

5ESSB 5857 - H COMM AMD

By Committee on General Government & Information Technology

ADOPTED AS AMENDED 03/04/2016

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

3 "Sec. 1. RCW 19.340.030 and 2014 c 213 s 2 are each amended to
4 read as follows:

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

9 (2) To register under this section, a pharmacy benefit manager
10 must:

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

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

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

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

17 (b) Pay a registration fee (~~of two hundred dollars~~) established
18 in rule by the commissioner. The registration fee must be set to
19 allow the registration and oversight activities to be self-
20 supporting.

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

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

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

1 (1) The commissioner shall have enforcement authority over this
2 chapter and shall have authority to render a binding decision in any
3 dispute between a pharmacy benefit manager, or third-party
4 administrator of prescription drug benefits, and a pharmacy arising
5 out of an appeal regarding drug pricing and reimbursement.

6 (2) Any person, corporation, third-party administrator of
7 prescription drug benefits, pharmacy benefit manager, or business
8 entity which violates any provision of this chapter shall be subject
9 to a civil penalty in the amount of one thousand dollars for each act
10 in violation of this chapter or, if the violation was knowing and
11 willful, a civil penalty of five thousand dollars for each violation
12 of this chapter.

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

15 The definitions in this section apply throughout this chapter
16 unless the context clearly requires otherwise.

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

20 (2) "Commissioner" means the insurance commissioner established
21 in chapter 48.02 RCW.

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

23 ~~((3))~~ (4) "Pharmacist" has the same meaning as in RCW
24 18.64.011.

25 ~~((4))~~ (5) "Pharmacy" has the same meaning as in RCW 18.64.011.

26 ~~((5))~~ (6)(a) "Pharmacy benefit manager" means a person that
27 contracts with pharmacies on behalf of an insurer, a third-party
28 payor, or the prescription drug purchasing consortium established
29 under RCW 70.14.060 to:

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

32 (ii) Pay pharmacies or pharmacists for prescription drugs or
33 medical supplies; or

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

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

38 ~~((6))~~ (7) "Third-party payor" means a person licensed under RCW
39 48.39.005.

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

3 (1) As used in this section:

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

6 ~~(b) "Maximum allowable cost" means the maximum amount that a~~
7 ~~pharmacy benefit manager will reimburse a pharmacy for the cost of a~~
8 ~~drug.~~

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

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

16 (c) "Multisource generic drug" means any covered outpatient
17 prescription drug for which there is at least one other drug product
18 that is rated as therapeutically equivalent under the food and drug
19 administration's most recent publication of "Approved Drug Products
20 with Therapeutic Equivalence Evaluations;" is pharmaceutically
21 equivalent or bioequivalent, as determined by the food and drug
22 administration; and is sold or marketed in the state during the
23 period.

24 (d) "Network pharmacy" means a retail drug outlet licensed as a
25 pharmacy under RCW 18.64.043 that contracts with a pharmacy benefit
26 manager.

27 (e) "Therapeutically equivalent" has the same meaning as in RCW
28 69.41.110.

29 (2) A pharmacy benefit manager:

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

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

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

39 (d) Shall make available to each network pharmacy at the
40 beginning of the term of a contract, and upon renewal of a contract,

1 the sources utilized to determine the ~~((maximum allowable cost~~
2 ~~pricing))~~ predetermined reimbursement costs for multisource generic
3 drugs of the pharmacy benefit manager;

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

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

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

14 (3) A pharmacy benefit manager must establish a process by which
15 a network pharmacy may appeal its reimbursement for a drug subject to
16 ~~((maximum allowable cost pricing))~~ predetermined reimbursement costs
17 for multisource generic drugs. A network pharmacy may appeal a
18 ~~((maximum allowable cost))~~ predetermined reimbursement cost for a
19 multisource generic drug if the reimbursement for the drug is less
20 than the net amount that the network pharmacy paid to the supplier of
21 the drug. ~~((An appeal requested under this section must be completed~~
22 ~~within thirty calendar days of the pharmacy making the claim for~~
23 ~~which an appeal has been requested.))~~ An appeal requested under this
24 section must be completed within thirty calendar days of the pharmacy
25 submitting the appeal. If after thirty days the network pharmacy has
26 not received the decision on the appeal from the pharmacy benefit
27 manager, then the appeal is considered denied.

28 The pharmacy benefit manager shall uphold the appeal if the
29 pharmacy or pharmacist can demonstrate that it is unable to purchase
30 a therapeutically equivalent interchangeable product from a supplier
31 doing business in Washington at the pharmacy benefit manager's list
32 price.

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

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

38 ~~((A final response to an appeal of a maximum allowable cost~~
39 ~~within seven business days; and~~

1 ~~(e))~~ If the appeal is denied, the reason for the denial and the
2 national drug code of a drug that ~~((may be))~~ has been purchased by
3 ~~((similarly situated))~~ other network pharmacies located in Washington
4 at a price that is equal to or less than the ~~((maximum allowable~~
5 ~~cost))~~ predetermined reimbursement cost for the multisource generic
6 drug.

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

12 (b) If the request for an adjustment has come from a critical
13 access pharmacy, as defined by the state health care authority by
14 rule for purposes related to the prescription drug purchasing
15 consortium established under RCW 70.14.060, the adjustment approved
16 under (a) of this subsection shall apply only to critical access
17 pharmacies.

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

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

29 (b) Upon resolution of the dispute, the commissioner shall
30 provide a copy of the decision to both parties within seven calendar
31 days.

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

35 (7) This section does not apply to the state medical assistance
36 program.

37 (8) This section applies only to a retail licensed pharmacy with
38 fewer than ten retail outlets, within the state of Washington, under
39 its corporate umbrella.

1 NEW SECTION. **Sec. 5.** A new section is added to chapter 19.340

2 RCW to read as follows:

3 (1) As used in this section:

4 (a) "List" means the list of drugs for which maximum allowable
5 costs have been established.

6 (b) "Maximum allowable cost" means the maximum amount that a
7 pharmacy benefit manager will reimburse a pharmacy for the cost of a
8 drug.

9 (c) "Multiple source drug" means a therapeutically equivalent
10 drug that is available from at least two manufacturers.

11 (d) "Network pharmacy" means a retail drug outlet licensed as a
12 pharmacy under RCW 18.64.043 that contracts with a pharmacy benefit
13 manager.

14 (e) "Therapeutically equivalent" has the same meaning as in RCW
15 69.41.110.

16 (2) A pharmacy benefit manager:

17 (a) May not place a drug on a list unless there are at least two
18 therapeutically equivalent multiple source drugs, or at least one
19 generic drug available from only one manufacturer, generally
20 available for purchase by network pharmacies from national or
21 regional wholesalers;

22 (b) Shall ensure that all drugs on a list are generally available
23 for purchase by pharmacies in this state from national or regional
24 wholesalers;

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

26 (d) Shall make available to each network pharmacy at the
27 beginning of the term of a contract, and upon renewal of a contract,
28 the sources utilized to determine the maximum allowable cost pricing
29 of the pharmacy benefit manager;

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

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

37 (g) Shall ensure that dispensing fees are not included in the
38 calculation of maximum allowable cost.

39 (3) A pharmacy benefit manager must establish a process by which
40 a network pharmacy may appeal its reimbursement for a drug subject to

1 maximum allowable cost pricing. A network pharmacy may appeal a
2 maximum allowable cost if the reimbursement for the drug is less than
3 the net amount that the network pharmacy paid to the supplier of the
4 drug. An appeal requested under this section must be completed within
5 thirty calendar days of the pharmacy making the claim for which an
6 appeal has been requested.

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

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

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

14 (c) If the appeal is denied, the reason for the denial and the
15 national drug code of a drug that may be purchased by similarly
16 situated pharmacies at a price that is equal to or less than the
17 maximum allowable cost.

18 (5)(a) If an appeal is upheld under this section, the pharmacy
19 benefit manager shall make an adjustment on a date no later than one
20 day after the date of determination. The pharmacy benefit manager
21 shall make the adjustment effective for all similarly situated
22 pharmacies in this state that are within the network.

23 (b) If the request for an adjustment has come from a critical
24 access pharmacy, as defined by the state health care authority by
25 rule for purposes related to the prescription drug purchasing
26 consortium established under RCW 70.14.060, the adjustment approved
27 under (a) of this subsection shall apply only to critical access
28 pharmacies.

29 (6) This section does not apply to the state medical assistance
30 program.

31 (7) This section applies only to a retail licensed pharmacy with
32 ten or more retail outlets, within the state of Washington, under its
33 corporate umbrella.

34 NEW SECTION. **Sec. 6.** A new section is added to chapter 48.02
35 RCW to read as follows:

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

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

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

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

17 NEW SECTION. **Sec. 8.** (1) The office of the insurance
18 commissioner shall conduct a study of the pharmacy chain of supply.
19 The commissioner or his or her designee may convene one or more
20 stakeholder work groups to address the components of the study, which
21 must include but are not limited to the following:

22 (a) Review the entire drug supply chain including plan and
23 pharmacy benefit manager reimbursements to network pharmacies,
24 wholesaler or pharmacy service administrative organization prices to
25 network pharmacies, and drug manufacturer prices to network
26 pharmacies;

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

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

32 (d) Review the telephone contacts and standards for response
33 times and availability; and

34 (e) Review the pharmacy acquisition cost from national or
35 regional wholesalers that serve pharmacies in Washington, and
36 consider when or whether to make an adjustment and under what
37 standards. The review may assess the timing of pharmacy purchases of

1 products and the relative risk of list price changes related to the
2 timing of dispensing the products.

3 (2) The study must be delivered to the legislature by November 1,
4 2016.

5 NEW SECTION. **Sec. 9.** Section 1 of this act takes effect January
6 1, 2017."

7 Correct the title.

EFFECT: (1) Removes the requirement that pharmacy benefit managers (PBMs) use the most up-to-date pricing data to calculate reimbursements for multisource generic drugs.

(2) Removes the requirement that at least one product with a current national drug code be available for drugs on a list.

(3) Removes the definition of "acquisition cost."

(4) Changes references to "maximum allowable cost" to predetermined reimbursement costs for multisource generic drugs."

(5) Restores the current law requirement allowing pharmacies to bring an appeal if a pharmacy's reimbursement is less than the net amount the pharmacy paid for the drug (the underlying bill allows such appeals if the reimbursement is less than the amount the pharmacy paid for the drug).

(6) Removes the ability for a pharmacy's contracting agent to bring an appeal to a PBM.

(7) Changes the amount of time a PBM has to complete an appeal from 10 days to 30 days.

(8) Requires a PBM to uphold an appeal if the pharmacy can demonstrate that it is unable to purchase a therapeutically equivalent interchangeable product from a supplier doing business in Washington at the PBM's list price.

(9) Requires, upon a successful appeal, the PBM to make a reasonable adjustment.

(10) Removes the requirement that the PBM provide, upon an unsuccessful appeal, the name of a Washington wholesaler at which the drug can be acquired by the challenging pharmacy.

(11) Applies the changes relating to PBM lists and appeals only to pharmacies that have fewer than 10 pharmacies, located in Washington, under their umbrellas.

(12) Requires the OIC to collaborate with the Department of Health when reviewing the use of independent review organizations (IROs) in appeals.

(13) Removes the requirement that the OIC review the use of IROs for other disputes between providers and insurance carriers.

(14) Removes the requirement that PBMs make disclosures on pricing to plan sponsors.

(15) Removes the recodification of provisions relating to PBMs and pharmacy audits.

(16) Allows pharmacies to appeal PBM appeal determinations to the OIC beginning July 1, 2017.

(17) Allows the Insurance Commissioner to authorize the appeals to be conducted by the Office of Administrative Hearings.

(18) Requires the Insurance Commissioner to perform a study of the pharmacy chain of supply.

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