5ESSB 5857 - H COMM AMD

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By Committee on General Government & Information Technology

ADOPTED AND ENGROSSED 3/4/2016

- Strike everything after the enacting clause and insert the 1 2 following:
- "Sec. 1. RCW 19.340.030 and 2014 c 213 s 2 are each amended to 3 4 read as follows:
- (1) To conduct business in this state, a pharmacy benefit manager 5 must register with the ((department of revenue's business licensing 6 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:
- (a) Submit an application requiring the following information: 11
 - (i) The identity of the pharmacy benefit manager;
- 13 (ii) The name, business address, phone number, and contact person for the pharmacy benefit manager; and 14
- 15 (iii) Where applicable, the federal tax employer identification number for the entity; and 16
- 17 (b) Pay a registration fee ((of two hundred dollars)) established in rule by the commissioner. The registration fee must be set to 18 allow the registration and oversight activities to be self-19 2.0 supporting.
- (3) To renew a registration under this section, a pharmacy 21 22 benefit manager must pay a renewal fee ((of two hundred dollars)) established in rule by the commissioner. The renewal fee must be set 23 24 to allow the renewal and oversight activities to be self-supporting.
- (4) All receipts from registrations and renewals collected by the 25 26 ((department)) commissioner must be deposited into the ((business 27 license account created in RCW 19.02.210)) insurance commissioner's regulatory account created in RCW 48.02.190. 28
- 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 chapter and shall have authority to render a binding decision in any dispute between a pharmacy benefit manager, or 3 third-party administrator of prescription drug benefits, and a pharmacy arising 4 out of an appeal under RCW 19.340.100(6) regarding drug pricing and 6 reimbursement.
- 7 Any person, corporation, third-party administrator (2) 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 13 of this chapter.
- RCW 19.340.010 and 2014 c 213 s 1 are each amended to 14 15 read as follows:
- 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 20 drug or for providing a medical supply or service.
- (2) "Commissioner" means the insurance commissioner established 21 22 in chapter 48.02 RCW.
- 23 (3) "Insurer" has the same meaning as in RCW 48.01.050.
- $((\frac{3}{1}))$ $\underline{(4)}$ "Pharmacist" has the same meaning as in RCW 24 25 18.64.011.
- 26 (((4))) (5) "Pharmacy" has the same meaning as in RCW 18.64.011.
- 27 (((5))) <u>(6)</u>(a) "Pharmacy benefit manager" means a person that 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:
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- (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 34 medical supplies; or
- 35 (iii) Negotiate rebates with manufacturers for drugs paid for or 36 procured as described in this subsection.
- (b) "Pharmacy benefit manager" does not include a health care 37 service contractor as defined in RCW 48.44.010. 38

- 1 $((\frac{6}{1}))$ "Third-party payor" means a person licensed under RCW 48.39.005. 2.
- RCW 19.340.100 and 2014 c 213 s 10 are each amended to 3 read as follows: 4
 - (1) As used in this section:

- (a) "List" means the list of drugs for which ((maximum allowable 6 7 costs have been established.
- (b) "Maximum allowable cost" means the maximum amount that a 8 pharmacy benefit manager will reimburse a pharmacy for the cost of a 9 10 drua.
- 11 (c))) predetermined reimbursement costs have been established, such as a maximum allowable cost or maximum allowable cost list or 12 any other benchmark prices utilized by the pharmacy benefit manager 13 and must include the basis of the methodology and sources utilized to 14 15 determine multisource generic drug reimbursement amounts.
- 16 "Multiple source drug" means a therapeutically equivalent 17 drug that is available from at least two manufacturers.
- (c) "Multisource generic drug" means any covered outpatient 18 prescription drug for which there is at least one other drug product 19 that is rated as therapeutically equivalent under the food and drug 20 21 administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations; " is pharmaceutically 22 equivalent or bioequivalent, as determined by the food and drug 23 24 administration; and is sold or marketed in the state during the 25 period.
- (d) "Network pharmacy" means a retail drug outlet licensed as a 26 27 pharmacy under RCW 18.64.043 that contracts with a pharmacy benefit 28 manager.
- (e) "Therapeutically equivalent" has the same meaning as in RCW 29 30 69.41.110.
 - (2) A pharmacy benefit manager:
- (a) May not place a drug on a list unless ((are is [there are])) 32 there are at least two therapeutically equivalent multiple source 33 drugs, or at least one generic drug available from only one 34 35 manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers; 36
- (b) Shall ensure that all drugs on a list are ((generally)) 37 readily available for purchase by pharmacies in this state from 38 national or regional wholesalers that serve pharmacies in Washington; 39

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

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- Shall make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, sources utilized to determine the ((maximum allowable cost 4 pricing)) predetermined reimbursement costs for multisource generic drugs of the pharmacy benefit manager;
 - (e) Shall make a list available to a network pharmacy upon request in a format that is readily accessible to and usable by the network pharmacy;
 - (f) Shall update each list maintained by the pharmacy benefit manager every seven business days and make the updated lists, including all changes in the price of drugs, available to network pharmacies in a readily accessible and usable format;
 - (g) Shall ensure that dispensing fees are not included in the calculation of ((maximum allowable cost)) the predetermined reimbursement costs for multisource generic drugs.
 - (3) A pharmacy benefit manager must establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to ((maximum allowable cost pricing)) predetermined reimbursement costs for multisource generic drugs. A network pharmacy may appeal a ((maximum allowable cost)) predetermined reimbursement cost for a multisource generic drug if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug. ((An appeal requested under this section must be completed within thirty calendar days of the pharmacy making the claim for which an appeal has been requested.)) An appeal requested under this section must be completed within thirty calendar days of the pharmacy submitting the appeal. If after thirty days the network pharmacy has not received the decision on the appeal from the pharmacy benefit manager, then the appeal is considered denied.
 - The pharmacy benefit manager shall uphold the appeal of a pharmacy with fewer than fifteen retail outlets, within the state of Washington, under its corporate umbrella if the pharmacy or pharmacist can demonstrate that it is unable to purchase a therapeutically equivalent interchangeable product from a supplier doing business in Washington at the pharmacy benefit manager's list price.
- 38 (4) A pharmacy benefit manager must provide as part of the 39 appeals process established under subsection (3) of this section:

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

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- (b) ((A final response to an appeal of a maximum allowable cost within seven business days; and
- (c))) If the appeal is denied, the reason for the denial and the national drug code of a drug that ((may be)) has been purchased by ((similarly situated)) other network pharmacies located in Washington at a price that is equal to or less than the ((maximum allowable cost)) predetermined reimbursement cost for the multisource generic drug. A pharmacy with fifteen or more retail outlets, within the state of Washington, under its corporate umbrella may submit information to the commissioner about an appeal under subsection (3) of this section for purposes of information collection and analysis.
- (5)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall make ((an)) a reasonable adjustment on a date no later than one day after the date of determination. ((The pharmacy benefit manager shall make the adjustment effective for all similarly situated pharmacies in this state that are within the network.))
- (b) If the request for an adjustment has come from a critical access pharmacy, as defined by the state health care authority by rule for purposes related to the prescription drug purchasing consortium established under RCW 70.14.060, the adjustment approved under (a) of this subsection shall apply only to critical access pharmacies.
- (6) Beginning July 1, 2017, if a network pharmacy appeal to the pharmacy benefit manager is denied, or if the network pharmacy is unsatisfied with the outcome of the appeal, the pharmacy or pharmacist may dispute the decision and request review by the commissioner within thirty calendar days of receiving the decision.
- (a) All relevant information from the parties may be presented to the commissioner, and the commissioner may enter an order directing the pharmacy benefit manager to make an adjustment to the disputed claim, deny the pharmacy appeal, or take other actions deemed fair and equitable. An appeal requested under this section must be completed within thirty calendar days of the request.
- (b) Upon resolution of the dispute, the commissioner shall 37 provide a copy of the decision to both parties within seven calendar 38 39 days.

- 1 (c) The commissioner may authorize the office of administrative 2 hearings, as provided in chapter 34.12 RCW, to conduct appeals under 3 this subsection (6).
 - (d) A pharmacy benefit manager may not retaliate against a pharmacy for pursuing an appeal under this subsection (6).

- 6 (e) This subsection (6) applies only to a pharmacy with fewer
 7 than fifteen retail outlets, within the state of Washington, under
 8 its corporate umbrella.
- 9 (7) This section does not apply to the state medical assistance 10 program.
- 11 (8) A pharmacy benefit manager shall comply with any requests for 12 information from the commissioner for purposes of the study of the 13 pharmacy chain of supply conducted under section 7 of this act.
- NEW SECTION. Sec. 5. A new section is added to chapter 48.02 15 RCW to read as follows:
- 16 (1) The commissioner shall accept registration of pharmacy 17 benefit managers as established in RCW 19.340.030 and receipts shall 18 be deposited in the insurance commissioner's regulatory account.
- 19 (2) The commissioner shall have enforcement authority over 20 chapter 19.340 RCW consistent with requirements established in 21 section 2 of this act.
- 22 (3) The commissioner may adopt rules to implement chapter 19.340 23 RCW and to establish registration and renewal fees that ensure the 24 registration, renewal, and oversight activities are self-supporting.
- 25 NEW SECTION. Sec. 6. The insurance commissioner, collaboration with the department of health, must 26 review potential to use the independent review organizations, established in 27 RCW 48.43.535, as an alternative to the appeal process for pharmacy 28 29 and pharmacy benefit manager disputes. By December 1, 2016, the 30 agencies must submit recommendations for use of the independent review organizations including detailed suggestions for modifications 31 to the process, and the possible transition of the process from the 32 department of health, established in RCW 43.70.235, to the office of 33 34 the insurance commissioner.
- NEW SECTION. Sec. 7. (1) The office of the insurance commissioner shall conduct a study of the pharmacy chain of supply.

 The commissioner or his or her designee may convene one or more

- 1 stakeholder work groups to address the components of the study, which must include but are not limited to the following: 2
 - (a) Review the entire drug supply chain including plan and pharmacy benefit manager reimbursements to network pharmacies, wholesaler or pharmacy service administrative organization prices to network pharmacies, and drug manufacturer prices to network pharmacies;
 - (b) Discuss suggestions that recognize the unique nature of small and rural pharmacies and possible options that support a viable business model that do not increase the cost of pharmacy products;
 - (c) Review the availability of all drugs on the maximum allowable cost list or any similar list for pharmacies;
 - (d) Review data submitted under RCW 19.340.100(4)(b) for patterns and trends in the denials of internal pharmacy benefit manager appeals involving pharmacies with fifteen or more retail outlets, within the state of Washington, under their corporate umbrellas;
 - (e) Review the telephone contacts and standards for response times and availability; and
 - (f) Review the pharmacy acquisition cost from national or regional wholesalers that serve pharmacies in Washington, and consider when or whether to make an adjustment and under what standards. The review may assess the timing of pharmacy purchases of products and the relative risk of list price changes related to the timing of dispensing the products.
- 25 (2) The study must be delivered to the legislature by November 1, 2016. 26
- 27 <u>NEW SECTION.</u> **Sec. 8.** Section 1 of this act takes effect January 1, 2017." 28
- 29 Correct the title.

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