SENATE BILL REPORT
E2SHB 1224

As Reported by Senate Committee On:
Health & Long Term Care, March 29, 2019
Ways & Means, April 9, 2019

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: Passed House: 3/08/19, 80-18.
Committee Activity: Health & Long Term Care: 3/18/19, 3/29/19 [DPA-WM].
Ways & Means: 4/03/19, 4/09/19 [DPA, DNP, w/oRec].

Brief Summary of Amended 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 purchases before increase the price of certain drugs.
- Requires HCA to analyze the data and provide an annual report to the Legislature.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: Do pass as amended and be referred to Committee on Ways & Means.
Signed by Senators Cleveland, Chair; Randall, Vice Chair; O'Ban, Ranking Member; Bailey, Becker, Dhingra, Keiser, Rivers and Van De Wege.

Staff: Greg Attanasio (786-7410)

SENATE COMMITTEE ON WAYS & MEANS

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: Do pass as amended.

Signed by Senators Rolfes, Chair; Frockt, Vice Chair, Operating, Capital Lead; Mullet, Capital Budget Cabinet; Billig, Carlyle, Conway, Darneille, Hasegawa, Hunt, Keiser, Liias, Palumbo, Pedersen, Van De Wege and Warnick.

Minority Report: Do not pass.

Signed by Senator Rivers.

Minority Report: That it be referred without recommendation.

Signed by Senators Braun, Ranking Member; Brown, Assistant Ranking Member, Operating; Honeyford, Assistant Ranking Member, Capital; Bailey, Becker, Schoesler and Wagoner.

Staff: Sandy Stith (786-7710)

Background: Prescription Drug Purchasing Consortium. Pursuant to statute, the 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 State 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. Pursuant to statute, 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 (DOH) convened a taskforce to evaluate factors contributing to out-of-pocket costs for patients, including prescription drug cost trends. The same year, HCA and 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 Managers. 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 OIC and renew the registration annually.

Summary of Amended Bill: Issuer Reporting. Beginning October 1, 2019, and yearly thereafter, issuers must provide HCA:

- the 25 most frequently prescribed prescription drugs by health care providers in their 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 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 issuer received rebates.

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

Manufacturer Reporting. Beginning October 1, 2019, manufacturers must provide the data organization with the following data for each new drug costing $10,000 or more for a course of treatment or 30-day supply, and each existing drug costing at least $100 for a course of treatment or 30-day supply that has a price increase of 20 percent or more in one year, or 50 percent or more in three years:

- 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.

Manufacturer Notice of New Drug Applications. Beginning October 1, 2019, manufacturers must report the following FDA filing information to 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 HCA.

HCA Requests to Manufacturers. Upon receipt of FDA approval notice from the manufacturer, 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 Purchasers. Beginning October 1, 2019, for drugs costing $100 or more for a course of treatment, a manufacturer must notify purchasers of a price increase of 20 percent or more over one year or 50 percent or more over three years, in writing, at least 60 days prior to the planned effective date of the increase for drugs. 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.

Pharmacy Services Administrative Organization Reporting. Beginning October 1, 2019, and yearly thereafter, pharmacy services administrative organizations (PSAOs) must provide 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.

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

HCA Report. 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.

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

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

EFFECT OF WAYS & MEANS COMMITTEE AMENDMENT(S):

- Adds requirement for manufacturers to provide notice of new drug applications filed with the Food and Drug Administration.
- Provides the information submitted by manufacturers pursuant to Section 5 is not subject to public disclosure and is a trade secret.
- Provides generic drug manufacturers flexibility on timing for submission of pricing data before raising the price of a covered drug.
- Requires Health Care Authority to develop strategies with California and Oregon to reduce prescription drug costs and increase price transparency.

EFFECT OF HEALTH & LONG TERM CARE COMMITTEE AMENDMENT(S):

- Adds additional carrier reporting requirements.
- Changes PBM reporting requirements to focus on aggregate rebate information and changes reporting authority to HCA.
- Adds PSAO reporting requirements.
- Changes covered drug definition to drugs costing at least $100 for a 30-day supply with a price increase of 20 percent or more in one year or 50 percent or more in three years.
- Consolidates the report to the Legislature into a single annual report from HCA.
- Changes the definition of prescription drug.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony on Engrossed Second Substitute House Bill (Health & Long Term Care): *The committee recommended a different version of the bill than what was heard.* PRO: Patients need drugs they can afford and information is necessary to address the issue. PBM transparency is an important part of the bill to help understand consumer prices.

CON: All members of the supply chain should be included in transparency legislation. Focusing on the list price does not help to explain what consumers pay for drugs. It is important to consider how rebates and discounts affect retail prices. The advanced notification requirement does not reflect how the generic drug market operates. PBMs and health carriers collaborate to keep drug prices down for consumers. PBMs are already transparency with their clients. PBMs do not have a direct relationship with patients so there is no fiduciary relationship.

OTHER: The manufacturer reporting requirements in the bill are strong, but the approach to PBMs in SB 5292 is better.

Persons Testifying (Health & Long Term Care): PRO: Representative June Robinson, Prime Sponsor; Sybill Hyppolite, SEIU Healthcare 1199NW; Dedi Little, Washington State Pharmacy Association; Rick Hughes, Ray's Pharmacy.

CON: Lee Newgent, Pharmaceutical Industry Labor-Management Association; Christine Brewer, Association of Washington Healthcare Plans; Carrie Tellefson, Pharmaceutical Care Management Association; Eric Lohnes, Pharmaceutical Research and Manufacturers of America; Brett Michelin, Association of Accessible Medicine; Brian Warren, Biotechnology Innovation Organization.

OTHER: Amber Ulvenes, Kaiser Permanente.

Persons Signed In To Testify But Not Testifying (Health & Long Term Care): No one.

Staff Summary of Public Testimony on the Bill as Amended by Health & Long Term Care (Ways & Means): *The committee recommended a different version of the bill than what was heard.* CON: This version of the bill added $680,000 in costs because of the contentiousness of reporting requirements for manufacturers. The only way to realize true savings is to look at the entirety of the prescription drug supply chain. We are opposed to this version of the bill. We are not opposed to SB 5292 as it passed the Senate.

OTHER: PBMs have complete transparency with health plans. We are not enthusiastic about this, but prefer this version because it mirrors the Affordable Care Act. A more granular level of reporting would probably be an issue because it would reveal proprietary information. If reporting is expanded beyond manufacturers, it should include the entire supply chain. The definition of prescription drugs in this version of the bill is now confusing. We support this version of the bill over the House version. This version of the bill does not get at PBMs closely enough. We recommend restoring the House version of the bill related to PBMs.

Persons Testifying (Ways & Means): CON: Jeff Gombosky , Pharmaceutical Research and Manufacturers of America; Bill Clarke, Biotechnology Innovation Organization.

OTHER: Meg Jones, Association of Washington Healthcare Plans; Carrie Tellefson, Pharmaceutical Care Management Association; Dedi Little, Washington State Pharmacy Association.

Persons Signed In To Testify But Not Testifying (Ways & Means): No one.