**2SHB 1541** - S COMM AMD
By Committee on Health & Long Term Care

Strike everything after the enacting clause and insert the following:

"NEW SECTION. **Sec. 1.** 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. 2.** DEFINITIONS. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(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 and verify prescription drug pricing data.

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

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

(5) "Pharmacy benefit manager" means the same as 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) "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. 3.** 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 and manufacturers under sections 4 and 5 of this act.

NEW SECTION. **Sec. 4.** ISSUER REPORTING AND DATA. (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; 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, school 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.

NEW SECTION. **Sec. 5.** MANUFACTURER REPORTING AND DATA. (1) 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.

(2) 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 thirty-day supply, whichever period is longer; or (ii) is currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than forty dollars for a course of treatment, and the manufacturer increases the wholesale acquisition cost at least sixteen percent, including the proposed increase and the cumulative increase that occurred two calendar years prior to the date of the proposed increase.

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

NEW SECTION. **Sec. 6.** REPORTING TO PURCHASERS. (1) A covered manufacturer must report the information required by subsection (2) of this section no later than sixty 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 sixty days prior to the planned effective date of the increase. The notice must 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; and

(ii) 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. 7.** 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, 5, and 6 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. 8.** DATA REPORT TO OFFICE. (1) The data organization must compile the data submitted by issuers under section 4 of this act and manufacturers under section 5 of this act and submit the data to the office in one report.

(2) The office shall perform an independent analysis of data submitted by the data organization under sections 4 and 5 of this act, and prepare a final report for the public and legislators synthesizing the data under sections 4 and 5 of this act that demonstrates 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 plans.

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

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

(5) Except for the report, the office and the office of the insurance commissioner shall keep confidential all of the information provided pursuant to sections 4 and 5 of this act, and the information shall not be subject to public disclosure under chapter 42.56 RCW.

(6) The office must also, using all available claims data from the statewide all-payer health care claims database established in RCW 43.371.020, collect data on drugs prescribed and prescription drug claims submitted to include billed charges and paid charges.

(7) By November 1, 2019, the office must produce a report for the legislature that includes charts demonstrating the variance in the billed charges and paid charges among carriers for the twenty-five drugs with higher than average variances in billed charges and paid charges based on the data collected in subsection (6) of this section.

NEW SECTION. **Sec. 9.** RULE MAKING. The office may adopt any rules necessary to implement the requirements of this chapter.

**Sec. 10.** 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 7 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. 11.** Sections 1 through 9 of this act constitute a new chapter in Title 43 RCW."

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On page 1, line 1 of the title, after "transparency;" strike the remainder of the title and insert "reenacting and amending RCW 74.09.215; adding a new chapter to Title 43 RCW; and prescribing penalties."

EFFECT: Changes the reporting requirements for manufacturers to the data organization. Manufacturers must provide the organization with the wholesale acquisition cost history, production and sale costs, and financial assistance provided for certain covered drugs. Provides a new requirement that manufacturers report certain price increase information to purchasers at least 60 days before the increase goes into effect for a covered drug. Removes specific requirements for the data organization's report to OFM and directs OFM to prepare a report based on the data collected by the organization that demonstrates the overall impact of drug costs on health care premiums. Requires OFM to produce a second report for the legislature based on prescription drug data collected from the all-payer health care claims database concerning variances in billed charges for prescription drugs.

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