HOUSE BILL REPORT
2SSB 5292

As Reported by House Committee On:
Health Care & Wellness

Title: An act relating to prescription drug cost transparency.

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 History:
Committee Activity:
Health Care & Wellness: 3/15/19, 3/27/19 [DPA].

Brief Summary of Second Substitute Bill
(As Amended by Committee)

- Requires issuers and drug manufacturers to report certain prescription drug pricing data to a data organization contracted by the Health Care Authority (HCA).
- Requires the data organization to summarize the prescription drug pricing data and provide reports to the Legislature and the HCA.
- Requires pharmacy benefit managers (PBMs) to submit certain information on discounts, rebates, and reimbursement for drugs in a PBM's formulary.
- Requires the Office of the Insurance Commissioner (OIC) to analyze and report on the data submitted by PBMs and allows OIC to audit a PBM's financial records to ensure the information submitted is accurate.
- Requires manufacturers to report drug shortages to the HCA within 30 days of a drug shortage occurring.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: Do pass as amended. Signed by 12 members: Representatives Cody, Chair; Macri, Vice Chair; Schmick, Ranking Minority Member; Caldier, Assistant Ranking

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Minority Member; Chambers, Davis, Jinkins, Riccelli, Robinson, Stonier, Thai and Tharinger.

Minority Report: Without recommendation. Signed by 2 members: Representatives DeBolt and Harris.

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 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.

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 Amended Bill:

The Health Care Authority (HCA) must conduct a competitive procurement process to select a data organization to collect, verify, and summarize prescription drug pricing data provided by drug manufacturers and issuers.

Definitions.
A covered drug is defined as:

- a drug the manufacturer intends to introduce to the market at a wholesale acquisition cost of $10,000 or more for a course of treatment lasting less than one month or a 30-day supply, whichever period is longer; or
- a drug currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than $100 for a course of treatment lasting less than one month or a 30-day supply, and the manufacturer increases the wholesale acquisition cost at least 20 percent, including the proposed increase and the cumulative increase that occurred two calendar years prior to the date of the proposed increase.

A qualified price increase is defined as a price increase for existing prescription drugs currently on the market as defined in the covered drug definition.

A covered manufacturer means a person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington. A covered manufacturer does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store, or a prescription drug repackager.

Insurance Carrier Obligations.
By March 1 of each year, a carrier must provide the data organization with the following information for the previous calendar year:

- the 25 most frequently prescribed prescription drugs by health care providers in the carrier's network;
- the 25 costliest prescription drugs, and the carrier's total spending on each drug;
- the 25 prescription drugs with the largest year-over-year increase in spending, including the percentage increase; and
- a summary of the impact of prescription drug costs on health plan premiums.

Employer-sponsored self-funded health plans and Taft-Hartley trust health plans may voluntarily provide this data.

Manufacturer Obligations.
Beginning October 1, 2019, a covered manufacturer must provide the data organization the following information for covered drugs:

- a description of the factors considered when increasing the wholesale acquisition cost of a covered drug, including an explanation of how these factors explain the increase in cost;
- a history of cost increases for the past five years if the drug was manufactured by the company during that time;
- if the drug was acquired by the manufacturer within the previous five years, the manufacturer must provide:
    - the wholesale acquisition cost of the drug at the time of the acquisition and in the calendar year prior to acquisition; and

    - the company from which the drug was purchased, the purchase price, and the date it was acquired;
- the year the drug was introduced to the market and the wholesale price at introduction;
- the patent expiration date;
- if 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, including costs related to advertising, research and development, and clinical trials and regulation; and
- the total financial assistance given through programs, rebates, and coupons.

A covered manufacturer must submit this information at least 60 days in advance of a qualifying price increase of a drug and within 30 days of release of a new covered drug.

A covered manufacturer must also notify the purchaser of a qualifying price increase in writing at least 60 days prior to the planned effective date of the increase for drugs, beginning October 1, 2019. 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, the manufacturer shall describe the change or improvement.

If a pharmacy benefit manager (PBM) receives a notice of an increase in wholesale acquisition cost it must notify its large contracting public and private purchasers, those that provide coverage to more than 500 lives, of the increase.

A covered manufacturer must report to the HCA within 30 days of a drug shortage occurring, an explanation of what cause the drug shortage and an estimated duration of the shortage. Within 180 days of submitting the notice to HCA, the manufacturer must report to the HCA whether the sales of other drugs manufactured by the covered manufacturer increased during the shortage period, and the name, wholesale acquisition cost, and the amount the sales increased for each drug that increased in sales during the shortage period.

Enforcement by the Health Care Authority.
The HCA may assess a fine of up to $1,000 per day if a carrier or manufacturer fails to comply with these requirements. Fines collected must be deposited in the Medicaid Fraud Penalty Account. The HCA must report any fines levied against a health carrier to the Office of the Insurance Commissioner (OIC).

Data Reporting by the Health Care Authority.
The data organization must compile the data collected from carriers and manufacturers into a report to the HCA. The HCA must conduct an independent analysis of the data and produce a report for the public and the Legislature demonstrating the impact of prescription drug costs on health care premiums. Beginning January 1, 2020, and each following January 1, the HCA must publish the report on its website. The HCA must also share the information provided by carriers with the OIC. Except for reporting purposes, the HCA and OIC must keep all information provided pursuant to these requirements confidential and the

information is not subject to public disclosure. The HCA must also collect data from the all-payers claims database on prescription drug claims to include billed and paid charges. By November 1, 2020, the HCA must produce a report for the Legislature that includes charts demonstrating the variance in billed and paid charges among the carriers for the 25 drugs with higher than average variances in billed and paid charges based on data from the all-payers claims database.

The HCA may only use the data reported by carriers and manufacturers for purposes of analyzing and reporting the data to the public and the Legislature. The data may not be used for any other purpose. The HCA may adopt rules necessary to implement these requirements.

Pharmacy Benefit Manager Obligations.
By March 1 of each year, a PBM must submit to the OIC 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. A PBM is defined to exclude health maintenance organizations from the definition.

Enforcement by the Office of Insurance Commissioner.
The OIC may examine or audit the financial records of a PBM for purposes of ensuring the information submitted is accurate. Information the OIC in the examination of financial records proprietary and confidential. The OIC may assess a fine of up to $1,000 per day for a violation or failure to comply with the requirements of the act.

Data Reporting by the Office of Insurance Commissioner.
The OIC must analyze the data submitted by PBMs and prepare a final report for the public and legislators. Beginning December 1, 2020, and each following December 1, the OIC must publish the report on its web site. The data in the report must be aggregated and must not

reveal information specific to individual health plans or PBMs. Except for the report, the OIC must keep all information submitted by PBMs confidential and the information is not subject to public disclosure.

A new chapter is created in Title 43 Revised Code of Washington.

If specific funding for the purposes of this act is not provided, the act is null and void.

Amended Bill Compared to Second Substitute Bill:

The amended bill:

- removes the reporting requirements on pharmacy services administrative organizations;
- removes the requirement on the Health Care Authority (HCA) to contact the appropriate agencies in California and Oregon to develop strategies to reduce prescription drug costs and increase prescription drug cost transparency, and make recommendations to implement joint strategies;
- modifies reporting requirements for health carriers and prescription drug manufacturers, and requires the data to be reported to a data organization contracted with the HCA rather than the HCA;
- modifies the report the HCA must produce to compile data submitted by carriers and manufacturers;
- requires manufacturers to provide advance notice to purchases regarding certain prescription drug cost increases;
- modifies the reporting requirements for pharmacy benefit managers (PBMs);
- prohibits a PBM from causing or knowingly permitting the use of any untrue, deceptive, or misleading advertisement, promotion, or offer;
- provides the Office of the Insurance Commissioner (OIC) enforcement authority over PBMs for purposes of the act, and requires the OIC to produce an annual report summarizing the data collected from PBMs;
- requires the HCA to produce a report demonstrating the variances in billed and paid charges among carriers for certain prescription drugs; and
- requires covered manufacturers to report to the Health Care Authority:
    - within 30 days of a drug shortage occurring, an explanation of what caused the shortage and an estimated duration of the shortage; and
    - within 180 days of submitting the notice, whether the sales of other drugs manufactured by the covered manufacturer increased during the shortage period; and the name, wholesale acquisition cost, and the amount the sales increased for each drug that increased in sales during the shortage period.

Appropriation: None.

Fiscal Note: Available.

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

Staff Summary of Public Testimony:

(In support) This bill has come a long ways, but there is one issue that is left to be addressed, the lack of advanced notice about drug price increases. Consumers, employers, and others can then use that information to make purchasing decisions. The original bill included 60-day advance notice to purchasers. An amendment along those lines adding back in the advance notice requirement would complete the bill and make it useable.

The provisions that apply to pharmacy benefit managers (PBMs) are not strong enough. The PBMs create, design, and implement the health plans prescription drug plans, decide the copays, the rebates, and how patients get their drugs. The PBMs are now charging providers multiple fees without explaining what the fees are or what they are for. These activities are done without any oversight.

Drug prices are a top issue for older Americans. The average Medicare Part D beneficiary is taking four to five drugs daily. Patients need drugs they can afford, but many drugs are completely unaffordable. Many medications cost only a small fraction to produce manufacturers charge. For example, one drug costs $3 per capsule to produce, but the manufacturer charges $750 per capsule. This is not good for patients or for tax payers. People deserve to know why drug costs are increasing so rapidly and deserve an explanation.

The government needs to step up and lower drug prices, rather than just shift money around. This version of the bill is missing strong reporting requirements for manufacturers, which are the only ones that can set the initial price and is the most important part of the picture. These requirements should be brought back into the bill.

Stronger transparency requirements are an important step to ensure patients get access to medicines they need. This bill is a solid first step towards transparency. It would require entities throughout the supply chain to provide transparency information to Health Care Authority.

(Opposed) None.

(Other) This bill was materially amended in the Senate and many positive changes were made. However, the manufacturer's list price and wholesale cost should be included. The list price is the baseline for what patients and plans pay for drugs. The pharmaceutical supply chain involves a number of entities and payers. The prices and payments along the supply chain are based upon the manufacturer's list price. Ultimately high list prices are the driver for high drug prices, and they impact how all other actors along the supply chain engage. In 2012, prescription drugs accounted for 12.8 percent of the insurance premium and in 2018 accounted for 23 percent. The net revenue for pharmacies is also significantly increasing, but patient payments are going down, driving up premiums.

When there are transparency requirements on manufacturers they may be less likely to increase list prices. This version of the bill is problematic because it does not include wholesalers and retail pharmacies in the transparency requirements. Carriers will have difficulty reporting on wholesale acquisition costs, because carriers do not track this information or may not be privy to this information.

While all entities in the supply chain should be included, this bill is a reasonable and fair step towards that end. The bill has the right balance of who is included and how they are included. Keeping trade secret disclosure and advance notice out of the bill keeps it out of the current litigation scenario and is a positive step. Patients should have access to information and this is a good step in that direction.

Pharmacy benefit managers already have transparency with their client, the health plans, and the plans work with PBMs to negotiate a contract, so there is total transparency. The PBM reporting requirements in this version of the bill are similar and consistent with reporting requirements under the Affordable Care Act.

Persons Testifying: (In support) Senator Keiser, prime sponsor; Dedi Little, Washington State Pharmacy Association; Joanna Grist, AARP; Sybill Hyppolite, Service Employee International Union Healthcare 1199 Northwest; and Michael Gaffney.

(Other) Meg Jones, Association of Washington Healthplans; Michael Transue, Oregon Biosciences Association; Michael Temple, Pharmaceutical Care Management Association; Amber Ulvenes, Kaiser Permanente; and Bill Clarke, Biotechnology Innovation Organization.

Persons Signed In To Testify But Not Testifying: None.