

# FINAL BILL REPORT

## E2SHB 1224

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Synopsis as Enacted

**Brief Description:** Concerning prescription drug cost transparency.

**Sponsors:** House Committee on Appropriations (originally sponsored by Representatives Robinson, Macri, Ryu, Peterson, Frame, Tharinger, Bergquist, Gregerson, Jinkins, Ortiz-Self, Lovick, Doglio, Stanford, Appleton, Slatter and Wylie).

**House Committee on Health Care & Wellness**  
**House Committee on Appropriations**  
**Senate Committee on Health & Long Term Care**  
**Senate Committee on Ways & Means**

### **Background:**

#### Prescription Drug Purchasing Consortium.

The Health Care Authority (HCA) established a prescription drug purchasing consortium. State purchased health care programs must purchase prescription drugs through the consortium, and local governments, private entities, labor organizations, uninsured, and underinsured residents may voluntarily participate in the consortium. In 2006 Washington and Oregon formed the Northwest Prescription Drug Consortium (Northwest Consortium) to expand their purchasing power. The Northwest Consortium offers access to retail pharmacy discounts, pharmacy benefit management services, rebate management services, and a prescription discount card for uninsured residents.

#### State Agency Work on Prescription Drug Costs.

In 2016 the Department of Health convened a task force to evaluate factors contributing to out-of-pocket costs for patients, including prescription drug cost trends. The same year, the HCA and the OFM prepared a report on prescription drug costs and potential purchasing strategies. The report describes increases in state agency spending on prescription drugs in recent years, current cost drivers, strategies to slow the rate of prescription drug spending, and policy options.

#### Pharmacy Benefit Manager.

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 is defined as a person that contracts with pharmacies on behalf of an

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insurer, a third-party payor, or the prescription drug purchasing consortium to: process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or pharmacists; pay pharmacies or pharmacists for prescription drugs or medical supplies; or negotiate rebates with manufacturers for drugs paid for or procured as described in this subsection. A PBM does not include a health care service contractor. A PBM must register with the Office of the Insurance Commissioner and renew the registration annually.

**Summary:**

Health Carrier Reporting.

Beginning October 1, 2019, and yearly thereafter, carriers must provide the Health Care Authority (HCA) the following information from the previous calendar year for each health plan it offers in Washington:

- the 25 most frequently prescribed prescription drugs by health care providers in their network;
- the 25 costliest prescription drugs and the plan's total spending on each drug;
- the 25 prescription drugs with the largest year-over-year increase in wholesale acquisition cost, including the percentage increase;
- the portion of the premium attributable to covered brand, generic, and specialty drugs after rebates and discounts;
- the year-over-year increase for covered brand, generic, and specialty drugs, both on a per member per month basis and as a percentage, after accounting for rebates and discounts;
- the year-over-year increase of covered drugs after rebates and discounts, calculated on a per member per month basis, as compared to other contributors to increases to premiums;
- the name of each covered specialty drug; and
- the names of the 25 most frequently prescribed drugs for which the plan received rebates.

Pharmacy Benefit Manager Reporting.

By March 1 of each year, a pharmacy benefit manager (PBM) must provide the HCA the following information from the previous calendar year:

- all discounts, including the total dollar amount and percentage discount, and all rebates received from a manufacturer for each drug on the PBM's formularies;
- the total dollar amount of all discounts and rebates that are retained by the PBM for each drug on the PBM's formularies;
- actual total reimbursement amounts for each drug the PBM pays retail pharmacies after all direct and indirect administrative and other fees that have been retrospectively charged to the pharmacies are applied;
- the negotiated price health plans pay the PBM for each drug on the PBM's formularies;
- the amount, terms, and conditions relating to copayments, reimbursement options, and other payments or fees associated with a prescription drug benefit plan;
- any ownership interest the PBM has in a pharmacy or health plan with which it conducts business;

- the results of any appeal filed by a network pharmacy against a PBM for reimbursement for a drug subject to predetermined reimbursement costs for multisource generic drugs; and
- a report for the preceding calendar year stating that the pharmacy benefit manager is in compliance with the requirements of the act.

A PBM may not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading. The HCA may examine or audit the financial records of a PBM for purposes of ensuring the information submitted is accurate.

#### Manufacturer Reporting.

Beginning October 1, 2019, manufacturers must provide the data organization with the following data for covered drugs:

- a description of the factors considered when setting or increasing the wholesale acquisition cost of the drug and an explanation of how the factors justify the increase;
- if the drug was produced by the manufacturer during the previous five years, a history of price increases during that time;
- if the drug was acquired by the manufacturer in the previous five years: (1) the price of the drug at the time of the acquisition; and (2) the company from which the drug was purchased, and the purchase price;
- the patent expiration date, if the drug is under patent;
- whether the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug;
- an itemized cost for the production and sale of each drug; and
- the total financial assistance given through programs, rebates, and coupons.

A manufacturer must submit this information at least 60 days in advance of a qualifying price increase for a covered drug and within 30 days of release a new covered drug to market. If 60 days' notice is not possible for a price increase of a generic drug, the notice should be made as soon as the increase is known and not later than the date of the price increase.

A "covered drug" is defined as a prescription drug that: (1) a covered manufacturer intends to introduce at a wholesale acquisition cost of \$10,000 or more for a course of treatment lasting less than one month or 30-day supply, whichever is longer; or (2) is currently on the market and has a wholesale acquisition cost of at least \$100 for a course of treatment lasting less than one month or 30-day supply that has a price increase of 20 percent or more including the proposed increase over one year, or 50 percent or more including the proposed increase over three years. A "prescription drug" is defined as a legend drug or controlled substance that is prescribed for outpatient use and distributed in a retail setting. A "qualifying price increase" is an increase in the wholesale acquisition cost of a drug that costs at least \$100 for a course of treatment or 30-day supply that is at least 20 percent or more including the proposed increase over one year, or 50 percent or more including the proposed increase over three years.

#### Manufacturer Notice of New Drug Applications.

Beginning October 1, 2019, manufacturers must report the following Food and Drug Administration (FDA) filing information to the HCA:

- a new drug application or biologics license application for a pipeline drug; or
- a biologics license application for a biologics product.

The manufacturer has 60 days to file a notice of FDA approval with the HCA.

Health Care Authority Requests to Manufacturers.

Upon receipt of FDA approval notice from the manufacturer, the HCA may request the following information from the manufacturer if it believes the drug will have significant impact on state expenditures:

- primary disease, condition, or therapeutic condition area studied in connection with the new drug;
- each route of administration studied for the drug;
- clinical trial comparators for the drug;
- date the FDA must complete its review of the application;
- whether the FDA designated the drug an orphan drug, fast-track product, or a breakthrough therapy; and
- whether the FDA designated the drug for accelerated approval, priority review, or the drug contains a new molecular entity.

Manufacturer Notice to Health Care Authority.

Beginning October 1, 2019, a manufacturer must notify the HCA, in writing, of a qualifying price increase of a covered drug at least 60 days prior to the planned effective date of the increase for drugs. If 60 days' notice is not possible for a price increase of a generic drug, the notice should be made as soon as the increase is known and not later than the date of the price increase. The notification must include:

- the date of the increase, the current wholesale acquisition cost of the prescription drug, and the dollar amount of the future increase in the wholesale acquisition cost of the prescription drug; and
- a statement regarding whether a change or improvement in the drug necessitates the price increase, and if so, a description of the change or improvement.

By December 1, 2020, the HCA must provide recommendations on how to provide advance notice of price increases to purchasers consistent with state and federal law.

Pharmacy Services Administrative Organization Reporting.

Beginning October 1, 2019, and yearly thereafter, pharmacy services administrative organizations (PSAOs) must provide the HCA:

- the negotiated reimbursement rate of the 25 prescription drugs with the highest reimbursement rate;
- the 25 prescription drugs with the highest year-to-year change in reimbursement rate, expressed as a dollar amount and percentage; and
- the schedule of fees charged to pharmacies by the PSAO.

Pharmacy services administrative organizations whose revenue is generated from flat service fees, not connected to drug prices or volume, are exempt from reporting.

Health Care Authority Report.

The HCA must compile the information collected from issuers, PBMs, manufacturers, and PSAOs and prepare an annual report for the Legislature demonstrating the overall impact of drug costs on health care premiums. Beginning January 1, 2021, the HCA must publish the report annually on its website. The data in the report must be aggregated and not reveal information specific to individual health carriers, PBMs, PSOsAs, prescription drugs, classes of prescription drugs, or manufacturers. The data collected under the act is not subject to public disclosure.

Upon the request of a legislator, the HCA must provide all data submitted under the act and any analysis prepared by the HCA. Any information provided must be kept confidential within the Legislature and may not be publicly released.

The HCA may assess fines of up to \$1,000 per day for failure to comply with reporting requirements.

The HCA must work with Oregon and California to develop strategies to reduce prescription drug costs and increase price transparency.

**Votes on Final Passage:**

House	80	18	
Senate	48	0	(Senate amended)
House			(House refused to concur)

Conference Committee

Senate	48	0
House	92	5

**Effective:** July 28, 2019