# ACT 242 H.B. NO. 254

A Bill for an Act Relating to Medicines.

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

SECTION 1. The legislature finds that biologics are a class of medicines available to treat disease. Unlike traditional drugs, which are chemically manufactured, biologics are manufactured in living cells. Common biologics in use today include human growth hormone, injectable treatments for arthritis and psoriasis, the Hepatitis B vaccine, and stem cell therapy.

The term "biosimilars" refers to substitute versions of brand-name biologics, similar to generic versions of brand-name drugs. These substitutes are not exactly identical to brand-name biologics but are designed to provide commensurate benefits to patients at lower costs. At least nineteen biosimilars are currently approved for use in the European Union.

The Patient Protection and Affordable Care Act, signed into law by President Barack Obama in 2010, created an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to or interchangeable with a biologic product licensed by the United States Food and Drug Administration (FDA). In early 2015, the FDA approved its first biosimilar drug, Zarxio for use in the United States. Zarxio is used to help prevent infections in cancer patients receiving chemotherapy and is a close copy of an existing medication called Neupogen. Market research reports that there are at least one hundred fifty biosimilars in development.

As of September 15, 2015, sixteen states and Puerto Rico have passed legislation to regulate the substitution of biosimilars for brand-name biologics by pharmacists, and at least thirty-one states have considered similar legislation. Other important issues relating to state regulation of biosimilars include the powers and duties of prescribing authorities, notice to patients, safety, and recordkeeping.

The legislature further finds that the drug product selection board is no longer necessary and its purpose, namely creating the Hawaii additions and deletions list, is better served by reassigning that responsibility to the director of health and combining the responsibility to amend the list of substitutable generic drug products and biological products with the responsibility the director already has for initially creating that same list.

The purpose of this Act is to:

(1) Allow for the regulation of biosimilar medicines to ensure patient safety and access to medicines at lower prices; and
(2) Repeal the drug product selection board and transfer the board's duties of creating the list of substitutable generic drug products and biological products to the director of health.

SECTION 2. Section 328-16, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(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) Except as otherwise authorized for expedited partner therapy in section 453-52, 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) In the case of the dispensing of an interchangeable biological product, the statement "interchangeable with (brand name of the biological product prescribed or the referenced biological drug name)", or words of similar meaning; and
[~~(10)~~] (11) 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."

SECTION 3. Section 328-91, Hawaii Revised Statutes, is amended as follows:

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

""Biological product" or "biologic product" has the same meaning as defined in Title 42 United States Code section 262, as the same may be amended.

"Drug product" means a drug as defined in section 328-1 other than a biological product as defined in this part.

"Hawaii list of equivalent generic drug products and interchangeable biological products" means the list of equivalent generic drug products and interchangeable biological products, which may include references to the Orange Book, the Purple Book, and other published findings and approvals of the United States Food and Drug Administration, created and published by the director pursuant to the director's authority in this part to approve drug products and biological products that pharmacists may substitute with equivalent generic drug products and interchangeable biological products.

"Interchangeable biological product" means a biological product approved by the director as substitutable by pharmacists and included in the Hawaii list of equivalent generic drugs and interchangeable biological products.

"Purple Book" means the United States Food and Drug Administration's "List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" publication and its cumulative supplements, which include a list of licensed biological products with biosimilarity and interchangeability evaluations."

2. By amending the definition of "equivalent generic drug product" to read:

""Equivalent generic drug product" means a drug product [~~with the same established name, active ingredient strength, quantity, and dosage form as the drug product identified in the prescription, and: (1) that is listed as therapeutically equivalent (i.e., addition) in the current Hawaii additions and deletions list; or (2) that is listed in the compendia of therapeutically equivalent generic drug products and is not listed as therapeutically inequivalent (i.e., deletion) in the Hawaii additions and deletions list.~~] approved by the director as substitutable by pharmacists and included in the Hawaii list of equivalent generic drug products and interchangeable biological products."

3. By amending the definition of "savings" to read:

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

4. By repealing the definition of "board".

[~~""Board" means the drug product selection board.~~"]

5. By repealing the definition of "compendia of therapeutically equivalent generic drug products".

[~~""Compendia of therapeutically equivalent generic drug products" means the Orange Book and any United States Food and Drug Administration documentation of any United States Food and Drug Administration approved generic drug product with therapeutic equivalency evaluations, 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 director.~~"]

6. By repealing the definition of "Hawaii additions and deletions list".

[~~""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 compendia of therapeutically equivalent generic drugs; and~~

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

7. By repealing the definition of "multiple source drug".

["~~"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.~~"]

SECTION 4. Section 328-92, Hawaii Revised Statutes, is amended to read as follows:

"**§328-92 Drug product and biological product selection.** (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 an equivalent generic drug product or an interchangeable biological product from the [~~formulary~~] Hawaii list of equivalent generic drug products and interchangeable biological products adopted pursuant to section 328-96; [~~and~~]

(2) Upon the request of the consumer, 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 or an interchangeable biological product if the practitioner does not prohibit substitution under subsection (b), and the substitute equivalent generic drug product or interchangeable biological product results in a savings. The pharmacist shall not substitute if the consumer refuses.

(b) The pharmacist shall not substitute an equivalent generic drug product or an interchangeable biological product if the practitioner indicates "brand medically necessary" or words of similar meaning on the 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 or an interchangeable biological product if a prescription is orally or electronically ordered and the practitioner or authorized employee of the practitioner 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.

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

(c) The pharmacist shall not substitute an equivalent generic drug product or an interchangeable biological 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) Within two business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the practitioner the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be

conveyed by making an entry that is electronically accessible to the practitioner through:

(1) An interoperable electronic medical records system;

(2) An electronic prescribing technology;

(3) A pharmacy benefit management system; or

(4) A pharmacy record.

(e) Entry into an electronic records system as described in subsection (d) is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

(1) There is no interchangeable biological product approved by the United States Food and Drug Administration for the product prescribed; or

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

[~~(d)~~] (f) 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 5. 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 an equivalent generic drug product or an interchangeable biological product for a prescribed brand name drug product as provided in this part."

SECTION 6. Section 328-96, Hawaii Revised Statutes, is amended to read as follows:

"**§328-96** [~~Drug formulary; Hawaii additions and deletions list.~~] Hawaii list of equivalent generic drug products and interchangeable biological products. (a) The [~~board~~] director may adopt rules, pursuant to chapter 91, to effectuate the purpose of this part. Without regard to chapter 91, the director may adopt as rules, and amend as necessary, the [~~compendia of therapeutically equivalent generic drug products 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. Upon the adoption of the compendia of therapeutically equivalent generic drug products by the director, the department shall notify all pharmacies in the State and other interested individuals, within thirty working days, that the formulary has been updated.~~] Hawaii list of equivalent generic drug products and interchangeable biological products, which shall serve as the state list of substitutable equivalent generic drug products and interchangeable biological products. The director's approval of the substitutability of equivalent generic drug products and interchangeable biological products shall be informed by the findings of the United States Food and Drug Administration, which are documented and periodically updated through the following:

(1) For a generic drug product: the Orange Book and any United States Food and Drug Administration documentation of any United States Food and Drug Administration-approved generic drug product with therapeutic equivalency, including:

(A) Letters of approval of Abbreviated New Drug Applications with therapeutic equivalency evaluations;

(B) Published listings of approved New Drug Applications or approved Abbreviated New Drug Applications with therapeutic equivalency evaluations; and

(C) Listing of first time generics with therapeutic equivalency evaluations;

(2) For a biological product: approval under the Public Health Service Act, the Purple Book, and any United States Food and Drug Administration documentation of any United States Food and Drug Administration-approved interchangeability determination, including:

(A) Letters of approval of Biologic Licensing Applications with a determination that the biological product meets the criteria for interchangeability as set forth in title 42 United States Code section 262(k)(4); and

(B) Published listings of approved Biologic Licensing Applications with a determination that the biological product meets the criteria for interchangeability as set forth in Title 42 United States Code section 262(k)(4); and

(3) For a biological product approved under the Federal Food, Drug, and Cosmetic Act: the Orange Book and any United States Food and Drug Administration documentation of any United States Food and Drug Administration-approved interchangeability determination, including:

(A) Letters of approval of approved New Drug Applications or approved Abbreviated New Drug Applications with therapeutic equivalency evaluations; and

(B) Published listings of approved New Drug Applications or approved Abbreviated New Drug Applications with therapeutic equivalency evaluations.

(b) The director shall maintain an official record of, and update as necessary, the Hawaii list of equivalent generic drugs and interchangeable biological products electronically on the department's website, which shall be accessible to pharmacists and other interested persons.

(c) The Hawaii [~~additions and deletions~~] list [~~may list additional~~] of equivalent generic drug products and interchangeable biological products shall only include substitutable generic drug products and interchangeable biological products that are determined by the [~~board~~] director to be safe, effective, and therapeutically equivalent[~~. The Hawaii additions and deletions list may delete drug products listed in the compendia of therapeutically equivalent generic drug~~] or interchangeable. The director shall not approve as substitutable, and the Hawaii list of equivalent generic drug products and interchangeable biological products shall not include, any biological products that the United States Food and Drug Administration has neither licensed and determined as meeting the standards for interchangeability pursuant to Title 42 United States Code section 262(k)(4) nor determined as therapeutically equivalent as set forth in the latest edition of or supplement to the United States Food and Drug Administration's approved drug products with therapeutic equivalence evaluations.

(d) The director may remove from the Hawaii list of equivalent generic drug products and interchangeable biological products any products upon the [~~board's~~] director's finding that [~~product~~] the safety, quality, efficacy, 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.~~]

(e) Any person who requests that any [~~change~~] modification be made to, or that a drug product or biological product be [~~included or~~] added to [~~or deleted~~] or removed from, the Hawaii [~~additions and deletions~~] list of equivalent generic drug products and interchangeable biological products shall have the burden of proof to show cause why the [~~change, inclusion,~~] modification, addition, or [~~deletion~~] removal 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 drug products 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 drug products. The amounts of the fees charged 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 drug products.~~

~~(e)~~] (f) Each pharmacy in the State shall[~~:~~

~~(1) Maintain and~~] update [~~the compendia of therapeutically equivalent generic drug products~~] and maintain its physical copies and electronic records of the Hawaii list of equivalent generic drug products and interchangeable biological products as it is approved and periodically updated and amended by the director[~~; and~~

~~(2) Obtain the Hawaii additions and deletions list~~].

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

SECTION 7. Section 328-97, Hawaii Revised Statutes, is amended to read as follows:

"[~~]~~§328-97[~~]~~ **Posting requirements.** Every pharmacy shall prominently display, in clear and unobstructed public view, a sign in block letters [~~which~~] that shall read:

"HAWAII LAW REQUIRES THAT LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG PRODUCTS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS BE OFFERED TO THE CONSUMER. CONSULT YOUR PHYSICIAN AND PHARMACIST CONCERNING THE AVAILABILITY OF THE LEAST EXPENSIVE DRUG PRODUCT FOR YOUR USE."

The letters must be at least one inch in height."

SECTION 8. Section 328-98, Hawaii Revised Statutes, is amended to read as follows:

"§328-98 **Pharmacist liability.** A pharmacist who selects an equivalent generic drug product or an interchangeable biological 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 9. Section 328-95, Hawaii Revised Statutes, is repealed.

SECTION 10. Statutory material to be repealed is bracketed and stricken.[1] New statutory material is underscored.

SECTION 11. This Act shall take effect on July 1, 2016.

(Approved July 12, 2016.)

**Note**

1. Edited pursuant to HRS §23G-16.5.