H-3935.2

# HOUSE BILL 2710

**State of Washington 66th Legislature 2020 Regular Session**

**By** Representatives Robinson, Tarleton, Cody, Tharinger, and Ormsby

Read first time 01/20/20. Referred to Committee on Health Care & Wellness.

AN ACT Relating to modifying the uses, disclosure, and requirement dates of prescription drug price transparency data; and amending RCW 43.71C.020, 43.71C.030, 43.71C.040, 43.71C.050, 43.71C.060, 43.71C.070, 43.71C.080, and 43.71C.100.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

**Sec. 1.** RCW 43.71C.020 and 2019 c 334 s 3 are each amended to read as follows:

Beginning October 1, ((~~2019~~)) 2020, 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.

**Sec. 2.** RCW 43.71C.030 and 2019 c 334 s 4 are each amended to read as follows:

(1) By March 1st of each year, beginning in 2021, a pharmacy benefit manager must submit to the authority the following data from the previous calendar year:

(a) 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;

(b) 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;

(c) 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;

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

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

(f) Disclosure of any ownership interest the pharmacy benefit manager has in a pharmacy or health plan with which it conducts business; and

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

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

(3) The authority may examine or audit the financial records of a pharmacy benefit manager for purposes of ensuring the information submitted under this section is accurate. Information the authority acquires in an examination of financial records pursuant to this subsection is proprietary and confidential.

**Sec. 3.** RCW 43.71C.040 and 2019 c 334 s 5 are each amended to read as follows:

(1) No later than March 1st of each calendar year, beginning in 2021, each pharmacy benefit manager must file with the authority, in the form and detail as required by the authority, a report for the preceding calendar year stating that the pharmacy benefit manager is in compliance with this chapter.

(2) 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.

(3) 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.

**Sec. 4.** RCW 43.71C.050 and 2019 c 334 s 6 are each amended to read as follows:

(1) Beginning October 1, ((~~2019~~)) 2020, 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 July 28, 2019, or a biosimilar approved under section 351(k) of the federal public health service act, as it existed on July 28, 2019, if submitting data in accordance with subsection (5)(a) of this section is not possible sixty days before the price increase, that submission must be made as soon as known 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.

**Sec. 5.** RCW 43.71C.060 and 2019 c 334 s 7 are each amended to read as follows:

(1) Beginning October 1, ((~~2019~~)) 2020, 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~~)) food and drug administration:

(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~~)) food and drug administration 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~~)) food and drug administration 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~~)) food and drug administration has designated the drug an orphan drug, a fast track product, or a breakthrough therapy; and

(f) Whether the ((~~FDA~~)) food and drug administration 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.

**Sec. 6.** RCW 43.71C.070 and 2019 c 334 s 8 are each amended to read as follows:

(1) Beginning October 1, ((~~2019~~)) 2020, a manufacturer of a covered drug must notify the authority of a qualifying price increase in writing at least sixty days prior to the planned effective date of the increase. The notice must include:

(a) 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

(b) 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.

(2) For any drug approved under section 505(j) of the federal food, drug, and cosmetic act, as it existed on July 28, 2019, or a biosimilar approved under section 351(k) of the federal public health service act, as it existed on July 28, 2019, if notification is not possible sixty days before the price increase, that submission must be made as soon as known but not later than the date of the price increase.

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

~~(4) By December 1, 2020, the authority must provide recommendations on how to provide advance notice of price increases to purchasers consistent with state and federal law.~~)) The data submitted under this section may be made publicly available on the authority's web site.

**Sec. 7.** RCW 43.71C.080 and 2019 c 334 s 9 are each amended to read as follows:

(1) Beginning October 1, ((~~2019~~)) 2020, 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.

**Sec. 8.** RCW 43.71C.100 and 2019 c 334 s 10 are each amended to read as follows:

(1) The authority shall compile and analyze the data submitted by health carriers, pharmacy benefit managers, manufacturers, and pharmacy services administrative organizations pursuant to this chapter 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, pharmacy services administrative organizations, ((~~individual prescription drugs, individual classes of prescription drugs,~~)) individual manufacturers, except in the case of single source drugs, or discount amounts paid in connection with individual prescription drugs.

(3) Data received pursuant to this section must be used only for the enumerated purposes of this chapter and other statutorily authorized purposes.

(4) Beginning January 1, 2021, and by each January 1st thereafter, the authority must publish the report on its web site.

((~~(4)~~)) (5) Except for the report, and as provided in subsection ((~~(5)~~)) (6) of this section, the authority shall keep confidential all data submitted pursuant to RCW 43.71C.020 through 43.71C.080.

((~~(5)~~)) (6) For purposes of public policy, upon request of ((~~a legislator~~)) the office of the governor, the office of the attorney general, or a committee or subcommittee of the legislature with jurisdiction over matters relating to drug transparency, the authority must provide all data provided pursuant to RCW 43.71C.020 through 43.71C.080 and any analysis prepared by the authority. Any information provided pursuant to this subsection must be kept confidential within the ((~~legislature~~)) office of the governor, the office of the attorney general, or a committee or subcommittee of the legislature with jurisdiction over matters relating to drug transparency and may not be publicly released.

((~~(6)~~)) (7) The data collected pursuant to this chapter is not subject to public disclosure under chapter 42.56 RCW.

(8) Recipients of data received pursuant to subsection (6) of this section must:

(a) Follow all rules adopted by the authority regarding appropriate data use and protection; and

(b) Sign a nondisclosure agreement that includes acknowledgments that the recipient is solely responsible for any liability arising from misuse of the data, that the recipient does not have any conflicts under the ethics in public service act that would prevent them from accessing or using the data, and that any violations of the nondisclosure agreement may result in losing the right to access or use the data.

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