DAVID Y. IGE
GOVERNOR OF HAWAII

BRUCE S. ANDERSON, PHD
DIRECTOR OF HEALTH

STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. Box 3378
Honolulu, HI 96801-3378
doh.testimony@doh.hawaii.gov

Testimony COMMENTING on HB1609
RELATING TO PHARMACY BENEFIT MANAGERS.

REP. JOHN M. MIZUNO, CHAIR
HOUSE COMMITTEE ON HEALTH
Hearing Date: January 28, 2020 Room Number: 329

Fiscal Implications: N/A.

Department Testimony: The Department of Health (DOH) takes no position on HB1609.

However, to improve consistency and conformity, the department recommends repeal of amendments enacted by Act 175, Session Laws of Hawaii (SLH) 2015 (HB252 HD1 SD1 CD1 Relating to Pharmacy Benefit Managers) that may complicate or conflict with HB1609 as currently drafted.

Act 175 SLH 2015 established requirements for a pharmacy benefit manager (PBM) that reimburses a contracting pharmacy for a drug on a maximum allowable cost basis to have a clearly defined process for a contracting pharmacy to appeal the maximum allowable cost for a drug on a maximum allowable cost list.

The amendments of Act 175 SLH 2015 are inconsistent with the purpose of part VI, chapter 328 "Drug Prodcut Selection," which is to assure that less expensive generically equivalent prescription pharmaceuticals are offered to the consumer. DOH believes that the department has insufficient authority pursuant to part VI, chapter 328 to meaningfully enforce reimbursements on a maximum allowable cost basis between a PBM and a retail pharmacy. Furthermore, since complaints and remedies are based on a single transaction, i.e. one appeal for one drug for one patient for one particular fill on one particular day, it is practically unenforceable.

Thank you for the opportunity to testify.

Offered Amendments:

SECTION . Section 329-91, Hawaii Revised Statutes, is amended as follows:

By repealing the definition of "maximum allowable cost":

["~~"Maximum allowable cost" means the maximum amount that a pharmacy benefit manager shall reimburse a pharmacy for the cost of a drug.~~"]

By repealing the definition of "maximum allowable cost list":

["~~"Maximum allowable cost list" means a list of drugs for which a maximum allowable cost has been established by a pharmacy benefit manager.~~"]

By repealing the definition of "obsolete":

["~~"Obsolete" means a drug that may be listed in a national drug pricing compendia but cannot be dispensed based on the expiration date of the last lot manufactured.~~"]

SECTION . Section 328-106, Hawaii Revised Statutes, is repealed.

"[~~**[§328-106] Pharmacy benefit manager; maximum allowable cost.** (a) A pharmacy benefit manager that reimburses a contracting pharmacy for a drug on a maximum allowable cost basis shall comply with the requirements of this section.~~

~~(b) The pharmacy benefit manager shall include the following in the contract information with a contracting pharmacy:~~

~~(1) Information identifying any national drug pricing compendia; or~~

~~(2) Other data sources for the maximum allowable cost list.~~

~~(c) The pharmacy benefit manager shall make available to a contracting pharmacy, upon request, the most up-to-date maximum allowable cost price or prices used by the pharmacy benefit manager for patients served by the pharmacy in a readily accessible, secure, and usable web-based or other comparable format.~~

~~(d) A drug shall not be included on a maximum allowable cost list or reimbursed on a maximum allowable cost basis unless all of the following apply:~~

~~(1) The drug is listed as "A" or "B" rated in the most recent version of the Orange Book or has a rating of "NR", "NA", or similar rating by a nationally recognized reference;~~

~~(2) The drug is generally available for purchase in this State from a national or regional wholesaler; and~~

~~(3) The drug is not obsolete.~~

~~(e) The pharmacy benefit manager shall review and make necessary adjustments to the maximum allowable cost of each drug on a maximum allowable cost list at least once every seven days using the most recent data sources available, and shall apply the updated maximum allowable cost list beginning that same day to reimburse the contracted pharmacy until the pharmacy benefit manager next updates the maximum allowable cost list in accordance with this section.~~

~~(f) The pharmacy benefit manager shall have a clearly defined process for a contracting pharmacy to appeal the maximum allowable cost for a drug on a maximum allowable cost list that complies with all of the following:~~

~~(1) A contracting pharmacy may base its appeal on one or more of the following:~~

~~(A) The maximum allowable cost for a drug is below the cost at which the drug is available for purchase by similarly situated pharmacies in this State from a national or regional wholesaler; or~~

~~(B) The drug does not meet the requirements of subsection (d);~~

~~(2) A contracting pharmacy shall be provided no less than fourteen business days following receipt of payment for a claim to file the appeal with the pharmacy benefit manager;~~

~~(3) The pharmacy benefit manager shall make a final determination on the contracting pharmacy's appeal no later than fourteen business days after the pharmacy benefit manager's receipt of the appeal;~~

~~(4) If the maximum allowable cost is upheld on appeal, the pharmacy benefit manager shall provide to the contracting pharmacy the reason therefor and the national drug code of an equivalent drug that may be purchased by a similarly situated pharmacy at a price that is equal to or less than the maximum allowable cost of the drug that is the subject of the appeal; and~~

~~(5) If the maximum allowable cost is not upheld on appeal, the pharmacy benefit manager shall adjust, for the appealing contracting pharmacy, the maximum allowable cost of the drug that is the subject of the appeal, within one calendar day of the date of the decision on the appeal and allow the contracting pharmacy to reverse and rebill the appealed claim.~~

~~(g) A contracting pharmacy shall not disclose to any third party the maximum allowable cost list and any related~~

~~information it receives, either directly from a pharmacy benefit manager or through a pharmacy services administrative organization or similar entity with which the pharmacy has a contract to provide administrative services for that pharmacy.~~]"

TESTIMONY OF
THE DEPARTMENT OF THE ATTORNEY GENERAL
THIRTIETH LEGISLATURE, 2020

ON THE FOLLOWING MEASURE:
H.B. NO. 1609, RELATING TO PHARMACY BENEFIT MANAGERS.

BEFORE THE:
HOUSE COMMITTEE ON HEALTH

DATE: Tuesday, January 28, 2020 **TIME:** 8:35 a.m.

LOCATION: State Capitol, Room 329

TESTIFIER(S): Clare E. Connors, Attorney General, or
Daniel Jacob, Deputy Attorney General

Chair Mizuno and Members of the Committee:

The Department of the Attorney General makes the following comments about the bill.

The purposes of this bill are to: (1) establish business practice and transparency reporting requirements for pharmacy benefit managers; (2) replace the registration requirement for pharmacy benefit managers with a licensing requirement; and (3) increase penalties for violations of the pharmacy benefit managers law.

The portion of the bill that establishes business practices and transparency reporting requirements for pharmacy benefit managers may be subject to an Employee Retirement Income Security Act (ERISA) preemption challenge. ERISA is a comprehensive federal legislative scheme that "supersede[s] any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C.A. § 1144(a).[1] A state law relates to an ERISA plan and is preempted if it has a prohibited connection with or reference to an ERISA plan. A state law has an impermissible connection with ERISA plans when it governs a central matter of plan administration or

[1] 29 U.S.C.A. § 1144(a), in full, provides as follows:

> Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title. This section shall take effect on January 1, 1975.

interferes with nationally uniform plan administration. *Egelhoff v. Egelhoff*, 532 U.S. 141, 148, 121 S.Ct. 1322, 149 L.Ed.2d 264 (2001).

With respect to the regulation of pharmacy benefit managers, there is a split among the circuits as to the extent of regulation that may be permissible. The United States Court of Appeals, Ninth Circuit has not issued a decision regarding the regulation of pharmacy benefit managers.

In *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005), the United States Court of Appeals, First Circuit, held that Maine's Unfair Prescription Drug Practices Act was not preempted by ERISA. The Unfair Prescription Drug Practices Act imposed a number of requirements on pharmacy benefit managers that entered into contracts with covered entities. In the *Rowe* Court's analysis, although the regulation may prompt ERISA plans to re-evaluate their working relations with the pharmacy benefit managers, nothing in the Unfair Prescription Drug Practices Act compelled them to do so, and ERISA plans still had a free hand to structure the plans as they wish. 429 F.3d at 303.

In *Pharm. Care Mgmt. Ass'n v. D.C.*, 613 F.3d 179 (D.C. Cir. 2010), the United States Court of Appeals, District of Columbia, reviewed the District of Columbia's Access RX Act, which was similar to Maine's Unfair Prescription Drug Practices Act. The United States Courts of Appeal, D.C. Circuit reached an opposite conclusion, finding that D.C.'s Access RX Act was preempted due to an improper "connection to" an ERISA plan. Rejecting the holding in *Rowe*, that the regulation of pharmacy benefit managers left ERISA plans with a free hand to structure the plans as they wish, the *D.C.* Court found that the Access RX Act binds plan administrator because the economies of scale, purchasing leverage, and network of pharmacies could only be offered by a pharmacy benefit manager. 613 F.3d at 188.

In this case, similar to both Maine's Unfair Prescription Drug Practices Act and D.C.'s Access RX Act, the bill would compel pharmacy benefit managers to act as a fiduciary when providing services to a covered entity, disclose conflicts of interest to covered entities, and file "transparency reports" with the Insurance Commissioner.

Accordingly, there is a split in jurisdictions as to whether one or more of these mandates may implicate areas central to plan administration and therefore be preempted.

In addition, an impermissible "express reference" and an "implicit reference" to an ERISA plan within the bill may also be an issue. A state law has a prohibited "reference to" ERISA or ERISA plans where it acts immediately and exclusively upon ERISA plans. *Gobelle v. Liberty Mutual Insurance Company*, 136 S. Ct. 936, 943 194 L. Ed. 2d 20 (2016). An "express reference" to an ERISA plan can be found on page 9, line 13 in the use of the words "self-insured plan." In order to avoid the possibility of preemption due to an "express reference" to an ERISA plan, we suggest removing the words "a self-insured plan" from page 9, line 13. The removal should not substantively change the proposed bill.

In *Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722 (8th Cir. 2017), the United States Court of Appeals for the Eighth Circuit found that an Iowa law contained an "implicit reference" to ERISA through regulation of pharmacy benefit managers who administer benefits for "covered entities," which by definition included entities that are necessarily subject to ERISA regulations. Because the benefits affected by the Iowa law were provided by ERISA covered programs, the requirements imposed on the management and administration of these benefits were found to be preempted. The use of the term "covered entity" on page 3, line 16, and page 4, line 9, might be an implicit reference pursuant to the decision in *Gerhart*. We note, however, that the United States Supreme Court has granted certiorari in this case and, therefore, there is no final decision.

Finally, we note two technical concerns. First the current bill contains two different definitions of "pharmacy benefit manager." *See* page 6, lines 10 through 17, and page 9, line 7, through page 10, line 2. Unless there is a purpose behind the different definitions, we recommend that the committee select a single definition.

Second, we recommend removing the words "or under an employment relationship" from page 9, line 12, to avoid unintended consequences. As written, the

bill would define an employee of a self insured plan as a pharmacy benefit manager. We do not believe that is the intent of this bill.

If the Committee wants to address the preemption concern we will be happy to work with the Committee.

Thank you for the opportunity to comment.

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 Health
Tuesday, January 28, 2020
8:35 a.m.
State Capitol, Conference Room 329

On the following measure:
H.B. 1609, RELATING TO PHARMACY BENEFIT MANAGERS

Chair Mizuno 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 purpose of this bill is to establish business practice and transparency reporting requirements for pharmacy benefit managers, replace the registration requirement for pharmacy benefit managers with a licensing requirement, and increase penalties for violations of the pharmacy benefit managers law.

Section 2 of the bill purports to regulate the conduct of "covered entities" (page 3, line 16 to page 4, line 16); however, the applicable definition of "covered entities" in Hawaii Revised Statutes (HRS) section 431S-1 includes entities over which the Insurance Division does not exercise jurisdiction, such as employers and labor unions. In addition, the bill requires pharmacy benefit managers to comply with unknown and overly broad requirements of other federal or state entities (page 3, lines 11 to 15).

Compliance may not be enforceable, as these entities may not be under the jurisdiction of the Insurance Division.

In section 3, the proposed amendments to the definition of "pharmacy benefit manager" may result in a definition that is overly broad.

Implementation of section 5 of this bill will be difficult, as the Insurance Division currently lacks staff expertise to assess pharmacy benefit managers under the licensing standards set forth in that section. In addition, licensing fees and the renewal framework are inconsistent with requirements for licensing other entities under the Insurance Division's jurisdiction.

Section 5 also appears inconsistent with section 6, insofar as section 5 indicates that licenses "shall be valid for a period of three calendar years from the date of issuance or renewal" (page 10, lines 9 to 11), while section 6 amends HRS section 431S-4(a) to require an annual license renewal (page 12, lines 5 to 7).

Significantly, section 5 changes the registration of pharmacy benefit managers to a licensure requirement and provides only broad criteria for the Insurance Commissioner to consider in determining whether to grant a license (page 11, lines 13 to 20). However, this bill does not require applicants to provide proof that they possess the "necessary organization, background expertise, and financial integrity to supply the services sought to be offered."

Further, section 5 authorizes the issuance of a restricted or limited license (page 11, lines 13 to 16), but section 7 (page 13, lines 1 to 16) does not give the Insurance Commissioner those same remedies as disciplinary sanctions for HRS chapter 431S violations. Lastly, there is no option to impose fines for violations.

Thank you for the opportunity to testify on this bill.

OFFICE OF INFORMATION PRACTICES

STATE OF HAWAII
NO. 1 CAPITOL DISTRICT BUILDING
250 SOUTH HOTEL STREET, SUITE 107
HONOLULU, HAWAII 96813
TELEPHONE: 808-586-1400 FAX: 808-586-1412
EMAIL: oip@hawaii.gov

To: House Committee on Health

From: Cheryl Kakazu Park, Director

Date: January 28, 2020, 8:35 a.m.
State Capitol, Conference Room 329

Re: Testimony on H.B. No. 1609
Relating to Pharmacy Benefit Managers

Thank you for the opportunity to submit testimony on this bill, which would establish business practice and transparency requirements for pharmacy benefit managers. The Office of Information Practices (OIP) takes no position on the substance of this bill, but seeks clarification of proposed section 431S-__, HRS, regarding transparency reporting, on bill pages 4 to 6.

As written, this section (on bill pages 5 to 6) requires a licensed pharmacy benefit manager to annually report listed information to the Insurance Commissioner, who is required to publish the reports online "in a way that does not violate chapter 482B," *i.e.,* that does not disclose a trade secret as defined in that chapter. (Later in the bill, "trade secret" is defined as having the same meaning as defined in section 482B-2, HRS.) The "transparency report" section also allows a pharmacy benefit manager to designate information in the report as a

> trade secret; provided that disclosure may be ordered by a court of this State for good cause shown or made in a court filing.

It is not clear how a pharmacy benefit manager's designation of information as a trade secret is intended to interact with chapter 92F, HRS, the Uniform Information Practices Act (Modified) (UIPA). The provision as written does not actually say that any information so designated is confidential or is exempt from public disclosure under the UIPA. Of course, if the designated information really is a trade secret as defined in section 482B-2 it can be withheld from disclosure under the UIPA's exceptions for information made confidential by law (based on the confidentiality provided by chapter 482B, HRS) and for information whose disclosure would frustrate a legitimate government function. If the information does not actually meet the definition of a trade secret, though, the mere fact that a pharmacy benefit manager designated it as such would not automatically require it to be withheld in response to a UIPA response – the Insurance Commissioner, as the agency maintaining the records, would instead need to assert that one or more of the UIPA's exceptions to disclosure applied.

The clause on bill page 6 allowing a court to order disclosure of information designated as a trade secret "for good cause shown" just adds to the confusion, because the UIPA already allows a person to challenge a denial of access to government records by appealing either to OIP or to court. Given the UIPA's pre-existing mechanism to challenge a denial of access to information, it is not clear what additional purpose is served by specifying that a court can order disclosure – is this intended to allow a court challenge even when no record request has been made? Or to supersede the UIPA's normal appeal process? Or is it simply an additional and possibly superfluous way for a member of the public to challenge the "trade secret" designation?

Finally, OIP notes that the definition of a "trade secret" in section 482B-2, HRS, encompasses information with its own economic value, such as a

secret formula, recipe, or client list, and this definition seems generally inapplicable to the sort of information the bill is requiring be reported, which is financial or business information that would be more appropriately described as being confidential business information. Confidential business information whose disclosure would frustrate a legitimate government function could be withheld from public disclosure under the UIPA.

Assuming that the intent of this provision was to ensure that a pharmacy benefit manager would have the opportunity to flag reported business information it considered confidential to prevent it from being automatically posted online, while still allowing members of the public to challenge whether that information should truly be withheld, **OIP recommends amending this bill to remove the references to trade secrets and instead refer to "confidential business information" that can be withheld under the UIPA's frustration exception, and to provide that any person can appeal a denial of access to reported information as provided in the UIPA.** Specifically, **OIP recommends (1) deleting the definition of "trade secret" on bill page 9 and (2) replacing proposed subsections 431S-__(c) and (d) on bill pages 5-6 with the following language:**

> (c) A pharmacy benefit manager that provides information under this section may designate that material as confidential business information whose disclosure would frustrate a legitimate government function as provided in section 92F-13; provided that any person may appeal a denial of access to information so designated in the manner set forth in part II of chapter 92F.
>
> (d) Within sixty calendar days of receipt, the commissioner shall publish the transparency report of each pharmacy benefit manager on the official website of the insurance division in a way that does not disclose information designated by a pharmacy benefit manager as confidential business information; provided that if a court or the office of information practices has determined that information is required to

be publicly disclosed, the commissioner shall include that information in the published transparency report.

Thank you for considering OIP's suggestions.

HB-1609
Submitted on: 1/24/2020 4:30:32 PM
Testimony for HLT on 1/28/2020 8:35:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
greg harmon	kAMEHAMEHA pHARMACY	Support	No

Comments:

Dear honorable legislature officials:

I strongly support this bill to create a transparent fair business practice model to protect the public and support all remaining community pharmacies in Hawaii. I am the only remaining rural pharmacy on the Big Island serving North Kohala. CVS Caremark and Longs Drugs have purchased and closed six pharmacies over the last 3 years beginning in 2017 on the Big Island. The PBM's under contract with the medical insurance company or directly with EUTF or Queens have steered members to mail order and their own stores Longs Drugs. This deceptive business practice is eliminating competition and eliminating pharmacy access that does not deliver healthy health outcomes. Please accept my support for HB 1609

Greg Harmon, Pharmacist President Kamehameha Pharmacy, P.O. Box 610, Kapaau, HI 96755

Akamai Cannabis Clinic
3615 Harding Ave, Suite 304
Honolulu, HI 96816

TESTIMONY ON HOUSE BILL 583
RELATING TO CANNABIS FOR MEDICAL USE
By
Clifton Otto, MD

House Committee on Health
Representative John M. Mizuno, Chair
Representative Bertrand Kobayashi, Vice Chair

Tuesday, January 28, 2020; 8:35 AM
State Capitol, Conference Room 329

Thank you for the opportunity to provide testimony on this measure. Please consider the following comments related to this bill:

Any changes to our Medical Cannabis Program require that we also address the misconception that our program is violating federal law in order to eliminate the injuries that the current situation is causing our patients and dispensaries.

These injuries include patients not being able to obtain employment because of a positive cannabis screening drug test, being terminated from employment because of failing a cannabis urine drug test that does not test for impairment in the workplace, being evicted from federally subsidized housing, not being able to obtain life insurance, not being able to enjoy the protections of the American with Disabilities Act, being discriminated against in child custody hearings, not being able to travel to other islands with their medicine, and dispensaries not being able to carry on normal banking activity, having to conduct a majority of their transactions in cash, not being able to enjoy standard business expense deductions which is creating a 70%+ tax burden that only raises product costs for patients, and not being able to conduct medical research with the University of Hawaii system.

Our patients and dispensaries should not be required to operate under the false assumption that they are violating federal law in order to engage in the medical use of cannabis in Hawaii.

"An Accepted Medical Use Supporter"

The State of Hawaii created this situation when it lawfully decided that cannabis has medical use in Hawaii, which means that the State cannot simply wait for Congress to fix a situation that it created. We can no longer stand for the federal regulation that has the non-medical use of cannabis on the Schedule I list being unconstitutionally applied to our medical cannabis program.

There is a simple solution to this problem, which is presented in Senator Ruderman's federal exemption bill, SB2462, which was recently introduced into the Senate:

In order to increase the chances that this important change will be made to our Medical Use of Cannabis Act this session, I ask that you please adopt the following language from SB2462 into the current bill before you:

"329D-25 Coordination among state and federal agencies. The department shall initiate ongoing dialogue among relevant state and federal agencies to identify processes and policies that ensure the privacy of qualifying patients and qualifying out-of-state patients and the compliance of qualifying patients, primary caregivers, qualifying out-of-state patients, and caregivers of qualifying out-of-state patients and medical cannabis dispensaries with state laws and regulations related to medical cannabis. The department shall submit a written request, in accordance with title 21 C.F.R. section 1307.03, to the Office of Diversion Control, Drug Enforcement Administration by September 1, 2020, stating that part IX of chapter 329 and this chapter do not create any positive conflict with state or federal drug laws and regulations and are consistent with title 21 U.S.C. section 903, and requesting formal written acknowledgement that the listing of marijuana as a controlled substance in federal schedule I does not apply to the nonprescription use of cannabis under the medical cannabis registry and dispensary programs established pursuant to chapters 329 and 329D."

Thank you for considering this necessary amendment.

Aloha.

"An Accepted Medical Use Supporter"

House of Representatives
The Thirtieth Legislature
Regular Session of 2020

Committee on Health (HLT)
Rep. John M. Mizuno, Chair
Rep. Bertrand Kobayashi, Vice Chair

Date of Hearing: Tuesday, January 28, 2020
Time of Hearing: 8:35 a.m.
Place of Hearing: Conference Room 329

TESTIMONY in Support of Authorizing the Department of Health to Implement a Program for Wholesale Drug Importation (HB1608)

By: Dayton M. Nakanelua,
State Director of the United Public Workers,
AFSCME, Local 646, AFL-CIO

My name is Dayton M. Nakanelua, State Director of the United Public Workers, AFSCME, Local 646, and AFL-CIO (UPW). The UPW is the exclusive representative for approximately 13,000 public employees, which include blue collar, non-supervisory employees in Bargaining Unit 01 and institutional, health and correctional employees in Bargaining Unit 10, in the State of Hawaii and the four counties.

The UPW supports the intent of HB1608 to reduce the cost of prescription drugs for the benefit of Hawaii's people. It is a bold idea whose time has come since the current sources for prescription drugs have failed to meet the needs of the public with astronomical prices.

According to Consumer Report (CR) dated November 26, 2019, "High drug prices are financially toxic for American workers," says Stacie B. Dusetzina, Ph.D, and Associate Professor of health policy at the Vanderbilt University School of Medicine. She is a co-author of a 2017 report on drug costs by the National Academies of Sciences, Engineering and Medicine. The CR stated that those persons who had spikes in their drug costs were not inclined to fill a prescription and just forgo medical treatment or tests, cut back on groceries or get second job.

A main reason for high prices is the lack of federal law or regulation to effectively keep drug prices in check. Another factor includes the "...drug supply system middlemen whose wheeling and dealing with drug makers contributes to rising drug costs, according to multiple reports by industry experts." A third reason is the shrinking insurance coverage with larger numbers of people paying a larger share of their medication. There were about 50 pieces of legislation to control drug prices in the U.S Congress over the years but all failed. It's time for state governments to step up to the plate. **HB1608 is an excellent bill to begin the conversation**.

Thank you for the opportunity to submit this testimony.

THE QUEEN'S HEALTH SYSTEMS

To: The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
Members, Committee on Health

From: Paula Yoshioka, Vice President, Government Relations & External Affairs, The Queen's Health Systems
Colette Masunaga, Manager, Government Relations & External Affairs, The Queen's Health Systems

Date: January 27, 2020

Hrg: House Committee on Health Hearing; Tuesday, January 28, 2020 at 8:35 AM in Room 329

Re: **Support the intent for H.B. 1609, Relating to Pharmacy Benefit Managers**

The Queen's Health Systems (Queen's) is a not-for-profit corporation that provides expanded health care capabilities to the people of Hawai'i and the Pacific Basin. Since the founding of the first Queen's hospital in 1859 by Queen Emma and King Kamehameha IV, it has been our mission to provide quality health care services in perpetuity for Native Hawaiians and all of the people of Hawai'i. Over the years, the organization has grown to four hospitals, 66 health care centers and labs, and more than 1,600 physicians statewide. As the preeminent health care system in Hawai'i, Queen's strives to provide superior patient care that is constantly advancing through education and research.

Queen's appreciates the opportunity to testify in support the intent for H.B. 1609, Relating to Pharmacy Benefit Managers. The measure establishes business practices and transparency reporting requirements for Pharmacy Benefit Managers (PBMs), as well as replaces the registration requirement with a licensing requirement, and increases penalties for violations. We appreciate moving oversight of PBMs to the Insurance Commissioner, prohibiting PBMs from retaining any portion of spread pricing, and focusing on transparency by requiring a report to the Commission on rebates and fees received by a PBM.

Queen's contracts with over 15 PBMs, with each PBM having their own way of doing business and some with little to no transparency. PBMs control the formularies for prices and have the ability create pricing uncertainty for pharmacies. Queen's outpatient pharmacies take on the responsibility of due diligence in working to find the lowest costs possible for our patients. However, when PBMs reimburse our pharmacies for half of what the costs are to acquire a drug, there is no process for us to know where that drug is being purchased, in what market, and/or if it is even available at that price in Hawaii.

In addition to price uncertainty, our pharmacies go through undue burdens when accessing PBMs prices for any given drug and we currently do not receive data in a standard and comprehensive list format, and must obtain prices on an individual prescription basis. With no guideline or

standard approach when it comes to the disclosure of pricing, each PBM has been able develop their own burdensome process which puts pharmacies at a disadvantage.

Transparency and oversight of PBMs will greatly benefit our pharmacies, patients, and community. Thank you for the opportunity to testify on this measure.

HPCA
HAWAI'I PRIMARY CARE ASSOCIATION

Testimony to the House Committee on Health
Tuesday, January 28, 2020; 8:35 a.m.
State Capitol, Conference Room 329

RE: HOUSE BILL NO. 1609, RELATING TO PHARMACY BENEFIT MANAGERS.

Chair Mizuno, Vice Chair Kobayashi, and Members of the Committee:

The Hawaii Primary Care Association (HPCA) is a 501(c)(3) organization established to advocate for, expand access to, and sustain high quality care through the statewide network of Community Health Centers throughout the State of Hawaii. The HPCA **SUPPORTS THE INTENT** of House Bill No. 1609, RELATING TO PHARMACY BENEFIT MANAGERS., and offers **PROPOSED AMENDMENTS** for your consideration.

The bill, as received by your Committee, would:

(1) Establish business practice and transparency reporting requirements for pharmacy benefit managers (PBMs);

(2) Replace registration requirements for PBMs pursuant to Chapter 431S, Hawaii Revised Statutes (HRS), with licensure requirements; and

(3) Increase penalties for violations of the PBM law.

By way of background, the HPCA represents Hawaii Federally-Qualified Health Centers (FQHCs). FQHCs provide desperately needed medical services at the frontlines in rural and underserved communities. Long considered champions for creating a more sustainable, integrated, and wellness-oriented system of health, FQHCs provide a more efficient, more effective and more comprehensive system of healthcare.

The federal 340B Drug Pricing Program (340B Program) provides eligible health care providers, such as FQHCs, the ability to purchase outpatient drugs for patients at significantly reduced costs. By purchasing medications at a much lower cost, FQHCs are able to pass the savings on to their patients through reduced drug prices and the expansion of access and service to underserved populations. The discounts provided in the Program are financed by the drug manufacturers, not the government.

ADD 1003 BISHOP STREET PAUAHI TOWER SUITE 1810 HONOLULU, HI 96813 TEL 808.536.8442 WEB HAWAIIPCA.NET

In recent years, a growing number of outside organizations called PBMs have determined how to access the 340B savings intended to accrue to FQHCs and other 340B providers. Among other things, PBMs have structured their contracts with FQHCs to retain part or all of the 340B savings. Examples of this include:

- A third party insurer determines that the FQHC is 340B eligible, but reduces reimbursement to the estimated 340B ceiling price;

- A retail pharmacy requests a sizeable percentage of the "spread" between the 340B purchase price and the insurance reimbursement of a higher dispensing fee than they charge for non-340B drugs; and

- A claims processor charges a higher fee for the 340B drugs (more than is justified by higher administrative costs) on the grounds that the health center is paying less for these drugs.

At this time, the federal 340B statute does not prohibit outside groups from accessing 340B savings intended for safety net providers and their patients. While the Congressional Record is clear that the 340B Program was intended to assist safety net providers to "stretch scarce federal resources", the statute does not explicitly prohibit the types of contracting arrangements described above. As such, FQHCs cannot reject these contracts on the grounds that they are illegal under law.

The practices of PBMs have had an enormous impact on limited State resources as well. In late 2018, the Ohio State Department of Medicaid required its five managed care plans to terminate contracts with PBMs after the State Auditor found that PBMs had been skimming hundreds of millions of dollars from the Ohio Medicaid Program through previously-hidden spread pricing tactics.

The HPCA notes that many of the concepts in this bill mirror laws enacted in Ohio (transparency), and West Virginia (fiduciary responsibility). However, other states have specifically included statutory protections for the 340B Program, which this bill, in its current form, does not have. These states include Oregon, Montana, and South Dakota.

Because of this, the HPCA supports any and all legislative efforts to protect the 340B Program, including House Bill No. 1609. To further strengthen these protections, we recommend that the bill be amended to include language found in Ohio statutes to specifically reference the 340B Program.

On page 4, line 16, we ask that the following language be added so that subsection (e) will appear as follows:

> (e) A covered entity or pharmacy benefit manager shall be prohibited from penalizing, requiring, or providing financial incentives, including variations in premiums, deductibles, copayments, or coinsurance, to covered persons as incentives to use a specific retail pharmacy, mail order pharmacy, or other network pharmacy provider in which a pharmacy benefit manager has an ownership interest or that has an ownership interest or that has an ownership interest in a pharmacy benefit manager. In addition, a pharmacy benefit manager shall not reimburse a 340B pharmacy differently than any other network pharmacy based on its status as a 340B pharmacy; provided that for purposes of this section, 340B pharmacy means a pharmacy that is authorized to purchase drugs at a discount under 42 U.S.C. 256b. [New material is highlighted.]

Regarding the penalty provisions, one could argue that the spread-pricing tactics of PBMs constitute an unfair method of competition and unfair or deceptive acts or practices in the conduct of a trade or commerce. If it is the desire of this Committee to conform the penalty provisions with Chapter 480, HRS, we suggest that the following language be added to page 13, line 16, to establish a new subsection (c) to Section 431S-5, HRS:

> (c) Notwithstanding section 480-11, or any other law to the contrary, in addition to any penalty authorized pursuant to this section, each

violation of this chapter shall also be a violation of chapter 480 and subject to any penalty authorized thereunder. [New material is highlighted.]

By cross-referencing Chapter 480, HRS, to Chapter 431S, HRS, this language would subject persons who violate this law with criminal and civil penalties, and allow injured persons to sue in tort and be eligible to receive, among other things, treble damages, and attorneys fees. Chapter 480, HRS, also allows for class actions by private persons.

Also, if this Committee is inclined to take a similar approach as did the Ohio Medicaid Program, we offer the following language to be added to page 13, line 17, for your consideration:

SECTION 8 (a) No contract for managed care entered into pursuant to Part II of Chapter 346, Hawaii Revised Statutes, after December 31, 2020, shall contain a provision that authorizes a pharmacy benefit manager to reimburse a contracting pharmacy on a maximum allowable cost basis in accordance with Section 328-106, Hawaii Revised Statutes, or Chapter 431S, Hawaii Revised Statutes.

(b) Any provision of a contract for managed care authorized pursuant to Part II of Chapter 346, Hawaii Revised Statutes, to reimburse a contracting pharmacy for a drug on a maximum allowable cost basis in accordance with Section 328-106, Hawaii Revised Statutes, or Chapter 431S, Hawaii Revised Statutes, that was in effect on or before December 31, 2020, shall be null and void. [New material is highlighted.]

This provision would establish a moratorium to allow the Legislature (and the State Auditor if this Committee is so inclined) to investigate whether the spread-pricing tactics of PBMs had resulted in overpayments by the Department of Human Services in Hawaii's Medicaid Program. The length of the moratorium would be indicated by clarifying the effective date to require SECTION 8 be repealed on a date certain. For example, if the Legislature was inclined to make the moratorium last for five years, the effective date on page 14, line 5 would be amended to read:

> SECTION . This Act shall take effect on January 1, 2021; provided that SECTION 8 shall be repealed on December 31, 2026. [New material is highlighted.]

Lastly, from a technical perspective, we note that Section 328-106, HRS, provides the Department of Health with regulatory authority over PBMs. If it is the desire of this Committee to transfer all regulatory authority to the Insurance Commissioner under Chapter 431S, HRS, the Committee may want to review that statute to determine whether there are any elements of that law that should be transferred to Chapter 431S, HRS, and repeal Section 328-106, HRS.

Thank you for the opportunity to testify. Should you have any questions, please do not hesitate to contact Public Affairs and Policy Director Erik K. Abe at 536-8442, or eabe@hawaiipca.net.

Testimony in Support for HB 1609

Dear Chair Mizuno, Vice Chair Kobayashi and Respected Members of the Committee,

My name is Derek Tengan and I am a pharmacist and a pharmacy owner of an independent pharmacy with four locations here on the island of Oahu. I am writing to testify my support for HB 1609 relating to Pharmacy Benefit Mangers (PBMs).

Pharmacy Benefit Managers are the middlemen who determine how much a pharmacy is reimbursed for a drug. What we ask for as independent pharmacies is transparency from these larger, billion dollar corporations who do business in the state of Hawaii.

HB 1609 will help protect independent pharmacies statewide and furthermore continue to provide valuable personalized services to our communities. Please protect our patients and communities who depend on our services by supporting HB 1609.

Thank you for the opportunity to submit testimony.

Testimony in support of H.B. 1609

Good morning Chair Mizuno, Vice Chair Kobayashi and Members of the Committee,

My name is Keri Oyadomari and I am a community pharmacist here in Honolulu. I am testifying my support for HB 1609.

Pharmacy Benefit Managers currently affect every aspect of a pharmacy's business operations. They work with both pharmacies and insurance providers in determining reimbursements for drugs that are dispensed. Many times, pharmacies are reimbursed below the cost of the drug. The pharmacy may appeal, but most of the time it is denied or ignored. This type of financial strain on pharmacies makes it very difficult to continue to provide free services to the community and in turn impacts access to care in the state of Hawaii. This bill will improve access to consumers, as well as allow retail pharmacies to better care for their patients.

Thank you for the opportunity to testify.

Testimony in Support for HB 1609

Dear Chair Mizuno, Vice Chair Kobayashi and Respected Members of the Committee,

My name is Joo Kim and I am a Business Director and active member of the community here in Honolulu. I am testifying my support for HB 1609. Pharmacy Benefit Managers currently affect every aspect of a pharmacy's business operations. They work with both pharmacies and insurance providers in determining reimbursements for drugs that are dispensed. HB1609 will provide transparency for these huge billion dollar corporations that operate in our state.

I believe HB1609 will promote better transparency of prescription drug pricing for patients, healthcare providers, and all pharmacies statewide.

Thank you for the opportunity to submit testimony.

Sincerely,
Joo Kim

HB-1609
Submitted on: 1/27/2020 10:34:56 AM
Testimony for HLT on 1/28/2020 8:35:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Ashok Kota	Individual	Support	No

Comments:

I strongly support this bill. A transparent Healthcare system is key to evaluate and control costs and will definitely benefit the state and taxpayers while protecting consumers. A transparent system provides a fair playing field for local businesses to compete with larger companies and will benefit the Hawaii state residents access to Healthcare.

Hawaii Association of Health Plans

January 26, 2020

The Honorable John Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
House Committee on Health

House Bill 1609 – Relating to Pharmacy Benefit Managers

Dear Chair Mizuno, Vice Chair Kobayashi, and Members of the Committee:

The Hawaii Association of Health Plans (HAHP) appreciates the opportunity to testify in opposition to HB 1609.

Pharmacy Benefit Managers help health plans to control drug costs. We believe that this bill will create more administrative burden and increase costs for Pharmacy Benefit Managers and health plans, which in turn will affect premiums for consumers. As this bill will increase costs to our members, we ask that it be deferred.

Should this bill move forward, we respectfully request amendments be made to §431S-Transparency report (c) which prevents unauthorized disclosure of any Pharmacy Benefit Manager "trade secrets." We believe that the "trade secret" protections be broadened to include any "confidential or proprietary information" and that, to the extent the information a PBM must disclose belongs to a third party, that the third party be afforded an opportunity to object to the disclosure and show cause to the Insurance Commissioner as to why it should not be published.

Thank you for allowing us to testify expressing concerns on HB 1609.

Sincerely,

HAHP Public Policy Committee

cc: HAHP Board Members

hmsa

An Independent Licensee of the Blue Cross and Blue Shield Association

LATE

January 26, 2020

The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
House Committee on Health

Re: HB 1609 – Relating to Pharmacy Benefit Managers

Dear Chair Mizuno, Vice Chair Kobayashi, and Members of the Committee:

The Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify expressing our serious concerns on HB 1609, which establishes business practice and transparency reporting requirements for pharmacy benefit managers. It also replaces the registration requirement for pharmacy benefit managers with a licensing requirement and increases penalties for violations of the pharmacy benefit managers law.

HMSA utilizes a Pharmacy Benefit Manager (PBM) to manage our drug benefit plans, which helps us and our members to control escalating drug costs. We believe this bill increases administrative burden and costs for our PBM, which will lead to increased costs for our members.

We also believe that the "trade secret" protections should be strengthened in this bill to protect any confidential or proprietary information and that, to the extent the information a PBM must disclose belongs to a third party, that the third party be afforded an opportunity to object to the disclosure and show cause to the Insurance Commissioner as to why it should not be published.

Thank you for the opportunity to testify on this measure. Your consideration of our concerns is appreciated.

Sincerely,

Pono Chong
Vice President, Government Relations

LATE

HB-1609
Submitted on: 1/27/2020 11:15:40 PM
Testimony for HLT on 1/28/2020 8:35:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Elie Kato	5 Minute Pharmacy	Support	Yes

Comments:

Rep. John Mizuno, Chair

Rep. Bertrand Kobayashi, Vice Chair

House of Representatives Committee on Health

Elie Kato

5 Minute Pharmacy

916 Gulick Ave. Suite A

Honolulu, HI 96819

Tuesday 1/28/2020

Support for HB1609

5 Minute Pharmacy is an independent pharmacy operating on Oahu. As an independent pharmacy we support these bills because they will increase transparency into drug pricing and provide an avenue for bending the medical cost curve downward instead of its current trajectory which is unsustainable.

Working at a pharmacy we see the patients, we know many of them by name and want to help them but because of the practices of PBM's our hands are tied. Measures in this bill such as not allowing patients to pay co-pays that are more than the cost of the drug can provide financial relief to Hawaii's residents.

For too long independent pharmacies have been subject to the mercurial pricing and regulations of the PBM's. HB1609 and its effort to increase transparency to PBM practices such as disclosing rebates can help affect costs by preventing PBM's from promoting medications based on the rebates the PBM gets from the manufacture.

Especially when there are other, sometimes better alternative medications that are more cost effective to the patient.

By approving HB1609 Hawaii would be joining one of many states that see the need to improve transparency with PBM's because it improves the lives of patients. We are aware that Hawaii's population is aging and with increased age comes need for more medical attention and medications. This bill will increase transparency in the drug pricing market and will help decrease the costs of medications to Hawaii's residents. Please support the passage of HB1609.

Thank you.

LATE

Times Pharmacy Strongly Supports HB1609

Aloha Chair Mizuno, Vice Chair Kobayashi and Respected Members of the Committee,

A number of local independent pharmacies have been forced to close their doors or sell to large mainland corporations. The few local independent pharmacies that remain are struggling to survive due to predatory practices employed by pharmacy benefit managers (PBMs). Pharmacies are being reimbursed below the cost of acquiring certain medications, sometimes losing up to hundreds of dollars per prescription. PBMs determine how much a pharmacy is reimbursed through a very opaque and confusing system and are not willing to justify or adjust their reimbursement rates when questioned. Meeting with PBMs has not done anything to solve this problem and yet local independent pharmacies continue to do everything they can to provide the best care for patients in their communities including dispensing medications at a loss.

If the current pharmacy reimbursement model remains the same and PBMs are not regulated or held accountable, it will only be a matter of time until all local independent pharmacies are forced to close or sell. Local pharmacies are not the only victims, PBM's also contract with health plans, employers, and government entities to manage their prescription drug coverage. Nationally a number a states have found that PBMs have been overcharging health plans and underpaying pharmacies and keeping the difference also known as "spread pricing." They have also been found to keep manufacturer rebates instead of passing the savings onto consumers. PBMs could potentially be making hundreds of millions of dollars a year at Hawaii's expense.

I humbly request that as legislatures you consider the larger picture and how this affects our state as a whole. PBMs are profiting from local plans, pharmacies, and consumers, where does that revenue go? Does it stay in Hawaii? Do PBMs help our local economy? Or communities? Or residents? Now think about local independent pharmacies that have been here for generations. Do they help our local economy? Our communities? Our residents?

Times Pharmacy strongly supports HB1609 because this bill will bring much needed transparency and accountability to PBMs in the State of Hawaii. Thank you for the opportunity to provide testimony.

LATE

HB-1609
Submitted on: 1/28/2020 9:30:05 AM
Testimony for HLT on 1/28/2020 8:35:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
NORA FINBERG	FOODLAND PHARMACY	Support	No

Comments:

To our honorable committee on Health members for the state of Hawaii,

I have been practicing as a pharmacist in the state of Hawaii for 30 years in retail and for the past 18 years with Foodland Pharmacy in Pukalani, Hawaii. I have seen the change that has occurred in my profession over these years and one of them has been the seemingly unlegislated actions of the PBMs in our state. The HB 1609 bill, if passed, will allow the PBM's that operate in our state to be under better supervision. This is a move forward in allowing pharmacists and other providers to give the care needed for the people of Hawaii. I give my support for this measure as a pharmacist and a citizen of this fine state.

Thank you for your consideration in this matter,

Juliana Massenburg, RPh

CVSHealth

LATE

1275 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

January 28, 2020

LATE TESTIMONY

LATE TESTIMONY

Representative John Mizuno, Chair
Representative Bertrand Kobayashi, Vice Chair
Committee on Health
415 South Beretania Street
Honolulu, Hawaii 96813

RE: HB 1609 Relating to Pharmacy Benefit Managers
January 28, 2020; 8:35 a.m., conference room 329

Aloha Chair Mizuno, Vice Chair Kobayashi, and members of the committee:

CVS Health is writing to share with you our concerns regarding House Bill 1609 ("HB 1609"), relating to pharmacy benefit managers (PBMs). This bill seeks to regulate private business contracts between PBMs, their clients, including employers and health plans, and pharmacies. We believe that provisions in this bill would compromise safety protections for patients who take specialty medications, interfere in private contracting, and greatly increase costs for Hawaii employers and health plans.

CVS Health is the nation's premier health innovation company helping people on their path to better health. Whether in one of its pharmacies or through its health services and plans, CVS Health is pioneering a bold new approach to total health by making quality care more affordable, accessible, simple, and seamless. CVS Health is community-based and locally focused, engaging consumers with the care they need when and where they need it. The Company has more than 9,800 retail locations, approximately 1,100 walk-in medical clinics, a leading pharmacy benefits manager with approximately 93 million plan members, a dedicated senior pharmacy care business serving more than one million patients per year, expanding specialty pharmacy services, and a leading stand-alone Medicare Part D prescription drug plan. CVS Health also serves an estimated 39 million people through traditional, voluntary, and consumer-directed health insurance products and related services, including a rapidly expanding Medicare Advantage offering. This innovative health care model increases access to quality care, delivers better health outcomes and lowers overall health care costs.

Fiduciary Duty

Historically, the concept of a fiduciary duty related to a PBM's contractual relationship with its clients was first raised and considered by federal courts in the early 2000s. ERISA defines the term "fiduciary" as a person who (i) exercises any discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets or (ii) has any discretionary authority or discretionary responsibility in the administration of such plan."[1]

The U.S. Supreme Court has ruled that a person is a fiduciary for an ERISA plan only "to the extent" a person has or exercises such discretionary authority or control on behalf of a plan.[2] Following this decision, multiple federal courts have ruled that the PBM was not acting in a fiduciary capacity in managing its PBM-related services (e.g., negotiating with drug manufacturers or retail pharmacies or managing its formulary), but rather managing its own business which did not involve the discretionary control of plan assets.[3]

[1] 29 U.S.C. § 1002(21)(A).
[2] Pegram, 530 U.S. at 223, 120 S. Ct. 2143.
[3] *See* Chicago District Council of Carpenters Welfare Fund. v. Caremark, 474 F.3d 463, (7th Cir. 2007); *see also* Moeckel v. Caremark, Inc., 622 F. Supp. 2d 663 (M.D. Tenn. 2007), and In re Express Scripts/Anthem ERISA Litigation, 2018 WL 339346 (S.D.N.Y. Jan. 5, 2018).

Overall, imposing a fiduciary duty on a PBM would pose a challenge for payers trying to control costs while the payer is providing a sustainable benefit to their plan members in an era of rising launch prices for drugs and ongoing, annual increases in drug prices.

The imposition of a fiduciary duty may reduce the flexibility that a plan sponsor has with regards to structuring their financial arrangement with their PBM and could lead to one-size-fits-all solutions. There may be only one way of contracting that would meet the definition of a fiduciary without some potential for incurring legal liability. Additionally, it could restrict payers' ability to uniquely design their benefit to meet their beneficiaries' specific needs while implementing ways to provide cost savings, including formulary preferences, exclusions, and utilization management techniques. There is also the possibility that it would prevent payers from having their PBM obtain better pricing from retail pharmacies through use of managed networks. The reality of the marketplace is that one-size-fits-all plan designs would not work for everyone because not all payers have the same level of economic resources or the same size and type of patient populations.

Accreditation and Certification

HB 1609 would limit Hawaii employers' and health plans' ability to provide their employees and members with high quality, affordable care by prohibiting the use of accreditation and certification standards for network pharmacies that helps ensure quality and safety. Certification standards are the foundational requirements that health plans, employers, and their PBMs use to validate pharmacy providers prior to enrollment and network contracting. State licensure evaluations by the Board of Pharmacy do not include measures to validate a pharmacy's ability to comply with contractual provisions and regulatory requirements, such as inventory control for claim payment audits, quality management, liability, patient compliance and adherence, safety, clinical programs, etc. Additionally, the Board of Pharmacy is charged with overseeing pharmacy practice and does not have expertise or visibility in managing a pharmacy benefit or creating provider networks.

With regard to specialty pharmacy, this legislation would allow any pharmacy to dispense specialty medications to patients without being required to meet the accreditation and certification standards used to ensure quality and patient safety. Allowing any pharmacy to dispense highly complex specialty medications would not only lead to patient safety issues that would result in increased costs, but it would also interfere with the use of pharmacy networks comprised of pharmacies with the necessary expertise and service level.

Spread Pricing

HB 1609 seeks to prohibit the use of spread pricing arrangements. CVS Health offers PBM clients a variety of contractual options to pay for our PBM services and they choose the one that is best for them based on the services they need and their plan membership. Each employer and plan sponsor evaluates and determines the financial arrangement that meets its needs for PBM services.

Many clients choose a spread pricing arrangement because it provides clients with more certainty in their pharmacy costs and allows them to budget in a more predictable manner. Reducing options in the marketplace that employer and plan sponsors are currently choosing takes away flexibility in contracting that may lower health care costs for them and their employees and members.

Transparency Report

HB 1609 would require the disclosure of competitively sensitive information. CVS Health believes that it is important to keep the competitive marketplace among drug manufacturers in place in order to drive down the cost of prescription medications. Any public disclosure of rebate information could allow manufacturers to learn what type of price concessions other manufacturers are giving and could disincentivize them from offering deeper discounts, which benefit plan sponsors and their beneficiaries.

CVSHealth

The FTC has reviewed a number of state legislative proposals that would have required the public disclosure of competitive rebate information and opined that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors, then tacit collusion among them is more feasible" and that such knowledge of competitors' pricing information would dilute incentives for manufacturers to bid aggressively "which leads to higher prices."[4] The FTC also concluded that "[a]ny such cost increases are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[5]

While the bill includes provisions to attempt to protect confidential, trade secret, or sensitive information provided to the state, we believe the risk of any disclosure at all of proprietary competitive information is too great.

Additional Concerns

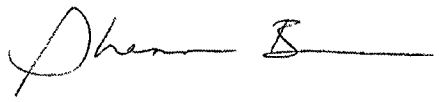
With regard to the provisions in HB 1609 that address patient cost sharing, we have some concerns with the way the bill is drafted but are happy to further discuss the issue and provide some amendments. Our contracts with all dispensing pharmacies in our network require that CVS Caremark members always get the benefit of at least the lower of the pharmacy's cash price (i.e., the price the consumer would pay out of pocket without insurance coverage) and the plan's copayment. We believe the language in the bill should more closely reflect this practice.

The provision prohibiting a PBM from penalizing, requiring, or providing financial incentives to members to use a specific pharmacy is already covered by existing law and is unnecessary. Please see Haw. Rev. Stat. § 431R-3 (2020).

Lastly, the new licensure requirements are unnecessary because existing code already requires PBMs to register with the Insurance Commissioner. Additionally, this section doesn't take into account that not only are we already registered as a PBM, but we have applied for a third party administrator license as well.

On behalf of CVS Health, I thank you for allowing us to express our concerns and we welcome the opportunity to work with you on these important issues.

Respectfully,



Shannon Butler
Senior Director of State Government Affairs
CVS Health

[4] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, Jul. 15, 2005.
[5] Id.

PCMA

LATE TESTIMONY

LATE TESTIMONY

January 28, 2020

LATE

Representative John Mizuno, Chair
Representative Bertrand Kobayashi, Vice Chair
Committee on Health

RE: HB 1609 Relating to Pharmacy Benefit Managers
January 28, 2020; 8:35 a.m., conference room 329
Submitted electronically

Aloha Chair Mizuno, Vice Chair Kobayashi and members of the committee:

On behalf of the Pharmaceutical Care Management Association (PCMA), we greatly appreciate the opportunity to testify on H.B. 1609 relating to Pharmacy Benefit Managers. We respectfully request the committee to consider our comments in the interest of payers and patients.

PCMA is the national trade association representing America's Pharmacy Benefit Managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 employers, health insurance plans, labor unions, and Medicare Part D. PBMs are engaged by clients including health insurers, government agencies, unions, school districts, and large and small employers, to manage pharmacy benefits pursuant to health insurance benefits and contracts. PBMs are projected to save payers over $30 billion through the next decade thanks to tools such as negotiating price discounts with drug manufacturers, establishing pharmacy networks and disease management and adherence programs.

Fiduciary

Federal law defines the term "fiduciary" as a person who (i) exercises any discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets or (ii) has any discretionary authority or discretionary responsibility in the administration of such plan."[1] PBMs have no such control or authority over a plan's management or assets.

The concept of a fiduciary duty related to a PBM's contractual relationship with its clients was first raised and considered by federal courts in the early 2000s. The U.S. Supreme Court has ruled that a person is a fiduciary for an ERISA plan only "to the extent" a person has or exercises such discretionary authority or control on behalf of a plan.[2] Following this decision, multiple federal courts have ruled that the PBM was not acting in a fiduciary capacity in managing its PBM-related services (e.g., negotiating with drug manufacturers or retail

[1] 29 U.S.C. § 1002(21)(A).
[2] Pegram, 530 U.S. at 223, 120 S. Ct. 2143.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

PCMA

pharmacies or managing its formulary), but rather managing its own business which did not involve the discretionary control of plan assets.[3]

Imposing a fiduciary duty may reduce the flexibility that a plan sponsor has with regards to structuring their financial arrangement with their PBM and could lead to one-size-fits-all solutions. There may be only one way of contracting that would meet the definition of a fiduciary without some potential for incurring legal liability. Additionally, it could restrict payers' ability to uniquely design their benefit to meet their beneficiaries' specific needs while implementing ways to provide cost savings, including formulary preferences, exclusions, and utilization management techniques. There is also the possibility that it would prevent payers from having their PBM obtain better pricing from retail pharmacies through use of managed networks. The reality of the marketplace is that one-size-fits-all plan designs would not work for everyone because not all payers have the same level of economic resources or the same size and type of patient populations.

Transparency Reporting

HB 1609 would require the disclosure of competitively sensitive information. It is important to keep the competitive marketplace among drug manufacturers in place in order to drive down the cost of prescription medications. Any public disclosure of rebate information could allow manufacturers to learn what type of price concessions other manufacturers are giving and could disincentivize them from offering deeper discounts, which benefit plan sponsors and their beneficiaries.

The Federal Trade Commission (FTC) has reviewed a number of state legislative proposals that would have required the public disclosure of competitive rebate information and opined that, "[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors, then tacit collusion among them is more feasible" and that such knowledge of competitors' pricing information would dilute incentives for manufacturers to bid aggressively "which leads to higher prices."[4] The FTC also concluded that "[a]ny such cost increases are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford."[5]

Accreditation

HB 1609 would limit Hawaii employers' and health plans' ability to provide their beneficiaries with high quality, affordable care by prohibiting the use of accreditation and certification standards for network pharmacies that helps ensure quality and safety. Certification standards are the foundational requirements that health plans, employers, and their PBMs use to validate pharmacy providers prior to enrollment and network contracting. State licensure evaluations by the Board of Pharmacy do not include measures to validate a pharmacy's ability to comply with contractual provisions and regulatory requirements, such as inventory control for claim payment audits, quality management, liability, patient compliance and adherence, safety, clinical programs, etc. Additionally, the Board of Pharmacy is charged with overseeing pharmacy

[3] *See* Chicago District Council of Carpenters Welfare Fund. v. Caremark, 474 F.3d 463, (7th Cir. 2007); *see also* Moeckel v. Caremark, Inc., 622 F. Supp. 2d 663 (M.D. Tenn. 2007), and In re Express Scripts/Anthem ERISA Litigation, 2018 WL 339346 (S.D.N.Y. Jan. 5, 2018).

[4] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, Jul. 15, 2005.
[5] Id.

PCMA

practice and does not have expertise or visibility in managing a pharmacy benefit or creating provider networks.

With regard to specialty pharmacy, this legislation would allow any pharmacy to dispense specialty medications to patients without being required to meet the accreditation and certification standards used to ensure quality and patient safety. Allowing any pharmacy to dispense highly complex specialty medications would not only lead to patient safety issues that would result in increased costs, but it would also interfere with the use of pharmacy networks comprised of pharmacies with the necessary expertise and service level, which health plans and employers use to help lower costs while providing a robust pharmacy benefit.

Patient Cost Sharing

With regard to patient cost sharing, we support the objective but have concerns with the language and are happy to discuss and provide suggested amendments. In their contracts with network pharmacies, our PBM members ensure patients pay the lower of the pharmacy's cash price (i.e., the price the consumer would pay out of pocket without insurance coverage) and the plan's copayment. We believe the language in the bill should more closely reflect this practice.

We believe that the provision prohibiting a PBM from penalizing, requiring, or providing financial incentives to members to use a specific pharmacy is already extensively covered by existing law and is unnecessary. Please see Haw. Rev. Stat. § 431R-3 (2020).

Spread Pricing

HB 1609 would prohibit the use of spread pricing arrangements. PBMs offer payer clients a variety of contractual options to pay for PBM services and they choose the one that is best for them based on the services they need and their plan membership. Each employer and plan sponsor evaluates and determines the financial arrangement that meets their specific needs for PBM services.

One option for clients is to elect a pass-through pricing arrangement for pharmacy reimbursement. Under a pass-through contract, the reimbursement negotiated with the retail pharmacies is passed along to the client to pay and the PBM collects fees from the client to pay for all of the services it performs for the client. In this case, there would be no difference between what the client pays the PBM and what the pharmacy is reimbursed by the PBM. This approach may involve more variation in cost along with drug price fluctuation due to drug shortages, patent expirations, and other market pressures.

Many PBM clients choose a spread pricing arrangement because it provides clients with more certainty in their pharmacy costs and allows them to budget in a more predictable manner. Reducing options in the marketplace employers and plan sponsors currently have will ultimately reduce their flexibility to contract in the best way to meet their needs.

Licensing

We believe the new licensure requirements are unnecessary. Existing code already requires PBMs to register with the Insurance Commissioner. Additionally, this section doesn't take into account that not only are we already registered as a PBM, but we have applied for a third-party administrator license as well.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

PCMA

Again, thank you for the opportunity to testify on H.B. 1609 and we look forward to working with the Committee to develop solutions that will demonstrably benefit Hawaii's residents.

Sincerely,

Bill Head
Assistant Vice President
State Affairs

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org