ACT 124

S.B. NO. 1119

A Bill for an Act Relating to Prescription Drugs.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Chapter 328, Hawaii Revised Statutes, is amended by adding to part I two new sections to be appropriately designated and to read as follows:

"**§328- Electronic prescription information.** (a) Prescription information may be transmitted electronically; provided that:

(1) The information shall be communicated only between the prescribing practitioner or the prescriber's authorized agent and pharmacies or medical oxygen distributors of the patient's choice;

(2) The information shall be communicated in a retrievable, recognizable format acceptable to the intended recipient;

(3) No electronic system, software, or other intervening mechanism or party shall alter the practitioner's prescription, order entry, selection, or intended selection without the practitioner's approval, on a per prescription or per order basis. Transmitted prescription information shall not be altered by any system, software, or other intervening mechanism or party prior to receipt by the intended pharmacy or medical oxygen distributor recipient;

(4) The prescription information processing system shall provide for adequate confidentiality safeguards provided by any applicable federal or state law; and

(5) Practitioners, pharmacists, and medical oxygen distributors shall exercise prudent and professional judgment regarding the accuracy, validity, and authenticity of any prescription information communicated, received, or transferred.

(b) Nothing in this section shall be construed or interpreted to prevent the transmission of health care information, including prescription information, between health plans and their authorized agents and prescribing practitioners, pharmacists, and medical oxygen distributors for the purpose of the adjudication or payment of claims.

§328- Supply of electronic equipment. No person shall supply prescription information processing system equipment, including computer hardware, software, facsimile machines, and related equipment, to practitioners, pharmacists, pharmacies, or medical oxygen distributors, on the condition, agreement, or understanding that the recipient of the equipment shall not deal in the commodity of a competitor, shall not deal with a competitor, or shall deal only with persons identified by the supplier of the equipment."

SECTION 2. Section 328-1, Hawaii Revised Statutes, is amended as follows:

1. By adding ten new definitions to be appropriately inserted and to read:

"'"Agent" means a person who acts on behalf of or under the direction of another person.

"Computer" means a programmable electronic device, capable of multiple functions including but not limited to storage, retrieval, and processing of information.

"Downtime" means the period of time that a prescription information processing system is not operable.

"Electronic prescription" means a prescription or certificate of medical necessity, which is electronically transmitted or conveyed, including a facsimile transmission.

"Legible" means information that is capable of being read and understood.

"Pharmacy" means a place of business operating as a pharmacy as permitted under chapter 461.

"Prescriber's authorized agent" means a person, including but not limited to an institutional facility, who acts on behalf of, and under the direction of, the prescribing practitioner.

"Prescription information processing system" means a system for creating, generating, sending, receiving, storing, displaying, or processing prescription information, including but not limited to any electronic hardware, software, or files.

"Record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium.

"Supply" means to sell, trade, distribute, exchange, barter, give, offer for sale, lease, rent, or provide."

2. By amending the definitions of "medical oxygen distributor" and "pharmacist" to read:

'"'Medical oxygen distributor" means any person, including a licensed prescription drug wholesale distributor, who [~~distributes or dispenses~~] holds a permit under chapter 461 to distribute or dispense medical oxygen pursuant to a prescription.

"Pharmacist" means a person who is licensed or holds a permit under chapter 461 to practice in a pharmacy[.], including a pharmacy intern under the immediate and direct supervision of a licensed pharmacist."

3. By repealing the definition of "pharmacy intern".

["~~"Pharmacy intern" means a student or graduate of a school or college of pharmacy issued a permit by the board of pharmacy to work under the immediate supervision of a pharmacist.~~"]

SECTION 3. Section 328-16, Hawaii Revised Statutes, is amended to read as follows:

"§328-16 Drugs limited to dispensing on prescription. (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 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 [~~of~~] the prescription [~~or of its filling;~~] 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 date the potency of the drug expires if the date is available from the manufacturer or principal labeler;
(8) The number of refills available, if any; and
(9) 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 [~~or a pharmacy intern~~] pursuant to a valid prescription;
(2) By a medical oxygen distributor pursuant to a [~~valid~~] prescription or [~~valid~~] 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 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;
    [~~(A)~~] (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 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][1]

[~~(B)~~] (C) The records described in subparagraph [~~(A)~~] (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 [~~valid~~] prescription may be communicated in writing, orally[2] [~~by facsimile,~~] or by electronic transmission, and shall include the following information:

[~~(1) The date of issuance;~~

~~(2)~~] (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 [~~reduced to writing~~] recorded by the pharmacist[~~, pharmacist intern,~~] or medical oxygen distributor[~~,~~] and shall include the practitioner's oral code designation; and

(C) [~~Facsimile or electronic~~] 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; or

(iii) A digital signature;

or by other means as approved by the director;

(2) The date of issuance;

(3) The practitioner's name [~~and business address;~~], 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 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 [~~filling~~] 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 [~~valid~~] certificate of medical necessity shall supersede any limitations or restrictions on refilling; and
(E) [~~The provisions of subparagraphs~~] Subparagraphs (A) to (D) shall apply only to pharmacies and medical oxygen distributors practicing in the State.

(d) Any [~~written or oral~~] prescription may be refilled by the pharmacy and a [~~written or oral~~] prescription for medical oxygen may be refilled by the medical oxygen distributor if that refilling is authorized by the practitioner either:
(1) In the original prescription; or
(2) By oral or electronic order, which shall be [~~reduced~~] promptly [~~to writing~~] recorded and filed by the receiving pharmacist[~~, pharmacy intern,~~] or medical oxygen distributor.

(e) Prescription information may be transferred between pharmacies, between a pharmacy and a medical oxygen distributor, and between medical oxygen distributors for dispensing purposes; provided that:
(1) Medical oxygen distributors may communicate or receive prescription information related only to the dispensing of medical oxygen;
(2) The prescription information includes all elements of subsection (c)(2) to (7) and the following:
(A) Authentication of the transmitting pharmacy or medical oxygen distributor who is providing the prescription information including the following:
(i) The name of the pharmacist or medical oxygen distributor providing the information;
(ii) The name, telephone number, and address or location of the pharmacy or medical oxygen distributor firm providing the information; and
(iii) The serial number, prescription number, control number, or other unique identifier of the prescription record from which the information was transferred;
(B) The date the original prescription was issued;
(C) The date of the last refill; and
(D) The number of refills remaining.

[~~(e)~~] (f) For the purposes of this section, a ''prescription drug'' is a drug intended for use by a person that:
(1) Is a habit forming drug to which section 328-15(4) applies;
(2) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner; or
(3) Is limited by an approved application under section 505 of the Federal Act, or section 328-17, to use under the professional supervision of a practitioner.

[~~(f)~~] (g) Any drug other than medical oxygen dispensed [~~by filling or refilling~~] pursuant to a prescription [~~of a practitioner~~] 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; [~~and~~
(~~4~~) ~~If stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription.~~]
(4) 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).

[~~(g)~~] (h) The director of health, by rule, may remove drugs subject to sections 328-15(4) and 328-17 from the requirements of subsection (a), (b), (c), or (d) when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued thereunder may also, by rules issued by the director, be removed from the requirements of subsection (a), (b), (c), or (d).

[~~(h)~~] (i) A drug that is subject to [~~subsection~~] subsections (a), (b), (c), [~~or~~] and (d) shall be deemed to be misbranded if, at any time prior to dispensing, its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription", [~~or~~] "Caution: State law prohibits dispensing without prescription"[~~.~~], or "Rx only". A drug to which [~~subsection~~] subsections (a), (b), (c), [~~or~~] and (d) [~~does~~] do not apply[~~,~~] shall be deemed to be misbranded if, at any time prior to dispensing, its label bears [~~the~~] a caution statement quoted in the preceding sentence.

[~~(i)~~] (j) Nothing in this section shall be construed to relieve any person from any requirement, prescribed by or under authority of law with respect to drugs now included or that may hereafter be included within the classifications of controlled substances as defined in the applicable federal and state laws relating to controlled substances.

[~~(j)~~] (k) Oral code numbers or designations shall be issued by the department of public safety, pursuant to applicable laws and rules.

(l) Any person who transmits, maintains, or receives any prescription or prescription refill orally, in writing, or electronically shall ensure the security, integrity, and confidentiality of the prescription and any information contained therein."

SECTION 4. Section 328-17.6, Hawaii Revised Statutes, is amended to read as follows:

"**§328-17.6 Out-of-state prescriptions.** (a) An out-of-state practitioner may issue a written [~~or~~], oral, or electronic prescription within the confines of the practitioner's license and in accordance with Hawaii laws and rules. An oral prescription shall be personally communicated by the out-of-state practitioner and received only by a pharmacist; provided that a medical oxygen order may be received by a medical oxygen distributor.

(b) An out-of-state pharmacy may transfer prescription information for refilling purposes and an out-of-state medical oxygen distributor may transfer prescription information for the purpose of refilling a medical oxygen order.

(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 Enforce-

ment Administration registration number, or other measures as appropriate; and

(3) 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 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.

(e) A pharmacist or medical oxygen distributor who fills or refills an out-of-state prescription shall be responsible if the prescription is not written in the form prescribed by Hawaii laws and rules.

(f) An out-of-state prescription record shall [~~be appropriately identified as "Out-of-State Filled" or "Out-of-State Refilled", and shall~~] state the date of filling or refilling and the local address of the person whose name appears on the prescription.

(g) All transferred prescriptions shall be maintained for a period of five years from the date of filling or refilling. Filled out-of-state prescriptions shall be kept [~~in a special~~] on file for five years. The department may establish additional recordkeeping and reporting procedures for filled and refilled out-of-state prescriptions.

(h) [~~This section shall not apply to prescriptions for controlled substances and habit-forming drugs.~~] Nothing in this section shall be construed to relieve any person from any requirement, prescribed by or under authority of law with respect to drugs now included or that may hereafter be included within the classifications of controlled substances as defined in the applicable federal and state laws relating to controlled substances including but not limited to chapter 329."

SECTION 5. Section 328-17.7, Hawaii Revised Statutes, is amended to read as follows:

"**§328-17.7 Record of prescriptions.** (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;

[~~(2) The prescribing practitioner;~~

~~(3) The patient;~~

~~(4) The date of prescribing or filling; and~~

~~(5) The name of the practitioner, pharmacist, or medical oxygen distributor dispensing the drug.~~]

(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 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.

[~~No prescription shall be compounded, sold, or delivered unless the name of the person compounding, selling, or delivering the same, or the name of the practitioner prescribing the same, is appended to the prescription in full, and every prescription shall be preserved for a period of not less than five years.~~] 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.

(b) Prescription records may be electronically maintained using an appropriate prescription information processing system; provided that:

(1) There are procedures to maintain the records, including but not limited to auxiliary procedures for backing up files, computer downtime, and the protection of patient confidentiality; and
(2) Upon request the prescription records, or a subset thereof, shall be provided to the director or the director's agent, in a form specified by the director, within forty-eight hours.

(c) Prescription records shall be maintained electronically or manually such that the information is readily retrievable during the pharmacy's normal operating hours."

SECTION 6. Act 304, Session Laws of Hawaii 1997, is repealed.

SECTION 7. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.[3]

SECTION 8. This Act shall take effect upon its approval.

(Approved May 18, 2001.)

Notes

1. So in original.
2. Prior to amendment "," appeared here.
3. Edited pursuant to HRS §23G-16.5.