

E2SHB 1224 - S AMD 667

By Senator Rivers

ADOPTED AS AMENDED 04/16/2019

1 Strike everything after the enacting clause and insert the
2 following:

3 "NEW SECTION. **Sec. 1.** FINDINGS. The legislature finds that the
4 state of Washington has substantial public interest in the following:

5 (1) The price and cost of prescription drugs. Washington state is
6 a major purchaser through the department of corrections, the health
7 care authority, and other entities acting on behalf of a state
8 purchaser;

9 (2) Enacting this chapter to provide notice and disclosure of
10 information relating to the cost and pricing of prescription drugs in
11 order to provide accountability to the state for prescription drug
12 pricing;

13 (3) Rising drug costs and consumer ability to access prescription
14 drugs; and

15 (4) Containing prescription drug costs. It is essential to
16 understand the drivers and impacts of these costs, as transparency is
17 typically the first step toward cost containment and greater consumer
18 access to needed prescription drugs.

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

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

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

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

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

5 (3) "Covered drug" means any prescription drug that:

6 (a) A covered manufacturer intends to introduce to the market at
7 a wholesale acquisition cost of ten thousand dollars or more for a
8 course of treatment lasting less than one month or a thirty-day
9 supply, whichever period is longer; or

10 (b) Is currently on the market, is manufactured by a covered
11 manufacturer, and has a wholesale acquisition cost of more than one
12 hundred dollars for a course of treatment lasting less than one month
13 or a thirty-day supply, and, taking into account only price increases
14 that take effect after the effective date of this section, the
15 manufacturer increases the wholesale acquisition cost at least:

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

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

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

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

29 (6) "Pharmacy benefit manager" means the same as in RCW
30 19.340.010.

31 (7) "Prescription drug" means a drug regulated under chapter
32 69.41 or 69.50 RCW, including generic, brand name, specialty drugs,
33 and biological products that are prescribed for outpatient use and
34 distributed in a retail setting.

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

37 (9) "Wholesale acquisition cost" or "price" means, with respect
38 to a prescription drug, the manufacturer's list price for the drug to
39 wholesalers or direct purchasers in the United States, excluding any
40 discounts, rebates, or reductions in price, for the most recent month

1 for which the information is available, as reported in wholesale
2 price guides or other publications of prescription drug pricing.

3 NEW SECTION. **Sec. 3.** HEALTH CARRIER REPORTING. Beginning
4 October 1, 2019, and on a yearly basis thereafter, a health carrier
5 must submit to the authority the following prescription drug cost and
6 utilization data for the previous calendar year for each health plan
7 it offers in the state:

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

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

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

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

- 20 (a) Brand name drugs;
- 21 (b) Generic drugs; and
- 22 (c) Specialty drugs;

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

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

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

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

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

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

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

9 (3) The aggregate retained rebate percentage.

10 NEW SECTION. **Sec. 5.** MANUFACTURER REPORTING. (1) Beginning
11 October 1, 2019, a covered manufacturer must submit to the authority
12 the following data for each covered drug:

13 (a) A description of the specific financial and nonfinancial
14 factors used to make the decision to set or increase the wholesale
15 acquisition cost of the drug. In the event of a price increase, a
16 covered manufacturer must also submit the amount of the increase and
17 an explanation of how these factors explain the increase in the
18 wholesale acquisition cost of the drug;

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

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

23 (d) The itemized cost for production and sales, including the
24 annual manufacturing costs, annual marketing and advertising costs,
25 total research and development costs, total costs of clinical trials
26 and regulation, and total cost for acquisition of the drug; and

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

29 (2) For all qualifying price increases of existing drugs, a
30 manufacturer must submit the year the drug was introduced to market
31 and the wholesale acquisition cost of the drug at the time of
32 introduction.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 (b) Each route of administration studied for the drug;
2 (c) Clinical trial comparators for the drug;
3 (d) The date at which the FDA must complete its review of the
4 drug application pursuant to the federal prescription drug user fee
5 act of 1992 (106 Stat. 4491; P.L. 102-571);

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

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

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

14 (5) The information collected pursuant to this section is not
15 subject to public disclosure under chapter 42.56 RCW and is
16 considered a trade secret as defined in RCW 19.108.010.

17 NEW SECTION. **Sec. 7.** MANUFACTURER NOTICE OF PRICE INCREASES.

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

22 (a) The date of the increase, the current wholesale acquisition
23 cost of the prescription drug, and the dollar amount of the future
24 increase in the wholesale acquisition cost of the prescription drug;
25 and

26 (b) A statement regarding whether a change or improvement in the
27 drug necessitates the price increase. If so, the manufacturer shall
28 describe the change or improvement.

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

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

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

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

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

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

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

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

25 (2) The data in the report must be aggregated and must not reveal
26 information specific to individual health carriers, pharmacy benefit
27 managers, pharmacy services administrative organizations, individual
28 prescription drugs, individual classes of prescription drugs,
29 individual manufacturers, or discount amounts paid in connection with
30 individual prescription drugs. Data submitted under sections 3, 4, 5,
31 and 8 of this act may not be released in any manner that has the
32 potential to compromise the financial, competitive, confidential, or
33 proprietary nature of the data.

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

36 (4) Except for the report, the authority shall keep confidential
37 all of the information provided pursuant to sections 3, 4, 5, and 8
38 of this act, and analysis of that information. The information and

1 analysis is not subject to public disclosure under chapter 42.56 RCW
2 and is considered a trade secret as defined in RCW 19.108.010.

3 NEW SECTION. **Sec. 10.** ENFORCEMENT. The authority may assess a
4 fine of up to one thousand dollars per day for failure to comply with
5 the requirements of sections 3 through 8 of this act. The assessment
6 of a fine under this section is subject to review under the
7 administrative procedure act, chapter 34.05 RCW. Fines collected
8 under this section must be deposited in the medicaid fraud penalty
9 account created in RCW 74.09.215.

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

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

19 **Sec. 13.** RCW 74.09.215 and 2013 2nd sp.s. c 4 s 1902, 2013 2nd
20 sp.s. c 4 s 997, and 2013 2nd sp.s. c 4 s 995 are each reenacted and
21 amended to read as follows:

22 The medicaid fraud penalty account is created in the state
23 treasury. All receipts from civil penalties collected under RCW
24 74.09.210, all receipts received under judgments or settlements that
25 originated under a filing under the federal false claims act, all
26 receipts from fines received pursuant to section 10 of this act, and
27 all receipts received under judgments or settlements that originated
28 under the state medicaid fraud false claims act, chapter 74.66 RCW,
29 must be deposited into the account. Moneys in the account may be
30 spent only after appropriation and must be used only for medicaid
31 services, fraud detection and prevention activities, recovery of
32 improper payments, for other medicaid fraud enforcement activities,
33 and the prescription monitoring program established in chapter 70.225
34 RCW. For the 2013-2015 fiscal biennium, moneys in the account may be
35 spent on inpatient and outpatient rebasing and conversion to the
36 tenth version of the international classification of diseases. For

1 the 2011-2013 fiscal biennium, moneys in the account may be spent on
2 inpatient and outpatient rebasing.

3 NEW SECTION. **Sec. 14.** Sections 1 through 12 of this act
4 constitute a new chapter in Title 43 RCW."

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5 On page 1, line 1 of the title, after "transparency;" strike the
6 remainder of the title and insert "reenacting and amending RCW
7 74.09.215; adding a new chapter to Title 43 RCW; and prescribing
8 penalties."

EFFECT: (1) Clarifies that the price increases described in the definition of covered drug only apply to price increases that take effect prospectively, after the effective date of the bill.

(2) Removes the requirement that manufacturers provide advance notice of price increases to purchasers and requires that advance notice be provided to HCA. Removes the definition of purchaser.

(3) Adds language providing that the data submitted by manufacturers is not subject to public disclosure and is considered a trade secret.

(4) Adds confidentiality protections for data submitted by manufacturers, and data related to individual prescription drugs, individual classes of prescription drugs, or discount amounts paid in connection with individual prescription drugs.

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

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

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

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