HOUSE BILL REPORT
5ESSB 5857

As Passed House - Amended:
March 4, 2016

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], 2/23/16, 2/26/16 [DPA];
General Government & Information Technology: 2/29/16 [DPA(GGIT w/o HCW)].
Floor Activity:
Passed House - Amended: 3/4/16, 94-3.

Brief Summary of Fifth Engrossed Substitute Bill
(As Amended by House)

- Transfers regulatory authority over pharmacy benefit managers from the Department of Revenue to the Office of the Insurance Commissioner (OIC).
- Changes requirements relating to maximum allowable cost lists maintained by pharmacy benefit managers.
- Changes the appeals process between certain pharmacies and pharmacy benefit managers and allows certain pharmacies to appeal adverse decisions in appeals to the OIC.
- Requires the OIC to make recommendations regarding the use of independent review organizations of disputes between pharmacies and pharmacy benefit managers.
- Requires the Insurance Commissioner to perform a study of the pharmacy chain of supply.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

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.

Majority Report: Do pass as amended. Signed by 15 members: Representatives Cody, Chair; Riccelli, Vice Chair; Schmick, Ranking Minority Member; Harris, Assistant Ranking Minority Member; Caldier, Clibborn, DeBolt, Jinkins, Johnson, Moeller, Robinson, Rodne, Short, Tharinger and Van De Wege.

Staff: Jim Morishima (786-7191).

HOUSE COMMITTEE ON GENERAL GOVERNMENT & INFORMATION TECHNOLOGY

Majority Report: Do pass as amended by Committee on General Government & Information Technology and without amendment by Committee on Health Care & Wellness. Signed by 7 members: Representatives Hudgins, Chair; Kuderer, Vice Chair; MacEwen, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Johnson, Morris and Senn.

Staff: Linda Merelle (786-7092).

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.

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 certifies IROs.

Summary of Amended 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. 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. All drugs on the list must be readily (instead of generally) available for purchase by network pharmacies from wholesalers that serve pharmacies in Washington.

"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.

A PBM must uphold an appeal if a pharmacy with fewer than 15 retail outlets in Washington can demonstrate that it is unable to purchase a therapeutically equivalent interchangeable product from a supplier doing business in Washington at the PBM's price. If an appeal is upheld for a pharmacy of any size, the PBM must make a reasonable adjustment. The

requirement that the PBM make an adjustment for similarly situated pharmacies is eliminated.

If an appeal is denied, the PBM must provide the pharmacy with the national drug code of a drug that has been purchased by another network pharmacy in Washington at a price less than or equal to the predetermined reimbursement cost. A pharmacy with 15 or more retail outlets in Washington may submit information about the appeal to the OIC for purposes of information collection and analysis.

Appeals must be completed within 30 days of the submission of the appeal. If after 30 days the pharmacy has not received the decision on the appeal from the PBM, the appeal is considered denied.

Beginning July 1, 2017, if the appeal is denied or the pharmacy is unsatisfied with the outcome, a pharmacy with fewer than 15 retail outlets in Washington may appeal the decision to the OIC within 30 days. The OIC has the authority to render a binding decision in such an appeal. 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. A PBM may not retaliate against the pharmacy for pursuing the appeal.

The OIC may authorize the Office of Administrative Hearings to conduct the appeals.

IV. Independent Review Organizations.

The OIC must collaborate with the Department of Health to review the potential to use IROs as an alternative to the appeal process for pharmacy-PBM disputes. The OIC must submit recommendations to the Legislature by December 1, 2016.

V. Study of the Pharmacy Chain of Supply.

The OIC must conduct a study of the pharmacy chain of supply. The OIC may convene one or more stakeholder work groups to address the components of the study, which must include:

- a review of the entire drug supply chain, including plan and PBM reimbursements to network pharmacies, wholesaler or pharmacy service administrative organization prices to network pharmacies, and drug manufacturer prices to network pharmacies;
- a discussion of suggestions that recognize the unique nature of small and rural pharmacies and possible options that support a viable business model that do not increase the cost of pharmacy products;
- a review of the availability of all drugs on the MAC list or any similar list;
- a review of data submitted by pharmacies with 15 or more retail outlets in Washington for patterns and trends in the denials of internal PBM appeals;
- a review of the telephone contacts and standards for response times and availability; and
- a review of the pharmacy acquisition cost from national or regional wholesalers that serve pharmacies in Washington and whether to make an adjustment and under what

standards—this review may assess the timing of pharmacy purchases of products and the relative risk of list price changes related to the timing of dispensing of the products.

A PBM must comply with any requests for information from the OIC for purposes of this study. The study be delivered to the Legislature by November 1, 2016.

Appropriation: None.

Fiscal Note: Available.

Effective Date of Amended Bill: The bill takes effect on January 1, 2017.

Staff Summary of Public Testimony (Health Care & Wellness):

(In support) The purpose of this bill is to establish an effective appeals process. Pharmacies are often reimbursed much less than their acquisition costs for prescription drugs. This leads to tremendous losses, especially for smaller pharmacies. Pharmacies incur more costs than are reflected in the invoice price—reimbursing a pharmacy the invoice price does not make them whole, but is a good start. These pharmacies are often the only pharmacies available for miles. Large pharmacies face the same challenges as small pharmacies. It is imperative to have the ability to appeal to a third party, which will not be an onerous process. This policy was put in place in 2014, but regulatory oversight of that policy is necessary. The OIC has the institutional experience to fill this role. Other agencies either contract with PBMs themselves or do not have the institutional knowledge. It is important to preserve local community access to pharmacy services. Pharmacies have the incentive to be prudent purchasers. The PBMs and insurers have the incentive to make reimbursements as low as possible. This problem needs to be solved this year.

(Opposed) The provisions and costs of this bill have not been thoroughly vetted by stakeholders. This bill will lead to results that may be difficult to unwind. Pharmacy claims are about 14 percent of processed claims—anything that adds to this cost should be carefully considered. Generic drug pricing is complicated. This issue should be carefully studied from the ground up. This bill was originally focused on rural pharmacies, but is now wide-sweeping enough to include big box stores, which are some of the most profitable companies. This bill should be limited to critical access pharmacies. Prescription drugs are a major health care cost driver for businesses and government—the one thing customers are asking for is controls on escalating drug costs. The appeals process in this bill will increase costs, which will end up being passed down to the consumers. This bill will also increase costs for the state and is a silent McCleary. There is no clinical or quality benefit from this, only higher costs. This bill expands the OIC's authority to include noninsurers and Medicaid plans, which will lead to dual regulation. This bill will lead to a slippery slope for additional asks from other types of providers. Pharmacy benefit managers make drugs safer and more affordable. The prices set by PBMs are often higher than a pharmacy's acquisition costs and are set in a manner that will lead to a net positive for the pharmacy. Drug prices are volatile and are skyrocketing. The MAC list is the benchmark for generic drugs and is set by the federal government and adopted by the private sector. The MAC lists for big chains are lower than for independent pharmacies, which have less buying power. A pharmacy's

acquisition costs are often lower than the actual cost due to discounts, rebates, etc. There is a lot of energy on this issue, but no energy on how much consumers are paying for the drugs or what pharmaceutical companies are charging for the drugs. This bill will increase costs for Taft-Hartley trusts, which are already experiencing higher drug costs.

(Other) Legislation will not necessarily resolve this issue. There is no understanding of the unintended consequences of this bill. This bill creates a confusing and costly appeals process and expands the regulatory authority of the OIC. This bill will shift costs to small businesses. The expansion of the IRO study to include other providers is beyond the scope of the title of the bill.

Staff Summary of Public Testimony (General Government & Information Technology):

(In support) If you are a drug store, whether a small independent or a chain, there is a problem when the reimbursement is much less than the cost of the drug. The goal of the bill is to set up an appeal process with enforcement. Currently, drug stores can appeal to the pharmacy benefit manager (PBM), but the PBMs reject 50 percent of the appeals. Drug pricing is very confusing; it is the patients that suffer at the end of the day. It is important to educate and make sure that there is a transparent mechanism through which to ensure that the drug-pricing chain does not impact access to patient care. Patients are being told that they cannot have certain medications. The PBMs are making these decisions, not the pharmacists. Any increase in drug pricing impacts the pharmacies, and there needs to be a way to get the invoice costs down for the purchase of drugs. There needs to be an ability to have an appeal process and to have oversight of an unregulated industry, an industry that impacts the access to drugs. The bill should not have a fiscal impact because the cost of the registration should cover the costs of the program and make it sustainable.

(Opposed) There appears to be a conflict in the scope of the application of the provisions of the bill. One section appears to limit it to generic drugs, but another section appears to go beyond that limitation. The amendment of the House Health Care and Wellness Committee reduces the adverse impact of an earlier version of the bill, but there is still a very significant cost-driving aspect to this bill, and close attention should be given to it. All provisions of the bill are aimed at the cost measures employed by the PBMs for the benefit of their customers. The fiscal note has not been fully fleshed out. Drug pricing is a very complicated system, and there has not been meaningful stakeholder involvement in the approaches put forward in this bill. This is a complex issue and needs significant study. Even if 0.5 percent of prescription claims were appealed, there would be more than 11,000 appeals per month. The OIC would not be able to handle that number of appeals. Independent pharmacies are remaining strong and growing and have 20 percent profit margins in some places.

(Other) Pharmacies have to dispense what is ordered, and many pharmacists take losses on prescriptions. There is support for allowing smaller pharmacies to go first in the appeal process of the OIC. The OIC should be able to contract with the Office of Administrative Hearings (OAH), if needed. The price differential between hiring staff and contracting with the OAH is significant.

Persons Testifying (Health Care & Wellness): (In support) Senator Parlette, prime sponsor; Holly Chisa, Northwest Grocery Association; Carolyn Logue, Washington Food Industry Association; and Kari VanderHouwen.

(Opposed) Sydney Smith Zvara, Association of Washington Health Care Plans; Jason Parrish, Express Scripts; Mel Sorenson, America's Health Insurance Plans, Cigna, and Washington Association of Health Underwriters; Maral Farsi, CVS Health; Bill Staulhatcher, Coordinated Care; Len Sorrin, Premera Blue Cross; Chris Bandoli, Regence BlueShield; Randy Scott, Washington State Pipe Trades Association; and Tom Kweiciak, Building Industry Association of Washington.

(Other) Sheri Nelson, Association of Washington Business.

Persons Testifying (General Government & Information Technology): (In support) Senator Parlette, prime sponsor; Representative Short; Jeff Rochon, Washington State Pharmacy Association; and Carolyn Logue, Washington Food Industry Association.

(Opposed) Michael Temple, Pharmaceutical Care Management Association; Mel Sorenson, Express Scripts and America's Health Insurance Plans; Carrie Tellefson, CVS Health; Bill Stauffacher, Coordinated Care; and Chris Bandoli, Regence BlueShield.

(Other) Holly Chisa, Northwest Grocery Association; and Lonnie Johns-Brown, Office of the Insurance Commissioner.

Persons Signed In To Testify But Not Testifying (Health Care & Wellness): None.

Persons Signed In To Testify But Not Testifying (General Government & Information Technology): None.