HOUSE BILL REPORT
HB 1224

As Reported by House Committee On:
Health Care & Wellness
Appropriations

Title: An act relating to prescription drug cost transparency.

Brief Description: Concerning prescription drug cost transparency.

Sponsors: Representatives Robinson, Macri, Ryu, Peterson, Frame, Tharinger, Bergquist, Gregerson, Jinkins, Ortiz-Self, Lovick, Doglio, Stanford, Appleton, Slatter and Wylie.

Brief History:
Committee Activity:
Health Care & Wellness: 2/6/19, 2/15/19 [DPS];
Appropriations: 2/27/19, 2/28/19 [DP2S(w/o sub HCW)].

Brief Summary of Second Substitute Bill

- 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.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 11 members: Representatives Cody, Chair; Macri, Vice Chair; Caldier, Assistant Ranking Minority Member; Chambers, Davis, Jinkins, Riccelli, Robinson, Stonier, Thai and Tharinger.

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

Minority Report: Do not pass. Signed by 2 members: Representatives Schmick, Ranking Minority Member; Maycumber.

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.

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. 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.

Summary of Substitute 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;
- a drug currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than $40 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 16 percent, including the proposed increase and the cumulative increase that occurred two calendar years prior to the date of the proposed increase; or

- a generic drug that is currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than $40 for a course of treatment lasting less than one month or a 30-day supply, and the wholesale acquisition cost increases a net of at least 16 percent over the prior calendar quarter, 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 and generic 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 other than a generic drug and within 30 days of a qualifying price increase of a generic drug or 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 other than generic 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 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.

Enforcement.
The HCA may assess a fine of up to $1,000 per day if an 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.
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.

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

Substitute Bill Compared to Original Bill:

The substitute bill:

- changes references of issuer to carrier;
- creates a new definition of covered drug for generic drugs, which is defined as generic drug that is currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than $40 for a course of treatment lasting less than one month or a 30-day supply, and the wholesale acquisition cost increases a net of at least 16 percent over the prior calendar quarter, including the proposed increase and the cumulative increase that occurred two calendar years prior to the date of the proposed increase;
- changes the agency responsible for contracting with the data organization and analyzing and reporting on the data to the Health Care Authority (HCA) from the Office of Financial Management;
- establishes timelines for when covered manufacturers must provide information on covered drugs to the data organization;
- removes new drugs from the requirement that covered manufacturers notify purchasers of a qualifying price increase;
- prohibits the HCA from using any data reported by covered manufacturers and health carriers for any purposes other than analysis and reporting of the data; and
- exempts private label distributors or retail pharmacies that sell a drug under the retail pharmacies' stores and prescription drug repackagers from the definition of covered manufacturer.

Appropriation: None.

Fiscal Note: Preliminary fiscal note available.

Effective Date of Substitute 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) The largest driver of health care costs is now new-to-market drugs. Healthcare plans do what they can to keep prices low, but prescription drugs make up 23 percent of each premium dollar and so it is a struggle to keep prices down. The cost of prescription drugs is now eclipsing in-patient hospital costs for the amount of every premium it takes. These costs are not due to increases in use, but are because of increases in price per drug. Some of the biggest increases in costs were driven by increases in prices of drugs that were already in the market. Drug companies have full control of the price of a drug. This bill is a first step legislators can take to address drug costs. Manufactures must play their part in keeping health care costs down and must share responsibility for their role in health care costs.

Many individuals have a difficult time affording necessary prescription drugs and some people have rationed drugs due to price. About 80 percent of the public support a policy that drug companies must make public how they decide on prices.

High list prices are important. List prices are the basis for negotiating rates and discounts. This bill sheds a light on where drug pricing begins, the list price. If there is an understanding about what the list price is and why, plans and others have a better opportunity to negotiate and react. It is important to have transparency and accountability start with those who set the price. This bill is largely consistent with California's law, which is an excellent model.

(Opposed) This bill mandates extensive reporting, but these companies already report significant amounts of data to federal agencies. Drug companies want people to afford drugs and they take that seriously. However, the increase in prices has slowed. Express Scripts announced spending increased only 0.4 percent in 2018, which is a 25-year low. Drug costs are the only part of the health care system that drop in price over time. Medicines also help save lives and save the health care system money. Prescription drugs can keep people out of more costly areas of health care. Studies have found that half of the spending slowdown on Medicare from 1999-2012 was because of a reduction in cardiovascular events, which is attributable to prescription drugs. There are also many rebates and programs, which drug companies spend hundreds of millions on. Often patients can pay more in co-insurance or co-pays than what the insurer or Pharmacy Benefit Manager actually pays for the drug.

No patient should have to worry about affording necessary health care, but these policies would halt new research and harm jobs. Innovation and research is very expensive.

If the goal is transparency, the entire supply chain should be included, so that we can see what is really forcing the costs when patients pick up the drugs at the pharmacy. The bill also ignores the supply chain where there are a number of opportunities to lower prices and costs.

Generic drugs account for 90 percent of prescriptions, but only 23 percent of the money spent on prescriptions. The prescription drug market works differently than other drugs and operates more like a commodity, where prices constantly fluctuate. Under the current requirements, generic drug manufacturers would have to continually be reporting under the requirements of the bill, even if changes in price are very small. Providing notice 60 days in advance would be impossible.

Persons Testifying: (In support) Representative Robinson, prime sponsor; Courtney Smith, Kaiser Permanente; Sybill Hyppolite, Service Employee International Union Healthcare 1999 Northwest; Meg Jones, Association of Washington Healthcare Plans; Mel Sorenson, America's Health Insurance Plans; and Thomas MacRobert.

(Opposed) Eric Lohnes, Pharmaceutical Research and Manufacturers of America; Lee Newgent, Pharmaceutical Industry Labor Management Association; and Abbey Moore, Association of Accessible Medicine.

Persons Signed In To Testify But Not Testifying: None.

Majority Report: The second substitute bill be substituted therefor and the second substitute bill do pass and do not pass the substitute bill by Committee on Health Care & Wellness. Signed by 23 members: Representatives Ormsby, Chair; Bergquist, 2nd Vice Chair; Robinson, 1st Vice Chair; Caldier, Cody, Dolan, Dye, Fitzgibbon, Hansen, Hudgins, Jinkins, Macri, Mosbrucker, Pettigrew, Pollet, Ryu, Schmick, Senn, Springer, Stanford, Sullivan, Tarleton and Tharinger.

Minority Report: Do not pass. Signed by 9 members: Representatives Stokesbary, Ranking Minority Member; MacEwen, Assistant Ranking Minority Member; Rude, Assistant Ranking Minority Member; Chandler, Hoff, Kraft, Steele, Sutherland and Ybarra.

Staff: Catrina Lucero (786-7192).

Summary of Recommendation of Committee On Appropriations Compared to Recommendation of Committee On Health Care & Wellness:

The second substitute bill removes the removes the specific definition for generic drugs within the covered drugs definition and removes the specific reporting timelines for generic drugs. It also increases the threshold for the wholesale acquisition cost of a course of treatment lasting less than one month or a 30-day supply for purposes of a covered drug from $40 to $100. Pharmacy benefit managers (PBMs) are required to submit the following information to the Office of the Insurance Commissioner (OIC) by March 1 each year:

- all discounts and rebates received from a manufacturer for each drug on the PMB's formularies;
- the total dollar amount of all discounts and rebates that are retained by the PBM for each drug on the 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;
- disclosure of any ownership interest the PBM has in a pharmacy or health plan with which it conducts business;
- the results of any appeals 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 stating that the PBM is in compliance with the act's requirements, which must also include the amount, terms, and conditions relating to copayments, reimbursement options, and other payments or fees associated with a prescription drug benefit plan.

The second substitute bill states that a PBM has a fiduciary duty to patients and beneficiaries to perform services in accordance with state and federal law.

The second substitute bill authorizes the OIC to:

- examine or audit the financial records of a PBM; and

- adopt rules necessary to implement the requirements of the provisions related to PBMs.

The OIC is allowed to assess a fine up to $1,000 for failure to comply with these requirements.

A null and void clause was added, making the bill null and void unless funded in the omnibus appropriations act.

Appropriation: None.

Fiscal Note: Available. New fiscal note requested on February 19, 2019.

Effective Date of Second Substitute Bill: The bill takes effect 90 days after adjournment of the session in which the bill is passed. However, the bill is null and void unless funded in the budget.

Staff Summary of Public Testimony:

(In support) High drug prices challenge affordability in healthcare. Most of the increases in prescription drug costs are driven by unit cost rather than prescription volume. Drug companies are in control of the original price of the drug. The bill's requirements that carriers and manufactures report on the most expensive drugs contributing to rising premiums is a step toward improved transparency and price control. Patients need drugs they can afford. One out of every four Americans report difficulty paying for their prescription drugs. One out of every eight Americans report that they or a family member have rationed dosages as a way to decrease prescription drug costs. The majority of Americans support policies that increase transparency on the drug price setting process. High list prices are important. They are the basis for negotiating discounts and rates. Drug pricing is a complicated issue. This is the first step we can take to identify solutions to the problem of high cost drugs.

(Opposed) The bill mandates a number of reporting requirements but does not acknowledge that much of this information is already reported to the Securities and Exchange Commission and the Food and Drug Administration much earlier in the process. The advanced notification requirements could create drug shortages. The bill focuses exclusively on list price. Manufactures set list price but also pay extensive rebates. This often does not get forwarded on to the consumer. List price is often blamed for the high cost of drugs. This obfuscates the role that carriers and other's play in this issue. If the state is going to invest in drug price transparency it should do so across the spectrum of entities that play a role in drug pricing. This would provide a more comprehensive look at transparency. The information collected in this bill will not help answer the question of why a person pays what they do at the pharmacy counter. Generic drug manufacturers do not always know 60 days in advance of a drug price increase, as there is a high level of fluctuation as manufactures compete with each other. The fines in the bill create a perverse incentive in this case.

Persons Testifying: (In support) Courtney Smith, Kaiser Permanente; and Sybill Hyppolite, Service Employees International Union Healthcare 1199NW.

(Opposed) Eric Lohnes, Pharmaceutical Research and Manufacturers of America; Bill Clarke, Biotechnology Innovation Organization; and Abby Moore, Association of Accessible Medicine.

Persons Signed In To Testify But Not Testifying: None.