THE SENATE
TWENTY-SIXTH LEGISLATURE, 2012
STATE OF HAWAII

S.B. NO. 2474

JAN 20 2012

A BILL FOR AN ACT

RELATING TO HEALTH.

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

SECTION 1. The legislature finds that methamphetamine is a highly addictive drug with dangerous long-term side effects including addiction, anxiety, insomnia, and violent behavior. The legislature also finds that pseudoephedrine, a safe, effective, and widely-used over the counter decongestant, is an essential ingredient used to make methamphetamine.

The legislature finds that some state governments have taken steps to address the growing number of methamphetamine labs in their states. Oregon and Mississippi have passed laws requiring prescriptions for pseudoephedrine. Oregon's prescription-only law has resulted in fewer methamphetamine lab incidents. According to the director of Mississippi's bureau of narcotics, Mississippi's law has also reduced the number of methamphetamine labs in the state.

The purpose of this Act is to:

(1) Classify pseudoephedrine as a schedule V drug that may only be dispensed with a prescription; and

(2) Exempt cold products that contain other active ingredients from the prescription requirement.

SECTION 2. 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, 2012, all drugs containing pseudoephedrine shall be subject to the requirements of section 329-38."

SECTION 3. 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) 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 in a cold product, mixture, or preparation containing

pseudoephedrine, its salts, optical isomers, or salts of optical isomers and is in combination with other active ingredients 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 4. 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;

(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 329-38, 329-73, 329-74, and 329-75."

SECTION 5. Section 329-75, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(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~~] a cold 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 quantity dispensed is limited to an amount adequate to treat the patient during a short period of time and does not exceed milligrams; provided further 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~~] five 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."

SECTION 6. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 7. This Act shall take effect upon its approval.

INTRODUCED BY: _____

S.B. NO. 2474

Report Title:
Pseudoephedrine; Prescription Drugs

Description:
Reclassifies pseudoephedrine as a schedule V drug that may only be dispensed with a prescription; exempts cold products that contain other active ingredients, with certain conditions.

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