

## ACT 209

S.B. NO. 1018

A Bill for an Act Relating to the Drug Formulary.

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

SECTION 1. Section 328-91, Hawaii Revised Statutes, is amended by adding two new definitions to be appropriately inserted and to read as follows:

““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; and
- (2) A list of drug products that are included in the Orange Book, but the board has determined not to be safe, effective, therapeutically equivalent, or bioequivalent generic drug products.

“Orange Book” means the United States Food and Drug Administration’s “Approved Drug Products with Therapeutic Equivalence Evaluations” publication and its cumulative supplements, which include a list of approved prescription drug products with therapeutic equivalence evaluations.”

SECTION 2. Section 328-96, Hawaii Revised Statutes, is amended to read as follows:

**“§328-96 Drug formulary.** (a) The board [shall] may adopt rules, pursuant to chapter 91, [for the establishment and maintenance of a state drug formulary of equivalent drug products, and] to effectuate the purpose of this part[; except that the board may, without]. Without regard to chapter 91, [establish in the formulary equivalent drug products that] 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, [has approved as safe and effective and has determined to be therapeutically equivalent. The formulary shall list all drug products that the Commissioner of Food and Drugs, United States Food and Drug Administration, has approved as safe and effective and has determined to be therapeutically equivalent.] as the state drug formulary of equivalent 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) shall apply, and no pharmacist shall substitute an equivalent drug product for any prescription for an anti-epileptic 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, the board shall notify all pharmacies in the State and other interested individuals, within thirty working days, that the formulary has been updated. The [formulary] Hawaii additions and deletions list may list additional substitutable drug products that are determined by the board to [meet requirements adequate to assure product quality and therapeutic equivalence.] be safe, effective, and therapeutically equivalent. The [formulary] Hawaii additions and deletions list may delete [approved drugs] drug products listed in the Orange Book upon [a] the board’s finding that product quality or therapeutic equivalency or bioequivalency, as appropriate, is not adequately assured.

(b) [The formulary] 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 be included or added to or deleted from the [formulary] 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 [provide for revision or supplementation of the formulary] revise or supplement the Hawaii additions and deletions list as necessary [but not less than annually].

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

(e) Each pharmacy in the State shall:

(1) Obtain, maintain, and update the Orange Book and its cumulative supplements; and

(2) Obtain the Hawaii additions and deletions list.

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

SECTION 3. Statutory material to be repealed is bracketed. New statutory material is underscored.

SECTION 4. This Act shall take effect upon its approval.

(Approved July 2, 1999.)