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## SUBSTITUTE HOUSE BILL 2266

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State of Washington 59th Legislature 2005 Regular Session

By House Committee on Health Care (originally sponsored by Representatives Campbell, Morrell, Green, Moeller, Lantz, Cody, McCune, Haler, Lovick, McDonald and Ahern)

READ FIRST TIME 03/04/05.

- AN ACT Relating to the sale of ephedrine, pseudoephedrine, and phenylpropanolamine; amending RCW 69.50.212, 18.64.044, 18.64.046, and 18.64.047; adding a new section to chapter 69.43 RCW; creating a new
- 4 section; and prescribing penalties.
- 5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- NEW SECTION. Sec. 1. Restricting access to certain precursor drugs used to manufacture methamphetamine to ensure that they are only sold at retail to individuals who will use them for legitimate purposes upon production of proper identification is an essential step to controlling the manufacture of methamphetamine.
- NEW SECTION. Sec. 2. A new section is added to chapter 69.43 RCW to read as follows:
- (1) For purposes of this section, "traditional Chinese herbal practitioner" means a person who is certified as a diplomate in Chinese herbology from the national certification commission for acupuncture and oriental medicine or who has received a certificate in Chinese herbology from a school accredited by the accreditation council on acupuncture and oriental medicine.

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(2) A pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW, or an employee thereof, a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner may not knowingly sell, transfer, or otherwise furnish to any person a product at retail that he or she knows to contain ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in combination with another active ingredient, without first obtaining photo identification of the person that shows the date of birth of the person, and having the person sign a written log or receipt showing the date of the transaction, the name of the person, and the amount of the product being sold, transferred, or otherwise furnished.

- (3) A person buying or receiving a product at retail containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in combination with another active ingredient, from a pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW, or an employee thereof, a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner must first produce photo identification of the person that shows the date of birth of the person, and sign a written log or receipt showing the date of the transaction, the name of the person, and the amount of the product being sold, transferred, or otherwise furnished.
- (4) Any product containing any amount of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in combination with another active ingredient, shall be kept in a location that is not accessible by customers without assistance of an employee of the merchant.
- (5) No pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW, or an employee thereof, a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner may sell any product containing any amount of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in combination with another active ingredient to a person that is not at least eighteen years old. This provision does not apply to products sold by prescription under RCW 69.50.212.

1 (6) The following products are exempt from the requirements of this 2 section:

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- (a) Any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers that is not the only active ingredient and that is in liquid, liquid capsule, or gel capsule form;
- (b) Any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, that consists of a glycerin matrix that inhibits conversion into a controlled substance; or
- (c) Any compounds, mixtures, or preparations containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, that the state board of pharmacy, by rule, has determined to have been formulated in such a way as to effectively prevent conversion of the active ingredient into methamphetamine.
- (7) A pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW, or an employee thereof, a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner shall provide access to the written log to the board of pharmacy or department of health if necessary for regulatory activities.
- (8) The board of pharmacy, by rule, may exempt other products from this section that are found not to be used in the illegal manufacture of methamphetamine or other controlled dangerous substances. manufacturer of a drug product may apply for removal of the product from this section if the product is determined by the board to have been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine. The burden of proof for exemption is upon the person requesting the exemption. The petitioner shall provide the board with evidence that the product has been formulated in such a way as to serve as an effective general deterrent to the conversion of pseudoephedrine into methamphetamine. evidence must include the furnishing of a valid scientific study, conducted by an independent, professional laboratory and evincing professional quality chemical analysis. Factors to be considered in whether a product should be excluded from this section include but are not limited to:

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- 1 (a) Ease with which the product can be converted to 2 methamphetamine;
  - (b) Ease with which pseudoephedrine is extracted from the substance and whether it forms an emulsion, salt, or other form;
  - (c) Whether the product contains a "molecular lock" that renders it incapable of being converted into methamphetamine;
  - (d) Presence of other ingredients that render the product less likely to be used in the manufacture of methamphetamine; and
  - (e) Any pertinent data that can be used to determine the risk of the substance being used in the illegal manufacture of methamphetamine or any other controlled substance.
    - (9) Nothing in this section applies:

- (a) To the sale of any compound, mixture, or preparation that contains ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, as its only active ingredient, that is a Schedule V controlled substance under RCW 69.50.212;
- (b) To the sale of a product that may only be sold upon the presentation of a prescription;
- (c) To the sale of a product by a traditional Chinese herbal practitioner to a patient; or
- (d) When the details of the transaction are recorded in a pharmacy profile individually identified with the recipient and maintained by a licensed pharmacy or registered shopkeeper or itinerant vendor.
- (10)(a) No pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW, a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner may retaliate against any employee that has made a good faith attempt to comply with the requirements of this section by requesting that a customer present photo identification and documenting the transaction in the written log.
- (b) No pharmacy licensed by, or shopkeeper or itinerant vendor registered with, the department of health under chapter 18.64 RCW, a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner is subject to prosecution under subsection (11) of this section if they made a good faith attempt to comply with the requirements of this section by requesting that a customer present photo identification, make a reasonable effort to determine the customer's age, and documenting the transaction in the written log.

1 (11) A violation of this section is a gross misdemeanor.

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2 **Sec. 3.** RCW 69.50.212 and 1993 c 187 s 12 are each amended to read as follows:

Unless specifically excepted by state or federal law or regulation or more specifically included in another schedule, the following controlled substances are listed in Schedule V:

- 7 (a) Any material, compound, mixture, or preparation containing any 8 of the following narcotic drug and its salts: Buprenorphine.
  - (b) Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth in this subsection, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:
- 16 (1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;
- 18 (2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;
- 20 (3) Not more than 100 milligrams of ethylmorphine per 100 21 milliliters or per 100 grams;
- 22 (4) Not more than 2.5 milligrams of diphenoxylate and not less than 23 25 micrograms of atropine sulfate per dosage unit;
  - (5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;
  - (6) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
    - (c) Any material, compound, mixture, or preparation containing any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers, and salts of isomers: Pyrovalerone.
- (d) Any compound, mixture, or preparation that contains ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, as its only active ingredient. The requirements related to photo identification, written logs, and age limitations of section 2 of this act do not apply to these compounds, mixtures, or preparations.

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The controlled substances listed in this section may be rescheduled or deleted as provided for in RCW 69.50.201.

- Sec. 4. RCW 18.64.044 and 2004 c 52 s 2 are each amended to read as follows:
- (1) A shopkeeper registered as provided in this section may sell nonprescription drugs, if such drugs are sold in the original package of the manufacturer.
- (2) Every shopkeeper not a licensed pharmacist, desiring to secure the benefits and privileges of this section, is hereby required to register as a shopkeeper through the master license system, and he or she shall pay the fee determined by the secretary for registration, and on a date to be determined by the secretary thereafter the fee determined by the secretary for renewal of the registration; and shall at all times keep said registration or the current renewal thereof conspicuously exposed in the location to which it applies. In event such shopkeeper's registration is not renewed by the master license expiration date, no renewal or new registration shall be issued except upon payment of the registration renewal fee and the master license delinquency fee under chapter 19.02 RCW. This registration fee shall not authorize the sale of legend drugs or controlled substances.
- (3) The registration fees determined by the secretary under subsection (2) of this section shall not exceed the cost of registering the shopkeeper.
- (4) Any shopkeeper who shall vend or sell, or offer to sell to the public any such nonprescription drug or preparation without having registered to do so as provided in this section, shall be guilty of a misdemeanor and each sale or offer to sell shall constitute a separate offense.
- (5) A shopkeeper who is not a licensed pharmacy may purchase products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in combination with another active ingredient, or as otherwise permitted under section 2 of this act, only from a wholesaler licensed by the department under RCW 18.64.046 or from a manufacturer licensed by the department under RCW 18.64.045. The board shall issue a warning to a shopkeeper who violates this subsection, and may suspend or revoke the registration of the shopkeeper for a subsequent violation.

(6) A shopkeeper who has purchased <u>products containing any quantity</u> <u>of</u> ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in a suspicious transaction as defined in RCW 69.43.035, is subject to the following requirements:

- (a) The shopkeeper may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed ten percent of the shopkeeper's total prior monthly sales of nonprescription drugs in March through October. In November through February, the shopkeeper may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed twenty percent of the shopkeeper's total prior monthly sales of nonprescription drugs. For purposes of this section, "monthly sales" means total dollars paid by buyers. The board may suspend or revoke the registration of a shopkeeper who violates this subsection.
- (b) The shopkeeper shall maintain inventory records of the receipt and disposition of nonprescription drugs, utilizing existing inventory controls if an auditor or investigator can determine compliance with (a) of this subsection, and otherwise in the form and manner required by the board. The records must be available for inspection by the board or any law enforcement agency and must be maintained for two years. The board may suspend or revoke the registration of a shopkeeper who violates this subsection. For purposes of this subsection, "disposition" means the return of product to the wholesaler or distributor.

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

(1) The owner of each place of business which sells legend drugs and nonprescription drugs, or nonprescription drugs at wholesale shall pay a license fee to be determined by the secretary, and thereafter, on or before a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, a like fee to be determined by the secretary, for which the owner shall receive a license of location from the department, which shall entitle such owner to either sell legend drugs and nonprescription drugs or nonprescription drugs at wholesale at the location specified for the period ending on a date to be determined by

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the secretary, and each such owner shall at the time of payment of such fee file with the department, on a blank therefor provided, a declaration of ownership and location, which declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of the ownership of such place of business mentioned therein. It shall be the duty of the owner to notify immediately the department of any 7 change of location and ownership and to keep the license of location or the renewal thereof properly exhibited in such place of business.

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- (2) Failure to conform with this section is a misdemeanor, and each day that the failure continues is a separate offense.
- (3) In event the license fee remains unpaid on the date due, no renewal or new license shall be issued except upon compliance with administrative procedures, administrative requirements, determined as provided in RCW 43.70.250 and 43.70.280.
- (4) No wholesaler may sell any quantity of drug products containing ephedrine, pseudoephedrine, phenylpropanolamine, or their isomers, or salts of isomers, if the total monthly sales of these products to persons within the state of Washington exceed five percent of the wholesaler's total prior monthly sales of nonprescription drugs to persons within the state in March through October. In November through February, no wholesaler may sell any quantity of drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers if the total monthly sales of these products to persons within the state of Washington exceed ten percent of the wholesaler's total prior monthly sales of nonprescription drugs to persons within the state. For purposes of this section, monthly sales means total dollars paid by buyers. The board may suspend or revoke the license of any wholesaler that violates this section.
- (5) The board may exempt a wholesaler from the limitations of subsection (4) of this section if it finds that the wholesaler distributes nonprescription drugs only through transactions between divisions, subsidiaries, or related companies when the wholesaler and the retailer are related by common ownership, and that neither the wholesaler nor the retailer has a history of suspicious transactions in precursor drugs as defined in RCW 69.43.035.
- (6) The requirements for a license apply to all persons, Washington and outside of Washington, who sell both legend drugs and

nonprescription drugs and to those who sell only nonprescription drugs, at wholesale to pharmacies, practitioners, and shopkeepers in Washington.

- (7)(a) No wholesaler may sell any product containing ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, as its only active ingredient, to any person in Washington other than a pharmacy licensed under this chapter or a practitioner as defined in RCW 18.64.011.
- (b) No wholesaler may sell any ((quantity)) product containing any amount of ephedrine, pseudoephedrine, phenylpropanolamine, or their salts, isomers, or salts of isomers in combination with another active ingredient, or as otherwise permitted under section 2 of this act, to any person in Washington other than a pharmacy licensed under this chapter, a shopkeeper or itinerant vendor registered under this chapter, ((or)) a practitioner as defined in RCW 18.64.011, or a traditional Chinese herbal practitioner as defined in section 2 of this act.
- 18 <u>(c)</u> A violation of this subsection is punishable as a class C 19 felony according to chapter 9A.20 RCW, and each sale in violation of 20 this subsection constitutes a separate offense.
- **Sec. 6.** RCW 18.64.047 and 2004 c 52 s 4 are each amended to read 22 as follows:
  - (1) Any itinerant vendor or any peddler of any nonprescription drug or preparation for the treatment of disease or injury, shall pay a registration fee determined by the secretary on a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280. The department may issue a registration to such vendor on an approved application made to the department.
  - (2) Any itinerant vendor or peddler who shall vend or sell, or offer to sell to the public any such nonprescription drug or preparation without having registered to do so as provided in this section, is guilty of a misdemeanor and each sale or offer to sell shall constitute a separate offense.
- 34 (3) In event the registration fee remains unpaid on the date due, 35 no renewal or new registration shall be issued except upon compliance 36 with administrative procedures, administrative requirements, and fees

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determined as provided in RCW 43.70.250 and 43.70.280. This registration shall not authorize the sale of legend drugs or controlled substances.

- (4) An itinerant vendor may purchase <u>products containing</u> ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers <u>in combination with another active ingredient</u>, or as <u>otherwise permitted under section 2 of this act</u> only from a wholesaler licensed by the department under RCW 18.64.046 or from a manufacturer licensed by the department under RCW 18.64.045. The board shall issue a warning to an itinerant vendor who violates this subsection, and may suspend or revoke the registration of the vendor for a subsequent violation.
- (5) An itinerant vendor who has purchased <u>products containing any quantity of</u> ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, in a suspicious transaction as defined in RCW 69.43.035, is subject to the following requirements:
- (a) The itinerant vendor may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed ten percent of the vendor's total prior monthly sales of nonprescription drugs in March through October. In November through February, the vendor may not sell any quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, or their salts, isomers, or salts of isomers, if the total monthly sales of these products exceed twenty percent of the vendor's total prior monthly sales of nonprescription drugs. For purposes of this section, "monthly sales" means total dollars paid by buyers. The board may suspend or revoke the registration of an itinerant vendor who violates this subsection.
- (b) The itinerant vendor shall maintain inventory records of the receipt and disposition of nonprescription drugs, utilizing existing inventory controls if an auditor or investigator can determine compliance with (a) of this subsection, and otherwise in the form and manner required by the board. The records must be available for inspection by the board or any law enforcement agency and must be maintained for two years. The board may suspend or revoke the registration of an itinerant vendor who violates this subsection. For

- 1 purposes of this subsection, "disposition" means the return of product
- 2 to the wholesaler or distributor.

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