HOUSE OF REPRESENTATIVES
TWENTY-EIGHTH LEGISLATURE, 2015
STATE OF HAWAII

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 growing class of medicines available to treat disease. Unlike traditional drugs, which are chemically manufactured, biologics are manufactured in living cells. 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 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 federal Food and Drug Administration. To date, the Food and Drug Administration has not approved a biologic product as biosimilar or interchangeable. It is not yet known

when the first biosimilar will be marketed in the United States. However, when the Food and Drug Administration deems a specific biosimilar interchangeable, state law will govern how substitutions will be allowed.

Since 2013, eight states have passed legislation to regulate the substitution of biosimilars for brand-name biologics by pharmacists, and other states have considered, but not approved, 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 establish a working group composed of health care stakeholders to begin the process of addressing issues related to biosimilars and potentially updating Hawaii's pharmacy laws.

SECTION 2. (a) There is established under the department of health for administrative purposes a working group on biosimilars.

(b) The working group shall examine issues related to state regulation of biosimilars, including but not limited to legislation approved in other states, the powers and duties of

prescribing authorities, notice to patients, safety, and record-keeping, and shall provide recommendations for updating Hawaii's pharmacy and insurance laws with regard to biosimilars.

(c) The following individuals or their designees shall serve as members of the working group:

(1) The director of health, who shall serve as the chairperson of the working group;

(2) The chairperson of the board of pharmacy; and

(3) The insurance commissioner.

(d) The director of health shall invite representatives from the following to also serve as members of the working group:

(1) The medical profession;

(2) Medical patients;

(3) The Hawaii Pharmacists Association;

(4) The health insurance industry; and

(5) Other representatives the members of the working group determine will contribute to completing its work.

(e) Members of the working group shall serve without compensation, but shall be reimbursed for necessary expenses incurred during the performance of their duties.

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(f) The working group shall report its findings and recommendations, including proposed legislation, if any, to the legislature no later than twenty days prior to the convening of the regular session of 2016.

(g) The working group shall cease to exist upon the adjournment sine die of the regular session of 2016.

SECTION 3. This Act shall take effect on July 1, 2015.

INTRODUCED BY: Cindy Evans

JAN 2 2 2015

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Report Title:
Health; Medicines; Biosimilars Working Group

Description:
Establishes a biosimilars working group to consider issues relating to the state regulation of biosimilar medicines and to make recommendations to the legislature.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.