E2SHB 1224 - S COMM AMD
By Committee on Ways & Means

OUT OF ORDER 04/16/2019

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) "Aggregate retained rebate percentage" means the percentage of all rebates received by a pharmacy benefit manager from all pharmaceutical manufacturers which is not passed on to the pharmacy benefit manager's health carrier clients. An aggregate retained rebate percentage must be expressed without disclosing any identifying information regarding any health plan, prescription drug, or therapeutic class, and must be calculated by dividing:

(a) The aggregate dollar amount of all rebates that the pharmacy benefit manager received during the prior calendar year from all pharmaceutical manufacturers and did not pass through to the pharmacy benefit manager's health carrier clients; by

(b) The aggregate dollar amount of all rebates that the pharmacy benefit manager received during the prior calendar year from all pharmaceutical manufacturers.

(2) "Authority" means the health care authority.

(3) "Covered drug" means any prescription 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 lasting less than one month or a thirty-day supply, whichever period is longer; or

(b) Is currently on the market, is manufactured by a covered manufacturer, and has a wholesale acquisition cost of more than one hundred dollars for a course of treatment lasting less than one month or a thirty-day supply, and the manufacturer increases the wholesale acquisition cost at least:

(i) Twenty percent, including the proposed increase and the cumulative increase over one calendar year prior to the date of the proposed increase; or

(ii) Fifty percent, including the proposed increase and the cumulative increase over three calendar years prior to the date of the proposed increase.

(4) "Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture of prescription drugs sold in or into Washington state. "Covered manufacturer" does not include a private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store, or a prescription drug repackager.

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

(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, including generic, brand name, specialty drugs, and biological products that are prescribed for outpatient use and distributed in a retail setting.

(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.

(9) "Qualifying price increase" means a price increase described in subsection (3)(b) of this section.

(10) "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.** HEALTH CARRIER REPORTING. Beginning October 1, 2019, and on a yearly basis thereafter, a health carrier must submit to the authority the following prescription drug cost and utilization data for the previous calendar year for each health plan it offers in the state:

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

(2) The twenty-five costliest prescription drugs expressed as a percentage of total plan prescription drug spending, and the plan's total spending for each of these prescription drugs;

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

(4) The portion of the premium that is attributable to each of the following categories of covered prescription drugs, after accounting for all rebates and discounts:

(a) Brand name drugs;

(b) Generic drugs; and

(c) Specialty drugs;

(5) The year-over-year increase, calculated on a per member, per month basis and expressed as a percentage, in the total annual cost of each category of covered drugs listed in subsection (4) of this section, after accounting for all rebates and discounts;

(6) A comparison, calculated on a per member, per month basis, of the year-over-year increase in the cost of covered drugs to the year-over-year increase in the costs of other contributors to premiums, after accounting for all rebates and discounts;

(7) The name of each covered specialty drug; and

(8) The names of the twenty-five most frequently prescribed drugs for which the health plan received rebates from pharmaceutical manufacturers.

NEW SECTION. **Sec. 4.** PHARMACY BENEFIT MANAGER REPORTING. Beginning October 1, 2019, and on a yearly basis thereafter, a pharmacy benefit manager must submit to the authority the following prescription drug data for the previous calendar year:

(1) The aggregate dollar amount of all rebates and fees received from pharmaceutical manufacturers for prescription drugs that were covered by the pharmacy benefit manager's health carrier clients during the calendar year, and are attributable to patient utilization of such drugs during the calendar year;

(2) The aggregate dollar amount of all rebates and fees received by the pharmacy benefit manager from pharmaceutical manufacturers that are not passed through to the health carrier clients; and

(3) The aggregate retained rebate percentage.

NEW SECTION. **Sec. 5.** MANUFACTURER REPORTING. (1) Beginning October 1, 2019, a covered manufacturer must submit to the authority the following data 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. In the event of a price increase, a covered manufacturer must also submit the amount of the increase and an explanation of how these factors explain the increase in the wholesale acquisition cost of the drug;

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

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

(d) The itemized cost for production and sales, including the 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 of the drug; and

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

(2) For all qualifying price increases of existing drugs, a manufacturer must submit the year the drug was introduced to market

and the wholesale acquisition cost of the drug at the time of introduction.

(3) If a manufacturer increases the price of an existing drug it has manufactured for the previous five years or more, it must submit a schedule of wholesale acquisition cost increases for the drug for the previous five years.

(4) If a manufacturer acquired the drug within the previous five years, it must submit:

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

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

(5) Except as provided in subsection (6) of this section, a covered manufacturer must submit the information required by this section:

(a) At least sixty days in advance of a qualifying price increase for a covered drug; and

(b) Within thirty days of release of a new covered drug to the market.

(6) For any drug approved under section 505(j) of the federal food, drug, and cosmetic act, as it existed on the effective date of this section, or a biosimilar approved under section 351(k) of the federal public health service act, as it existed on the effective date of this section, if submitting data in accordance with subsection (5)(a) of this section is not practicable sixty days before the price increase, that submission must be made as soon as practicable but not later than the date of the price increase.

(7) The information submitted pursuant to this section is not subject to public disclosure under chapter 42.56 RCW and is considered a trade secret as defined in RCW 19.108.010.

NEW SECTION. **Sec. 6.** MANUFACTURER NOTICE OF NEW DRUG APPLICATIONS. (1) Beginning October 1, 2019, a manufacturer must submit written notice, in a form and manner specified by the authority, informing the authority that the manufacturer has filed with the FDA:

(a) A new drug application or biologics license application for a pipeline drug; or

(b) A biologics license application for a biological product.

(2) The notice must be filed within sixty days of the manufacturer receiving the applicable FDA approval date.

(3) Upon receipt of the notice, the authority may request from the manufacturer the following information if it believes the drug will have a significant impact on state expenditures:

(a) The primary disease, condition, or therapeutic area studied in connection with the new drug, and whether the drug is therapeutically indicated for such disease, condition, or therapeutic area;

(b) Each route of administration studied for the drug;

(c) Clinical trial comparators for the drug;

(d) The date at which the FDA must complete its review of the drug application pursuant to the federal prescription drug user fee act of 1992 (106 Stat. 4491; P.L. 102-571);

(e) Whether the FDA has designated the drug an orphan drug, a fast track product, or a breakthrough therapy; and

(f) Whether the FDA has designated the drug for accelerated approval, priority review, or if the drug contains a new molecular entity.

(4) A manufacturer may limit the information reported pursuant to this section to that which is otherwise in the public domain or publicly reported.

(5) The information collected pursuant to this section is not subject to public disclosure under chapter 42.56 RCW.

NEW SECTION. **Sec. 7.** REPORTING TO PURCHASERS. (1)(a) Beginning October 1, 2019, a manufacturer of a covered drug must notify purchasers 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.

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

(3) For any drug approved under section 505(j) of the federal food, drug, and cosmetic act, as it existed on the effective date of this section, or a biosimilar approved under section 351(k) of the federal public health service act, as it existed on the effective date of this section, if notification is not practicable sixty days before the price increase, that submission must be made as soon as practicable but not later than the date of the price increase.

NEW SECTION. **Sec. 8.** PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION REPORTING. (1) Beginning October 1, 2019, and on a yearly basis thereafter, a pharmacy services administrative organization representing a pharmacy or pharmacy chain in the state must submit to the authority the following data from the previous calendar year:

(a) The negotiated reimbursement rate of the twenty-five prescription drugs with the highest reimbursement rate;

(b) The twenty-five prescription drugs with the largest year-to-year change in reimbursement rate, expressed as a percentage and dollar amount; and

(c) The schedule of fees charged to pharmacies for the services provided by the pharmacy services administrative organization.

(2) Any pharmacy services administrative organization whose revenue is generated from flat service fees not connected to drug prices or volume, and paid by the pharmacy, is exempt from reporting.

NEW SECTION. **Sec. 9.** DATA COLLECTION AND ANNUAL REPORT. (1) The authority shall compile and analyze the data submitted by health carriers, pharmacy benefit managers, manufacturers, and pharmacy services administrative organizations under sections 3, 4, 5, and 8 of this act and prepare an annual report for the public and the legislature synthesizing the data to demonstrate the overall impact that drug costs, rebates, and other discounts have on health care premiums.

(2) The data in the report must be aggregated and must not reveal information specific to individual health carriers, pharmacy benefit managers, or pharmacy services administrative organizations.

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

(4) Except for the report, the authority shall keep confidential all of the information provided pursuant to sections 3, 4, 5, and 8 of this act, and analysis of that information. The information and analysis is not subject to public disclosure under chapter 42.56 RCW and is considered a trade secret as defined in RCW 19.108.010.

NEW SECTION. **Sec. 10.** ENFORCEMENT. The authority may assess a fine of up to one thousand dollars per day for failure to comply with the requirements of sections 3 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.

NEW SECTION. **Sec. 11.** The authority must contact the California office of statewide health planning and development and the Oregon department of consumer and business services to develop strategies to reduce prescription drug costs and increase prescription drug cost transparency. The authority must make recommendations to the legislature for implementing joint state strategies, which may include a joint purchasing agreement, by January 1, 2020.

NEW SECTION. **Sec. 12.** RULE MAKING. The authority may adopt any rules necessary to implement the requirements of this chapter.

Sec. 13. 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 10 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. 14.** Sections 1 through 12 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: (1) Provides that information submitted by manufacturers is not subject to public disclosure.

(2) Provides generic drug manufacturers flexibility on the timing for submission of pricing data before raising the price of a covered drug.

(3) Adds a requirement for HCA to develop strategies with California and Oregon to reduce prescription drug costs and increase price transparency.

(4) Adds a requirement for manufacturers to provide notice of new drug applications filed with the FDA.

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