ACT 56

S.B. NO. 1361

A Bill for an Act Relating to Prescription Drugs.

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

SECTION 1. Section 328-1, Hawaii Revised Statutes, is amended by adding two new definitions to be appropriately inserted and to read as follows:

"""Brand" or "brand name" means any registered trade name commonly used to identify a drug.

"Established name" or "generic name" when applied to a drug has the meaning given in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §352(e)(3))."

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

1. By amending subsection (a) 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 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 [~~the potency of the drug expires if the date is available from the manufacturer or principal labeler;~~] 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; [~~and~~]
(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."

2. By amending subsection (c) to read:

"(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 li-

cense number or other identifier if the prescriber is an out-of-state practitioner);
(ii) An electronic signature; [~~or~~]
(iii) A digital signature; or [~~by~~]
(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 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."

SECTION 3. Section 328-17.6, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

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

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 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. Section 328-91, Hawaii Revised Statutes, is amended as follows:

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

"""Compendia of therapeutically equivalent generic drugs" means the Orange Book and any United States Food and Drug Administration documentation of any United States Food and Drug Administration-approved therapeutic equivalency, including but not limited to:

(1) Letters of approval of Abbreviated New Drug Applications with therapeutic equivalency evaluations;
(2) Published listings of approved New Drug Applications or approved Abbreviated New Drug Applications with therapeutic equivalency evaluations; and
(3) Listings of first time generics with therapeutic equivalency evaluations,

adopted by the board.

"Multiple source drug" means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different brand names, or both, under a brand name and without such a name.

"Savings" means the financial benefit derived from utilizing the substituted equivalent generic drug product from the perspective of the consumer or the ultimate payer, including third party payers."

2. By amending the definition of "Hawaii additions and deletions list" to read:

"""Hawaii additions and deletions list" means:

(1) A list of drug products that the board has determined to be safe, effective, and therapeutically equivalent generic drug products but are not in the [~~Orange Book;~~] compendia of therapeutically equivalent generic drugs; and

(2) A list of drug products that are included in the [~~Orange Book,~~] compendia of therapeutically equivalent generic drugs, but that the board has determined not to be safe, effective, therapeutically equivalent, or bioequivalent generic drug products."

3. By repealing the definition of "established name".

["~~"Established name" has the meaning given in section 502(e)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 352(e)(3)).~~"]

SECTION 6. Section 328-92, Hawaii Revised Statutes, is amended to read as follows:

"**§328-92 Drug product selection.** (a) [~~A~~] When filling a prescription order for a drug prescribed by its brand name, a pharmacist or the pharmacist's authorized agent shall:

(1) Offer to the consumer [~~substitutable and lower cost~~] an equivalent generic drug [~~products~~] product from the formulary adopted pursuant to section 328-96; and

(2) [~~Inform~~] Upon the request of the consumer [~~of the retail price difference between the brand name drug product and the substitutable drug product; and~~], inform the consumer of the savings; and

(3) Inform the consumer of the consumer's right to refuse substitution.

The pharmacist shall substitute an equivalent generic drug product if [~~the consumer consents,~~] the practitioner does not prohibit substitution under subsection (b), and the [~~price of the~~] substitute equivalent generic drug product [~~is less than the price of the prescribed drug product.~~] results in a savings. The pharmacist shall not substitute if the consumer refuses.

(b) [~~In filling initial or original prescriptions, the~~] The pharmacist shall not substitute an equivalent generic drug product if the practitioner [~~, and only the practitioner, handwrites "do not substitute"~~] indicates "brand medically necessary" or words of similar meaning on the [~~written~~] prescription. The designation "brand medically necessary" or other similar words or phrases must be handwritten by the practitioner and shall not be preprinted or stamped on the written prescription. The pharmacist shall not substitute an equivalent generic drug product if a prescription is [~~ordered~~] orally or electronically ordered and the practitioner or authorized employee of the practitioner [~~orally orders "do not substitute".~~] indicates "brand medically necessary" or other similar words or phrases.

The pharmacist shall note the practitioner's instructions on the prescription record required to be maintained under section 328-17.7.

[~~In refilling prior written prescriptions, the pharmacist shall not substitute an equivalent drug product if the oral prescription is a refill of a prior written prescription for which selection of an equivalent drug product was not permitted; provided that if the prior written prescription permitted the selection of an equivalent drug product, substitution shall be permitted. The pharmacist, however, shall not substitute an equivalent drug product if a refill of a prescription is ordered orally and the practitioner or authorized employee of the practitioner orally orders "do not substitute".~~

~~The designation of "do not substitute" and the practitioner's signature shall not be preprinted or stamped on the prescription.~~

~~(c) The pharmacist shall not substitute an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.~~]

This subsection shall not apply when it does not comply with any federal requirement for services reimbursable by medicaid or medicare.

[~~(d)~~] (c) The pharmacist shall not substitute an equivalent generic drug product for any prescription for an anti-epileptic drug, except upon the consent of the

practitioner and the patient or the patient's parent or guardian. This narrow exception for epileptic patients shall not be construed as a policy decision to make exceptions for any other conditions.

[~~(e)~~] (d) The county prosecutors and the attorney general may bring action upon complaint by an aggrieved person or upon their own motion in the name of the State against any person to enjoin any violation of this part."

SECTION 7. Section 328-94, Hawaii Revised Statutes, is amended to read as follows:

"**§328-94 Prescription record.** Each pharmacist or practitioner shall maintain a record of any substitution of [~~a generically~~] an equivalent generic drug product for a prescribed brand name drug product as provided in this part."

SECTION 8. Section 328-96, Hawaii Revised Statutes, is amended to read as follows:

"**§328-96 Drug formulary.** (a) The board may adopt rules, pursuant to chapter 91, to effectuate the purpose of this part. Without regard to chapter 91, the board may adopt as rules the [~~Orange Book and its cumulative supplements once they are issued by the Commissioner of Food and Drugs, United States Food and Drug Administration,~~] compendia of therapeutically equivalent generic drugs as the state drug formulary of equivalent multiple source drug products. The board may adopt rules[~~,~~] pursuant to chapter 91[~~,~~] to establish a Hawaii additions and deletions list; provided that section [~~328-92(d)~~] 328-92(c) shall apply, and no pharmacist shall substitute an equivalent generic drug product for any prescription for an antiepileptic drug to treat epilepsy, except upon the consent of the practitioner and the patient or the patient's parent or guardian. Upon the adoption of the [~~Orange Book or its cumulative supplements,~~] compendia of therapeutically equivalent generic drugs by the board, the board shall notify all pharmacies in the State and other interested individuals, within thirty working days, that the formulary has been updated. The Hawaii additions and deletions list may list additional substitutable drug products that are determined by the board to be safe, effective, and therapeutically equivalent. The Hawaii additions and deletions list may delete drug products listed in the [~~Orange Book~~] compendia of therapeutically equivalent generic drugs upon the board's finding that product quality or therapeutic equivalency or bioequivalency, as appropriate, is not adequately assured.

(b) Pursuant to chapter 91, the Hawaii additions and deletions list may be changed, added to, or deleted from as the board deems appropriate. Any person who requests that any change be made or that a [~~generic name or brand name~~] drug product be included or added to or deleted from the Hawaii additions and deletions list shall have the burden of proof to show cause why the change, inclusion, addition, or deletion should be made.

(c) The board shall revise or supplement the Hawaii additions and deletions list as necessary.

(d) The department shall provide for distribution of the Hawaii additions and deletions list and its revisions and supplements, and the dissemination of notices of changes to the compendia of therapeutically equivalent generic drugs, to all pharmacies in the State and to any other interested individuals. The department may establish fees to be charged to persons who receive the Hawaii additions and deletions list and its revisions and supplements[~~,~~], and notices of changes to the compendia of therapeutically equivalent generic drugs. The amounts of the fees charged [~~for the Hawaii additions and deletions list and its revisions and supplements~~] shall be approximately the same as the costs of producing and distributing the

Hawaii additions and deletions list and its revisions and supplements[.], and the notices of changes to the compendia of therapeutically equivalent generic drugs.

(e) Each pharmacy in the State shall:

(1) [~~Obtain, maintain,~~] Maintain and update the [~~Orange Book and its cumulative supplements;~~] compendia of therapeutically equivalent generic drugs as it is approved by the board; and

(2) Obtain the Hawaii additions and deletions list.

(f) The department shall provide for public education regarding the provisions of this part and shall monitor the effects of this part."

SECTION 9. Section 328-93, Hawaii Revised Statutes, is repealed.

SECTION 10. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun, before its effective date.

SECTION 11. Statutory material to be repealed is bracketed and stricken.[1] New statutory material is underscored.

SECTION 12. This Act shall take effect upon its approval.

(Approved May 14, 2003.)

Note

1. Edited pursuant to HRS §23G-16.5.