HB
267
HD1

HOUSE OF REPRESENTATIVES
THIRTIETH LEGISLATURE, 2019
STATE OF HAWAII

H.B. NO. 267 H.D. 1

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

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

SECTION 1. 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 $40 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."

SECTION 2. 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 3. 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 will be posted on a public website for purposes of receiving notifications pursuant to section 431R- ."

SECTION 4. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 5. This Act shall take effect on July 1, 2050.

H.B. NO. 267 H.D. 1

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

Description:
Requires that if a proposed increase in the wholesale price of certain drugs would result in a 16% or more price increase over a 2-year period, the drug manufacturer shall notify various drug insurance providers. (HB267 HD1)

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

DAVID Y. IGE
GOVERNOR

JOSH GREEN
LT. GOVERNOR

STATE OF HAWAII
OFFICE OF THE DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
335 MERCHANT STREET, ROOM 310
P.O. BOX 541
HONOLULU, HAWAII 96809
Phone Number: 586-2850
Fax Number: 586-2856
cca.hawaii.gov

CATHERINE P. AWAKUNI COLÓN
DIRECTOR

JO ANN M. UCHIDA TAKEUCHI
DEPUTY DIRECTOR

Testimony of the Department of Commerce and Consumer Affairs

Before the
House Committee on Consumer Protection and Commerce
Wednesday, February 20, 2019
2:00 p.m.
State Capitol, Conference Room 329

On the following measure:
H.B. 267, H.D. 1, RELATING TO PRESCRIPTION DRUGS

Chair Takumi 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.

This bill requires that if a proposed increase in the wholesale price of certain drugs would result in a 16% or more price increase over a two-year period, the drug manufacturer shall provide notice to various drug insurance providers. The Department is concerned the Insurance Division will be unable to enforce the measure's proposed amendments to Hawaii Revised Statutes chapter 431R, as the Insurance Division does not have regulatory oversight over drug manufacturers.

Thank you for the opportunity to testify on this measure.

An Independent Licensee of the Blue Cross and Blue Shield Association

February 18, 2019

The Honorable Roy M. Takumi, Chair
The Honorable Linda Ichiyama, Vice Chair
House Committee on Consumer Protection & Commerce

Re: HB 267 HD1 – Relating to Prescription Drugs

Dear Chair Takumi, Vice Chair Ichiyama, and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on HB 267, HD1, which requires that if a proposed increase in the wholesale price of certain drugs would result in a 16% or more price increase over a 2-year period, the drug manufacturer shall notify various drug insurance providers.

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 will 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,

Jennifer Diesman
Senior Vice President, Government Relations

February 19, 2019

TO: Chair Roy M. Takumi
Vice Chair Linda Ichiyama
Members of the House Committee on Consumer Protection & Commerce

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

RE: **HB 267, HD1** - Relating to Prescription Drugs
Hearing Date: February 20, 2019
Time: 2:00 pm

PhRMA opposes the passage of **HB 267, HD1**. Attached is PhRMA's testimony in opposition.

Thank you for considering this testimony.

STATEMENT

PhRMA
RESEARCH • PROGRESS • HOPE

In Opposition to House Bill 267, HD1

February 19, 2019

Position: The Pharmaceutical Research and Manufacturers of America (PhRMA) strongly opposes HB 267, HD1, which would require prescription drug manufacturers to notify state purchasers and private payers about certain price increases and the price of new drugs. The bill would not help patients better afford their medicine and would create increased administrative and financial burdens on the state.

Discussions about the cost and affordability of medicines are important. No patient should have to worry about whether they can afford the health care they need. However, the notion that spending on medicines is the primary driver of health care cost growth is false - and ignores cost savings that medicines provide to the health care system overall. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs. New medicines are making crucial contributions to medical advances and changing the direction of healthcare as we know it.

The information disclosed by this legislation would not help patients and ignores all other players in the prescription drug supply chain.

There are a variety of stakeholders involved in determining what consumers ultimately pay for a medicine, including insurers, pharmacy benefit managers (PBMs), wholesalers, and government agencies like Medicaid. For example, pharmacy benefit managers and payers which dictate the terms of coverage for medicines use their control over which medicines patients can access as leverage to negotiate substantial rebates and discounts. The role these entities play and the impact they have on patient cost and access is not acknowledged in this legislation. By not addressing these entities, this bill does not help patients with improved access or change practices that impact patient out-of-pocket costs.

Contrary to common belief, the growth rate of prescription drug costs has slowed in recent years: Net spending, or costs after accounting for discounts and rebates, on medicines grew by 0.6% in 2017, according to the IQVIA Institute. Express Scripts, a major PBM, announced drug spending increased only 1.5% in 2017, down from 3.8% in 2016, CVS Health reported growth in drug spending was only 1.9% in 2017, down from 3.2% in 2016, Prime Therapeutics reported negative growth in drug spending, at -0.2% in 2017, down from 2.5% in 2016, and CMS reported that retail prescription drug spending growth was only 0.4% in 2017, down from 2.3% in 2016. Prescription drug spending is at a historic low. And prescription drug costs are expected to remain a relatively small and stable share of total health care costs into the future. This, of course, does not necessarily reconcile with what patients are feeling at the pharmacy counter, which is why looking at the whole system is so important.

Advance notice of price increases raises constitutionality concerns, and could be harmful to consumers and interfere with market competition

HB 267, HD1 mandates 60-day advance price notification of wholesale acquisition cost (WAC) for branded and generic drugs. The constitutionality of advance notification requirements is questionable and is currently the subject of litigation in California.

Advance price notification creates a new incentive for some distributors — especially those that do not enter into contractual agreements with manufacturers — to profit from purchasing medicine at the "old" price and selling them at the "new" price once the increase is made public. Such speculative purchasing could, in turn, lead to downstream effects such as product stockpiling and medicine shortages, while not reducing costs to patients in Hawaii.

Gray Market Incentives

Advance notification of WAC price increases creates financial incentives for secondary distributors to enter the pharmaceutical supply chain, thus creating a "gray" market. As the medicines are sold from one secondary distributor to another, the possibility of counterfeit medicines augmenting the supply of legitimate medicines increases, thereby threatening patient safety.

This type of purchasing has caused great difficulty for hospitals. During medicine shortages, hospitals are sometimes unable to buy medicines from their normal trading partners, usually one of the three large national "primary" distributors, AmerisourceBergen, Cardinal Health, or McKesson. At the same time, hospitals are deluged by sales solicitations from gray market companies offering to sell the shortage medicines for prices that are often hundreds of times higher than the prices they normally pay.

The Hawaii advanced notice bill would create an increased administrative burden for the state.

The cost of SB 17, the advanced notice legislation passed in California, is estimated to be $1.4 million dollars in the first two years, and $850,000 annually thereafter. The costs are for California to enforce the manufacturer reporting requirements, and costs to collect, coordinate and publish information to the Office of Statewide Health Planning and Development (OSHPD), the entity collecting information in that state. Also, it is important to note that the California law requires that notice be given to entities that purchase drugs through national contracts, so information in the advance notification is likely to spread outside the state of California. Hawaii would be required to duplicate efforts already mandated in California, which has a fiscal note of approximately $1.4 million dollars. This is an unnecessary duplication for residents in Hawaii.

PhRMA recognizes the access challenges faced by patients in Hawaii with serious diseases. We stand ready to work with the Hawaii legislature to develop solutions that help patients. We believe this bill would not help patients' access to breakthrough innovations or better afford their medicines and accordingly strongly oppose the passage of House Bill 267, HD1.

Association for Accessible Medicines

Your Generics & Biosimilars Industry

Letter in Opposition of House Bill 267
House Committee on Consumer Protection & Commerce - February 20, 2019

Chairman Takumi, Vice-Chairwoman Ichiyama, and members of the House Committee on Consumer Protection & Commerce,

AAM is the nation's leading trade association for manufacturers and distributors of generic and biosimilar prescription medicines. Our core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. Our members provide more than 36,000 jobs at nearly 150 facilities and manufacture more than 61 billion doses of prescription medicines in the U.S. every year. AAM supports policies that help reduce overall prescription drug costs while ensuring access to affordable medications. AAM opposes Hawaii HB 267 because we do not believe it would not accomplish this goal and could, instead, cause harm to patients in Hawaii by reducing access to needed medication.

HB 267 is modeled on SB 17, a 2017 California bill that required manufacturer reporting as well as reporting by other supply chain entities, including insurers and pharmacy benefit managers (PBMs). California's 2018 report (attached) was issued by the California Department of Managed HealthCare and is based on reporting required under SB 17. The report found that generics accounted for nearly 90% of all prescribed drugs but represented only 23.6% of the state's total pharmaceutical spend. It further found that the 25 generics drugs with the highest year-over-year increase accounted for only 4.7% of the total annual spend on prescription drugs.

Generic and biosimilar medicines drive cost savings. In 2017, generics and biosimilars saved Hawaii $815 million while saving the U.S. health care system $265 billion, about $5 billion every week. Over the past decade, generic medicines have saved U.S. healthcare system $1.79 trillion. And, patients thrive with access to generic medicines, both in terms of health outcomes and financial savings. Insured patients benefit from an average copay for generics of only $6.06, while paying more than $40 for brand drugs. In fact, 93% of generic prescriptions are filled for $20 or less out-of-pocket, as compared to just 39% for brand drugs. Thus, the solution to lowering prescription drug prices is not by increasing regulatory and administrative burdens on generic manufacturers but in finding ways to ensure robust access to these more affordable medicines. Generic drugs play a critical role in achieving healthcare savings and enacting legislation that infringes on the generic drug market could have serious consequences in Hawaii.

By focusing on low percentage increases, this measure ignores the actual cost impact on the health care system. Minimal price changes on low-cost generic products can result in large percentage increases. Including a higher wholesale acquisition cost (WAC) floor and a more significant percentage increase could avoid disturbing the market for low-cost products subject to pricing variability. For example, as drafted HB 267 would require reporting on drugs with a WAC floor of $40 which means they cost $1.33 per day or as low as $0.44 for a medication taken three times per day. And, with the 16% increase over more than two years, the bill would capture price increases as low as $6.40 over more than two years. Low percentage-based thresholds tied to a low WAC will jeopardize patient access to lower-cost products by placing undue burdens on generic manufactures. The burden will not only be felt in the generic market but will also place unwarranted stress on the system put in place by this legislation to review these costs and could lead to wasted government resources analyzing data related to drugs that are helping to reduce the state spending in the healthcare system.

Brands and generic drugs function differently in the market and create different incentives for entities throughout the supply chain. Patent protections protect brand drugs from direct price competition.

Generics, on the other hand, compete within a multi-competitor model with drug prices decreasing as competitors enter the market. Generic drugs typically enter the market significantly lower than the brand reference product price. And, while brands maximize revenue through price rather than volume and negotiate discounts or rebates with other supply chain stakeholders, generic companies compete solely on price and the ability to supply. As a result, generic companies retain only 36% of their revenue, leaving others in the supply chain to capture 64% while brand companies retain 76% of their revenue.

The differences in the two markets also leads to different financial incentives for other stakeholders in the supply chain who each play a role in patient costs. Once a generic manufacturer sells its products to a wholesaler, the company no longer plays a role in the price of the products. Unlike brand manufacturers who sell to PBMs and negotiate formulary placement based on rebates, generic manufacturers sell to wholesalers – 3 of which control more than 90% of the market for generic drug purchasing.

The price patients pay for a generic drug is affected not only by wholesaler and pharmacy price markups, but also by insurance copay and formulary design choices made by insurance plans and PBMs. For instance, between 2011-2015, Part D health plans moved generics to higher cost sharing tiers. In 2011, 71% of generics were on tier 1, the lowest tier in the formulary. By 2015, only 19% of generics were on tier 1 causing patient out of pocket spending on these products to increase by $6.2 billion (93%) even though the price of the products increased by only 1% and the volume of sales for the products increased by only 22% In 2011, 71% of generics were on Part D formulary tiers. By 2015, only 19% of generics were on Part D formulary tiers. As a result, patient out of pocket spending on these products increased by $6.2 billion (93%) – even though the price of these products increased by only 1% and the volume of sales for the products increased by only 22%.

In 2017, the market share for generics increased to 90% of all prescriptions. At the same time, however, the net value of those generic sales fell by more than $5 billion. Conversely, the overall price of brand name drugs has risen 208% since 2008. The competitive generic market can prevent generic manufacturers from raising prices to reflect changing demand or increases in manufacturing costs for products. This results in a dynamic landscape in which manufacturers regularly enter and exit markets as conditions change. Hawaii should focus on high brand and specialty drug prices that contribute to significant state spending and directly impact patient out-of-pocket costs.

I would be happy to discuss AAM's concerns as HB 267 moves through the legislative process.

Sincerely,

Tara C. F. Ryan
Vice President, State Government Affairs