THE SENATE
TWENTY-SIXTH LEGISLATURE, 2011
STATE OF HAWAII

S.B. NO. 40 S.D. 2

A BILL FOR AN ACT

RELATING TO PSEUDOEPHEDRINE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Section 329-22, Hawaii Revised Statutes, is amended to read as follows:

"**§329-22 Schedule V.** (a) The controlled substances listed in this section are included in schedule V.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, 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:

(1) Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

(3) Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams; and

(6) Not more than 0.5 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers[~~.~~]: pseudoephedrine or any drug containing pseudoephedrine.

(d) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide], (Vimpat); and

(2) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].

(e) No later than July 1, 2011, all drugs containing pseudoephedrine shall be subject to the requirements of section 329-38, and all retail sellers of drugs containing pseudoephedrine shall remove these drugs from all public areas where over-the-counter drugs are available for sale."

SECTION 2. Section 329-38, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) No controlled substance in schedule II or pseudoephedrine may be dispensed without a written prescription of a practitioner, [~~except:~~] with the following exceptions:

(1) [~~In~~] For purposes of a controlled substance in schedule II, in the case of an emergency situation, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization from a prescribing practitioner; provided that:

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a

written prescription signed by the prescribing practitioner);

(B) If the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the prescribing practitioner using the phone number in the telephone directory or other good faith efforts to identify the prescriber; and

(C) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of this subsection, the prescription shall have written on its face "Authorization for Emergency Dispensing". The written prescription may be delivered to the pharmacist in person or by mail, and if by mail, the prescription shall be postmarked within the seven-day period. Upon

receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the administrator if the prescribing practitioner fails to deliver a written prescription to the pharmacy within the allotted time. Failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner. Any practitioner who fails to deliver a written prescription within the seven-day period shall be in violation of section 329-41(a)(1); [~~or~~]

(2) [~~When~~] For purposes of a controlled substance in schedule II, when dispensed directly by a practitioner, other than a pharmacist, to the ultimate user. The practitioner in dispensing a controlled substance in schedule II shall affix to the package a label showing:

(A) The date of dispensing;

(B) The name, strength, and quantity of the drug dispensed;

(C) The dispensing practitioner's name and address;

(D) The name of the patient;

(E) The "use by" date for the drug, which shall be:

(i) The expiration date on the [~~,~~]manufacturer's[~~,~~] or principal labeler's container; or

(ii) One year from the date the drug is dispensed, whichever is earlier; and

(F) Directions for use, and cautionary statements, if any, contained in the prescription or as required by law.

A complete and accurate record of all schedule II controlled substances ordered, administered, prescribed, and dispensed shall be maintained for five years. Prescriptions and records of dispensing shall otherwise be retained in conformance with the requirements of section 329-36. No prescription for a controlled substance in schedule II may be refilled[~~.~~]; or

(3) For purposes of a controlled substance in schedule V, in the case of a drug containing pseudoephedrine, as classified under schedule V, when dispensed by a pharmacist without a prescription, under the following circumstances:

(A) The quantity dispensed is limited to an amount adequate to treat the patient during a short period of time and does not exceed _____ milligrams; provided that dispensing _____ milligrams or more shall be pursuant to a written prescription signed by the prescribing practitioner; and

(B) Prior to dispensing the drug, the pharmacist enters the patient's name and signature into a log that:

(i) Is maintained by the pharmacy as a complete and accurate record of all of the patients who were administered drugs containing pseudoephedrine without a prescription;

(ii) Includes the date the drugs described in clause (i) were dispensed, the names and

signatures of the patients, and the quantities of the drugs administered; and

(iii) Is maintained for at least five years."

SECTION 3. Section 329-64, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) The requirements imposed by sections 329-62 and 329-63(a) of this part shall not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian;

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to patients; and

(3) Any manufacturer or wholesaler licensed by the State who sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian[~~; and~~

~~(4) Any sale, transfer, furnishing, or receipt of any drug that contains pseudoephedrine or norpseudoephedrine that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 United States~~

~~Code section 301 et seq.) or regulations adopted thereunder as long as it complies with the requirements of sections 329-73, 329-74, and 329-75~~]."

SECTION 4. Section 329-73, Hawaii Revised Statutes, is repealed.

["~~**[§329-73] Pseudoephedrine permit.** (a) Beginning January 1, 2006, any person transporting by any means more than three packages of any product the sale of which is restricted by section 329-75 shall obtain a pseudoephedrine permit.~~

~~(b) The requirements imposed by [subsection] (a) shall not apply to persons registered with the department under section 329-67. A pseudoephedrine permit shall be issued by the department in a form and manner as prescribed by the department by rule. A pseudoephedrine permit shall be valid for one year and renewable annually.~~"]

SECTION 5. Section 329-74, Hawaii Revised Statutes, is repealed.

["~~**[§329-74] Unlawful transport of pseudoephedrine.** (a) A person commits the offense of unlawful transport of pseudoephedrine if the person transports more than three packages of any product the sale of which is restricted by section 329-75 without a permit issued from the department.~~

~~(b) For purposes of this section, "transportation" means the transfer of a pseudoephedrine product by a person other than a wholesaler, distributor, or retailer of such product authorized to conduct business as such by the State.~~

~~(c) Unlawful transport of pseudoephedrine is a misdemeanor.~~"]

SECTION 6. Section 329-75, Hawaii Revised Statutes, is repealed.

["~~**§329-75 Sales of products, mixtures, or preparations containing pseudoephedrine; reporting requirement for wholesalers.** (a) Notwithstanding any other law to the contrary, a pharmacy or retailer may sell or distribute to a person without a prescription not more than 3.6 grams per day, without regard to the number of transactions, of any product, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts, optical isomers, or salts of optical isomers as the only active ingredient or in combination with other active ingredients; provided that the pharmacy or retailer shall comply with the following conditions:~~

~~(1) The product, mixture, or preparation shall be sold or distributed from an area not accessible by customers or the general public, such as behind the counter or~~

~~in a locked display case and where the seller delivers the product directly into the custody of the purchaser;~~

~~(2) Any person purchasing or otherwise acquiring any product, mixture, or preparation shall produce proper identification containing the photograph, date of birth, printed name, signature, and address of the individual obtaining the substance;~~

~~(3) The pharmacy or retailer shall record, in an electronic log on software provided by the narcotics enforcement division of the department and approved by the administrator:~~

~~(A) The date of any transaction under paragraph (2);~~

~~(B) The name, address, and date of birth of the person;~~

~~(C) The type of identification provided by the individual obtaining the substance;~~

~~(D) The agency issuing the identification used; and~~

~~(E) The name of the compound, mixture, or preparation, and the amount; and~~

~~(4) The pharmacy or retailer shall:~~

~~(A) Record the information required under paragraph (3) on an electronic worksheet on software provided by the narcotics enforcement division of the department; and~~

~~(B) Electronically mail the worksheet record to the narcotics enforcement division once a month.~~

~~The information shall be retained by the pharmacy or retailer for a period of two years. The electronic log shall be capable of being checked for compliance against all state and federal laws, including interfacing with other states to ensure comprehensive compliance, and shall be subject to random and warrantless inspection by county or state law enforcement officers.~~

~~(b) No person shall knowingly purchase, possess, receive, or otherwise acquire more than nine grams of any product, mixture, or preparation containing any detectable quantity of pseudoephedrine or its salts, isomers, or salts of optical isomers within a thirty-day period, except that this limit shall not apply to any quantity of such product, mixture, or preparation dispensed pursuant to a valid prescription.~~

~~(c) Any person who violates subsection (b) is guilty of a class C felony.~~

~~(d) The department, by rule, may exempt other products from this section, if the administrator finds that the products are not used in the illegal manufacture of methamphetamine or other controlled substances. A manufacturer of a drug product may apply for removal of the product from this section if the product is determined by the administrator to have been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.~~

~~(e) Notwithstanding any other provision of this chapter to the contrary, every wholesaler shall report to the administrator all sales made to any retailer, of any product, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts, optical isomers, or salts of optical isomers, as the only active ingredient or in combination with other active ingredients. The department shall provide a common reporting form that contains at least the following information about the product, mixture, or preparation:~~

~~(1) Generic or other name;~~

~~(2) Quantity sold;~~

~~(3) Date of sale;~~

~~(4) Name and address of the wholesaler; and~~

~~(5) Name and address of the retailer.~~

~~(f) Intentional or knowing failure of a retailer or pharmacy to transmit any information as required by this section shall be a misdemeanor and shall result in the immediate suspension of that retailer's ability to sell any product, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts, optical isomers, or salts of optical isomers as the only active ingredient or in combination with other active ingredients until authorized by the administrator.~~"]

SECTION 7. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun before its effective date.

SECTION 8. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 9. This Act shall take effect on July 1, 2050.

Report Title:
Pseudoephedrine; Prescription Drugs

Description:
Reclassifies pseudoephedrine as a schedule V drug that may only be dispensed with a prescription with certain exceptions; makes conforming amendments. Requires retail sellers of drugs containing pseudoephedrine to remove these drugs from their over-the-counter inventories no later than 7/1/2011. Effective 7/1/2050. (SD2)

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.