

FEB 06 2013

A BILL FOR AN ACT

RELATING TO HEALTH.

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

1 SECTION 1. Chapter 453, Hawaii Revised Statutes, is
2 amended by adding a new part to be appropriately designated and
3 to read as follows:

4 **"PART . EXPEDITED PARTNER THERAPY**

5 **§453-A Definitions.** As used in this part:

6 "Expedited partner therapy" means the indirect treatment of
7 partners of a patient who has been diagnosed as having a
8 sexually transmitted disease through the dispensing or
9 prescribing of antibiotic therapy for the treatment of the
10 partners to the patient without the physical examination of the
11 partners by a health professional.

12 "Health professional" means any of the following:

13 (1) A person licensed or otherwise authorized by law to
14 practice medicine or surgery under this chapter and
15 whose scope of practice includes the diagnosis and
16 treatment of sexually transmitted diseases; or

17 (2) For the purpose of dispensing antibiotic therapy under
18 this section, a pharmacist who is licensed or



1 otherwise authorized to engage in the practice of
2 pharmacy under chapter 461.

3 "Sexual activity" means sexual intercourse, cunnilingus,
4 fellatio, anal intercourse, or any other intrusion, however
5 slight, of any part of a person's body or of any object into the
6 genital or anal openings of another person's body, but emission
7 of semen is not required.

8 "Sexually transmitted disease" means any sexually
9 transmitted disease recommended by the Centers for Disease
10 Control and Prevention for expedited partner therapy, including
11 but not limited to chlamydia, gonorrhea, and human
12 immunodeficiency virus.

13 **§453-B Expedited partner therapy.** (a) A health
14 professional may in addition to treating a patient, provide
15 expedited partner therapy to the partners of the patient if all
16 of the following requirements are met:

- 17 (1) The patient has a laboratory-confirmed or suspected
18 clinical diagnosis of a sexually transmitted disease;
- 19 (2) The patient indicates that the patient has partners
20 with whom the patient has engaged in sexual activity
21 within the sixty-day period immediately preceding the
22 diagnosis of a sexually transmitted disease; and



1 (3) The patient indicates that the patient's partners are
2 unable or unlikely to seek clinical services in a
3 timely manner.

4 (b) A health professional who provides expedited partner
5 therapy as authorized in this section shall do all of the
6 following:

- 7 (1) Dispense or prescribe antibiotic therapy in the name
8 of the partners, if known, without the physical
9 examination of the partners by the health
10 professional. Notwithstanding any law to the
11 contrary, if the name of the partners are not known,
12 the health professional shall dispense or prescribe
13 the antibiotic therapy in the name of "Expedited
14 Partner Therapy";
- 15 (2) Convey to the patient that it is important to notify
16 the patient's partners of the patient's diagnosis and
17 that it is important for the partners to obtain
18 medical care for a complete evaluation, testing for
19 sexually transmitted diseases, counseling, and
20 treatment; and
- 21 (3) Distribute to the patient the information sheet
22 developed pursuant to section 453-C.



1 **§453-C Information sheet.** The department of health shall
2 develop and, upon request, distribute to health professionals
3 subject to this part an information sheet that includes all of
4 the following:

- 5 (1) A description of expedited partner therapy and its
6 purpose;
- 7 (2) A notice that an individual who has been treated for a
8 sexually transmitted disease should be retested after
9 treatment to detect possible persistent or recurrent
10 infection, including information on the timing of
11 retesting, as recommended by the Centers for Disease
12 Control and Prevention;
- 13 (3) A warning about the possible dangers of administering
14 antibiotic therapy to a pregnant individual;
- 15 (4) Information about antibiotics dispensed or prescribed
16 and dosages of those antibiotics dispensed or
17 prescribed, as recommended by the Centers for Disease
18 Control and Prevention;
- 19 (5) A warning about the risk of allergies to and drug
20 interactions with the antibiotics described in
21 paragraph (4);



- 1 (6) Information about sexually transmitted diseases, the
2 treatment of sexually transmitted diseases, and the
3 prevention of sexually transmitted diseases;
- 4 (7) A notice that the patient and the patient's partners
5 should abstain from sexual activity for seven days
6 after the patient and the partners have completed the
7 antibiotic therapy;
- 8 (8) A notice that the partners should be tested for
9 sexually transmitted diseases;
- 10 (9) A notice of the risk to the patient, the partners, and
11 others, including the public health, if a sexually
12 transmitted disease is not completely treated;
- 13 (10) A notice of the responsibility of the patient to
14 notify sexual partners of the risk of sexually
15 transmitted diseases and the importance of examination
16 and treatment for sexually transmitted diseases; and
- 17 (11) A statement advising any individual who has any
18 questions regarding anything in the information sheet
19 to contact a health professional or the department of
20 health.

21 **§453-D Limitation of liability.** A health care
22 professional who provides expedited partner therapy as



1 authorized under section 453-B shall not be subject to
2 prosecution in a criminal proceeding, liable for damages in a
3 civil action, or subject to disciplinary action under sections
4 453-8 and 453-8.2 for personal injury, death, or other
5 consequences arising from or related in any way to the provision
6 of expedited partner therapy by the health care professional;
7 provided that this section shall not apply if the action of the
8 health care professional in providing expedited partner therapy
9 is gross negligence."

10 SECTION 2. Section 328-16, Hawaii Revised Statutes, is
11 amended as follows:

12 1. By amending subsections (a), (b), and (c) to read:

13 "(a) A prescription drug shall be dispensed only if its
14 label bears the following:

15 (1) The name, business address, and telephone number of
16 the seller. The business address shall be the
17 physical location of the pharmacy or the dispensing
18 practitioner's office;

19 (2) [~~The~~] Except as otherwise authorized for expedited
20 partner therapy in section 453-B, the name of the
21 person for whom the drug was prescribed or the name of



- 1 the owner of the animal for which the drug was
- 2 prescribed;
- 3 (3) The serial number of the prescription;
- 4 (4) The date the prescription was prepared;
- 5 (5) The name of the practitioner if the seller is not the
- 6 practitioner;
- 7 (6) The name, strength, and quantity of the drug;
- 8 (7) The "use by" date for the drug, which shall be:
- 9 (A) The expiration date on the manufacturer's
- 10 container; or
- 11 (B) One year from the date the drug is dispensed,
- 12 whichever is earlier;
- 13 (8) The number of refills available, if any;
- 14 (9) In the case of the dispensing of an equivalent generic
- 15 drug product, the statement "same as (brand name of
- 16 the drug product prescribed or the referenced listed
- 17 drug name)", or words of similar meaning; and
- 18 (10) Specific directions for the drug's use; provided that
- 19 if the specific directions for use are too lengthy for
- 20 inclusion on the label, the notation "take according
- 21 to written instructions" may be used if separate
- 22 written instructions for use are actually issued with



1 the drug by the practitioner or the pharmacist, but in
2 no event shall the notation "take as directed",
3 referring to oral instructions, be considered
4 acceptable.

5 If any prescription for a drug does not indicate the number of
6 times it may be refilled, if any, the pharmacist shall not
7 refill that prescription unless subsequently authorized to do so
8 by the practitioner. The act of dispensing a prescription drug
9 other than a professional sample or medical oxygen contrary to
10 this subsection shall be deemed to be an act that results in a
11 drug being misbranded while held for sale.

12 (b) In addition to the requirements enumerated in
13 subsection (a), a prescription drug shall be dispensed only:

14 (1) By a pharmacist pursuant to a valid prescription [~~ex~~],
15 section 461-1[+], or section 453-B;

16 (2) By a medical oxygen distributor pursuant to a
17 prescription or certificate of medical necessity;
18 provided that the drug to be dispensed is medical
19 oxygen; or

20 (3) By a practitioner to an ultimate user; provided that:

21 (A) [~~The~~] Except as otherwise authorized for
22 expedited partner therapy in section 453-B, the



1 practitioner shall inform the patient, prior to
2 dispensing any drug other than a professional
3 sample, that the patient may have a written,
4 orally ordered, or electronically transmitted or
5 conveyed prescription directed to a pharmacy or a
6 medical oxygen distributor of the patient's own
7 choice;

8 (B) The practitioner shall promptly record in the
9 practitioner's records:

10 (i) The prescription in full;

11 (ii) The name, strength, and quantity of the
12 drug, and specific directions for the drug's
13 use;

14 (iii) The date the drug was dispensed; ~~and~~

15 (iv) ~~The~~ Except as otherwise authorized for
16 expedited partner therapy in section 453-B,
17 the name and address of the person for whom
18 the drug was prescribed or the name of the
19 owner of the animal for which the drug was
20 prescribed; and



1 (v) Prescription drugs dispensed or prescribed
2 for expedited partner therapy as authorized
3 under section 453-B.

4 (C) The records described in subparagraph (B) shall
5 be subject to the inspection of the department or
6 its agents at all times; and

7 (D) No undisclosed rebate, refund, commission,
8 preference, discount, or other consideration,
9 whether in the form of money or otherwise, has
10 been offered to the practitioner as compensation
11 or inducement to dispense or prescribe any
12 specific drug in preference to other drugs that
13 might be used for the identical therapeutic
14 indication.

15 (c) A prescription may be communicated in writing, orally,
16 or by electronic transmission, and shall include the following
17 information:

18 (1) The authorization of the practitioner noted as
19 follows:

20 (A) Written prescriptions shall include the original
21 signature of the practitioner;



- 1 (B) Oral prescriptions shall be promptly recorded by
- 2 the pharmacist or medical oxygen distributor and
- 3 shall include the practitioner's oral code
- 4 designation; and
- 5 (C) Electronic prescriptions shall be irrefutably
- 6 traceable to the prescribing practitioner by a
- 7 recognizable and unique practitioner identifier
- 8 such as:
 - 9 (i) A bitmap or graphic image of the
 - 10 prescriber's handwritten signature and the
 - 11 prescriber's oral code designation (or
 - 12 license number or other identifier if the
 - 13 prescriber is an out-of-state practitioner);
 - 14 (ii) An electronic signature;
 - 15 (iii) A digital signature; or
 - 16 (iv) By other means as approved by the director;
- 17 (2) The date of issuance;
- 18 (3) The practitioner's name, business telephone number,
- 19 and business address, unless the practitioner is
- 20 otherwise uniquely identified and the pharmacy or
- 21 medical oxygen distributor dispensing the prescription



- 1 has the prescriber's contact information on file
2 accessible within the dispensing area;
- 3 (4) The name, strength, and quantity of the drug to be
4 dispensed, and specific directions for the drug's use;
- 5 (5) [The] Except as otherwise authorized for expedited
6 partner therapy in section 453-B, the name and address
7 of the person for whom the prescription was written or
8 the name of the owner of the animal for which the drug
9 was prescribed, unless the pharmacy or medical oxygen
10 distributor dispensing the prescription has the
11 address on file accessible within the dispensing area;
- 12 (6) The room number and route of administration, if the
13 patient is in an institutional facility; and
- 14 (7) The number of allowable refills, if the prescription
15 is refillable. If the number of refills authorized by
16 the practitioner is indicated using the terms "as
17 needed" or "prn", the prescription may be refilled up
18 to twelve months from the date the original
19 prescription was written. After the twelve-month
20 period, the "as needed" or "prn" prescription may be
21 refilled for a subsequent three-month period;
22 provided:



- 1 (A) The prescription is refilled only once during the
- 2 three-month period;
- 3 (B) The refill does not exceed a thirty-day supply of
- 4 the drug;
- 5 (C) The refill does not provide any amount of the
- 6 drug fifteen months beyond the date the original
- 7 prescription was written;
- 8 (D) In the case of medical oxygen, the duration of
- 9 therapy indicated on a certificate of medical
- 10 necessity shall supersede any limitations or
- 11 restrictions on refilling; and
- 12 (E) Subparagraphs (A) to (D) shall apply only to
- 13 pharmacies and medical oxygen distributors
- 14 practicing in the State."

15 2. By amending subsection (g) to read:

16 "(g) Any drug other than medical oxygen dispensed pursuant
17 to a prescription shall be exempt from the requirements of
18 section 328-15 (except paragraphs (1), (9), (11), and (12), and
19 the packaging requirements of paragraphs (7) and (8)), if the
20 drug bears a label containing:

- 21 (1) The name and address of the pharmacy;



- 1 (2) The serial number and the date of the prescription or
- 2 of its filling;
- 3 (3) The name of the practitioner;
- 4 (4) [~~The~~] Except as otherwise authorized for expedited
- 5 partner therapy in section 453-B, the name of the
- 6 patient;
- 7 (5) The directions for use; and
- 8 (6) Any cautionary statements contained in the
- 9 prescription.

10 This exemption shall not apply to any drug dispensed in the
 11 course of the conduct of a business of dispensing drugs pursuant
 12 to diagnosis by mail, or to a drug dispensed in violation of
 13 subsection (a), (b), (c), or (d)."

14 SECTION 3. Section 328-17.6, Hawaii Revised Statutes, is
 15 amended as follows:

16 1. By amending subsections (c) and (d) to read:
 17 "(c) Any pharmacist or medical oxygen distributor who
 18 fills or refills a prescription from an out-of-state
 19 practitioner shall:

- 20 (1) Note the following on the prescription record: the
- 21 out-of-state practitioner's full name, address, and
- 22 telephone number;



- 1 (2) Be responsible for validating and verifying the
2 practitioner's prescriptive authority by virtue of a
3 valid out-of-state license, a Drug Enforcement
4 Administration registration number, or other measures
5 as appropriate; and
- 6 (3) [~~Demand~~] Except as otherwise authorized for expedited
7 partner therapy in section 453-B, demand proper
8 identification from the person whose name appears on
9 the prescription prior to filling the prescription, in
10 addition to complying with any identification
11 procedures established by the department for filling
12 and refilling an out-of-state prescription.
- 13 (d) Before refilling a transferred out-of-state
14 prescription, a pharmacist or medical oxygen distributor shall:
- 15 (1) [~~Advise~~] Except as otherwise authorized for expedited
16 partner therapy in section 453-B, advise the person
17 whose name appears on the prescription that the
18 prescription on file at the originating out-of-state
19 pharmacy or medical oxygen distributor may be
20 canceled; and
- 21 (2) Record all information required to be on a
22 prescription, including:



- 1 (A) The date of issuance of the original
- 2 prescription;
- 3 (B) The number of refills authorized on the original
- 4 prescription;
- 5 (C) The date the original prescription was dispensed;
- 6 (D) The number of valid refills remaining and the
- 7 date of the last refill;
- 8 (E) The out-of-state pharmacy's or out-of-state
- 9 medical oxygen distributor's name, telephone
- 10 number, and address, and the original
- 11 prescription number or control number from which
- 12 the prescription information was transferred; and
- 13 (F) The name of the transferor pharmacist or the
- 14 medical oxygen distributor's agent."

15 2. By amending subsection (f) to read:

16 "(f) An out-of-state prescription record shall state the
17 date of filling or refilling and, except as otherwise authorized
18 for expedited partner therapy in section 453-B, the local
19 address of the person whose name appears on the prescription."

20 SECTION 4. Section 328-17.7, Hawaii Revised Statutes, is
21 amended by amending subsection (a) to read as follows:



1 "(a) Every practitioner, pharmacist, or medical oxygen
2 distributor who compounds, sells, or delivers any prescribed
3 drug to a patient or a patient's agent shall maintain records
4 that identify:

- 5 (1) The specific drug product dispensed, including:
- 6 (A) The product's national drug code (NDC) number; or
 - 7 (B) The brand name or the established name and the
8 name or commonly accepted abbreviation of the
9 principal labeler of the drug product dispensed,
10 the product strength, and the dosage form;
- 11 (2) The quantity of the drug;
- 12 (3) Directions for use;
- 13 (4) The number of allowable refills;
- 14 (5) The date of initial dispensing and the dates of all
15 refilling;
- 16 (6) The date of any transfer of the prescription;
- 17 (7) The name, business address, and telephone number of
18 the recipient pharmacist or medical oxygen distributor
19 for any transfer of prescription;
- 20 (8) The prescribing practitioner, including name, business
21 address, and telephone number;



- 1 (9) The format (oral, written, or electronic) in which the
2 prescription was received;
- 3 (10) [~~The~~] Except as otherwise authorized for expedited
4 partner therapy in section 453-B, the patient,
5 including name, address, and telephone number;
- 6 (11) The date of prescribing; and
- 7 (12) The name of the practitioner, pharmacist, or medical
8 oxygen distributor dispensing the drug.

9 Every prescription dispensed shall have the name of the
10 pharmacist, dispensing practitioner, or medical oxygen
11 distributor responsible for the dispensing appended to the
12 prescription record, and every prescription record shall be
13 preserved and legible for a period of not less than five years.
14 The prescription records shall be subject at all times to the
15 inspection of the director of health or the director's agent."

16 SECTION 5. In codifying the new sections added by section
17 1 of this Act, the revisor of statutes shall substitute
18 appropriate section numbers for the letters used in designating
19 the new sections in this Act.

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

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



Report Title:

Medicine and Surgery; Sexually Transmitted Diseases; Expedited Partner Therapy; Prescription Drugs; Labeling; Record Keeping

Description:

Allows health care professionals, subject to certain requirements, to treat the partners of patients diagnosed as having a sexually transmitted disease recommended by the Centers for Disease Control and Prevention for expedited partner therapy, such as chlamydia, by dispensing or prescribing medication to the partners without examining the partners. Provides protection from criminal liability, legal liability, and disciplinary action for health care professionals who provide expedited partner therapy as authorized. Requires the department of health to develop an information sheet about sexually transmitted diseases for use by health care professionals who provide expedited partner therapy. Creates exceptions to prescription drug labeling and reporting requirements for expedited partner therapy. (SD1)

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