Title: An act relating to prescription drug cost transparency.

Brief Description: Concerning prescription drug cost transparency.

Sponsors: Senators Keiser, Cleveland, Randall, Hasegawa, Das, Saldaña, Wilson, C., Lias, Conway, Kuderer, Nguyen, Van De Wege and Wellman.

Brief History:

Committee Activity: Health & Long Term Care: 1/28/19, 2/08/19 [DPS-WM, DNP].
Ways & Means: 2/19/19, 2/26/19 [DP2S].

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 HCA of new drug applications filed with the Food and Drug Administration and allows HCA to collect additional information from the manufacturer about the drug.

• Requires 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 HCA.

• Requires HCA to analyze the pricing data and provide annual reports to the Legislature.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: That Substitute Senate Bill No. 5292 be substituted therefor, and the substitute bill do pass and be referred to 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.
Signed by Senators Cleveland, Chair; Randall, Vice Chair; Dhingra, Frockt, Keiser and Van De Wege.

**Minority Report**: Do not pass.
Signed by Senators O'Ban, Ranking Member; Becker.

**Staff**: Greg Attanasio (786-7410)

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**SENATE COMMITTEE ON WAYS & MEANS**

**Majority Report**: That Second Substitute Senate Bill No. 5292 be substituted therefor, and the second substitute bill do pass.
Signed by Senators Rolfses, Chair; Frockt, Vice Chair, Operating, Capital Lead; Mullet, Capital Budget Cabinet; Braun, Ranking Member; Brown, Assistant Ranking Member, Operating; Honeyford, Assistant Ranking Member, Capital; Bailey, Becker, Billig, Carlyle, Conway, Darneille, Hasegawa, Hunt, Keiser, Lias, Palumbo, Pedersen, Rivers, Schoesler, Van De Wege, Wagoner, Warnick and Wilson, L..

**Staff**: Sandy Stith (786-7710)

**Background**: Prescription Drug Purchasing Consortium. Pursuant to statute, 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 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, 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.

**Summary of Bill (Second Substitute)**: 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.

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 PSOA.

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

Manufacturer Reporting to HCA. 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; and
- 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.

**Annual Drug List.** Beginning January 1, 2020, and yearly thereafter, HCA must prepare a list of ten prescription drugs that have significant impact on state expenditures, and are critical for public health.

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

HCA must make this information public on its website.

**HCA Report.** HCA must compile the information collected from issuers, PBMs, and PSOAs 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 CHANGES MADE BY WAYS & MEANS COMMITTEE (Second Substitute):**

- Requires carriers, PBMs, and PSOAs to provide rebate and pricing data to HCA and for HCA to produce an annual report demonstrating the impact of drug prices on health care premiums, with a focus on how rebates are accounted for in premiums.
• Requires drug manufacturers to notify HCA of new drug applications filed with the Food and Drug Administration and allows HCA to collect additional information from the manufacturer about the drug.
• Requires 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 HCA.

EFFECT OF CHANGES MADE BY HEALTH & LONG TERM CARE COMMITTEE (First Substitute):

• Changes the covered drug definition from drugs costing $40 per one month supply to drugs costing $100 per one month supply and requires WSIPP to study the effect of drug price transparency laws on drug prices.

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 Original Bill (Health & Long Term Care): The committee recommended a different version of the bill than what was heard. PRO: Manufacturers set the initial price of drugs and the requirements in the bill are a good starting point for understanding increases in prices. The experience in California after passing a similar bill has been positive and this should be the model for Washington.

CON: Any bill should require all parts of the supply chain to submit data and should have protections against releasing trade secrets. The thresholds that trigger manufacturer reporting requirements are too low and will likely only capture generic drugs. Further burdens on manufacturers will cause a slowdown in construction, which will hurt union jobs.

Persons Testifying (Health & Long Term Care): PRO: Senator Karen Keiser, Prime Sponsor; Meg Jones, Association of Washington Healthcare Plans; Jennifer Crowder, Washington CAN; Joelle Craft, Washington CAN; Sybill Hyppolite, citizen; Brenda Weist, Teamsters Local 117; Amber Ulvenes, Kaiser Permanente; Mel Sorensen, America's Health Insurance Plans.

CON: Brian Warren, Biotechnology Innovation Organization; Lee Newgent, PILMA; Brett Michelin, Association of Accessible Medicine; Eric Lohnes, Pharmaceutical Research and Manufacturers of America.

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

Staff Summary of Public Testimony on First Substitute (Ways & Means): The committee recommended a different version of the bill than what was heard. PRO: We provide care and
coverage to over 800,000 people in Washington. High prescription drug costs challenge affordability in healthcare. Doctors and pharmacists work together to leverage better prices, but those price increases for drugs are real. These drug price increase impact premium costs. The vast majority of increases are in the cost per drug. Drug companies have full control over the starting price of drugs and therefore the discount is just a discount off a high list price. This is a great first step to address rising drug costs. Patients need drugs they can afford. Twenty-five percent of people report difficulty affording medications. One out of eight people say they have rationed doses because of increased costs. And, 80 percent of Americans support policy that would make drug companies make public how they set prices. Last month a study was released showing last year brand name drugs increased by over 9 percent per year. For injectable brand name drugs, those increased by over 15 percent per year. The main takeaway was that the lead indicator was that the main price increases were of drugs that were already on the market. High list prices matter. They are the basis for negotiating discounts and rates along the supply chain. We think it is appropriate to focus this on manufacturers because they set the list prices. It is important to focus on this because prescription drug costs now are greater than inpatient hospital spending.

CON: Our primary concern is the report required in the bill will not share all of the relevant information. Our chief criticism with the bill are that there are seven different portions of the supply chain where transparency does not exist that are not manufacturers. None of this is accounted for in this bill. Prescription drugs are the only place in healthcare where prices decline over time. Drugs go from brand to generic and over time, prices decline by 80 percent. A recent consumer report showed, when checking with pharmacies, the national average for the five most common generic drugs varied by a factor of 20. In a single city, the cost of a 30-day supply of a single generic drug varied by a factor of 10 to 17, depending on the drug. The information gathered under this bill would not tell us why those prices varied. We are opposed based on an unintended consequence we believe this bill will create. When a version of a generic comes on the market, competition ensues and prices go down, similar to commodities. This bill requires 60-day advance notice of a price increase, or we pay a fine. Because of our volatile nature, this creates a perverse nature to build in some increases to accommodate this volatility in our supply chain. When you look at which version of the bill to move out of committee, we suggest you look to Section 8 and the reference a Connecticut law. We suggest that you look at Connecticut as a model. This will help you track the entire supply chain.

Persons Testifying (Ways & Means): PRO: Senator Karen Keiser, Prime Sponsor; Mel Sorensen, America's Health Insurance Plans; Sybill Hyppolite, Service Employees International Union Healthcare 1199NW; Courtney Smith, Kaiser Permanente.

CON: Jeff Gombosky, Pharmaceutical Research and Manufacturers of America; Bill Clarke, Biotechnology Innovation Organization; Abby Moore, Association of Accessible Medicine.

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