costs have been established, including a MAC list, must include the basis of the methodology and sources used to determine multi-source generic drug reimbursement amounts. The list must utilize the most up-to-date pricing data to calculate pharmacy reimbursement for multi-source generic drugs within one day of any price update or modification. All drugs on the list must be readily (instead of generally) available for purchase by network pharmacies from wholesalers that serve pharmacies in Washington—this means that at least one product with a current national drug code must be available in this manner.

"Multi-source generic drug" is defined to mean a drug for which there is at least one other drug product that is rated therapeutically equivalent under the United States Food and Drug Administration's (FDA's) most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations," is pharmaceutically equivalent or bio-equivalent as determined by the FDA, and is sold or marketed in Washington.

III. Appeals.

The entities that may bring an appeal to a PBM include a pharmacy's contracting agent. Appeals are limited to reimbursements for multi-source generic drugs.

Upon receipt of an appeal, a PBM must supply the network pharmacy with the national drug code for a product available to the network pharmacy from a national or regional wholesaler operating in Washington at a price less than or equal to the reimbursed amount. The requirement that the PBM make a price adjustment after a successful appeal is eliminated.

If an appeal is denied, the PBM must provide the pharmacy with:

- the national drug code of an equivalent multi-source generic drug that has been purchased by another network pharmacy in Washington at a price less than or equal to the PBM's list price within seven days of the appealed claim; and
- the name of a pharmaceutical wholesaler operating in Washington from which the drug can be acquired by the challenging pharmacy.

Appeals must be completed within 10 days of the submission of the appeal. The requirement that the PBM provide the pharmacy with the final response to an appeal within seven days is eliminated.

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 must review the potential to use IROs as an alternative to the appeal process for pharmacy-PBM disputes and other disputes between providers and insurance carriers. The OIC must submit recommendations to the Legislature by December 1, 2016.

V. Disclosures to Plan Sponsors.

A PBM must disclose to each plan sponsor in all contracts between the PBM and the plan sponsor providing prescription drug coverage a written explanation of the methodology and sources used by the PBM to determine multi-source generic drug prices. Multi-source generic drug prices must be updated and transmitted in writing to every plan sponsor providing prescription drug coverage in Washington within seven days whenever there is a pricing change under any contract it utilizes. If a PBM uses different prices for multi-source generic drugs dispensed by network pharmacies and multi-source generic drugs dispensed through mail order or other non-retail pharmacies, the PBM must disclose the difference in pricing to each plan sponsor no later than five business days from the utilization of the multi-source generic drug pricing.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.