S-0630.1

SENATE BILL 5251

State of Washington 66th Legislature 2019 Regular Session

By Senators Mullet, Rivers, Palumbo, and Rolfes

Read first time 01/16/19. Referred to Committee on Health & Long Term Care.

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. 1.** FINDINGS. (1) The legislature finds that the state of Washington has substantial public interest in the price and cost of prescription drugs.

(2) The legislature finds that it is essential to understand the drivers and impacts of these costs, and transparency is typically the first step toward cost containment and greater consumer access to needed prescription drugs.

(3) The legislature intends to enact this chapter to provide notice and disclosure of information relating to the cost and pricing of prescription drugs in order to provide accountability at all levels of the supply chain to the state for prescription drug pricing.

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

(1) "Accelerated approval," "breakthrough therapy," and "fast track product" mean the same as in 21 U.S.C. Sec. 356.

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

(3) "Biological product" means the same as in 42 U.S.C. Sec. 262(i).

(4) "Biologics license application" means a request for permission from the FDA to introduce, or deliver for introduction, a biological product into interstate commerce.

(5) "FDA" means the United States food and drug administration.

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

(7) "New molecular entity" means a drug or chemical in development that is not a version or derivative of an existing and previously investigated, trialed, and approved substance.

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

(9) "Orphan drug" means a drug intended for the treatment, diagnosis, or prevention of a rare disease or disorder that affects fewer than two hundred thousand people in the United States, or a drug intended for the treatment, diagnosis, or prevention of a rare disease or disorder that affects more than two hundred thousand people but is not expected to recover the development and marketing costs.

(10) "Pharmacy" means the same as in RCW 18.64.011.

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

(12) "Pharmacy services administrative organization" means an entity that provides contracting and other administrative services to pharmacies to assist them in their interaction, including reimbursement rate negotiations, with third-party payers, pharmacy benefit managers, drug wholesalers, and other entities.

(13) "Pipeline drug" means a drug containing a new molecular entity for which a manufacturer has filed a new drug application or biologics license application with, and received an action date from the FDA.

(14) "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.

(15) "Priority review" means the FDA will take action on a new drug application or biologics license application within six months.

(16) "Rebate" means a discount or concession on the cost of a prescription drug provided by a prescription drug manufacturer directly to a health carrier or to a pharmacy benefit manager after a claim from a pharmacy for the sale of the drug is processed.

(17) "Specialty drug" means a prescription drug that exceeds the threshold for the specialty tier of the medicare Part D prescription drug formulary as established by the centers for medicare and medicaid services.

(18) "Wholesale acquisition cost" 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.** ISSUER REPORTING. 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:

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

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

(3) The twenty-five drugs with the highest year-over-year increase in prescription drug spending, 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:

(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;

(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;

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

(8) The names of the twenty-five most frequently prescribed drugs for which the issuer 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 office the following prescription drug data for the previous calendar year:

(1) The aggregate dollar amount of all rebates received from pharmaceutical manufacturers for prescription drugs that were covered by the pharmacy benefit manager's issuer 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 received by the pharmacy benefit manager from pharmaceutical manufacturers that are not passed through to the issuer clients.

NEW SECTION. **Sec. 5.** PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION REPORTING. 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 office the following data from the previous calendar year:

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

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

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

NEW SECTION. **Sec. 6.** DATA COLLECTION AND ANNUAL REPORT. (1) The office shall compile and analyze the data submitted by issuers, pharmacy benefit managers, and pharmacy services administrative organizations under sections 3, 4, and 5 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 report must include but is not limited to:

(a) An explanation of the manner in which issuers accounted for rebates in calculating premiums for health care plans delivered, issued for delivery, renewed, amended, or continued during such year;

(b) A statement disclosing whether, and describing the manner in which, issuers made rebates available to enrollees at the point of purchase during such year;

(c) Any other manner in which issuers applied rebates during the year.

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

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

(4) Except for the report, the office shall keep confidential all of the information provided pursuant to sections 3, 4, and 5 of this act, and the information is not subject to public disclosure under chapter 42.56 RCW.

NEW SECTION. **Sec. 7.** 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 or biosimilar drug.

(2) The notice must be filed within sixty days of the manufacturer receiving an action date from the FDA.

(3) Upon receipt of the notice, the authority may conduct a study of the manufacturer if it believes the drug will have a significant impact on state expenditures.

(4) A manufacturer subject to a study must provide the following information to the authority:

(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.

NEW SECTION. **Sec. 8.** ANNUAL DRUG LIST. (1) Beginning January 1, 2020, and yearly thereafter, the authority must prepare a list of ten prescription drugs that:

(a) Have a significant impact on state expenditures; or

(b) Are critical to public health.

(2) The authority may only include prescription drugs with a wholesale acquisition cost, less rebates received by the state during the preceding calendar year, that:

(a)(i) Increased by at least twenty percent during the preceding calendar year, or (ii) increased by at least fifty percent in the preceding three calendar years; and

(b) Cost at least one hundred dollars for a thirty-day supply or a course of treatment lasting less than thirty days.

(3) The authority must notify manufacturers of drugs appearing on the list.

NEW SECTION. **Sec. 9.** MANUFACTURER DRUG PRICE REPORTING. (1) Manufacturers of drugs appearing on the list created pursuant to section 8 of this act must provide the following information to the authority within thirty days of receipt of the notice provided by the authority pursuant to section 8(3) of this act:

(a) A written, narrative description, suitable for public release, of specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug;

(b) 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;

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

(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; and

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

(2) The authority must establish a standardized form for reporting information and data pursuant to this section after consulting with manufacturers. The form must be designed to minimize the administrative burden and cost of reporting on the authority and manufacturers.

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

NEW SECTION. **Sec. 10.** ENFORCEMENT. The office or the authority may assess a fine of up to one thousand dollars per day for failure to comply with the requirements of sections 3, 4, 5, 7 or 9 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.** RULE MAKING. The office and the authority may adopt any rules necessary to implement the requirements of this chapter.

Sec. 12. 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. 13.** Sections 1 through 11 of this act constitute a new chapter in Title 43 RCW.

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