Washington State
House of Representatives
Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

2SSB 5292

Brief Description: Concerning prescription drug cost transparency.

Sponsors: Senate Committee on Ways & Means (originally sponsored by Senators Keiser, Cleveland, Randall, Hasegawa, Das, Saldaña, Wilson, C., Liias, Conway, Kuderer, Nguyen, Van De Wege and Wellman).

Brief Summary of Second Substitute Bill

- Requires issuers, carriers, pharmacy benefit managers, and pharmacy services administrative organizations to report certain prescription drug pricing data on a yearly basis to the Health Care Authority (HCA).
- Requires drug manufacturers to notify the HCA of new drug applications filed with the Food and Drug Administration and allows the HCA to collect additional information from the manufacturer about the drug.
- Requires the HCA to compile an annual list of ten drugs that meet a threshold price increase and have significant impact on state expenditures.
- Requires manufacturers to provide price increase justification and other information about those drugs to the HCA.
- Requires the HCA to analyze the pricing data and provide annual reports to the Legislature.

Hearing Date: 3/15/19

Staff: Kim Weidenaar (786-7120).

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

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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.

All-Payer Health Care Claims Database.
The Office of Financial Management (OFM) established the all-payer claims database to support transparent public reporting of health care information. The database collects claims data from the Medicaid program, Public Employees' Benefits Board programs, all health carriers, third party administrators, and Department of Labor and Industries programs. Claim files submitted to the database include pharmacy claims.

State Agency Work on Prescription Drug Costs.
In 2016 the Department of Health convened a taskforce 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 at the request of legislators. 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 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 of Bill:

Issuer Reporting.
Beginning October 1, 2019, and yearly thereafter, issuers must provide the Health Care Authority (HCA):

- the 25 most frequently prescribed prescription drugs by health care providers in the issuer's network;
- the 25 costliest prescription drugs and the issuer'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 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 specialty drug; and
- the names of the 25 most frequently prescribed drugs for which the issuer received rebates.

Pharmacy Benefit Manager Reporting.
Beginning October 1, 2019, and yearly thereafter, pharmacy benefit managers (PBMs) must provide the HCA:

- the aggregate dollar amount of all rebates and fees received from pharmaceutical manufacturers for prescription drugs covered by the PBM's issuer clients during the calendar year and are attributable to the patient utilization during the calendar year;
- the aggregate dollar amount of all rebates and fees received from pharmaceutical manufacturers for prescription drugs covered by the PBM's issuer clients during the calendar year that are not passed through to the issuer clients; and
- the aggregate retained rebate percentages.

Pharmacy Services Administrative Organization Reporting.
Beginning October 1, 2019, and yearly thereafter, pharmacy services administrative organizations (PSAOs) representing a pharmacy or pharmacy chain in Washington 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 PSOA.

Any PSOA whose revenue is generated from flat service fees, not connected to drug prices or volume, are exempt from reporting.

Manufacturer Reporting to Health Care Authorities.
Beginning October 1, 2019, manufacturers must report the following federal Food and Drug Administration (FDA) filing information to the HCA:

- a new drug application or biologics license application for a pipeline drug; and
- 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 Authorities 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 if the drug contains a new molecular entity.

Annual Drug List.
Beginning January 1, 2020, and yearly thereafter, the HCA must prepare a list of 10 prescription drugs that have significant impact on state expenditures, and are critical for public health. The HCA may only include prescription drugs with a wholesale acquisition cost, less rebates received by the state, that:

- increased by at least 20 percent during the preceding calendar year or increased by at least 50 percent in the preceding three calendar years; and
- cost at least one hundred dollars for a 30-day supply or course of treatment lasting less than 30 days.

The HCA must notify manufacturers of drugs appearing on the list.

Manufacturer Drug Price Reporting.
Manufacturers of drugs appearing on the annual drug list must provide the following information within 30 days of the notice from the HCA:

- a written description, suitable for public release, detailing the financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug;
- a schedule of the drug's wholesale acquisition cost increases over the previous five calendar years;
- the manufacturer's aggregate, company level research and development and other capital expenditures for the most recent year for which final audited data is available;
- the year the drug was introduced to the market and the wholesale acquisition cost at the time the drug was introduced; and
- whether the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug.

The HCA must create a standardized form for reporting this information. The form must be designed in a way to minimize the administrative burden and cost of reporting on the manufacturers and the HCA. A manufacturer may limit the information reported to that which is otherwise in the public domain or publically reported. Information collected from the manufacturers for this purpose is not subject to public disclosure and is considered a trade secret.

Health Care Authority Report.
The HCA must compile the information collected from issuers, PBMs, and PSOAs and prepare an annual report for the public and the Legislature demonstrating the overall impact of drug costs on health care premiums. The data in the report must be aggregated and not reveal information about specific entities, and the HCA must keep all obtained information and data confidential, except for the report. Beginning January 1, 2020, and each January 1 after, the HCA must publish the report on its website.

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.

A new chapter is created in Title 43 Revised Code of Washington. The HCA may adopt rules necessary to implement the requirements of the new chapter.

Definitions.
"Aggregate retained rebate percentage" means the percentage of all rebates received by a PBM from all pharmaceutical manufacturers which is not passed on to the PBM's health plan or issuer clients. An aggregate retained rebate percentage must be calculated by dividing: the aggregate dollar amount of all rebates that the PBM received during the prior calendar year from all pharmaceutical manufacturers and did not pass through to the PBM's health plan or issuer clients; by the aggregate dollar amount of all rebates that the PBM received during the prior calendar year from all pharmaceutical manufacturers.

"A pharmacy services administrative organization" is defined as an entity that contracts with a pharmacy to act as the pharmacy's agent with respect to matters involving a PBM, third party payor, or other entities, including negotiating, executing, or administering contracts with the pharmacy benefit manager, third party payor, or other entities and provides administrative services to pharmacies.

"Wholesale acquisition cost" means the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding any discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of prescription 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.