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Testimony of the Department of Commerce and Consumer Affairs

Before the
Senate Committee on Judiciary
Tuesday, February 25, 2020
12:30 p.m.
State Capitol, Conference Room 016

On the following measure:
S.B. 2276, S.D. 1, RELATING TO PRESCRIPTION DRUGS

WRITTEN TESTIMONY ONLY

Chair Rhoads and Members of the Committee:

My name is Colin Hayashida, and I am the Insurance Commissioner of the Department of Commerce and Consumer Affairs' (Department) Insurance Division. The Department offers comments on this bill.

The purposes of this bill are to: (1) require drug manufacturers to notify prescription drug benefit plans and pharmacy benefit managers if a proposed increase in the wholesale price of certain drugs would result in an unspecified per cent or more price increase over a two-year period; (2) require the drug manufacturer to identify and report to the Insurance Commissioner information on certain drugs whose wholesale acquisition cost increases by a certain amount during a specified time frame; (3) require the Insurance Commissioner to post price information on the Department's website and (4) impose fines.

The bill's amendments to Hawaii Revised Statutes chapter 431R would be difficult to enforce, as the Insurance Division has no regulatory oversight over drug manufacturers and lacks the requisite expertise to regulate wholesale prescription drugs. In addition, the Insurance Division would need sufficient funds and time to retain an outside expert consultant on prescription drug wholesale pricing to assist with implementation and enforcement of this bill.

Thank you for the opportunity to testify on this bill.

OFFICE OF INFORMATION PRACTICES

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To: Senate Committee on Judiciary

From: Cheryl Kakazu Park, Director

Date: February 25, 2020, 12:30 p.m.
State Capitol, Conference Room 016

Re: Testimony on S.B. No. 2276, S.D. 1
Relating to Prescription Drugs

Thank you for the opportunity to submit testimony on this bill, which among other things would require drug manufacturers to identify and report to the insurance commissioner information on drugs whose wholesale acquisition cost increases by a certain amount during a specified time frame. The Office of Information Practices (OIP) takes no position on the substance of this bill, but seeks clarification of provisions requiring both public release and confidentiality for information reported by prescription drug manufacturers and provides a possible amendment.

Proposed subsection 431R-__(f), HRS, at bill page 5, provides that information reported to the Insurance Commissioner under subsection (e) is "exempt from public inspection and copying" under chapter 92F, HRS, the Uniform Information Practices Act (Modified) (UIPA). However, the information required to be reported to the Insurance Commissioner under proposed subsection 431R-__(e) specifically includes as item (2) a written description "suitable for public release" of factors contributing to a drug's cost increase. In other words, under this proposal a

written description specifically intended for public release would be exempt from public disclosure under the UIPA. Further, in addition the complete exemption from public disclosure already set out for information reported under subsection (e), Subsection (f) goes on to also prohibit release of that information "in a manner that would allow for the identification" of a drug or related information or "in a manner that is likely to compromise the financial competitive, or proprietary nature of the information[.]"

It is possible that these seemingly contradictory provisions were intended to mean that an individual member of the public cannot obtain any information reported under subsection (e) through a UIPA request but the Insurance Commissioner can nonetheless choose to disclose some portion of the information so long as the disclosure does not allow identification of a drug or reveal confidential business information. However, it is far from clear whether that or any other interpretation reflects the intent behind the confidentiality and disclosure provisions in this measure.

Given the measure's apparent intent that at some reported information be made public, specifically the written description "suitable for public release" that is required to be included in a drug manufacturer's report, OIP recommends that subsection (f) be amended to remove the complete exemption from disclosure under the UIPA and instead (1) specify that the written description "suitable for public release" is public and (2) affirmatively provide confidentiality for the remaining information to the extent that it would identify an individual drug or related information, or would cause competitive harm. **Specifically, OIP recommends replacing subsection (f) on bill page 5 with the following language:**

> (f) Information provided to the insurance commissioner is limited to the information listed in subsection (e). The written

narrative description suitable for public release required by subsection (e)(2) shall be made public upon request as provided in chapter 92F. Other information reported by a drug manufacturer under subsection (e) shall be confidential, shall be exempt from disclosure under chapter 92F, and shall not be subject to discovery; provided that the insurance commissioner may publicly release aggregated or deidentified information that does not allow identification of an individual drug, therapeutic class of drugs, or manufacturer and would not cause competitive harm to the drug manufacturer who submitted it.

Thank you for considering OIP's proposed amendment.

DAVID Y. IGE
GOVERNOR

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TESTIMONY BY DEREK MIZUNO
ADMINISTRATOR, HAWAII EMPLOYER-UNION HEALTH BENEFITS TRUST FUND
DEPARTMENT OF BUDGET AND FINANCE
STATE OF HAWAII
TO THE SENATE COMMITTEE ON JUDICIARY
ON SENATE BILL NO. 2276 S.D. 1

February 25, 2020
12:30 p.m.
Room 016

RELATING TO PRESCRIPTION DRUGS

Chair Rhoads, Vice Chair Keohokalole, and Members of the Committee:

The Hawaii Employer-Union Health Benefits Trust Fund (EUTF) Board of Trustees has not taken a position on this bill. EUTF staff would like to provide comments.

We appreciate the intent to provide transparency in pricing of prescription drugs by pharmaceutical manufacturers and possibly limit future price increases. Because of the complexity of the prescription drug industry it is very difficult to draft a bill that fulfills this intent. EUTF staff noted that the bill does not address the impact of rebates on pricing. A manufacturer could maintain the same wholesale acquisition cost (WAC) but reduce rebates over time resulting in higher net costs to health plans. For example, in year 1, the WAC for a 30-day supply is $100 with a $30 rebate to the plan. On Day 91, the WAC could still be $100 but with a lower rebate of $10. This equates to a 28.6%

increase in 90-days to the net cost to the health plan despite the WAC remaining the same.

Thank you for the opportunity to testify.

February 24, 2020

LATE

TO: Chair Karl Rhoads
Vice Chair Jarrett Keohokalole
Members of the Senate Committee on Judiciary

FROM: Pharmaceutical Research and Manufacturers of America (PhRMA)
(William Goo)

RE: **SB 2276 SD1** - Relating to Prescription Drugs
SB 2276, Proposed SD2 - Relating to Prescription Drugs
Date: February 25, 2020
Time: 12:30 pm

PhRMA **opposes SB 2276 SD1**.

This bill requires the manufacturer of a prescription drug which has a wholesale acquisition cost (WAC) of more than $50 for a course of therapy to notify each drug plan and pharmacy benefit manager of any increase of an undetermined percentage in the WAC over any 2-year period and the reason for the increase at least 60 days before it's effective date.

The mandatory advance notification of the WAC of a prescription drug is not information that will be very meaningful to patients who are primarily concerned about the affordability and accessibility of medications to them. Patients want to know about what a prescription drug will cost them regardless of what the WAC is. If anything, other factors such as rebates and discounts have a more direct impact on drug pricing.

Advance notification of an increase in pricing will also result in the unnecessary disclosure of proprietary information at the expense of drug manufacturers that would potentially be advantageous to drug plans or pharmacy benefit managers who may make bulk purchases prior to any price increase taking place and sell them at a higher price later. The constitutionality of mandatory advance price notification is also questionable and the subject of litigation in California and Oregon. A California state court has also ruled that the California Correctional Health Care Services (CCHCS) could not release such information provided by a drug manufacturer and that the CCHCS could be liable for attorneys' fees as well.

Further, there will be startup and maintenance costs associated with implementing the advance notification requirement which again would not be of meaningful benefit to

patients and hence, unnecessary and unneeded. Although not identical in content, the California law (SB 17) upon which this legislation is based is estimated to cost $1.4 million in the first two years and $850,000 annually thereafter. Included would be the costs to enforce the manufacturer reporting requirements as well as to collect, coordinate and publish information to the entity collecting the information. Moreover, since California law requires that notice be given to entities that purchase drugs through national contracts, the advance notification would mean that the WAC is likely to be accessible to parties outside California which would make the current bill an unnecessary duplication of efforts.

Instead, PhRMA proposes that the Proposed SD2 attached hereto be used in place of the current language which creates more meaningful transparency in drug pricing.

The Proposed SD2 incorporates most of the language already set forth in sections (d) and (e) of the original bill and provides for a manufacturer of a prescription drug to identify drugs in which the WAC increased by a total of fifty percent or more during the prior two years or by twenty percent or more during the prior year. For each prescription drug identified, the drug manufacturer would report increases in the WAC for the previous five years, and information including but not limited to the factors contributing to the price increases and the amount of expenditures for research and development of the drug. This information would be available to the patient wanting to know of why and how the price of a drug was arrived and is currently at without the disclosure of proprietary information. The assessment of fines set forth in the penalty provision should also be reasonable in amount.

Thank you for considering this testimony.

THE SENATE
THIRTIETH LEGISLATURE, 2020
STATE OF HAWAII

S.B. NO. 2276 S.D.2 PROPOSED

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that one of the greatest threats to the affordability of health care coverage is the pharmaceutical industry's pricing of new and existing medications. New drugs are being approved and marketed at higher prices than their predecessor treatments, often with no difference in effectiveness of safety. Because hospitals and health plans are already reporting pricing information, it is appropriate for pharmaceutical manufacturers to do the same when implementing major price increases.

The purpose of this Act is to:

[~~(1) Require drug manufacturers to notify prescription drug benefit plans and pharmacy benefit managers if a proposed increase in the wholesale price of certain drugs would result in a per cent or more price increase over a two-year period; and~~]

[~~(2)~~](1) Require drug manufacturers to identify and report to the insurance commissioner information on certain

drugs whose wholesale acquisition cost increases by a certain amount during a specified time frame; and

[~~(3)~~](2) Require the insurance commissioner to make certain information available on the insurance division's website.

SECTION 2. Chapter 431R, Hawaii Revised Statutes, is amended [~~by adding a new section to be appropriately designated and to read~~]as follows:

"§431R- Mandatory notification of prescription drug price increases. [~~(a) A manufacturer of a prescription drug with a wholesale acquisition cost of more than $50 for a course of therapy shall notify the insurance commissioner, each prescription drug benefit plan, and pharmacy benefit manager of any planned price increase if that increase will result in a per cent or more increase in the wholesale acquisition cost of the prescription drug over any two-year period.~~

~~(b) The notice required by subsection (a) shall:~~

~~(1) Be provided in writing at least sixty days prior to the planned effective date of the price increase; and~~

~~(2) Include:~~

~~(A) The date the price increase shall take effect;~~

~~(B) The current wholesale acquisition cost of the prescription drug;~~

~~(C) The dollar amount of the future price increase in the wholesale acquisition cost of the prescription drug; and~~

~~(D) A statement regarding whether a change or improvement in the drug necessitates the price increase, and if so, a description of the change or improvement.~~

~~(c) The insurance commissioner shall post on the website of the department of commerce and consumer affairs the names and addresses of the prescription drug benefit plans and pharmacy benefit managers required to receive notice pursuant to this section, in addition to the price information received pursuant to subsections (a) and (b).~~]

[~~(d)~~](a) A manufacturer of a prescription drug shall identify annually ~~up to ten prescription~~ drugs ~~on which the State spends significant health care moneys and~~ for which the wholesale acquisition cost increased by a total of fifty per cent or more during the prior two calendar years or by twenty per cent or more during the prior calendar year. The drugs

identified shall represent different drug classes and shall include generic drugs.

[~~(e)~~](b) For each prescription drug identified pursuant to subsection [~~(d)~~](a), the insurance commissioner shall require the drug manufacturer to report the following information:

(1) A schedule of the drug's wholesale acquisition cost increases over the previous five calendar years;

(2) A written narrative description, suitable for public release, of the factors that have contributed to the drug's recent cost increase;

(3) The date and price of acquisition of the identified drug if it was not developed by the manufacturer, and the drug's wholesale acquisition cost at the time of acquisition, if known;

(4) The manufacturer's aggregate, company-level research and development and other relevant capital expenditures, such as facility construction, for the most recent year for which final audited data are available;

(5) The sales volume of the drug;

(6) The five-year history of revenue and costs associated with the drug;

(7) Any patient assistance programs associated with the drugs, including the benefits of the program and the number of people who have applied and are participating or were refused from participating;

(8) Any price concessions that are offered to other parties; and

(9) Marketing costs associated with the drug.

[~~(f)~~](c) Information provided to the insurance commissioner is limited to the information pursuant to subsection ~~(e)~~(b), and is exempt from public inspection and copying under the Uniform Information Practices Act described in chapter 92F, and shall not be released in a manner that would allow for the identification of an individual drug, therapeutic class of drugs, or manufacturer, or in a manner that is likely to compromise the financial, competitive, or proprietary nature of the information, including privileged and confidential information under 21 C.F.R. section 20.61."

(d) Information provided by a manufacturer under this section shall be generally consistent with the level and type of data made available in a manufacturer's 10-k filing or to other publicly available data sources. The insurance commissioner shall consult with representatives of manufacturers to establish

a single, standard format for reporting information under this section that minimizes administrative burden for the State and manufacturers.

SECTION 3. Section 431R-1, Hawaii Revised Statutes, is amended by adding a new definition to be appropriately inserted and to read as follows:

""Course of therapy" means:

(1) The recommended daily dosage units of a prescription drug for thirty days, pursuant to its prescribing label as approved by the federal Food and Drug Administration; or

(2) The recommended daily dosage units of a prescription drug pursuant to its prescribing label for a normal course of treatment that is less than thirty days, as approved by the federal Food and Drug Administration."

SECTION 4. Section 431R-4, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) No later than March 31 of each calendar year, each prescription drug benefit plan, health benefits plan under chapter 87A, and pharmacy benefit manager shall file with the insurance commissioner, in [~~such~~] a form and detail as the insurance commissioner shall prescribe, a report for the

preceding calendar year stating that the pharmacy benefit manager or prescription drug benefit plan is in compliance with this chapter. The report shall fully disclose the amount, terms, and conditions relating to copayments, reimbursement options, and other payments associated with a prescription drug benefit plan. Each report shall disclose an address that shall be posted on a public website[~~for purposes of receiving notifications pursuant to section 431R- ~~]."

SECTION 5. Section 431R-5, Hawaii Revised Statutes, is amended to read as follows:

""431R-5 Violations; penalties. (a) The insurance commissioner may assess a fine of up to $10,000 for each violation by a pharmacy benefit manager or prescription drug benefit plan provider who is in violation of section 431R-2 or 431R-3. In addition, the insurance commissioner may order the pharmacy benefit manager to take specific affirmative corrective action or make restitution.

(b) Failure of a pharmacy benefit manager to comply with a previously agreed upon contractual retail pharmacy network agreement pursuant to section 431R-2 or 431R-3 shall be an unfair or deceptive act or practice as provided in section 431:13-102.

(c) The insurance commissioner may assess a fine of not less than $ nor more than $ for each violation by a manufacturer of a prescription drug or prescription drug benefit plan provider who is in violation of section 431R- .

[~~(c)~~] (d) A pharmacy benefit manager [~~or~~], prescription drug benefit plan provider, or manufacturer of a prescription drug may appeal any decision made by the insurance commissioner in accordance with chapter 91.

[~~(d)~~] (e) Every person and its officers, employees, and representatives subject to investigation or examination by the commissioner under this chapter shall produce and make freely accessible to the commissioner the accounts, records, documents, and files in the person's possession or control relating to the subject of the investigation or examination and shall otherwise facilitate the investigation or examination.

[~~(e)~~] (f) Every person and its officers, employees, and representatives subject to investigation or examination by the commissioner under this chapter shall issue a written response no later than fifteen working days after receiving a written inquiry from the commissioner regarding a claim or complaint. The response shall be more than an acknowledgment that the

commissioner’s communication has been received and shall adequately address the concerns stated in the communication."

SECTION 6. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 7. This Act shall take effect on July 1, 2050.

AARP Real Possibilities in Hawaii

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THE SENATE
Committee on Judiciary
Tuesday, February 25, 2020
12:30 p.m.
Conference Room 016

To: Senator Karl Rhoads, Chair

Re: SB 2276 SD1 Relating to Prescription Drugs

Dear Chair Karl Rhoads, Vice-Chair Keohokalole, and Members of the Committee,

My name is Keali'i Lopez and I am the State Director for AARP Hawai'i. AARP is a membership organization of people age fifty and over, with nearly 145,000 members in Hawai'i. AARP advocates for issues that matter to Hawai'i families, including the high cost of long-term care; access to affordable, quality health care for all generations; and serving as a reliable information source on issues critical to people over the age of fifty.

SB 2276 SD1 requires drug manufacturers to notify prescription drug benefit plans and pharmacy benefit managers if a proposed increase in the wholesale price of certain drugs would result in a significant percentage or more price increase over a two-year period. Also, it requires them to report to the insurance commissioner information on certain drugs whose wholesale acquisition cost increases.

AARP Hawaii supports SB 2276 SD1. AARP believes that increased disclosure around pricing practices will result in more meaningful and actionable information for the state and accountability for manufacturers.

- Drug pricing transparency helps payers determine whether a drug price or price increase is justified. The increased transparency would provide the rationale for how drugs are priced.
- Moreover, the scrutiny could encourage drug manufacturers to reconsider their standard practice of setting high launch prices and then increasing them year after year.

AARP fully supports polices that will help reduce prescription drug prices and make them more affordable for consumers, especially older Americans who depend on life-saving and life-improving medications.

Thank you for the opportunity to testify and support SB 2276 SD1.

An Independent Licensee of the Blue Cross and Blue Shield Association

February 24, 2020

The Honorable Karl Rhoads, Chair
The Honorable Jarrett Keohokalole, Vice Chair
Senate Committee on Judiciary

Re: SB 2276 SD1 – Relating to Prescription Drugs

Dear Chair Rhoads, Vice Chair Keohokalole, and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on SB 2276, SD1, which requires drug manufacturers to notify the insurance commissioner, prescription drug benefit plans, and pharmacy benefit managers if a proposed increase in the wholesale price of certain drugs would result in a blank per cent or more price increase over a two-year period. Requires the drug manufacturer to identify and report to the insurance commissioner information on certain drugs whose wholesale acquisition cost increases by a certain amount during a specified time frame. Requires the insurance commissioner to post price information on the Department of Commerce and Consumer Affair's website. Imposes fines. Effective 1/1/2050.

HMSA supports requiring prescription drug manufacturers to notify prescription drug benefit plans and pharmacy benefit managers of any planned price increases. We believe this measure may assist in our attempt to keep costs down for our members and is an important step towards reigning in the skyrocketing costs of prescription drugs.

Thank you for the opportunity to provide testimony on this measure.

Sincerely,

Pono Chong
Vice President, Government Relations

Hawaii Association of Health Plans

February 24, 2020

The Honorable Karl Rhoads, Chair
The Honorable Jarrett Keohokalole, Vice Chair
Senate Committee on Judiciary

Senate Bill 2276 SD1 – Relating to Prescription Drugs

Dear Chair Rhoads, Vice Chair Keohokalole, and Members of the Committee:

The Hawaii Association of Health Plans (HAHP) appreciates the opportunity to testify in support of SB 2276, SD1.

We agree that pharmaceutical drug prices are a threat to the affordability of health care coverage in Hawaii and we believe drug manufacturers should report price increases. This measure is an important step to helping to reign in the high cost of pharmaceutical drugs.

Thank you for allowing us to testify in support of SB 2276, SD1.

Sincerely,

HAHP Public Policy Committee

cc: HAHP Board Members