
SECOND SUBSTITUTE HOUSE BILL 1316

State of Washington

59th Legislature

2005 Regular Session

By House Committee on Appropriations (originally sponsored by Representatives Schual-Berke, Simpson, Kessler, Morrell, Kilmer, Upthegrove, Clibborn, Hasegawa, Conway, Roberts, Takko, Moeller, Kagi, Dickerson, Campbell and Ormsby; by request of Governor Gregoire)

READ FIRST TIME 02/11/05.

1 AN ACT Relating to importation of prescription drugs from Canadian
2 wholesalers; amending RCW 18.64.046; adding a new section to chapter
3 18.64 RCW; and creating new sections.

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

5 NEW SECTION. **Sec. 1.** The legislature finds that as consumers'
6 prescription drug costs continue to rise, people across the state of
7 Washington are seeking opportunities to purchase lower cost
8 prescription drugs from Canada for their personal use. The state has
9 a strong interest in promoting the safe use of prescription drugs by
10 consumers in Washington state. To address this interest, the
11 legislature intends to seek authorization from the federal government
12 to license Canadian prescription drug wholesalers, thereby providing
13 licensed retail pharmacies the opportunity to purchase prescription
14 drugs from approved Canadian wholesalers and pass those savings on to
15 consumers, and providing consumers the opportunity to purchase
16 prescription drugs from a trusted community pharmacist who is aware of
17 all of their prescription drug needs.

1 NEW SECTION. **Sec. 2.** A new section is added to chapter 18.64 RCW
2 to read as follows:

3 (1) By September 1, 2005, the board shall, in consultation with the
4 department and the health care authority, submit a waiver request to
5 the federal food and drug administration that will authorize the state
6 of Washington to license Canadian prescription drug wholesalers under
7 RCW 18.64.046, thereby providing retail pharmacies licensed in
8 Washington state the opportunity to purchase prescription drugs from
9 approved Canadian wholesalers and pass those savings on to consumers.
10 The waiver shall provide that:

11 (a) Canadian prescription drug wholesalers meet the requirements of
12 RCW 18.64.046 and any rules adopted by the board to implement those
13 requirements;

14 (b) The board must ensure the integrity of the prescription drug
15 products being distributed by:

16 (i) Requiring that prescription drugs purchased from Canadian
17 wholesalers originate only from approved manufacturing locations;

18 (ii) Routinely testing prescription drugs purchased from Canadian
19 wholesalers for safety;

20 (iii) Establishing safe labeling, tracking, and shipping procedures
21 for prescription drugs purchased from Canadian wholesalers; and

22 (iv) Closely monitoring compliance with RCW 18.64.046 and any rules
23 adopted to implement the waiver;

24 (c) The prescription drugs purchased from Canadian wholesalers must
25 be limited to those for which potential savings to consumers can be
26 demonstrated;

27 (d) To ensure that the program benefits those consumers without
28 insurance coverage for prescription drugs who are most in need of price
29 relief, prescription drug purchases from pharmacies under the waiver
30 will be limited to those not eligible for reimbursement by third party
31 insurance coverage, whether public or private; and

32 (e) Savings associated with purchasing prescription drugs from
33 Canadian wholesalers will be passed on to consumers.

34 (2) By December 1, 2005, the board, in consultation with the
35 department and the health care authority, shall submit a detailed
36 implementation plan to the governor and appropriate committees of the
37 legislature that details the mechanisms that the board will use to

1 implement each component of the waiver under subsection (1) of this
2 section.

3 (3) The board shall adopt rules as necessary to implement this act.

4 **Sec. 3.** RCW 18.64.046 and 2004 c 52 s 3 are each amended to read
5 as follows:

6 (1) The owner of each place of business which sells legend drugs
7 and nonprescription drugs, or nonprescription drugs at wholesale shall
8 pay a license fee to be determined by the secretary, and thereafter, on
9 or before a date to be determined by the secretary as provided in RCW
10 43.70.250 and 43.70.280, a like fee to be determined by the secretary,
11 for which the owner shall receive a license of location from the
12 department, which shall entitle such owner to either sell legend drugs
13 and nonprescription drugs or nonprescription drugs at wholesale at the
14 location specified for the period ending on a date to be determined by
15 the secretary, and each such owner shall at the time of payment of such
16 fee file with the department, on a blank therefor provided, a
17 declaration of ownership and location, which declaration of ownership
18 and location so filed as aforesaid shall be deemed presumptive evidence
19 of the ownership of such place of business mentioned therein. It shall
20 be the duty of the owner to notify immediately the department of any
21 change of location and ownership and to keep the license of location or
22 the renewal thereof properly exhibited in such place of business.

23 (2) Failure to conform with this section is a misdemeanor, and each
24 day that the failure continues is a separate offense.

25 (3) In event the license fee remains unpaid on the date due, no
26 renewal or new license shall be issued except upon compliance with
27 administrative procedures, administrative requirements, and fees
28 determined as provided in RCW 43.70.250 and 43.70.280.

29 (4) No wholesaler may sell any quantity of drug products containing
30 ephedrine, pseudoephedrine, phenylpropanolamine, or their salts,
31 isomers, or salts of isomers, if the total monthly sales of these
32 products to persons within the state of Washington exceed five percent
33 of the wholesaler's total prior monthly sales of nonprescription drugs
34 to persons within the state in March through October. In November
35 through February, no wholesaler may sell any quantity of drug products
36 containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their
37 salts, isomers, or salts of isomers if the total monthly sales of these

1 products to persons within the state of Washington exceed ten percent
2 of the wholesaler's total prior monthly sales of nonprescription drugs
3 to persons within the state. For purposes of this section, monthly
4 sales means total dollars paid by buyers. The board may suspend or
5 revoke the license of any wholesaler that violates this section.

6 (5) The board may exempt a wholesaler from the limitations of
7 subsection (4) of this section if it finds that the wholesaler
8 distributes nonprescription drugs only through transactions between
9 divisions, subsidiaries, or related companies when the wholesaler and
10 the retailer are related by common ownership, and that neither the
11 wholesaler nor the retailer has a history of suspicious transactions in
12 precursor drugs as defined in RCW 69.43.035.

13 (6) The requirements for a license apply to all persons, in
14 Washington and outside of Washington, including those in Canadian
15 provinces, who sell both legend drugs and nonprescription drugs and to
16 those who sell only nonprescription drugs, at wholesale to pharmacies,
17 practitioners, and shopkeepers in Washington.

18 (7) No wholesaler may sell any quantity of ephedrine,
19 pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts
20 of isomers, to any person in Washington other than a pharmacy licensed
21 under this chapter, a shopkeeper or itinerant vendor registered under
22 this chapter, or a practitioner as defined in RCW 18.64.011. A
23 violation of this subsection is punishable as a class C felony
24 according to chapter 9A.20 RCW, and each sale in violation of this
25 subsection constitutes a separate offense.

26 (8) If the board is unable to develop a reciprocal licensing
27 agreement with Health Canada or an applicable Canadian province, the
28 board shall develop a process to license participating Canadian
29 wholesalers through on-site inspection and certification.

30 NEW SECTION. Sec. 4. If any part of this act is found to be in
31 conflict with federal requirements that are a prescribed condition to
32 the allocation of federal funds to the state, the conflicting part of
33 this act is inoperative solely to the extent of the conflict and with
34 respect to the agencies directly affected, and this finding does not
35 affect the operation of the remainder of this act in its application to
36 the agencies concerned. Rules adopted under this act must meet federal

1 requirements that are a necessary condition to the receipt of federal
2 funds by the state.

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