THE SENATE
TWENTY-SEVENTH LEGISLATURE, 2013
STATE OF HAWAII

S.B. NO. 655

JAN 18 2013

A BILL FOR AN ACT

RELATING TO HEALTH.

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

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

"**PART . EXPEDITED PARTNER THERAPY**

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

"Expedited partner therapy" means the indirect treatment of a partner of a patient who has been diagnosed as having a chlamydia or gonorrhea infection, through the dispensing or prescribing of single-dose antibiotic therapy for the treatment of the partner without the physical examination of the partner by a health professional.

"Health professional" means any of the following:

(1) A person licensed or otherwise authorized by law to practice medicine or surgery under this chapter and whose scope of practice includes the diagnosis and treatment of chlamydia and gonorrhea infections; or

(2) For the purpose of dispensing single-dose antibiotic therapy under this section, a pharmacist who is

licensed or otherwise authorized to engage in the practice of pharmacy under chapter 461.

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

"Sexually transmitted disease" includes chlamydia, gonorrhea, human immunodeficiency virus, and other diseases or infections generally acquired through sexual activity.

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

(1) The patient has a laboratory-confirmed or suspected clinical diagnosis of a chlamydia or gonorrhea infection;

(2) The patient indicates that the patient has a partner with whom the patient has engaged in sexual activity within the sixty-day period immediately preceding the diagnosis of a chlamydia or gonorrhea infection; and

(3) The patient indicates that the patient's partner is unable or unlikely to seek clinical services in a timely manner.

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

(1) Dispense or prescribe single-dose antibiotic therapy in the name of the partner, if known, without the physical examination of the partner by the health professional. Notwithstanding any law to the contrary, if the name of the partner is not known, the health professional shall dispense or prescribe the single-dose antibiotic therapy in the name of "Expedited Partner Therapy";

(2) Convey to the patient that it is important to notify the patient's partner of the patient's diagnosis and that it is important for the partner to obtain medical care for a complete evaluation, testing for sexually transmitted diseases, counseling, and treatment; and

(3) Distribute to the patient the information sheet developed pursuant to section 453-C.

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

(1) A description of expedited partner therapy and its purpose;

(2) A notice that an individual who has been treated for a chlamydia or gonorrhea infection should be retested three months after treatment to detect possible persistent or recurrent chlamydia or gonorrhea infection;

(3) A warning about the dangers of administering single-dose antibiotic therapy to a pregnant individual;

(4) Information about antibiotics dispensed or prescribed in single-dose antibiotic therapy and dosages of those antibiotics dispensed or prescribed;

(5) A warning about the risk of allergies to and drug interactions with the antibiotics described in paragraph (4);

(6) Information about sexually transmitted diseases, the treatment of sexually transmitted diseases, and the prevention of sexually transmitted diseases;

(7) A notice that the patient and the patient's partner should abstain from sexual activity for seven days after the patient and the partner have both completed the single-dose antibiotic therapy;

(8) A notice that the partner should be tested for sexually transmitted diseases;

(9) A notice of the risk to the patient, the partner, and others, including the public health, if a sexually transmitted disease is not completely treated;

(10) A notice of the responsibility of the patient to notify sexual partners of the risk of sexually transmitted diseases and the importance of examination and treatment for sexually transmitted diseases; and

(11) A statement advising any individual who has any questions regarding anything in the information sheet to contact a health professional or the department of health.

§453-D Limitation of liability. A health care professional who provides expedited partner therapy as authorized under section 453-B shall not be subject to prosecution in a criminal proceeding, liable for damages in a civil action, or subject to disciplinary action under sections

453-8 and 453-8.2 for personal injury, death, or other consequences arising from or related in any way to the provision of expedited partner therapy by the health care professional; provided that this section shall not apply if the action of the health care professional in providing expedited partner therapy is gross negligence."

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

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

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

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

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

(3) The serial number of the prescription;

(4) The date the prescription was prepared;

(5) The name of the practitioner if the seller is not the practitioner;

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

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

(A) The expiration date on the manufacturer's container; or

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

(8) The number of refills available, if any;

(9) In the case of the dispensing of an equivalent generic drug product, the statement "same as (brand name of the drug product prescribed or the referenced listed drug name)", or words of similar meaning; and

(10) Specific directions for the drug's use; provided that if the specific directions for use are too lengthy for inclusion on the label, the notation "take according to written instructions" may be used if separate written instructions for use are actually issued with the drug by the practitioner or the pharmacist, but in no event shall the notation "take as directed", referring to oral instructions, be considered acceptable.

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

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

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

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

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

(A) [~~The~~] Except as otherwise authorized for expedited partner therapy in section 453-B, the practitioner shall inform the patient, prior to dispensing any drug other than a professional sample, that the patient may have a written, orally ordered, or electronically transmitted or

conveyed prescription directed to a pharmacy or a medical oxygen distributor of the patient's own choice;

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

(i) The prescription in full;

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

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

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

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

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

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

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

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

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

(B) Oral prescriptions shall be promptly recorded by the pharmacist or medical oxygen distributor and shall include the practitioner's oral code designation; and

(C) Electronic prescriptions shall be irrefutably traceable to the prescribing practitioner by a

recognizable and unique practitioner identifier such as:

(i) A bitmap or graphic image of the prescriber's handwritten signature and the prescriber's oral code designation (or license number or other identifier if the prescriber is an out-of-state practitioner);

(ii) An electronic signature;

(iii) A digital signature; or

(iv) By other means as approved by the director;

(2) The date of issuance;

(3) The practitioner's name, business telephone number, and business address, unless the practitioner is otherwise uniquely identified and the pharmacy or medical oxygen distributor dispensing the prescription has the prescriber's contact information on file accessible within the dispensing area;

(4) The name, strength, and quantity of the drug to be dispensed, and specific directions for the drug's use;

(5) [~~The~~] Except as otherwise authorized for expedited partner therapy in section 453-B, the name and address of the person for whom the prescription was written or

the name of the owner of the animal for which the drug was prescribed, unless the pharmacy or medical oxygen distributor dispensing the prescription has the address on file accessible within the dispensing area;

(6) The room number and route of administration, if the patient is in an institutional facility; and

(7) The number of allowable refills, if the prescription is refillable. If the number of refills authorized by the practitioner is indicated using the terms "as needed" or "prn", the prescription may be refilled up to twelve months from the date the original prescription was written. After the twelve-month period, the "as needed" or "prn" prescription may be refilled for a subsequent three-month period; provided:

(A) The prescription is refilled only once during the three-month period;

(B) The refill does not exceed a thirty-day supply of the drug;

(C) The refill does not provide any amount of the drug fifteen months beyond the date the original prescription was written;

(D) In the case of medical oxygen, the duration of therapy indicated on a certificate of medical necessity shall supersede any limitations or restrictions on refilling; and

(E) Subparagraphs (A) to (D) shall apply only to pharmacies and medical oxygen distributors practicing in the State."

2. By amending subsection (g) to read:

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

(1) The name and address of the pharmacy;

(2) The serial number and the date of the prescription or of its filling;

(3) The name of the practitioner;

(4) [~~The~~] Except as otherwise authorized for expedited partner therapy in section 453-B, the name of the patient;

(5) The directions for use; and

(6) Any cautionary statements contained in the prescription.

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

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

1. By amending subsections (c) and (d) to read:

"(c) Any pharmacist or medical oxygen distributor who fills or refills a prescription from an out-of-state practitioner shall:

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

(2) Be responsible for validating and verifying the practitioner's prescriptive authority by virtue of a valid out-of-state license, a Drug Enforcement Administration registration number, or other measures as appropriate; and

(3) [~~Demand~~] Except as otherwise authorized for expedited partner therapy in section 453-B, demand proper

identification from the person whose name appears on the prescription prior to filling the prescription, in addition to complying with any identification procedures established by the department for filling and refilling an out-of-state prescription.

(d) Before refilling a transferred out-of-state prescription, a pharmacist or medical oxygen distributor shall:

(1) [~~Advise~~] Except as otherwise authorized for expedited partner therapy in section 453-B, advise the person whose name appears on the prescription that the prescription on file at the originating out-of-state pharmacy or medical oxygen distributor may be canceled; and

(2) Record all information required to be on a prescription, including:

(A) The date of issuance of the original prescription;

(B) The number of refills authorized on the original prescription;

(C) The date the original prescription was dispensed;

(D) The number of valid refills remaining and the date of the last refill;

(E) The out-of-state pharmacy's or out-of-state medical oxygen distributor's name, telephone number, and address, and the original prescription number or control number from which the prescription information was transferred; and

(F) The name of the transferor pharmacist or the medical oxygen distributor's agent."

2. By amending subsection (f) to read:

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

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

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

(1) The specific drug product dispensed, including:

(A) The product's national drug code (NDC) number; or

(B) The brand name or the established name and the name or commonly accepted abbreviation of the

principal labeler of the drug product dispensed, the product strength, and the dosage form;

(2) The quantity of the drug;

(3) Directions for use;

(4) The number of allowable refills;

(5) The date of initial dispensing and the dates of all refilling;

(6) The date of any transfer of the prescription;

(7) The name, business address, and telephone number of the recipient pharmacist or medical oxygen distributor for any transfer of prescription;

(8) The prescribing practitioner, including name, business address, and telephone number;

(9) The format (oral, written, or electronic) in which the prescription was received;

(10) [~~The~~] Except as otherwise authorized for expedited partner therapy in section 453-B, the patient, including name, address, and telephone number;

(11) The date of prescribing; and

(12) The name of the practitioner, pharmacist, or medical oxygen distributor dispensing the drug.

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

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

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. 655

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 with chlamydia or gonorrhea by dispensing or prescribing medication to the partner without examining the partner. 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.

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