S-1536.1

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**SUBSTITUTE SENATE BILL 5292**

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**State of Washington 66th Legislature 2019 Regular Session**

**By** Senate Health & Long Term Care (originally sponsored by Senators Keiser, Cleveland, Randall, Hasegawa, Das, Saldaña, Wilson, C., Liias, Conway, Kuderer, Nguyen, Van De Wege, and Wellman)

AN ACT Relating to prescription drug cost transparency; reenacting and amending RCW 74.09.215; adding a new chapter to Title 43 RCW; and prescribing penalties.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec.**  FINDINGS. The legislature finds that the state of Washington has substantial public interest in the following:

(1) The price and cost of prescription drugs. Washington state is a major purchaser through the department of corrections, the health care authority, and other entities acting on behalf of a state purchaser;

(2) Enacting this chapter to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability to the state for prescription drug pricing;

(3) Rising drug costs and consumer ability to access prescription drugs; and

(4) Containing prescription drug costs. It is essential to understand the drivers and impacts of these costs, as transparency is typically the first step toward cost containment and greater consumer access to needed prescription drugs.

NEW SECTION. **Sec.**  DEFINITIONS. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Covered drug" means a drug that:

(a) A covered manufacturer intends to introduce to the market at a wholesale acquisition cost of ten thousand dollars or more for a course of treatment or a thirty-day supply, whichever period is longer; or

(b)(i) Is produced by a covered manufacturer with a price of one hundred dollars or more for a one-month supply or for a course of treatment lasting less than one month; and (ii) the covered manufacturer intends to increase in price by sixteen percent or more, including the most current proposed increase and the cumulative increase that occurred in the two calendar years prior to the date of the proposed increase.

(2) "Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington state.

(3) "Health care provider," "health plan," and "issuer" have the same meanings as defined in RCW 48.43.005.

(4) "Office" means the office of financial management.

(5) "Pharmacy benefit manager" has the same meaning as defined in RCW 19.340.010.

(6) "Prescription drug" means a drug regulated under chapter 69.41 or 69.50 RCW. It includes generic, brand name, and specialty drugs, as well as biological products.

(7) "Price" or "wholesale acquisition cost" means, with respect to a prescription drug, the covered manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding any discounts, rebates, or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of prescription drug pricing.

(8) "Purchaser" means a public or private purchaser of prescription drugs in the state including, but not limited to:

(a) The health care authority;

(b) The department of labor and industries;

(c) The department of corrections;

(d) The department of social and health services;

(e) Health plans; and

(f) Pharmacy benefit managers.

NEW SECTION. **Sec.**  ISSUER REPORTING. (1) Beginning October 1, 2019, and on a yearly basis thereafter, an issuer must submit to the office the following prescription drug cost and utilization data for the previous calendar year:

(a) The twenty-five prescription drugs most frequently prescribed by health care providers participating in the issuer's network;

(b) The twenty-five costliest prescription drugs by total health plan spending, and the issuer's total spending for each of these prescription drugs;

(c) The twenty-five drugs with the highest year-over-year increase in spending, excluding drugs made available for the first time that plan year, and the percentages of the increases for each of these prescription drugs; and

(d) A summary analysis of the impact of prescription drug costs on health plan premiums or on spending per medical assistance enrollee under chapter 74.09 RCW, as applicable, disaggregated by the state medicaid program, public employees' benefits board programs, and the individual, small group, and large group markets.

(2) An employer-sponsored self-funded health plan or a Taft-Hartley trust health plan may voluntarily provide the data described in subsection (1) of this section.

(3) Except for aggregated information produced by the office pursuant to section 7 of this act, the information collected pursuant to section 7 of this act is not subject to public disclosure.

NEW SECTION. **Sec.**  MANUFACTURER REPORTING. (1) Beginning October 1, 2019, and on a yearly basis thereafter, a covered manufacturer must report the following data to the office for each covered drug:

(a) A description of the specific financial and nonfinancial factors used to make the decision to set or increase the wholesale acquisition cost of the drug and the amount of the increase including, but not limited to, an explanation of how these factors explain the initial wholesale acquisition cost or increase in the wholesale acquisition cost of the drug;

(b) If the drug was produced by the manufacturer during the previous five years, a schedule of wholesale acquisition cost increases for the drug over that time;

(c) If the drug was acquired by the manufacturer within the previous five years, the following information:

(i) The wholesale acquisition cost of the drug at the time of acquisition and in the calendar year prior to acquisition; and

(ii) The name of the company from which the drug was acquired, the date acquired, and the purchase price;

(d) The year the drug was introduced to market and the wholesale acquisition cost of the drug at the time of introduction;

(e) The patent expiration date of the drug if it is under patent;

(f) Whether the drug is a multiple source drug, an innovator multiple source drug, a noninnovator multiple source drug, or a single source drug;

(g) The itemized cost for production and sales, including annual manufacturing costs, annual marketing and advertising costs, total research and development costs, total costs of clinical trials and regulation, and total cost for acquisition for the drug, if applicable; and

(h) The total financial assistance given by the covered manufacturer through assistance programs, rebates, and coupons.

(2) Except for aggregated information produced by the office pursuant to section 7 of this act, the information collected pursuant to section 7 of this act is not subject to public disclosure.

NEW SECTION. **Sec.**  MANUFACTURER REPORTING TO PURCHASERS. (1) Beginning October 1, 2019, a covered manufacturer must notify purchasers and the office sixty days in advance of the introduction or price increase of a covered drug.

(2) In the event of a price increase, the notice must include:

(a) The date of the increase, the current price of the prescription drug, and the dollar amount of the future increase;

(b) A statement regarding whether a change or improvement in the drug necessitates the price increase. If so, the manufacturer must describe the change or improvement.

(3) If a pharmacy benefit manager receives a notice of a price increase, it must notify its contracting public and private purchasers that provide coverage to more than five hundred covered lives.

(4) The data submitted under this section must be made publicly available on the office's web site.

NEW SECTION. **Sec.**  ENFORCEMENT. The office may assess a fine of up to one thousand dollars per day for failure to comply with the requirements of section 3, 4, or 5 of this act. The assessment of a fine under this section is subject to review under the administrative procedure act, chapter 34.05 RCW. Fines collected under this section must be deposited in the medicaid fraud penalty account created in RCW 74.09.215.

NEW SECTION. **Sec.**  DATA REPORT. (1) The office shall compile and analyze the data submitted by issuers and manufacturers under sections 3 and 4 of this act and prepare an annual report for the public and the legislature synthesizing the data to demonstrate the overall impact of drug costs on health care premiums. The data in the report must be aggregated and must not reveal information specific to individual health insurers.

(2) Beginning January 1, 2020, and by each January 1st thereafter, the office must publish the report on its web site.

(3) Except for the report, the office shall keep confidential all of the information provided pursuant to sections 3 and 4 of this act, and the information is not subject to public disclosure under chapter 42.56 RCW.

NEW SECTION. **Sec.**  STUDY. The Washington state institute for public policy must review the implementation of statutes similar to this act enacted in other states, including Connecticut Public Act No. 18-41 and 2017 California Senate Bill No. 17 (chapter 603, Laws of 2017). The review must include an analysis of evidence, if available, on the impact of prescription drug price transparency laws on prescription drug prices. The institute must report its findings to the legislature by January 1, 2025.

NEW SECTION. **Sec.**  RULE MAKING. The office may adopt any rules necessary to implement the requirements of this chapter.

**Sec.**  RCW 74.09.215 and 2013 2nd sp.s. c 4 s 1902, 2013 2nd sp.s. c 4 s 997, and 2013 2nd sp.s. c 4 s 995 are each reenacted and amended to read as follows:

The medicaid fraud penalty account is created in the state treasury. All receipts from civil penalties collected under RCW 74.09.210, all receipts received under judgments or settlements that originated under a filing under the federal false claims act, all receipts from fines received pursuant to section 6 of this act, and all receipts received under judgments or settlements that originated under the state medicaid fraud false claims act, chapter 74.66 RCW, must be deposited into the account. Moneys in the account may be spent only after appropriation and must be used only for medicaid services, fraud detection and prevention activities, recovery of improper payments, for other medicaid fraud enforcement activities, and the prescription monitoring program established in chapter 70.225 RCW. For the 2013-2015 fiscal biennium, moneys in the account may be spent on inpatient and outpatient rebasing and conversion to the tenth version of the international classification of diseases. For the 2011-2013 fiscal biennium, moneys in the account may be spent on inpatient and outpatient rebasing.

NEW SECTION. **Sec.**  Sections 1 through 9 of this act constitute a new chapter in Title 43 RCW.

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