CONFERENCE COMMITTEE REP. NO. 68 -16

Honolulu, Hawaii
April 28, 2016

RE: H.B. No. 254
H.D. 2
S.D. 1
C.D. 1

Honorable Joseph M. Souki
Speaker, House of Representatives
Twenty-Eighth State Legislature
Regular Session of 2016
State of Hawaii

Honorable Ronald D. Kouchi
President of the Senate
Twenty-Eighth State Legislature
Regular Session of 2016
State of Hawaii

Sirs:

Your Committee on Conference on the disagreeing vote of the House of Representatives to the amendments proposed by the Senate in H.B. No. 254, H.D. 2, S.D. 1, entitled:

"A BILL FOR AN ACT RELATING TO MEDICINES,"

having met, and after full and free discussion, has agreed to recommend and does recommend to the respective Houses the final passage of this bill in an amended form.

The purpose of this measure is to ensure patient safety and access to medicines at lower prices by allowing for and regulating interchangeable biological products, or biological products that are biosimilar to and interchangeable with the biological product identified in a prescription and to which there are no clinically significant differences in terms of safety or effectiveness.

This measure also:

(1) Requires a pharmacist or authorized agent to offer to the consumer, an equivalent generic drug product or interchangeable biological product from the Hawaii list of

equivalent generic drug products and interchangeable biological products (Hawaii list), and inform the consumer of the differences between the brand name drug and equivalent generic drug product or interchangeable biological product, when the pharmacist fills a prescription for a brand name drug;

(2) Requires a pharmacist to substitute an interchangeable biological product when consented to by the practitioner and consumer or when the substitute results in savings;

(3) Specifies the conditions in which a pharmacist is prohibited from substituting an interchangeable biological product;

(4) Requires that within 24 hours of dispensing a biological product, the dispensing pharmacist or designee must communicate to the provider, the specific product provided to the patient;

(5) Authorizes the Director of Health, rather than the Drug Production Selection Board (Board), to adopt rules for drug production selection;

(6) Specifies that the Hawaii list serves as the state list of approved therapeutically equivalent generic drug products; and

(7) Repeals the Board and transfers the Board's duties of creating the list of substitutable generic drug products and biological products to the Department of Health.

Upon consideration, your Committee on Conference has amended this measure by:

(1) Amending the definitions of "equivalent generic drug product", "Hawaii list of equivalent generic drug products and interchangeable biological products", and "interchangeable biological product";

(2) Deleting the requirement that pharmacists or authorized agents inform consumers of the differences between the brand name drug and equivalent generic drug product or interchangeable biological product when filling a prescription order for a brand name drug;

(3) Amending the conditions in which a pharmacist can substitute an equivalent generic drug product or an interchangeable biological product;

(4) Requiring that within two business days, rather than within 24 hours, following the dispensing of a biological product, a dispensing pharmacist or designee must communicate to the practitioner, the specific product provided to the patient;

(5) Making the adoption of rules by the Director of Health subject to the Administrative Procedure Law;

(6) Changing the specifications and means by which pharmacies shall be notified of the Hawaii list;

(7) Deleting the provision prohibiting the Director of Health from approving as substitutable, any biological products that the United States Food and Drug Administration has neither licensed nor determined as meeting standards for interchangeability;

(8) Deleting requirements relating to the distribution, publishing, notice, and establishment of fees to persons who request copies of the Hawaii list by the Department of Health with respect to distribution of the Hawaii list;

(9) Changing its effective date to July 1, 2016; and

(10) Making technical, nonsubstantive amendments for clarity, consistency, and style.

As affirmed by the record of votes of the managers of your Committee on Conference that is attached to this report, your Committee on Conference is in accord with the intent and purpose of H.B. No. 254, H.D. 2, S.D. 1, as amended herein, and recommends that it pass Final Reading in the form attached hereto as H.B. No. 254, H.D. 2, S.D. 1, C.D. 1.

Respectfully submitted on behalf of the managers:

ON THE PART OF THE SENATE

ROSALYN H. BAKER, Chair

ON THE PART OF THE HOUSE

DELLA AU BELATTI, Co-Chair

ANGUS L.K. MCKELVEY, Co-Chair

Hawaii State Legislature

Record of Votes of a Conference Committee

CCR 68-16

Bill / Concurrent Resolution No.: **HB 254, HD 2, SD 1**	Date/Time: 4/28/16 10:30 am

☒ The recommendation of the House and Senate managers is to pass with amendments (CD).

☐ The Committee is reconsidering its previous decision.

☐ The recommendation of the Senate Manager(s) is to AGREE to the House amendments made to the Senate Measure

☐ The recommendation of the House Manager(s) is to AGREE to the Senate amendments made to the House Measure.

Senate Managers	A	WR	N	E
BAKER, Rosalyn H., Chr.	✓			
ESPERO, Will				✓
KIDANI, Michelle N.	✓			

House Managers	A	WR	N	E
BELATTI, Della Au, Co-Chr.	✓			
MCKELVEY, Angus L.K., Co-Chr.	✓			
CREAGAN, Richard P.	✓			
TUPOLA, Andria P.L.	✓			

TOTAL	2	–	–	1

TOTAL	4	–	–	–

A = Aye **WR** = Aye with Reservations **N** = Nay **E** = Excused

Senate Recommendation is: ☒ Adopted ☐ Not Adopted

House Recommendation is: ☒ Adopted ☐ Not Adopted

Senate Lead Chair's or Designee's Signature: Rosalyn H Baker

House Lead Chair's or Designee's Signature: Della A Belatti

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