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 record keeping.

The purpose of this Act is to allow for the regulation of biosimilar medicines to ensure patient safety and access to medicines at lower prices.

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 drug product, the statement "interchangeable with (brand name of the drug product prescribed or the referenced listed 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 three new definitions to be appropriately inserted and to read:

""Biological product" means the same as defined in title 42 United States Code section 262.

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

"Interchangeable biological product" means a biological product that the United States Food and Drug Administration:

(1) Has licensed and has determined meets the standards for interchangeability pursuant to title 42 United States Code section 262(k)(4); or

(2) Has determined is 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"."

2. By amending the definition of "compendia of therapeutically equivalent generic drugs" to read:

""Compendia of therapeutically equivalent generic [~~drug~~] drugs and interchangeable biological products" means:

(1) For a "drug product" as defined in this part, 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)~~] (A) Letters of approval of Abbreviated New Drug Applications with therapeutic equivalency evaluations;

[~~(2)~~] (B) Published listings of approved New Drug Applications or approved Abbreviated New Drug Applications with therapeutic equivalency evaluations; and

[~~(3)~~] (C) Listings of first time generics with therapeutic equivalency evaluations, adopted by the [~~director.~~] board;

(2) For a "biological product" as defined in this part, approved 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 Application 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" as defined in this part, 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."

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."

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

"**§328-92 Drug product and interchangeable 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 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 five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate 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 prescriber 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 approved 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.** (a) The board 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 the compendia of therapeutically equivalent generic drug products and interchangeable biological products as the state drug formulary of equivalent multiple source drug products[~~.~~] and interchangeable biological products. The board may adopt rules pursuant to chapter 91 to establish a Hawaii additions and deletions list[~~.~~]; provided that section 328-92(c) shall apply,

and no pharmacist shall substitute an equivalent generic drug product or an interchangeable biological 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 compendia of therapeutically equivalent generic [~~drug~~] drugs and interchangeable biological products by the [~~director,~~] board, the [~~department~~] 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 not include as substitutable any biologic products that the United States Food and Drug Administration has not either licensed and determined meet the standards for interchangeability pursuant to title 42 United States Code section 262(k)(4) or determined are 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. The Hawaii

additions and deletions list may delete drug products listed in the compendia of therapeutically equivalent generic [~~drug~~] drugs and interchangeable biological products upon the board's finding that product quality or therapeutic equivalency or bioequivalency, as appropriate, is not adequately assured.

(b) Pursuant to chapter 91, and subject to the limitations for biological products set forth above in section 328-96(a), 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 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[~~.~~], subject to the limitations for biological products set forth above in section 328-96(a).

(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~~] drugs and

interchangeable biological 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~~] drugs and interchangeable biological 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~~] drugs and interchangeable biological products.

(e) Each pharmacy in the State shall:

(1) Maintain and update the compendia of therapeutically equivalent generic [~~drug~~] drugs and interchangeable biological products as [~~it is~~] they are approved by the [~~director;~~] 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 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~~] a generically equivalent 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. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 10. This Act shall take effect upon its approval.

H.B. NO. 254 H.D. 1 PROPOSED

Report Title:
Biosimilar Medicines; Interchangeable Biological Products

Description:
Allows for the dispensing of biosimilar medicines under specified conditions. Regulates interchangeable biological drug products. (HB254 HD1 PROPOSED)

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