5ESSB 5857 - H COMM AMD
By Committee on Health Care & Wellness

NOT ADOPTED 03/04/2016

Strike everything after the enacting clause and insert the following:

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

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

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

(a) Submit an application requiring the following information:

(i) The identity of the pharmacy benefit manager;

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

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

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

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

(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:

(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 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) As used in this section:

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

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

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

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

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

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

(2) A pharmacy benefit manager:

(a) May not place a drug on a list unless ((~~are is [there are]~~)) there are at least two therapeutically equivalent multiple source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network pharmacies 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.

(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 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.

(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) 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 provide a copy of the decision to both parties within seven calendar days.

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

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

NEW SECTION. **Sec. 5.** A new section is added to chapter 19.340 RCW to read as follows:

(1) As used in this section:

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

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

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

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

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

(2) A pharmacy benefit manager:

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

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

(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 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.

(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. A network pharmacy may appeal a maximum allowable cost 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.

(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;

(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 purchased by similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost.

(5)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall make an 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) This section does not apply to the state medical assistance program.

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

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

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

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

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

NEW SECTION. **Sec. 7.** 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. 8.** Section 1 of this act takes effect January 1, 2017."

Correct the title.

EFFECT: Removes the requirement for pharmacy benefit managers (PBMs) to use the most up-to-date pricing data to calculate reimbursements for multisource generic drugs. Removes the requirement that at least one product with a current national drug code be available for drugs on a list.

Removes the definition of "acquisition cost." Changes references to "maximum allowable cost" to "predetermined reimbursement costs for multisource generic drugs."

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). Removes the ability for a pharmacy's contracting agent to bring an appeal to a PBM. Changes the amount of time a PBM has to complete an appeal from 10 days to 30 days. Provides that an appeal is deemed denied if not completed within 30 days. 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. Requires, upon a successful appeal, the PBM to make a reasonable adjustment. 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.

Removes the start date of January 1, 2017, for appeals to the Office of the Insurance Commissioner (OIC). Removes the requirement that the OIC appeals be conducted under the Administrative Procedure Act. Removes the ability for the OIC to delegate the appeals to the Office of Administrative Hearings.

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

Requires the OIC to collaborate with the Department of Health when reviewing the use of independent review organizations (IROs) in appeals. Removes the requirement that the OIC review the use of IROs for other disputes between providers and insurance carriers.

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

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

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