
A BILL FOR AN ACT

RELATING TO PSEUDOEPHEDRINE.

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

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

3 "§329-22 **Schedule V.** (a) The controlled substances
4 listed in this section are included in schedule V.

5 (b) Narcotic drugs containing nonnarcotic active medicinal
6 ingredients. Any compound, mixture, or preparation containing
7 limited quantities of any of the following narcotic drugs, which
8 also contains one or more nonnarcotic active medicinal ingredients
9 in sufficient proportion to confer upon the compound, mixture, or
10 preparation, valuable medicinal qualities other than those
11 possessed by the narcotic drug alone:

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

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

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



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

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

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

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

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

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



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

3 (e) No later than July 1, 2011, all drugs containing
4 pseudoephedrine shall be subject to the requirements of section
5 329-38 and all retail sellers of drugs containing
6 pseudoephedrine shall remove these drugs from all public areas
7 where over-the-counter drugs are available for sale."

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

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

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

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



1 written prescription signed by the prescribing
2 practitioner);

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

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



1 receipt, the dispensing pharmacist shall attach
2 this prescription to the oral emergency
3 prescription, which had earlier been reduced to
4 writing. The pharmacist shall notify the
5 administrator if the prescribing practitioner
6 fails to deliver a written prescription to the
7 pharmacy within the allotted time. Failure of
8 the pharmacist to do so shall void the authority
9 conferred by this paragraph to dispense without a
10 written prescription of a prescribing individual
11 practitioner. Any practitioner who fails to
12 deliver a written prescription within the
13 seven-day period shall be in violation of section
14 329-41(a)(1); [~~or~~]

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

21 (A) The date of dispensing;



- 1 (B) The name, strength, and quantity of the drug
- 2 dispensed;
- 3 (C) The dispensing practitioner's name and address;
- 4 (D) The name of the patient;
- 5 (E) The "use by" date for the drug, which shall be:
- 6 (i) The expiration date on the
- 7 [] manufacturer's [] or principal labeler's
- 8 container; or
- 9 (ii) One year from the date the drug is
- 10 dispensed, whichever is earlier; and
- 11 (F) Directions for use, and cautionary statements, if
- 12 any, contained in the prescription or as required
- 13 by law.

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



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

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

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

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

19 (ii) Includes the date the drugs described in
20 clause (i) were dispensed, the names and
21 signatures of the patients, and the
22 quantities of the drugs administered; and



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

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

4 "(a) The requirements imposed by sections 329-62 and
5 329-63(a) of this part shall not apply to any of the following:

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

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

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

16 ~~(4) Any sale, transfer, furnishing, or receipt of any drug~~
17 ~~that contains pseudoephedrine or norpseudoephedrine~~
18 ~~that is lawfully sold, transferred, or furnished over~~
19 ~~the counter without a prescription pursuant to the~~
20 ~~federal Food, Drug, and Cosmetic Act (21 United States~~
21 ~~Code section 301 et seq.) or regulations adopted~~



1 ~~thereunder as long as it complies with the~~
2 ~~requirements of sections 329-73, 329-74, and 329-75]."~~

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

5 ~~["§329-73] Pseudoephedrine permit. (a) Beginning~~
6 ~~January 1, 2006, any person transporting by any means more than~~
7 ~~three packages of any product the sale of which is restricted by~~
8 ~~section 329-75 shall obtain a pseudoephedrine permit.~~

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

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

17 ~~["§329-74] Unlawful transport of pseudoephedrine. (a) A~~
18 ~~person commits the offense of unlawful transport of~~
19 ~~pseudoephedrine if the person transports more than three~~
20 ~~packages of any product the sale of which is restricted by~~
21 ~~section 329-75 without a permit issued from the department.~~



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

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

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

9 ~~["§329-75 Sales of products, mixtures, or preparations~~
10 ~~containing pseudoephedrine; reporting requirement for~~
11 ~~wholesalers. (a) Notwithstanding any other law to the~~
12 ~~contrary, a pharmacy or retailer may sell or distribute to a~~
13 ~~person without a prescription not more than 3.6 grams per day,~~
14 ~~without regard to the number of transactions, of any product,~~
15 ~~mixture, or preparation containing any detectable quantity of~~
16 ~~pseudoephedrine, its salts, optical isomers, or salts of optical~~
17 ~~isomers as the only active ingredient or in combination with~~
18 ~~other active ingredients; provided that the pharmacy or retailer~~
19 ~~shall comply with the following conditions:~~

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



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

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

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

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

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

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

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

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

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



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

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

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

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



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

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

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

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

21 ~~(2) Quantity sold;~~

22 ~~(3) Date of sale;~~



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

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

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

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

18



Report Title:

Pseudoephedrine; Prescription Drugs

Description:

Reclassifies pseudoephedrine as a schedule V drug which 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. (SD1)

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

