# ACT 209

S.B. NO. 2773

A Bill for an Act Relating to Drug Product Selection.

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

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

"**§328- Criminal penalty.** Any person who wilfully violates this part or rules adopted under this part shall be guilty of a misdemeanor.

**§328- Administrative penalties.** (a) Any person who violates this part or any rule adopted by the department of health pursuant to this part shall be fined not more than $10,000 for each separate offense. Any action taken to collect the penalty provided for in this subsection shall be considered a civil action.

(b) In addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this part, the director of health may impose by order the administrative penalty specified in this section. Factors to be considered in imposing the administrative penalty include the nature and history of the violation and of any prior violations, and the opportunity, difficulty, and history of corrective action. For any judicial proceeding to recover the administrative penalty imposed, the director of health need only show that notice was given, a hearing was held or the time granted for requesting a hearing has expired without such a request, the administrative penalty was imposed, and the penalty remains unpaid.

**§328- Injunctive relief.** The director of health may institute a civil action in any court of competent jurisdiction for injunctive relief to prevent any violation of this part or of any rule adopted under this part. The court shall have the power to grant relief in accordance with the Hawaii rules of civil procedure.

**§328- Powers and duties.** The department of health shall enforce this part and shall have, in connection therewith, all the powers and duties conferred and imposed upon it pursuant to part I."

SECTION 2. Section 328-91, Hawaii Revised Statutes, is amended as follows:

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

""Pharmacist" means a person licensed under chapter 461 to practice in a pharmacy.

"Practitioner" means an individual licensed by the State to prescribe prescription drugs within the scope of the person's practice."

2. By amending the definition of "agent" to read:

""Agent" means a person under the direct supervision of a [dispenser,] pharmacist, acting in the [dispenser's] pharmacist's presence."

3. By deleting the definition of "dispenser".

["Dispenser" means a person authorized to dispense drugs in the State."]

4. By deleting the definition of "prescriber".

["Prescriber" means a person licensed by the State to prescribe drug products."]

SECTION 3. Section 328-92, Hawaii Revised Statutes, is amended to read as follows:

"**§328-92 Drug product selection.** (a) A [dispenser] pharmacist or the [dispenser's] pharmacist's authorized agent shall:

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

(2) Inform the consumer of the retail price difference between the brand name drug product and the substitutable drug product; and

(3) Inform the consumer [on his or her] of the consumer's right to refuse substitution.

The [dispenser] pharmacist shall substitute if the consumer consents, the [prescriber] practitioner does not prohibit substitution under subsection (b), and the price of the substitute equivalent drug product is less than the price of the prescribed drug product. The [dispenser] pharmacist shall not substitute if the consumer refuses.

(b) In filling initial or original prescriptions, the [dispenser] pharmacist shall not substitute an equivalent drug product if the [prescriber,] practitioner, and only the [prescriber,] practitioner, handwrites "do not substitute" on the written prescription. The [dispenser] pharmacist shall not substitute an equivalent drug product if a prescription is ordered orally and the [prescriber] practitioner or authorized employee of the [prescriber] practitioner orally orders "do not substitute".

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 [dispenser] 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, [such] substitution [may be allowed. However, the dispenser] shall be permitted. The pharmacist, however, shall not substitute an equivalent drug product if a refill of a prescription is ordered orally and the [prescriber] practitioner or authorized employee of the [prescriber] practitioner orally orders "do not substitute".

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

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

(d) The pharmacist shall not substitute an equivalent 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.

[(d) Enforcement. Any wilful violation of this part shall be a misdemeanor.] (e) 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 4. Section 328-93, Hawaii Revised Statutes, is amended to read as follows:

"**§328-93 Prescription label.** Every [dispenser] pharmacist or practitioner shall indicate on the label affixed to the immediate container in which the drug product is sold or dispensed the name and strength of the drug product and the name or commonly accepted abbreviation of the principal labeler, and the statement "Substituted for (Brand name of the drug product prescribed)" unless the [prescriber] practitioner specifically states otherwise. The [dispenser] pharmacist shall record on the prescription form the brand name or the name or commonly accepted abbreviation of the principal labeler of the drug product dispensed."

SECTION 5. Section 328-94, Hawaii Revised Statutes, is amended to read as follows:

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

SECTION 6. Section 328-96, Hawaii Revised Statutes, is amended by amending subsection (d) to read as follows:

"(d) The department of health shall provide for distribution of the formulary, revisions, and supplements to all [dispensers] pharmacists and [prescribers] practitioners licensed and practicing in this State and to other appropriate individuals. The department of health may establish fees to be charged to persons who receive the formulary, revisions, and supplements. The amounts of the fees charged for the formulary, revisions, and supplements shall be approximately the same as the costs of producing and distributing the formulary, revisions, and supplements."

SECTION 7. Section 328-98, Hawaii Revised Statutes, is amended to read as follows:

"**[[]§328-98[] Dispenser] Pharmacist liability.** A [dispenser] pharmacist who selects an equivalent drug product pursuant to this part assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name."

SECTION 8. Statutory material to be repealed is bracketed. New statutory material is underscored.[1]

SECTION 9. This Act shall take effect upon its approval.

(Approved June 17, 1996.)

**Note**

1. Edited pursuant to HRS §23G-16.5.