

CERTIFICATION OF ENROLLMENT

FIFTH ENGROSSED SUBSTITUTE SENATE BILL 5857

64th Legislature
2016 Regular Session

Passed by the Senate March 8, 2016
Yeas 49 Nays 0

President of the Senate

Passed by the House March 4, 2016
Yeas 94 Nays 3

Speaker of the House of Representatives

Approved

Governor of the State of Washington

CERTIFICATE

I, Hunter G. Goodman, Secretary of the Senate of the State of Washington, do hereby certify that the attached is **FIFTH ENGROSSED SUBSTITUTE SENATE BILL 5857** as passed by Senate and the House of Representatives on the dates hereon set forth.

Secretary

FILED

**Secretary of State
State of Washington**

FIFTH ENGROSSED SUBSTITUTE SENATE BILL 5857

AS AMENDED BY THE HOUSE

Passed Legislature - 2016 Regular Session

State of Washington 64th Legislature 2015 Regular Session

By Senate Ways & Means (originally sponsored by Senators Parlette, Conway, Becker, and Pearson)

READ FIRST TIME 02/27/15.

1 AN ACT Relating to registration and regulation of pharmacy
2 benefit managers; amending RCW 19.340.030, 19.340.010, and
3 19.340.100; adding a new section to chapter 19.340 RCW; adding a new
4 section to chapter 48.02 RCW; creating new sections; prescribing
5 penalties; and providing an effective date.

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

7 **Sec. 1.** RCW 19.340.030 and 2014 c 213 s 2 are each amended to
8 read as follows:

9 (1) To conduct business in this state, a pharmacy benefit manager
10 must register with the (~~department of revenue's business licensing~~
11 ~~service~~) office of the insurance commissioner and annually renew the
12 registration.

13 (2) To register under this section, a pharmacy benefit manager
14 must:

15 (a) Submit an application requiring the following information:

16 (i) The identity of the pharmacy benefit manager;

17 (ii) The name, business address, phone number, and contact person
18 for the pharmacy benefit manager; and

19 (iii) Where applicable, the federal tax employer identification
20 number for the entity; and

1 (b) Pay a registration fee (~~(of two hundred dollars)~~) established
2 in rule by the commissioner. The registration fee must be set to
3 allow the registration and oversight activities to be self-
4 supporting.

5 (3) To renew a registration under this section, a pharmacy
6 benefit manager must pay a renewal fee (~~(of two hundred dollars)~~)
7 established in rule by the commissioner. The renewal fee must be set
8 to allow the renewal and oversight activities to be self-supporting.

9 (4) All receipts from registrations and renewals collected by the
10 (~~(department)~~) commissioner must be deposited into the (~~(business~~
11 ~~license account created in RCW 19.02.210)~~) insurance commissioner's
12 regulatory account created in RCW 48.02.190.

13 NEW SECTION. Sec. 2. A new section is added to chapter 19.340
14 RCW to read as follows:

15 (1) The commissioner shall have enforcement authority over this
16 chapter and shall have authority to render a binding decision in any
17 dispute between a pharmacy benefit manager, or third-party
18 administrator of prescription drug benefits, and a pharmacy arising
19 out of an appeal under RCW 19.340.100(6) regarding drug pricing and
20 reimbursement.

21 (2) Any person, corporation, third-party administrator of
22 prescription drug benefits, pharmacy benefit manager, or business
23 entity which violates any provision of this chapter shall be subject
24 to a civil penalty in the amount of one thousand dollars for each act
25 in violation of this chapter or, if the violation was knowing and
26 willful, a civil penalty of five thousand dollars for each violation
27 of this chapter.

28 **Sec. 3.** RCW 19.340.010 and 2014 c 213 s 1 are each amended to
29 read as follows:

30 The definitions in this section apply throughout this chapter
31 unless the context clearly requires otherwise.

32 (1) "Claim" means a request from a pharmacy or pharmacist to be
33 reimbursed for the cost of filling or refilling a prescription for a
34 drug or for providing a medical supply or service.

35 (2) "Commissioner" means the insurance commissioner established
36 in chapter 48.02 RCW.

37 (3) "Insurer" has the same meaning as in RCW 48.01.050.

1 ~~((3))~~ (4) "Pharmacist" has the same meaning as in RCW
2 18.64.011.

3 ~~((4))~~ (5) "Pharmacy" has the same meaning as in RCW 18.64.011.

4 ~~((5))~~ (6)(a) "Pharmacy benefit manager" means a person that
5 contracts with pharmacies on behalf of an insurer, a third-party
6 payor, or the prescription drug purchasing consortium established
7 under RCW 70.14.060 to:

8 (i) Process claims for prescription drugs or medical supplies or
9 provide retail network management for pharmacies or pharmacists;

10 (ii) Pay pharmacies or pharmacists for prescription drugs or
11 medical supplies; or

12 (iii) Negotiate rebates with manufacturers for drugs paid for or
13 procured as described in this subsection.

14 (b) "Pharmacy benefit manager" does not include a health care
15 service contractor as defined in RCW 48.44.010.

16 ~~((6))~~ (7) "Third-party payor" means a person licensed under RCW
17 48.39.005.

18 **Sec. 4.** RCW 19.340.100 and 2014 c 213 s 10 are each amended to
19 read as follows:

20 (1) As used in this section:

21 (a) "List" means the list of drugs for which ~~((maximum allowable
22 costs have been established.~~

23 ~~(b) "Maximum allowable cost" means the maximum amount that a
24 pharmacy benefit manager will reimburse a pharmacy for the cost of a
25 drug.~~

26 ~~(c))~~ predetermined reimbursement costs have been established,
27 such as a maximum allowable cost or maximum allowable cost list or
28 any other benchmark prices utilized by the pharmacy benefit manager
29 and must include the basis of the methodology and sources utilized to
30 determine multisource generic drug reimbursement amounts.

31 (b) "Multiple source drug" means a therapeutically equivalent
32 drug that is available from at least two manufacturers.

33 (c) "Multisource generic drug" means any covered outpatient
34 prescription drug for which there is at least one other drug product
35 that is rated as therapeutically equivalent under the food and drug
36 administration's most recent publication of "Approved Drug Products
37 with Therapeutic Equivalence Evaluations;" is pharmaceutically
38 equivalent or bioequivalent, as determined by the food and drug

1 administration; and is sold or marketed in the state during the
2 period.

3 (d) "Network pharmacy" means a retail drug outlet licensed as a
4 pharmacy under RCW 18.64.043 that contracts with a pharmacy benefit
5 manager.

6 (e) "Therapeutically equivalent" has the same meaning as in RCW
7 69.41.110.

8 (2) A pharmacy benefit manager:

9 (a) May not place a drug on a list unless (~~are is [there are]~~)
10 there are at least two therapeutically equivalent multiple source
11 drugs, or at least one generic drug available from only one
12 manufacturer, generally available for purchase by network pharmacies
13 from national or regional wholesalers;

14 (b) Shall ensure that all drugs on a list are (~~generally~~)
15 readily available for purchase by pharmacies in this state from
16 national or regional wholesalers that serve pharmacies in Washington;

17 (c) Shall ensure that all drugs on a list are not obsolete;

18 (d) Shall make available to each network pharmacy at the
19 beginning of the term of a contract, and upon renewal of a contract,
20 the sources utilized to determine the (~~maximum allowable cost~~
21 ~~pricing~~) predetermined reimbursement costs for multisource generic
22 drugs of the pharmacy benefit manager;

23 (e) Shall make a list available to a network pharmacy upon
24 request in a format that is readily accessible to and usable by the
25 network pharmacy;

26 (f) Shall update each list maintained by the pharmacy benefit
27 manager every seven business days and make the updated lists,
28 including all changes in the price of drugs, available to network
29 pharmacies in a readily accessible and usable format;

30 (g) Shall ensure that dispensing fees are not included in the
31 calculation of (~~maximum allowable cost~~) the predetermined
32 reimbursement costs for multisource generic drugs.

33 (3) A pharmacy benefit manager must establish a process by which
34 a network pharmacy may appeal its reimbursement for a drug subject to
35 (~~maximum allowable cost pricing~~) predetermined reimbursement costs
36 for multisource generic drugs. A network pharmacy may appeal a
37 (~~maximum allowable cost~~) predetermined reimbursement cost for a
38 multisource generic drug if the reimbursement for the drug is less
39 than the net amount that the network pharmacy paid to the supplier of
40 the drug. (~~An appeal requested under this section must be completed~~

1 ~~within thirty calendar days of the pharmacy making the claim for~~
2 ~~which an appeal has been requested.))~~ An appeal requested under this
3 section must be completed within thirty calendar days of the pharmacy
4 submitting the appeal. If after thirty days the network pharmacy has
5 not received the decision on the appeal from the pharmacy benefit
6 manager, then the appeal is considered denied.

7 The pharmacy benefit manager shall uphold the appeal of a
8 pharmacy with fewer than fifteen retail outlets, within the state of
9 Washington, under its corporate umbrella if the pharmacy or
10 pharmacist can demonstrate that it is unable to purchase a
11 therapeutically equivalent interchangeable product from a supplier
12 doing business in Washington at the pharmacy benefit manager's list
13 price.

14 (4) A pharmacy benefit manager must provide as part of the
15 appeals process established under subsection (3) of this section:

16 (a) A telephone number at which a network pharmacy may contact
17 the pharmacy benefit manager and speak with an individual who is
18 responsible for processing appeals; and

19 ~~(b) ((A final response to an appeal of a maximum allowable cost~~
20 ~~within seven business days; and~~

21 ~~(c))~~ If the appeal is denied, the reason for the denial and the
22 national drug code of a drug that ~~((may be))~~ has been purchased by
23 ~~((similarly situated))~~ other network pharmacies located in Washington
24 at a price that is equal to or less than the ~~((maximum allowable~~
25 ~~cost))~~ predetermined reimbursement cost for the multisource generic
26 drug. A pharmacy with fifteen or more retail outlets, within the
27 state of Washington, under its corporate umbrella may submit
28 information to the commissioner about an appeal under subsection (3)
29 of this section for purposes of information collection and analysis.

30 (5)(a) If an appeal is upheld under this section, the pharmacy
31 benefit manager shall make ~~((an))~~ a reasonable adjustment on a date
32 no later than one day after the date of determination. ~~((The pharmacy~~
33 ~~benefit manager shall make the adjustment effective for all similarly~~
34 ~~situated pharmacies in this state that are within the network.))~~

35 (b) If the request for an adjustment has come from a critical
36 access pharmacy, as defined by the state health care authority by
37 rule for purposes related to the prescription drug purchasing
38 consortium established under RCW 70.14.060, the adjustment approved
39 under (a) of this subsection shall apply only to critical access
40 pharmacies.

1 (6) Beginning July 1, 2017, if a network pharmacy appeal to the
2 pharmacy benefit manager is denied, or if the network pharmacy is
3 unsatisfied with the outcome of the appeal, the pharmacy or
4 pharmacist may dispute the decision and request review by the
5 commissioner within thirty calendar days of receiving the decision.

6 (a) All relevant information from the parties may be presented to
7 the commissioner, and the commissioner may enter an order directing
8 the pharmacy benefit manager to make an adjustment to the disputed
9 claim, deny the pharmacy appeal, or take other actions deemed fair
10 and equitable. An appeal requested under this section must be
11 completed within thirty calendar days of the request.

12 (b) Upon resolution of the dispute, the commissioner shall
13 provide a copy of the decision to both parties within seven calendar
14 days.

15 (c) The commissioner may authorize the office of administrative
16 hearings, as provided in chapter 34.12 RCW, to conduct appeals under
17 this subsection (6).

18 (d) A pharmacy benefit manager may not retaliate against a
19 pharmacy for pursuing an appeal under this subsection (6).

20 (e) This subsection (6) applies only to a pharmacy with fewer
21 than fifteen retail outlets, within the state of Washington, under
22 its corporate umbrella.

23 (7) This section does not apply to the state medical assistance
24 program.

25 (8) A pharmacy benefit manager shall comply with any requests for
26 information from the commissioner for purposes of the study of the
27 pharmacy chain of supply conducted under section 7 of this act.

28 NEW SECTION. Sec. 5. A new section is added to chapter 48.02
29 RCW to read as follows:

30 (1) The commissioner shall accept registration of pharmacy
31 benefit managers as established in RCW 19.340.030 and receipts shall
32 be deposited in the insurance commissioner's regulatory account.

33 (2) The commissioner shall have enforcement authority over
34 chapter 19.340 RCW consistent with requirements established in
35 section 2 of this act.

36 (3) The commissioner may adopt rules to implement chapter 19.340
37 RCW and to establish registration and renewal fees that ensure the
38 registration, renewal, and oversight activities are self-supporting.

1 NEW SECTION. **Sec. 6.** The insurance commissioner, in
2 collaboration with the department of health, must review the
3 potential to use the independent review organizations, established in
4 RCW 48.43.535, as an alternative to the appeal process for pharmacy
5 and pharmacy benefit manager disputes. By December 1, 2016, the
6 agencies must submit recommendations for use of the independent
7 review organizations including detailed suggestions for modifications
8 to the process, and the possible transition of the process from the
9 department of health, established in RCW 43.70.235, to the office of
10 the insurance commissioner.

11 NEW SECTION. **Sec. 7.** (1) The office of the insurance
12 commissioner shall conduct a study of the pharmacy chain of supply.
13 The commissioner or his or her designee may convene one or more
14 stakeholder work groups to address the components of the study, which
15 must include but are not limited to the following:

16 (a) Review the entire drug supply chain including plan and
17 pharmacy benefit manager reimbursements to network pharmacies,
18 wholesaler or pharmacy service administrative organization prices to
19 network pharmacies, and drug manufacturer prices to network
20 pharmacies;

21 (b) Discuss suggestions that recognize the unique nature of small
22 and rural pharmacies and possible options that support a viable
23 business model that do not increase the cost of pharmacy products;

24 (c) Review the availability of all drugs on the maximum allowable
25 cost list or any similar list for pharmacies;

26 (d) Review data submitted under RCW 19.340.100(4)(b) for patterns
27 and trends in the denials of internal pharmacy benefit manager
28 appeals involving pharmacies with fifteen or more retail outlets,
29 within the state of Washington, under their corporate umbrellas;

30 (e) Review the telephone contacts and standards for response
31 times and availability; and

32 (f) Review the pharmacy acquisition cost from national or
33 regional wholesalers that serve pharmacies in Washington, and
34 consider when or whether to make an adjustment and under what
35 standards. The review may assess the timing of pharmacy purchases of
36 products and the relative risk of list price changes related to the
37 timing of dispensing the products.

38 (2) The study must be delivered to the legislature by November 1,
39 2016.

1 NEW SECTION. **Sec. 8.** Section 1 of this act takes effect January
2 1, 2017.

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