CERTIFICATION OF ENROLLMENT

FIFTH ENGROSSED SUBSTITUTE SENATE BILL 5857

Chapter 210, Laws of 2016

64th Legislature 2016 Regular Session

PHARMACY BENEFIT MANAGERS--VARIOUS PROVISIONS

EFFECTIVE DATE: 6/9/2016 - Except for section 1, which takes effect 1/1/2017.

Passed by the Senate March 8, 2016 CERTIFICATE Yeas 49 Nays 0 I, Hunter G. Goodman, Secretary of Senate of the State BRAD OWEN Washington, do hereby certify that President of the Senate the attached is FIFTH ENGROSSED SUBSTITUTE SENATE BILL 5857 as passed by Senate and the House of Representatives on the dates hereon Passed by the House March 4, 2016 set forth. Yeas 94 Nays 3 HUNTER G. GOODMAN FRANK CHOPP Secretary Speaker of the House of Representatives Approved April 1, 2016 4:40 PM FILED April 4, 2016 Secretary of State JAY INSLEE State of Washington

Governor of the 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 self4 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 ((department)) commissioner must be deposited into the ((business license account created in RCW 19.02.210)) insurance commissioner's regulatory account created in RCW 48.02.190.
- NEW SECTION. Sec. 2. A new section is added to chapter 19.340 RCW to read as follows:

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- (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 third-party administrator of prescription drug benefits, and a pharmacy arising out of an appeal under RCW 19.340.100(6) regarding drug pricing and reimbursement.
- (2) Any person, corporation, third-party administrator of prescription drug benefits, pharmacy benefit manager, or business entity which violates any provision of this chapter shall be subject to a civil penalty in the amount of one thousand dollars for each act in violation of this chapter or, if the violation was knowing and willful, a civil penalty of five thousand dollars for each violation of this chapter.
- 28 **Sec. 3.** RCW 19.340.010 and 2014 c 213 s 1 are each amended to 29 read as follows:
- The definitions in this section apply throughout this chapter 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) <u>"Commissioner" means the insurance commissioner established</u> 36 in chapter 48.02 RCW.
- 37 (3) "Insurer" has the same meaning as in RCW 48.01.050.

- 1 $((\frac{3}{3}))$ $\underline{(4)}$ "Pharmacist" has the same meaning as in RCW 2 18.64.011.
- (((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 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 $((\frac{(+6)}{(+6)}))$ "Third-party payor" means a person licensed under RCW 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:

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- 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.
 - (c))) predetermined reimbursement costs have been established, such as a maximum allowable cost or maximum allowable cost list or any other benchmark prices utilized by the pharmacy benefit manager and must include the basis of the methodology and sources utilized to determine multisource generic drug reimbursement amounts.
- 31 <u>(b)</u> "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 <u>administration; and is sold or marketed in the state during the</u> 2 <u>period.</u>
- 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.
 - (2) A pharmacy benefit manager:

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- 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;
 - (b) Shall ensure that all drugs on a list are ((generally)) readily available for purchase by pharmacies in this state from national or regional wholesalers that serve pharmacies in Washington;
 - (c) Shall ensure that all drugs on a list are not obsolete;
 - (d) Shall make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the ((maximum allowable cost 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.
- 33 (3) A pharmacy benefit manager must establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to 34 ((maximum allowable cost pricing)) predetermined reimbursement costs 35 for multisource generic drugs. A network pharmacy may appeal a 36 ((maximum allowable cost)) predetermined reimbursement cost for a 37 multisource generic drug if the reimbursement for the drug is less 38 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

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.
- (4) A pharmacy benefit manager must provide as part of the 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
- (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.

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

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- (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.
- 12 <u>(b) Upon resolution of the dispute, the commissioner shall</u>
 13 <u>provide a copy of the decision to both parties within seven calendar</u>
 14 <u>days.</u>
- 15 <u>(c) The commissioner may authorize the office of administrative</u> 16 <u>hearings, as provided in chapter 34.12 RCW, to conduct appeals under</u> 17 this subsection (6).
- 18 <u>(d) A pharmacy benefit manager may not retaliate against a</u> 19 pharmacy for pursuing an appeal under this subsection (6).
- (e) This subsection (6) applies only to a pharmacy with fewer than fifteen retail outlets, within the state of Washington, under its corporate umbrella.
- 23 <u>(7)</u> This section does not apply to the state medical assistance 24 program.
- 25 <u>(8) A pharmacy benefit manager shall comply with any requests for</u> 26 <u>information from the commissioner for purposes of the study of the</u> 27 <u>pharmacy chain of supply conducted under section 7 of this act.</u>
- NEW SECTION. Sec. 5. A new section is added to chapter 48.02 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.

NEW SECTION. Sec. 6. The insurance commissioner, in collaboration with the department of health, must review the potential to use the independent review organizations, established in RCW 48.43.535, as an alternative to the appeal process for pharmacy and pharmacy benefit manager disputes. By December 1, 2016, the agencies must submit recommendations for use of the independent review organizations including detailed suggestions for modifications to the process, and the possible transition of the process from the department of health, established in RCW 43.70.235, to the office of 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 stakeholder work groups to address the components of the study, which must include but are not limited to the following:
- (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;
- 30 (e) Review the telephone contacts and standards for response 31 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.
- 38 (2) The study must be delivered to the legislature by November 1, 39 2016.

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

Passed by the Senate March 8, 2016. Passed by the House March 4, 2016. Approved by the Governor April 1, 2016. Filed in Office of Secretary of State April 4, 2016.