HOUSE BILL REPORT
E2SHB 1224

As Passed Legislature

Title: An act relating to prescription drug cost transparency.

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).

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)].

Floor Activity:

Passed House: 3/8/19, 80-18.
Senate Amended.
Passed Senate: 4/16/19, 48-0.
House Refused to Concur.
Conference Committee.
Passed Senate: 4/25/19, 48-0.
Passed House: 4/25/19, 92-5.
Passed Legislature.

Brief Summary of Engrossed Second Substitute Bill

- Requires health carriers, pharmacy benefit managers, pharmacy services administrative organizations, and drug manufacturers to report certain prescription drug pricing data to the Health Care Authority (HCA).
- Requires manufacturers to provide advance notice to HCA before increase the price of certain drugs.
- Requires HCA to analyze the data and provide an annual report to the Legislature.

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: 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.

Staff: Kim Weidenaar (786-7120).

HOUSE COMMITTEE ON APPROPRIATIONS

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).

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 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 Engrossed Second Substitute Bill:

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

- 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 spending, 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 each category of drug listed above, 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 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 price 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 year the drug was introduced to the market and at what 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 if 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, the manufacturer shall describe 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, PSOAs, 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.

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

Appropriation: None.

Fiscal Note: Available.

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

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

(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.

Staff Summary of Public Testimony (Appropriations):

(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 (Health Care & Wellness): (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 Testifying (Appropriations): (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 (Health Care & Wellness): None.

Persons Signed In To Testify But Not Testifying (Appropriations): None.