2SSB 5292 - H COMM AMD
By Committee on Health Care & Wellness

NOT CONSIDERED 12/23/2019

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) "Authority" means the health care authority.

(2) "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 twenty percent, including the proposed

increase and the cumulative increase that occurred two calendar years prior to the date of the proposed increase.

(3) "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.

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

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

(6) "Pharmacy benefit manager" means the same as in RCW 19.340.010. "Pharmacy benefit manager" does not include a health maintenance organization as defined in RCW 48.46.020.

(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) "Qualifying price increase" means a price increase described in subsection (2)(b) of this section.

(9) "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 authority 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 carriers and manufacturers under sections 4 and 5 of this act.

NEW SECTION. **Sec. 4.** CARRIER REPORTING AND DATA. (1) By March 1st of each year, a carrier 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 carrier's network;

(b) The twenty-five costliest prescription drugs by total health plan spending, and the carrier'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, 2019, 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) A covered manufacturer must submit this information:

(a) At least sixty days in advance of a qualifying price increase for a covered drug defined in section 2(2)(b) of this act; and

(b) Within thirty days of release of a new covered drug to the market as defined in section 2(2)(a) of this act.

NEW SECTION. **Sec. 6.** (1) In the event of a drug shortage, a covered manufacturer must report the following information to the authority within thirty days of the shortage occurring:

(a) An explanation of what caused the shortage; and

(b) The estimated duration of the shortage.

(2) Within one hundred eighty days of submitting the notice required in subsection (1) of this section, the covered manufacturer must report to the authority:

(a) Whether the sales of other drugs manufactured by the covered manufacturer increased during the shortage period; and

(b) The name, wholesale acquisition cost, and the amount the sales increased for each drug that increased in sales during the shortage period.

NEW SECTION. **Sec. 7.** 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 qualifying price increase for a covered drug defined in section 2(2)(b) of this act.

(2)(a) Beginning October 1, 2019, 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 authority's web site.

NEW SECTION. **Sec. 8.** ENFORCEMENT. The authority may assess a fine of up to one thousand dollars per day for failure to comply with the requirements of sections 4, 5, 6, and 7 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 authority shall report any fines levied pursuant to this section against a health carrier to the office of the insurance commissioner.

NEW SECTION. **Sec. 9.** DATA REPORT TO AUTHORITY. (1) The data organization must compile the data submitted by carriers under section 4 of this act and manufacturers under section 5 of this act and submit the data to the authority in one report.

(2) The authority shall perform an independent analysis of data submitted by the data organization under sections 4, 5, and 6 of this act, and prepare a final report for the public and legislators synthesizing the data under sections 4, 5, and 6 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, 2020, and by each January 1st thereafter, the authority shall publish the report on its web site.

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

(5) Except for the report, the authority and the office of the insurance commissioner shall keep confidential all of the information

provided pursuant to sections 4, 5, and 6 of this act, and the information shall not be subject to public disclosure under chapter 42.56 RCW.

(6) The authority may only use the data reported under this chapter for purposes of analyzing and reporting the data to the public and the legislature. The data may not be used for any other purpose.

(7) The authority 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.

(8) By November 1, 2020, the authority 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. 10.** RULE MAKING. The authority may adopt any rules necessary to implement the requirements of sections 1 through 9 of this act.

NEW SECTION. **Sec. 11.** By March 1st of each year, a pharmacy benefit manager must submit to the office of the insurance commissioner the following data from the previous calendar year:

(1) All discounts, including the total dollar amount and percentage discount, and all rebates received from a manufacturer for each drug on the pharmacy benefit manager's formularies;

(2) The total dollar amount of all discounts and rebates that are retained by the pharmacy benefit manager for each drug on the pharmacy benefit manager's formularies;

(3) Actual total reimbursement amounts for each drug the pharmacy benefit manager pays retail pharmacies after all direct and indirect administrative and other fees that have been retrospectively charged to the pharmacies are applied;

(4) The negotiated price health plans pay the pharmacy benefit manager for each drug on the pharmacy benefit manager's formularies;

(5) The amount, terms, and conditions relating to copayments, reimbursement options, and other payments or fees associated with a prescription drug benefit plan;

(6) Disclosure of 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. 12.** (1) No later than March 1st of each calendar year, each pharmacy benefit manager must file with the office of the insurance commissioner, in the form and detail as required by the insurance commissioner, a report for the preceding calendar year stating that the pharmacy benefit manager is in compliance with this chapter.

(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.

NEW SECTION. **Sec. 13.** A pharmacy benefit manager may not cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading.

NEW SECTION. **Sec. 14.** The office of the insurance commissioner shall have the authority to examine or audit the financial records of a pharmacy benefit manager for purposes of ensuring the information submitted under section 11 of this act is accurate. Information the office of the insurance commissioner acquires in an examination of financial records pursuant to this section is proprietary and confidential.

NEW SECTION. **Sec. 15.** (1) The office of the insurance commissioner shall analyze the data submitted by the pharmacy benefit managers under section 11 of this act, and prepare a final report for the public and legislators synthesizing the data under section 11 of this act. The data in the report must be aggregated and must not reveal information specific to individual health plans or pharmacy benefit managers.

(2) Beginning December 1, 2020, and by each December 1st thereafter, the office of the insurance commissioner shall publish the report on its web site.

(3) Except for the report, the office of the insurance commissioner shall keep confidential all of the information provided pursuant to sections 11 and 14 of this act, and the information is not subject to public disclosure under chapter 42.56 RCW.

NEW SECTION. **Sec. 16.** The office of the insurance commissioner may assess a fine of up to one thousand dollars per day for a violation or failure to comply with the requirements of sections 11, 12, 13, and 14 of this act. The assessment of a fine under this section is subject to review under the administrative procedure act, chapter 34.05 RCW.

NEW SECTION. **Sec. 17.** The insurance commissioner may adopt any rules necessary to implement the requirements of sections 11 through 16 of this act.

Sec. 18. 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 8 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. 19.** Sections 1 through 17 of this act constitute a new chapter in Title 43 RCW.

NEW SECTION. **Sec. 20.** If specific funding for the purposes of this act, referencing this act by bill or chapter number, is not provided by June 30, 2019, in the omnibus appropriations act, this act is null and void."

Correct the title.

EFFECT: (1) Removes the reporting requirements on pharmacy services administrative organizations.

(2) Removes the requirement on the Health Care Authority (HCA) to contact the appropriate agencies in California and Oregon to develop strategies to reduce prescription drug costs and increase prescription drug cost transparency, and make recommendations to implement joint strategies.

(3) Modifies reporting requirements for health carriers and prescription drug manufacturers, and requires the data to be reported to a data organization contracted with the HCA rather than the HCA.

(4) Modifies the report HCA must produce to compile data submitted by carriers and manufacturers.

(5) Requires manufacturers to provide advance notice to purchases regarding certain prescription drug cost increases.

(6) Modifies the reporting requirements for pharmacy benefit managers (PBMs).

(7) Prohibits a PBM from causing or knowingly permitting the use of any untrue, deceptive, or misleading advertisement, promotion, or offer.

(8) Provides the Office of the Insurance Commissioner (OIC) enforcement authority over PBMs for purposes of the act, and requires OIC to produce an annual report summarizing the data collected from PBMs.

(9) Requires HCA to produce a report demonstrating the variances in billed and paid charges among carriers for certain prescription drugs.

(10) Requires covered manufacturers to report to the Health Care Authority:

(a) Within 30 days of a drug shortage occurring, an explanation of what caused the shortage and an estimated duration of the shortage; and

(b) Within 180 days of submitting the notice, whether the sales of other drugs manufactured by the covered manufacturer increased during the shortage period; and the name, wholesale acquisition cost, and the amount the sales increased for each drug that increased in sales during the shortage period.

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