THE SENATE
THIRTIETH LEGISLATURE, 2020
STATE OF HAWAII

JAN 17 2020

S.B. NO. 2276

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 or 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 sixteen per cent or more price increase over a two-year period; and

(2) 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.

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 each prescription drug benefit plan and pharmacy benefit manager of any planned price increase if that increase will result in a sixteen 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.

(d) 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) For each prescription drug identified pursuant to subsection (d), 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) Information provided to the insurance commissioner is limited to the information pursuant to subsection (e), 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."

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, 2020.

INTRODUCED BY: _____

S.B. NO. 2276

Report Title:
Department of Commerce and Consumer Affairs; Prescription Drugs; Price Increases; Notification; Insurance Commissioner; Fines

Description:
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 sixteen 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. Imposes fines.

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