S-4657.1

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECOND SUBSTITUTE SENATE BILL 5586**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**State of Washington 65th Legislature 2018 Regular Session**

**By** Senate Ways & Means (originally sponsored by Senators Ranker, Rivers, Kuderer, Cleveland, Miloscia, Mullet, Saldaña, Keiser, Conway, and Hasegawa)

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

(2) "Data organization" means an organization selected by the office under section 3 of this act to collect, verify, and summarize prescription drug pricing data.

(3) "Department" means the department of health.

(4) "Health care provider," "health plan," and "issuer" mean the same as in RCW 48.43.005.

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

(6) "Pharmacy benefit manager" means the same as in RCW 19.340.010.

(7) "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.

(8) "Wholesale acquisition cost" or "price" means, with respect to a prescription drug, the 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.

NEW SECTION. **Sec.**  PROCUREMENT PROCESS. The office shall use a competitive procurement process in accordance with chapter 39.26 RCW to select a data organization to collect, verify, and summarize the prescription drug pricing data provided by issuers, manufacturers, pharmacy benefit managers, and wholesalers under sections 4, 5, 7, and 8 of this act.

NEW SECTION. **Sec.**  ISSUER REPORTING. (1) By March 1st of each year, an issuer must submit to the data organization 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 prescription drug spending, and the percentages of the increases for each of these prescription drugs;

(d) Any discounts, including the total dollar amount and percentage discount, and any rebate received from a pharmacy benefit manager for each drug described in (a), (b), and (c) of this subsection; and

(e) 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 to the data organization.

(3)(a) The data organization shall compile the information reported pursuant to subsection (1) of this section into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health plans.

(b) Beginning January 1, 2019, and by each January 1st thereafter, the department shall publish the report on its web site.

(4) The department shall share the information provided by the organization with the office of the insurance commissioner.

(5) Except for the report, the department and the office of the insurance commissioner shall keep confidential all of the information provided pursuant to this section, and the information shall not be subject to public disclosure under chapter 42.56 RCW.

NEW SECTION. **Sec.**  MANUFACTURER REPORTING. (1) For purposes of this section:

(a) "Covered drug" means any prescription drug that: (i) 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 twelve-month period, whichever period is longer; or (ii) is manufactured by a covered manufacturer and has a wholesale acquisition cost of more than forty dollars for a course of therapy, and the manufacturer increases the wholesale acquisition cost more than ten percent, including the proposed increase and the cumulative increase that occurred within the previous three calendar years prior to the current year.

(b) "Qualifying price increase" means a price increase described in (a)(ii) or (iii) of this subsection.

(2) Beginning October 1, 2018, a covered manufacturer must report the following data for each covered drug to the data organization:

(a) A description of the specific financial and nonfinancial factors used to make the decision to 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 increase in the wholesale acquisition cost of the drug;

(b) A schedule of wholesale acquisition cost increases for the drug for the previous five years if the drug was manufactured by the company;

(c) If the drug was acquired by the manufacturer within the previous five years, all of 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) If 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; and

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

NEW SECTION. **Sec.**  REPORTING TO PURCHASERS. (1) A covered manufacturer must report the information required by subsection (2) of this section no later than ninety days in advance of:

(a) The introduction of a covered drug, as defined in section 5 of this act, to the market; or

(b) A qualifying price increase for a covered drug, as defined in section 5 of this act.

(2)(a) Beginning October 1, 2018, a manufacturer of a covered drug shall notify the purchaser of a qualifying price increase in writing at least ninety days prior to the planned effective date of the increase. The notice shall include:

(i) 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;

(ii) 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

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

(b) If a pharmacy benefit manager receives a notice of an increase in wholesale acquisition cost consistent with (a) of this subsection, it shall notify its large contracting public and private purchasers of the increase. For the purposes of this section, a "large purchaser" means a purchaser that provides coverage to more than five hundred covered lives.

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

NEW SECTION. **Sec.**  PHARMACY BENEFIT MANAGER REPORTING. By March 1st of each year, a pharmacy benefit manager must submit to the data organization the following data from the previous calendar year:

(1) The wholesale acquisition cost of each drug on the pharmacy benefit manager's formulary;

(2) Any discounts, including the total dollar amount and percentage discount, and any rebate received from a manufacturer for each drug on the formulary;

(3) The total dollar amount of all discounts and rebates described in subsection (2) of this section that are retained by the pharmacy benefit manager for each drug on the formulary;

(4) Any reimbursements the pharmacy benefit manager pays retail pharmacies for each drug on the formulary;

(5) The negotiated price health plans pay the pharmacy benefit manager for each drug on the formulary;

(6) Any ownership interest the pharmacy benefit manager has in a pharmacy or health plan with which it conducts business; and

(7) The results of any appeal filed pursuant to RCW 19.340.100(3).

NEW SECTION. **Sec.**  WHOLESALER REPORTING. By March 1st of each year, a prescription drug wholesaler that does business in the state must submit to the data organization the following data from the previous calendar year:

(1) Any discounts, including the total dollar amount and percentage discount, and any rebate received from a manufacturer for the twenty-five most frequently sold prescription drugs; and

(2) The wholesale price for the twenty-five most frequently sold prescription drugs to pharmacies and hospitals.

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 sections 4 through 8 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. The office shall report any fines levied pursuant to this section against a health carrier to the office of the insurance commissioner.

NEW SECTION. **Sec.**  DATA REPORT TO OFFICE. (1)(a) The data organization must compile the data submitted by issuers, manufacturers, pharmacy benefit managers, and wholesalers under sections 4, 5, 7, and 8 of this act and prepare an annual report for the public and the legislature summarizing the data.

(b) The report must include, for all covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs dispensed at a plan pharmacy, network pharmacy, or mail order pharmacy for outpatient use:

(i) The twenty-five most frequently prescribed drugs;

(ii) The twenty-five most costly drugs by total annual plan spending; and

(iii) The twenty-five drugs with the highest year-over-year increase in total annual plan spending.

(2) The department shall compile the information reported pursuant to subsection (1) of this section into a report for the public and legislators that demonstrates the overall impact of drug costs on health care premiums. The data in the report shall be aggregated and shall not reveal information specific to individual health insurers.

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 9 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 11 of this act constitute a new chapter in Title 43 RCW.

**--- END ---**