

STATE OF HAWAII
DEPARTMENT OF HEALTH
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Testimony COMMENTING on HB712 HD1
RELATING TO HEALTH.

REP. SCOT Z. MATAYOSHI, CHAIR
HOUSE COMMITTEE ON CONSUMER PROTECTION AND COMMERCE

Hearing Date: February 11, 2025

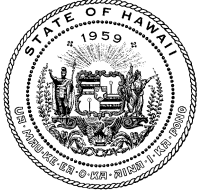
Room Number: 329

Department Testimony: Department Testimony: The Department of Health (DOH) recognizes the importance of resolving the claims of unfair and deceptive trade practices associated with the 340B drug pricing program and between private entities but does not possess the expertise to enforce HB712 HD1 as drafted. Nevertheless, DOH recommends this measure move forward to allow stakeholder to come to an agreement.

DOH acknowledges current state of affairs with the 340B drug pricing program and the role of contract pharmacies. The 340B drug pricing program is critical to Hawaii's public health and health care systems. For example, Hawaii's Federally Qualified Health Centers, the largest of which attends to over 40,000 lives relies on 340B savings for patients and organization to continue providing quality services due to less-than-market reimbursement.

Although contract pharmacies are not common in DOH to deliver services, the overall integrity of the program is vital. For example, the Sexually Transmitted Infection clinic participates in the 340B program but does not use contract pharmacies since it can dispense to clients immediately. However, others such as the HIV Drug Assistance Program, which deals with a much larger number of medications that are often prescribed by clinicians who are not internal to DOH, may require a contracted pharmacy in the future given changes in patient needs and threats from federal health policy.

- 1 Despite the critical need for a strong and fair 340B drug pricing program, the core issue is the
- 2 enforcement of contracts between private sector entities. This is clearly outside the scope of the
- 3 department's core capability and it is inappropriate for public health civil servants to regulate
- 4 unfair or deceptive acts or practices in the private sector.
- 5 Thank you for the opportunity to testify.



**STATE HEALTH PLANNING
AND DEVELOPMENT AGENCY**
DEPARTMENT OF HEALTH - KA 'OIHANA OLAKINO

JOSH GREEN, M.D.
GOVERNOR OF HAWAII
KE KIA'ĀINA O KA MOKU'ĀINA 'O HAWAII

KENNETH S. FINK, MD, MGA, MPH
DIRECTOR OF HEALTH
KA LUNA HO'ŌKELE

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ADMINISTRATOR

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February 7, 2025

To: House Committee on Consumer Protection and Commerce
Representative Scot Matayoshi, Chair
Representative Cory Chun, Vice Chair,
And Honorable Members

From: John C (Jack) Lewin MD, Administrator, SHPDA; and
Senior Advisor to Governor Green On Healthcare Innovation

Re: HB 712 HD1 – RELATING TO HEALTH (340B Drug Access)

Position: SUPPORT

Testimony:

SHPDA supports this bill, which protects access to necessary medications for safety net and rural populations.

The federal 340B drug discounting program (340B program) is essential for providing health care access to low-income and uninsured populations. The 340B program requires drug manufacturers to offer significant discounts on outpatient medications to eligible nonprofit hospitals and safety net providers, rural hospitals, community health centers, and Native Hawaiian health centers.

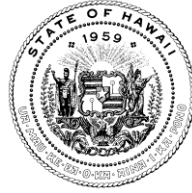
The 340B program helps stretch limited resources, allowing hospitals to reinvest savings into essential community benefits. These benefits include financial assistance for low-income patients, free wellness visits, screenings, vaccinations, transportation to appointments, health education classes, and workforce development programs. The 340B program also supports unique services such as integrating Native Hawaiian health practices into patient care.

Despite the 340B program's importance, drug manufacturers have consistently tried to undermine the benefits provided by the program by limiting the use of contract pharmacies by 340B covered entities, which has made it particularly difficult for patients living in rural areas of the State. Contract pharmacies play a vital role in ensuring that

patients can access medications, especially in rural areas where many hospitals do not have an in-house pharmacy. .

Contract pharmacies are crucial in Hawaii, where geographic barriers make access to health care difficult for many residents.

Current restrictions imposed by drug manufacturers not only limit a patient's access to affordable medication, but also jeopardize the financial savings that hospitals, and especially rural hospitals, depend on.



LATE

JOSH GREEN, M.D.
GOVERNOR | KE KIA'ĀINA

SYLVIA LUKE
LIEUTENANT GOVERNOR | KA HOPE KIA'ĀINA

STATE OF HAWAII | KA MOKU'ĀINA 'O HAWAI'I
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NADINE Y. ANDO
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DEAN I HAZAMA
DEPUTY DIRECTOR | KA HOPE LUNA HO'OKELE

Testimony of the Department of Commerce and Consumer Affairs

Office of Consumer Protection

Before the
House Committee on Consumer Protection and Commerce
February 11, 2025
2:00 PM
Via Videoconference
Conference Room 329

On the following measure:
H.B. 712, H.D. 1 Relating to Health

Chair Matayoshi and Members of the Committee:

My name is Mana Moriarty, and I am the Executive Director of the Office of Consumer Protection (OCP) at the Department of Commerce and Consumer Affairs (Department). The Department offers comments on this bill, highlighting concerns about how this bill will be enforced.

The 340B Drug Discount Program enables eligible hospitals and other safety net providers to purchase outpatient prescription drugs at discounted prices.

Recently, drug manufacturers began imposing restrictions on 340B covered entities that distribute 340B drugs using contract pharmacies. These restrictions vary but generally aim to limit covered entities' use of contract pharmacies. These restrictions lead to financial consequences for covered entities, who may not be able to generate 340B savings as a result of certain restrictions. These 340B savings have reportedly

been used by 340B covered entities to fund services for low-income community members, although OCP is not currently aware of the extent to which they fund such services in Hawaii.

The Department appreciates the purpose of the bill and the significance of the 340B program. However, OCP, as consumer counsel for the State, is responsible for reviewing, investigating, and prosecuting allegations of unfair or deceptive trade practices in *consumer* transactions. The department has concerns that this bill would require government enforcers to enforce the law not on behalf of consumers but instead on behalf of entities (i.e. healthcare providers who participate in the 340B program) who are not consumers.

Thank you for the opportunity to testify on this bill.

Tuesday, February 11, 2025 at 2:00 PM
Via Video Conference; Conference Room 329

House Committee on Consumer Protection & Commerce

To: Representative Scott Matayoshi, Chair
Representative Cory Chun, Vice Chair

From: Michael Robinson
Vice President, Government Relations & Community Affairs

**Re: Testimony in Support of HB 712, HD1
Relating to Health**

My name is Michael Robinson, and I am the Vice President of Government Relations & Community Affairs at Hawai'i Pacific Health. Hawai'i Pacific Health is a not-for-profit health care system comprised of its four medical centers – Kapi'olani, Pali Momi, Straub and Wilcox and over 70 locations statewide with a mission of creating a healthier Hawai'i.

HPH writes in SUPPORT of HB 712, HD1 which prohibits drug manufacturers and wholesale distributors from restricting or denying access for pharmacies contracted with 340B covered entities to purchase 340B drugs at a discounted price under the federal 340B Drug Pricing Program (340B Program).

The federal 340B drug pricing program is essential for providing health care access to low-income and uninsured populations. Under the 340B program, drug manufacturers are required to offer significant discounts on outpatient medications to eligible nonprofit hospitals and safety-net providers, rural hospitals, community health centers and Native Hawaiian health centers. The discounts allowed under the 340B program enable hospitals to use those resources to provide other benefits such as financial assistance for low-income patients, free wellness visits, screenings, vaccinations, transportation to appointments, health education classes, and workforce development efforts as well as integrating Native Hawaiian health practices into patient care.

Contract pharmacies are vital in ensuring that patients are able to have access to the medications they need. This is critical in rural and underserved communities where many hospitals do not have an in-house pharmacy. More than 80% of rural 340B hospitals nationwide rely on contract pharmacies to dispense medication to patients who may be unable to obtain their medication otherwise. This is especially problematic in Hawai'i because of geographic barriers including location, size, and transportation challenges. However, drug manufacturers have consistently attempted to undermine the benefits of

the program by limiting the use of contract pharmacies by 340B covered entities, thereby limiting access to care for many patients.

By prohibiting drug manufacturers from engaging in conduct that limits or denies access to 340B drugs, this measure would ensure that patients, especially those residing in rural areas of the state, are able to obtain the medications they need.

Thank you for the opportunity to testify.



**Testimony to the House Committee on Consumer Protection and Commerce
Tuesday, February 11, 2025; 2:00 p.m.
State Capitol, Conference Room 329
Via Videoconference**

RE: HOUSE BILL NO. 0712, HOUSE DRAFT 1, RELATING TO HEALTH.

Chair Matayoshi, Vice Chair Chun, 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** House Bill No. 0712, House Draft 1, RELATING TO HEALTH., and offers a **FRIENDLY AMENDMENT** for your consideration.

By way of background, the HPCA represents Hawaii's Federally Qualified Health Centers (FQHCs). FQHCs provide desperately needed medical services at the frontlines to over 150,000 patients each year who live 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 measure, as received by your Committee, would preserve the integrity of the 340B Drug Pricing Program by prohibiting drug manufacturers from restricting the use of contract pharmacies by any 340B-covered entity in the State.

This measure would take effect on July 1, 3000.

For more than thirty years, the 340B Program has provided critical resources that enable FQHCs and other program participants to deliver affordable and accessible health care services to the most underserved and vulnerable communities.

By law, FQHCs:

“ . . . must document that any non-grant funds generated from health center program project activities in excess of what is necessary to support the total health center project budget were utilized. . . to benefit the current or proposed patient population and were not utilized for purposes that are specifically prohibited by the health center program. . . ”
[See, HRSA, Health Center Program Compliance Manual, August 20, 2018, p. 63.]

Over the past few years, statutory ambiguities have allowed other parties to claim the savings that were intended to accrue to the patients of FQHCs and other 340B providers. Because of this, the HPCA believes that the 340B Program must be preserved to ensure stability for Hawaii's safety net providers and enable them to effectively care for patients that otherwise would not have access to affordable health care services and medications.

The HPCA notes that this measure, as received, is substantively similar to House Bill No. 0562. This measure was introduced to address many of the technical concerns raised by the Departments of Health and the Attorney General that resulted in the subsequent amendments made to House Bill No. 0712. To further alleviate a possible challenge on grounds that this bill conflicts with the requirements of Section 26H-6, Hawaii Revised Statutes, the HPCA recommends that language be inserted into the Committee report, to wit:

“ . . . Your Committee asserts that this measure in no way should be construed as regulation under Hawaii's professional and vocational licensing laws. Rather, this measure is intended to prohibit certain business activities that your Committee determines to be repugnant to the health, welfare, and safety of the consuming public. . . . ”

In addition, House Bill No. 0562 also includes a provision that would permit the Attorney General to bring a civil action on behalf of any person or persons aggrieved by the prohibited activities. [See, House Bill No. 0562, page 5, lines 3 through 7.] Accordingly, the HPCA recommends that this language be added to the bill. For your review, a copy of House Bill No. 0562 is attached.

With this friendly amendment, the HPCA respectfully requests your favorable consideration of this measure.

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.

A BILL FOR AN ACT

RELATING TO CONSUMER PROTECTION.

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

1 SECTION 1. The legislature finds that the federal 340B
2 drug pricing program is essential for providing Hawaii's
3 low-income and uninsured populations with access to healthcare
4 and medications. The federal program requires drug
5 manufacturers to offer significant discounts on outpatient
6 medications to eligible nonprofit hospitals and safety net
7 providers, rural hospitals, community health centers, and Native
8 Hawaiian health centers.

9 The legislature further finds that the 340B drug pricing
10 program helps healthcare providers stretch limited resources,
11 allowing hospitals to reinvest savings into essential community
12 benefits. These benefits include financial assistance for
13 low-income patients, free wellness visits, screenings,
14 vaccinations, transportation to appointments, health education
15 classes, and workforce development programs. In Hawaii, the
16 drug pricing program also helps support unique services, like



1 the integration of Native Hawaiian health practices into patient
2 care.

3 The legislature recognizes that, despite the importance of
4 the drug pricing program, drug manufacturers have consistently
5 tried to undermine its benefits. Since 2020, some drug
6 manufacturers have limited the ability of 340B entities to
7 prescribe drugs through contract pharmacies. This is an unfair
8 practice that creates a barrier to health care, especially for
9 patients in rural areas, where many hospitals do not have
10 in-house pharmacies. More than eighty per cent of rural 340B
11 hospitals nationwide rely on contract pharmacies to dispense
12 medications to patients who might otherwise go without
13 critically needed treatments.

14 The legislature notes that contract pharmacies are
15 particularly crucial in Hawaii, where geographic isolation makes
16 it difficult for many residents to access medications.
17 Partnering with contract pharmacies in the State's rural
18 communities allows hospitals, federally qualified health centers
19 and federal Ryan White program participants to ensure that their
20 patients receive their prescribed medications without needing to
21 travel long distances. Additionally, the partnerships provide



1 Hawaii's patients access to some specialty drugs that are only
2 available through specific pharmacy channels.

3 The legislature believes that the restrictions imposed by
4 drug manufacturers on contract pharmacy partnerships not only
5 limit patients' access to affordable medications but also
6 jeopardize the financial status of critical healthcare
7 providers. Hospitals, federally qualified health centers, and
8 federal Ryan White program participants rely on the opportunity
9 to reinvest in their operations the difference between the 340B
10 discounted drug price and the amount reimbursed by insurance.
11 Without access to contract pharmacies, hospitals face reduced
12 savings, which could result in cutbacks to essential healthcare
13 programs.

14 Accordingly, the purpose of this Act is to preserve the
15 integrity of the 340B program and prevent unfair practices that
16 are harmful to consumers by:

17 (1) Prohibiting covered entities in the State from
18 entering into contracts with drug manufacturers that
19 limit the covered entities' use of contract
20 pharmacies;



- 1 (2) Voiding contract provisions that are based on the
2 maximum allowable cost payment model; and
3 (3) Authorizing the attorney general to bring a civil
4 action for violations of this Act.

5 SECTION 2. Chapter 481B, Hawaii Revised Statutes, is
6 amended by adding a new section to part I to be appropriately
7 designated and to read as follows:

8 "§481B- 340B contract pharmacies; maximum allowable
9 cost basis; prohibited. (a) Beginning June 30, 2025:

- 10 (1) No 340B covered entity in the State shall enter into a
11 contract with a drug manufacturer, wholesale
12 distributor, or an agent or affiliate of a drug
13 manufacturer or wholesale distributor, if provisions
14 of the contract directly or indirectly restrict or
15 prohibit the acquisition of a 340B drug through a
16 contract pharmacy, unless the acquisition of that drug
17 through a contract pharmacy is prohibited by the
18 United States Department of Human Services; and
19 (2) Any provision of a contract entered into for a drug
20 sold based on the maximum allowable cost payment



1 model, where the payment model was in effect on or
2 before June 30, 2025, shall be void.

3 (b) In addition to any other remedy authorized by
4 section 481B-25, the attorney general may bring a civil action
5 on behalf of any person or persons whose rights under this
6 section have been violated, against any person responsible for
7 violating this section.

8 (c) For purposes of this section:

9 "340B covered entity" means an entity that participates in
10 the 340B drug discount program authorized by 42 United States
11 Code section 256b.

12 "340B drug" means a drug dispensed by a pharmacy and
13 purchased by a 340B covered entity through the 340B drug
14 discount program authorized by 42 United States Code section
15 256b.

16 "Contract pharmacy" means a pharmacy that is not owned or
17 operated by a covered entity but is contracted with to dispense
18 prescription drugs to eligible patients.

19 "Manufacturer" has the same meaning as defined in
20 section 328-112.



1 "Maximum allowable cost" is a payment model for generic
2 drugs that specifies the maximum amount that a pharmacy can be
3 reimbursed for a specific generic drug, regardless of a
4 manufacturer's price.

5 "Pharmacy" has the same meaning as defined in
6 section 461-1.

7 "Wholesale distributor" has the same meaning as defined
8 in section 328-112."

9 SECTION 3. This Act does not affect rights and duties that
10 matured, penalties that were incurred, and proceedings that were
11 begun before its effective date.

12 SECTION 4. New statutory material is underscored.

13 SECTION 5. This Act shall take effect upon its approval.

14
INTRODUCED BY: _____



JAN 17 2025



Report Title:

Consumer Protection; 340B Drug Discount Program; Maximum Allowable Cost

Description:

Prohibits covered entities in the State from entering into contracts with drug manufacturers that limit the covered entities' use of contract pharmacies. Voids contract provisions for certain drugs if the provisions are based on the maximum allowable cost payment model. Authorizes the attorney general to bring a civil action for violations.

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





February 11, 2025 at 2:00 pm
Conference Room 329

House Committee on Consumer Protection and Commerce

To: Chair Scot Z. Matayoshi
Vice Chair Cory M. Chun

From: Hilton R. Raethel
President and CEO
Healthcare Association of Hawaii

Re: **Strong Support**
HB 712 HD 1, Relating to Health

The Healthcare Association of Hawaii (HAH), established in 1939, serves as the leading voice of healthcare on behalf of 170 member organizations who represent almost every aspect of the health care continuum in Hawaii. Members include acute care hospitals, skilled nursing facilities, home health agencies, hospices, assisted living facilities and durable medical equipment suppliers. In addition to providing access to appropriate, affordable, high-quality care to all of Hawaii's residents, our members contribute significantly to Hawaii's economy by employing over 30,000 people statewide.

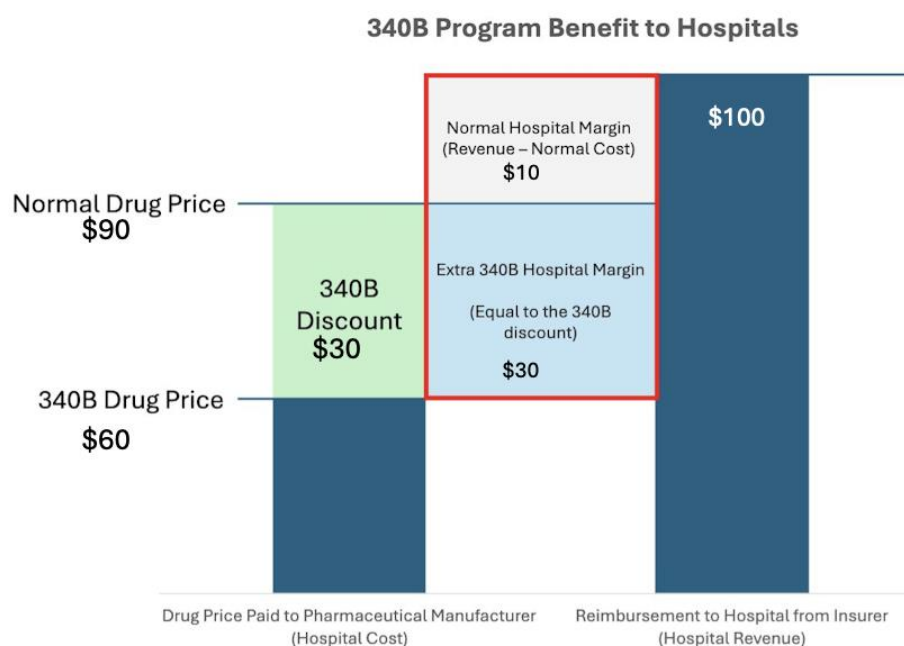
I am writing today in **strong support** of this measure, which would prohibit unfair practices by drug manufacturers to limit the ability of safety-net providers to access discounted outpatient drugs through the 340B drug pricing program. We are suggesting amendments to the measure to strengthen the measure, with language that largely reflects laws that have withstood legal challenge.

More than 20 states have taken action to preserve the integrity of the program and to ensure that community hospitals, health centers, and other essential providers can continue to provide key services and benefits to residents in Hawaii. These unfair practices are currently costing the state at least \$30 million in savings that would be best used to support underserved communities in the state.

Specifically, we are asking the legislature to prohibit drug manufacturers from imposing limitations on the use of contract pharmacies by 340B providers. These unfair, unilateral restrictions take important funding away from non-profit hospitals, community health centers, and other safety net providers, while increasing profits for drug companies. We will provide background in this testimony to help ensure a full understanding of the issue—however, we do not believe that this issue, at its core, is complicated. The major decision to be made is whether \$30 million should stay with Hawaii providers or go to multinational corporations.

History and Mechanics of the 340B Program

The 340B drug pricing program was passed by Congress in 1992 to address two main issues: persistently high drug prices, and access to care for millions of Americans. The 340B program works by increasing the margin that a hospital makes when dispensing a drug. The margin on any transaction is equal to revenue minus cost. A hospital will receive reimbursement from an insurance company for any drug dispensed to a patient to cover the costs of the drug, along with any overhead costs such as labor or space. Under the 340B program, a hospital can acquire eligible drugs at a reduced rate and still receive the same reimbursement. Since their revenue is the same, but the costs are down, then the margin for the hospital increases. This increased margin is often referred to as “savings” generated through the 340B program.



These savings are used by 340B providers for programs such as financial assistance; free wellness visits; transportation to appointments; health education classes, such as comprehensive weight management; free care to indigent patients; and investments in clinical training and workforce development. These savings are especially important for rural hospitals, which are critical facilities that anchor communities and often run zero to negative margins.

Who is Eligible in Hawaii

The federal statute allows non-profit hospitals that serve largely low-income and rural populations to participate in the program. In Hawaii, 15 hospitals qualify to participate in the program—many of which as HHSC facilities. Further, all federally qualified community health centers and Native Hawaiian health centers qualify for the program.

Hospital
Adventist Health Castle
Hilo Medical Center
Kahuku Medical Center
Kapiolani Medical Center for Women and Children
Ka'u Hospital
Kauai Veterans Memorial Hospital
Kona Community Hospital
Maui Health System
Molokai General Hospital
Pali Momi Medical Center
North Hawaii Community Hospital
Samuel Mahelona Memorial Hospital
Straub Clinic and Hospital
Queen's Medical Center
Wilcox Memorial Hospital

All eligible providers run negative, no, or extremely small budget margins. Any additional source of revenue is exceptionally important to providing basic care and ensuring that they are able to stay open and serve their communities.

The Appropriate Role of Contract Pharmacies

Contract pharmacies are a legitimate and important part of the healthcare system. Safety net hospitals typically have limited to no retail pharmacy services, meaning that they are unable to dispense many if not all of the drugs their patients might need on-site. As a result, they must partner (or contract) with pharmacies in the community in order to access the wider inventory needed to adequately serve their patient populations. This is especially true for specialty drugs that require specialized handling, storage, and dispensing. In some cases, those drugs are so specialized that they can only be accessed through specialty pharmacies located outside of the state.

The intent of the 340B program is to provide a *discount on every dose*. The federal statute is indifferent on whether that dose comes directly from a hospital pharmacy, or a partner pharmacy in the community. The federal agency with oversight of the program, the Health Resources and Services Administration, agrees with this interpretation and has long allowed

safety-net providers in the program to partner, or contract with, pharmacies in the community to ensure that providers can realize the full benefits of the program.

Drug companies are exploiting the fact that the federal statute is silent on the use of contract pharmacies, and imposing unilateral, unfair restrictions on their use. As a result, \$30 million in funding that has traditionally been used to support safety-net providers is going directly back to the pockets of drug companies as profit.

What Hawaii Can Do

Hawaii can join the majority of states in the nation in fighting back against these unfair restrictions by passing this measure. The language in this bill largely mirrors measures passed in other states that have successfully withstood legal challenges by the drug industry. The measure allows Hawaii as a state to exercise its right to control drug distribution by prohibiting drug companies from limiting the use of contract pharmacies. We can join the increasing number of states who are protecting safety net providers in their community in passing this court-tested language. *Importantly, states have prevailed in every single case that has been decided on this issue and we believe Hawaii will also be successful if this measure is passed.*

We will continue to work with our state partners on determining the best placement for this measure in statute. We know that the Department of Health, the Attorney General, and other stakeholders have and continue to express strong support of ensuring that the integrity of this program is secured in Hawaii.

At its core, the 340B program is about preserving and expanding healthcare access for people who need it most. This is particularly critical as the current administration and Congress looks to drastically cut funding for safety net providers, including hospitals in Hawaii. Restricting contract pharmacies undermines the ability of hospitals and clinics to serve their communities and, in turn, threatens the health and well-being of the people of Hawaii. We must join with other states to protect our residents and patients and pass this critical legislation.

February 10, 2025

TO: Chair Scot Z. Matayoshi
Vice Chair Cory M. Chun
Members of the House Committee on Consumer Protection and
Commerce
FROM: Pharmaceutical Research and Manufacturers of America (PhRMA)
(William Goo)
RE: **HB 712, HD1** - Relating to Health
Hearing Date: February 11, 2025
Time: 2:00 pm

PhRMA opposes **HB 712, HD1**. Attached is PhRMA's testimony in opposition.

Thank you for considering this testimony.



STATEMENT

In Opposition to Hawaii HB 712

Position: The Pharmaceutical Research and Manufacturers of America ("PhRMA") respectfully opposes HB 712. HB 712 would require biopharmaceutical manufacturers to ship 340B drugs to all pharmacies that contract with 340B "covered entities" and by extension offer 340B pricing at these locations. This type of provision not only raises constitutional concerns but also exacerbates existing problems with the 340B program without ensuring that vulnerable patients needing discounted medicines will benefit.

The 340B hospital markup program has become a hidden tax on employers, patients, and state employees.

Marking up the costs of 340B medicines for employer-sponsored commercial plans and patients with private insurance generates significant revenue for 340B hospitals. These 340B hospitals collect 7 times as much as independent physician offices for the sale of medicines administered to commercially insured patientsⁱ and average spending per patient in the commercial market on outpatient medicines was more than 2.5 times higher at 340B hospitals than non-340B hospitals.ⁱⁱ

In addition, the current design of the program directly increases costs for employers by an estimated 4.2%, or \$5.2 billion, due to reduced rebates from manufacturers, and indirectly increases employer costs by incentivizing provider consolidation and use of higher cost medicines.^{iii,iv} With no obligation to invest profits from 340B markups at satellite facilities into underserved communities, 340B hospitals frequently purchase independent physician offices so they can then buy more medicines and increase their 340B profits. Further, incentives in the 340B program increase the use of higher-cost medicines as hospitals participating in 340B program generally obtain substantially larger profits from more expensive medicines.

In an unprecedented report examining 340B hospital practices in its state, the North Carolina State Treasurer found North Carolina 340B hospitals charged state employees massive markups for oncology medicines. According to the report, North Carolina 340B hospitals charged state employees, on average, a price markup of 5.4 times the hospitals' discounted 340B acquisition cost for outpatient infused cancer medicines. This resulted in billing the North Carolina State Health Plan for Teachers and State Employees a price markup that was 84.8% higher than North Carolina hospitals outside of the 340B program.^v

There is little evidence to suggest that patients have benefited from contract pharmacy growth.

Since 2010, the number of contracts with pharmacies has grown by more than 8,000%, with roughly 33,000 pharmacies participating in the program today. Because the program has no transparency or guardrails on how hospitals and clinics use 340B profits, the money often is not going to help low-income and uninsured patients access medicines. An analysis of contract pharmacy claims for brand medicines only found evidence that patients were directly receiving a discount for 1.4% of prescriptions eligible for 340B.^{vi} Additional studies have found that 65% of the roughly 3,000 hospitals that participate in the 340B program are not located in medically underserved areas,^{vii} and in Hawaii, only 30% of contract pharmacies are located in medically underserved areas.

Research has also found that more than 77% of 340B hospitals provide less charity care than the national average for all hospitals, and they often spend less on charity care and community investment than the estimated value of their tax breaks as nonprofits. In fact, 93% of 340B hospitals in Hawaii are below the national average for charity care levels.

HB 712 will line the pockets of pharmacy benefit managers (PBMs), pharmacy chains, and large hospital systems.

Many contract pharmacies charge a patient based on a drug's full retail price because they are not required to share any of the discount with those in need.^{viii} Big-box retailers such as Walgreens, CVS Health, and Walmart are major participants in the 340B program through contract pharmacy arrangements. Because of vertical integration in the supply chain, PBMs now own the vast majority of pharmacies, meaning they also make a profit from contract pharmacy arrangements. In fact, the five largest for-profit pharmacy chains comprise 60 percent of 340B contract pharmacies, but only 35 percent of all pharmacies nationwide.^{ix} 340B covered entities and their contract pharmacies generated an estimated \$13 billion in gross profits on 340B purchased medicines in 2018, which represents more than 25% of pharmacies' and providers' total profits from dispensing or administering brand medicines.^x Today, the program stands at \$66.3 billion, a 23% growth increase from the previous year.^{xi}

In 2023, the Minnesota Legislature passed legislation^{xii} that requires the Minnesota Department of Health (MDH) to collect and aggregate data from Minnesota providers that participate in the federal 340B program. The Minnesota 340B report provides further evidence that for-profit middlemen are profiting from the 340B program. Payments to contract pharmacies and third-party administrators (TPAs) were over \$120 million, representing approximately \$16 of every \$100 of gross 340B revenue generated paid to external parties. In fact, 10% of safety-net federal grantees reported a negative net 340B revenue due to payments made to middlemen. The top 10% of critical access hospitals and disease-specific grantees with the highest external operational costs lost at least half their gross 340B revenue to TPAs and contract pharmacies.^{xiii}

The Minnesota 340B report also sheds light on the massive profits 340B hospitals retain from the 340B program. Minnesota providers participating in the 340B program earned a collective net^{xiv} 340B revenue of at least \$630 million for the 2023 calendar year. Based on national data, MDH believes this figure may represent as little as half to one-third of the actual total 340B revenue for Minnesota providers due to lack of reporting from the covered entities for office administered drugs.^{xv} Most entities did not report data for office administered drugs, which are estimated to account for 80% of all 340B drug spending.^{xvi} The state's largest 340B hospitals benefitted most from the 340B program, accounting for 13% of reporting entities but representing 80%—more than \$500 million—of net 340B revenue.^{xvii}

The 340B program is a comprehensive federal program that is governed exclusively by federal law. States do not have the authority to create new requirements that are not in the federal statute or that conflict with the statute. Whether manufacturers can be required to ship drugs to contract pharmacies for 340B providers is currently being litigated in multiple federal courts across the country.

PhRMA respectfully opposes the provisions outlined above and appreciates your consideration prior to advancing HB 712.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than \$800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

ⁱ Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance, New England Journal of Medicine, 390, 4, (338-335), (2024). DOI: [10.1056/NEJMsa2306609](https://doi.org/10.1056/NEJMsa2306609)

ⁱⁱ Hunter MT, et al. "Analysis of 2020 Commercial Outpatient Drug Spend at 340B Participating Hospitals." Milliman, September 2022. https://www.milliman.com/-/media/milliman/pdfs/2022-articles/9-13-22_phrma-340b-commercial-analysis.ashx

ⁱⁱⁱ Sun C, Zeng S, Martin R. "The Cost of the 340B Program Part 1: Self-Insured Employers." IQVIA, March 2024. <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/iqvia-cost-of-340b-part-1-white-paper-2024.pdf>

^{iv} Sun C, Zeng S, Martin R. "The Cost of the 340B Program Part 2: 340B Revenue Sharing." IQVIA, March 2024. <https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2024/the-cost-of-the-340b-program-part-2-340b-revenue-sharing.pdf>

^v North Carolina State Treasurer. "Overcharged: State Employees, Cancer Drugs, and the 340B Drug Pricing Program." May 2024. Access: <https://www.shpnc.org/documents/overcharged-state-employees-cancer-drugs-and-340b-drug-price-program/download?attachment>

^{vi} IQVIA. "Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies." Oct. 10, 2022. Access: <https://www.iqvia.com/locations/united-states/library/fact-sheets/are-discounts-in-the-340b-drug-discount-program-being-shared-with-patients-at-contract-pharmacies>.

^{vii} Alliance for Integrity & Reform. "340B – A Missed Opportunity to Address Those That Are Medically Underserved." 2023 Update. Access: https://340breform.org/wp-content/uploads/2023/07/340B_MUA_July23-4.pdf.

^{viii} Conti, Rena M., and Peter B. Bach. "Cost consequences of the 340B drug discount program." *Jama* 309.19 (2013): 1995-1996.

^{ix} Government Accountability Office, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," GAO-18-480, June 2018.

^x Berkeley Research Group. For-Profit Pharmacy Participation in the 340B Program. October 2020.

^{xi} Fein, Adam. The 340B Program Reached \$66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions. Drug Channels. Oct. 22, 2024.

<https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html>

^{xii} 2023 Minnesota Statutes, Section 62J.312

^{xiii} Minnesota Department of Public Health, "340B Covered Entity Report," Nov. 25, 2024. <https://www.health.state.mn.us/data/340b/docs/2024report.pdf>

^{xiv} MDH defines "net" as the difference between the payments received for discounted drugs (\$1.5 billion), and the cost of acquiring those drugs (\$734 million) plus payments to external administrators (\$120 million). (see p.7)

^{xv} The Minnesota Legislature amended the transparency law in 2024 to explicitly require covered entities to report data for office-administered drugs. See 2024 Minnesota Statutes, Section 62J.461

^{xvi} Spending in the 340B Drug Pricing Program, 2010 to 2021 (<https://www.cbo.gov/system/files/2024-06/60339-340B-DrugPricing-Program.pdf>)

^{xvii} Minnesota Department of Public Health, "340B Covered Entity Report," Nov. 25, 2024. <https://www.health.state.mn.us/data/340b/docs/2024report.pdf>



Hawai'i Island Community Health Center

75-5751 Kuakini Highway Suite 203, Kailua Kona, HI 96740

(808) 326-5629

www.hicommunityhealthcenter.org

February 10, 2025

The Honorable Scot Matayoshi
Chair, House District 49
Hawai'i State Capitol, Room 422
Phone: (808) 586-8470

The Honorable Cory Chun
Vice Chair, House District 35
Hawai'i State Capitol, Room 406
Phone: (808) 586-6170

RE: CALL FOR SUPPORT OF HB-712, RELATING TO THE 340B DRUG PRICING PROGRAM

Dear Representative Matayoshi & Representative Chun,

On behalf of the Hawai'i Island Community Health Center (HICHC), I am writing to express our strong support for HB-712, which seeks to prohibit drug manufacturers from restricting access to 340B medications at contract pharmacies. This critical legislation will help ensure that community health centers, rural clinics, and other safety-net providers can continue to offer affordable medications and essential healthcare services to our most vulnerable patients.

In 2022, Bay Clinic and West Hawai'i Community Health Center, both non-profit Federally Qualified Health Centers, merged operations as Hawai'i Island Community Health Center. This bold move created an integrated system focused on quality care and the delivery comprehensive health services island wide. Our mission is to provide accessible, high-quality, patient-centered healthcare that is culturally responsive and advances health equity for all individuals on Hawai'i Island. Our vision is a healthier island community where everyone has the opportunity to thrive. We are guided by our core values of compassion, respect, humility, advocacy, and excellence in everything we do.

The 340B Drug Pricing Program is a vital tool that enables health centers like HICHC to stretch scarce federal resources, reinvest in patient care, and provide comprehensive services to those in need, regardless of their ability to pay. The savings from the 340B program allow us to offer a sliding fee discount on prescriptions, ensuring that patients can afford their medications. Last year, we leveraged the 340B Drug Pricing Program to save our patients over 1.4 million dollars in direct medication costs through our sliding fee discount program. Additionally, we provide clinical pharmacy services, dental care, behavioral health, enabling services, women's health services, medication mail order, medication delivery, durable medical equipment services, prior authorization processing, and prescription refills by protocol. These services are critical to ensuring that patients, especially those in rural and underserved communities, receive the care they need without financial barriers.

However, in recent years, drug manufacturers have implemented restrictive policies that severely limit our ability to access 340B-priced medications through contract pharmacies. These restrictions disproportionately impact patients in rural and underserved communities, where contract pharmacies serve as an essential point of access for affordable medications. This is especially true in our health system as we have only one Entity-Owned Pharmacy to service the prescription needs of the 38,000 patients we serve.

As a result of these contract pharmacy restrictions, HICHC has experienced significant financial strain, forcing us to reassess the scope of critical services we provide. If these restrictions continue, the ability to sustain key programs, including those offered by our clinical pharmacy team, such as Hepatitis C treatment and anticoagulation services will be severely compromised. Hepatitis C treatment is essential for preventing liver disease and cancer in our community, while anticoagulation services are critical for patients managing conditions such as atrial fibrillation and clotting disorders. Without access to discounted 340B medications, the cost burden on our patients will increase, and reduced funding will limit our capacity to provide these lifesaving treatments.

By prohibiting these harmful restrictions, HB-712 will help protect the integrity of the 340B program and ensure that patients continue to receive the care and medications they need. We urge you and your colleagues to advance this bill to safeguard healthcare access for the residents of Hawai'i.

Thank you for your leadership and commitment to protecting healthcare access for our communities. We appreciate your consideration and support for this important legislation. Please feel free to contact us if you have any questions or if we can provide further information.

With Aloha,

A handwritten signature in black ink, appearing to read 'MelniB', with a long horizontal flourish extending to the right.

Melissa Bumgardner, Pharm.D., BCPS,
Director of Pharmacy Services



To: The Honorable Scot Z. Matayoshi, Chair
The Honorable Cory M. Chun, Vice Chair
Members, House Committee on Consumer Protection & Commerce

From: Jace Mikulanec, Director, Government Relations, The Queen's Health System

Date: February 11, 2025

Re: Support for HB712 HD1: Relating to Health

The Queen's Health Systems (Queen's) is a nonprofit 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, and more than 10,000 affiliated physicians, caregivers, and dedicated medical staff 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 provide testimony in support of HB712 HD1, which prohibits drug manufacturers and wholesale distributors from restricting or denying access for pharmacies contracted with 340B covered entities to purchase 340B drugs at a discounted price under the federal 340B Drug Pricing Program. We appreciate the amendments made in the previous committee with regard to wholesale manufacturers, however, we do believe this language is better suited in HRS321. We are working with the relevant state Departments to further clarify our position on this later issues.

The Queen's Health Systems' hospitals relies on 340B program savings to stretch scarce federal resources to reach more patients and provide more comprehensive services exactly as Congress intended when they created the 340B program over 30 years ago. QHS 340B hospitals use affiliated and community based retail and specialty mail order pharmacies to expand the reach of the 340B program to allow patients to receive 340B drugs close to their home or work via a well-defined contract pharmacy network. These contract pharmacy relationships are required to adhere to all of the same rules and regulations governing the 340B program as the covered entity 340B hospitals.

Queen's 340B contract pharmacy networks have operated with great integrity since their inception, but in early 2020 as Hawai'i and the rest of the world was trying to deal with the Covid-19 pandemic, a handful of the world's most profitable drug manufactures created unnecessary and burdensome barriers to 340B pricing. More than four years later, the number of manufactures nationally who restrict access to 340B pricing for hospitals has grown to 38. Many of the

The mission of The Queen's Health System is to fulfill the intent of Queen Emma and King Kamehameha IV to provide in perpetuity quality health care services to improve the well-being of Native Hawaiians and all of the people of Hawai'i.

manufactures only allow shipping of their drugs to the 340B hospital parent or hospital outpatient clinics directly which is in direct conflict of the 340B program's intent of reaching more patients. These unilateral and arguably unlawful manufacture restrictions cost hospitals billions of dollars annually in increased drug cost and lost revenue. This is particularly troubling in today's healthcare landscape where rural and critical access hospitals are asked to do more with less and are ceasing to exist with greater frequency; the result creating increasing challenges to access for populations who need services the most.

In Hawai'i, the manufactures' 340B contract pharmacy policies, again in direct conflict with the Congress' stated intent for 340B, cost Queen's and other Hawai'i hospitals and health center millions in excess drug cost and lost revenue from their contract pharmacies. We implore you to take action to hold these companies accountable and protect the hospital and healthcare safety net that our communities depend on.

Thank you for the opportunity to testify in strong support of HB712 HD1.



HAWAI'I HEALTH
& HARM REDUCTION CENTER
The New Chapter for Life Foundation and The CHOW Project

LATE

TESTIMONY IN SUPPORT OF HB 712, HD 1

TO: Chair Matayoshi, Vice Chair Chun, & CPC Committee Members

FROM: Nikos Leverenz
Policy & Advancement Manager

DATE: February 11, 2025 (2:00 PM)

Hawai'i Health & Harm Reduction Center (HHHRC) **strongly supports** HB 712, HD 1, which prohibits drug manufacturers and wholesale distributors from restricting or denying access for pharmacies contracted with 340B covered entities to purchase 340B drugs at a discounted price under the federal 340B Drug Pricing Program.

The 340B Drug Discount Program was established in 1992 to help safety-net providers such as critical access hospitals and federally qualified health centers stretch their scarce resources to serve the most vulnerable populations. The savings realized by these covered entities through the 340B program are required, by statute, to be reinvested back into the communities they serve by expanding patient access to services that would normally be unfunded. These services include adult dental care, enabling services, clinical pharmacy programs, and affordable medication programs. Contract pharmacies serve as extensions of the covered entities, increasing patient access by reducing geographic and financial access barriers. 4 out of 10 health centers rely solely on contract pharmacies and 9 out of 19 health centers use contract pharmacies to meet their community's medication access needs.

Since 2020, drug manufacturers have begun restricting access to 340B priced medications at contract pharmacies such that 39 manufacturers now restrict shipments of their medications with limitations varying by covered entity type. This has resulted in dramatic decreases in the financial resources needed to support these otherwise unfunded patient access programs. Patient access to care and clinical outcomes suffer as a result.

HHHRC's mission is to reduce harm, promote health, create wellness, and fight stigma in Hawai'i and the Pacific. We work with many individuals who are impacted by poverty, housing instability, and other social determinants of health. Many have behavioral health problems, including those relating to substance use and underlying mental health conditions. Many of our clients and participants have been deeply impacted by trauma, including histories of physical, sexual, and psychological abuse.



**WAIANAE COAST
COMPREHENSIVE
HEALTH CENTER**

LATE

**Monday, February 11, 2025 at 2:00 PM
State Capitol, Conference Room 329 & Videoconference**

HOUSE COMMITTEE ON CONSUMER PROTECTION & COMMERCE

**To: Chair Scot Z. Matayoshi
Vice Chair Cory M. Chun**

**From: Ian Ross
Public Affairs Director
ianross@wcchc.com | 808-652-3380**

RE: TESTIMONY IN SUPPORT OF HOUSE BILL 712 HD1 - RELATING TO HEALTH

Aloha Chair Matayoshi, Vice Chair Chun, and Members of the Committee,

I am submitting this testimony on behalf of the Waianae Coast Comprehensive Health Center (WCCHC) in **support of House Bill 712 HD1**, which protects the 340B Drug Pricing Program and ensures that covered entities, such as Federally Qualified Health Centers (FQHCs), can continue to access prescription medications at prices that support the communities we serve.

Waianae Coast Comprehensive Health Center (WCCHC) is a Federally Qualified Health Center dedicated to improving the health and well-being of the West O'ahu community through accessible and affordable medical and traditional healing services, including outreach to people experiencing homelessness, crucial for our community's wellbeing. With 52 years of service, WCCHC remains committed to providing comprehensive healthcare by addressing social determinants of health. The 340B Drug Pricing Program helps us to fulfill this mission.

The 340B program allows WCCHC to purchase medications at significantly reduced costs. These savings fund critical healthcare services that otherwise would not be financially sustainable. Through 340B, WCCHC is able to expand access to chronic disease management, social services, community outreach, and transportation assistance to help patients reach the care they need.

In recent years, pharmaceutical industry restrictions have increasingly limited the ability of FQHCs to fully participate in the 340B program. These restrictions have led to millions of dollars in lost savings, which in turn jeopardize essential healthcare services. Without action, community health centers will be forced to scale back critical programs, ultimately making healthcare less accessible.

House Bill 712 protects FQHCs from being unfairly limited access to 340B pricing and that covered entities can continue using contract pharmacies to serve their patients. **We humbly ask the Committee to pass House Bill 712 HD1** to safeguard the 340B program, which remains a vital tool in advancing health equity and ensuring that underserved communities receive the care they need.



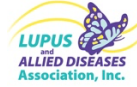
Biomarker
Collaborative



COALITION OF HEMATOLOGY
AND ONCOLOGY PRACTICES



HISPANIC
BUSINESS
ALLIANCE



MET
CRUSADERS



NATIONAL
INFUSION CENTER
ASSOCIATION



Neuropathy
Action
Foundation
Research • Education • Empowerment

PDL1
Amplifieds

LATE

Dear Hawaii Legislator:

On behalf of 10+ patient and provider advocacy organizations, we are writing to express our concerns regarding Senate Bill 480. While we appreciate the intent of this bill to improve healthcare access in Hawaii, we believe it is premature to advance new policies without first addressing existing challenges within the 340B program to ensure it effectively serves vulnerable populations.

Despite Hawaii having the lowest healthcare costs in the nation due to strong state laws, access to healthcare remains a challenge, particularly in rural and underserved areas. Hawaii's healthcare spending per capita was \$12,024 in 2020, and only 3.94% of residents were uninsured in 2021. However, the state faces significant barriers, including geographic, sociocultural, and economic challenges.

The 340B Drug Pricing Program was established in 1992 to increase access to affordable medications for underserved patients by providing discounted pricing for drugs purchased by eligible healthcare entities. Despite its intended purpose of expanding healthcare access for underserved communities, the 340B program's growth has increasingly favored higher-income areas, contributed to rising healthcare costs, and failed to deliver proportional reinvestment in charity care.

- **Growth in Wealthier Areas:** 60% of 340B sites are in areas with higher median incomes, with expansion favoring high-income neighborhoods (+5%) while declining in low-income areas (-5.6%).
- **Higher Costs, No Clear Benefit:** 340B growth added \$32B annually in Medicaid spending (2014-2021), yet care disparities persist. Prescription costs at 340B entities are 150% higher for commercially insured patients.
- **Declining Charity Care:** Top 340B entities reinvest just \$1 in charity care for every \$10 in profit. In Hawaii, the charity care rate (0.6%) falls below the national average (2.5%), while 340B earnings outpace charity spending 12:1.

Reform of the 340B program is critical to ensuring it fulfills its original purpose of improving access to affordable medications for underserved communities. Any legislative action on 340B should emphasize transparency, accountability, and equity by ensuring that program savings directly benefit patients, incentivizing service expansion in rural and underserved areas, and requiring 340B entities to demonstrate how revenues are reinvested in the communities they serve. Expanding the program without addressing its shortcomings risks harming patients and local providers while perpetuating inefficiencies in the healthcare system.

We need to be sure the program works as originally intended: to improve access and health equity in Hawaii.

Sincerely,

Alliance for Safe Biologic Medicines
Biomarker Collaborative
Coalition of Hematology & Oncology Practices
Exon20 Group
H.E.A.L.S. of the South
Hispanic Business Alliance

International Cancer Advocacy Network (ICAN)
Lupus and Allied Diseases Association, Inc.
MET Crusaders
National Infusion Center Association (NICA)
Neuropathy Action Foundation
PDL1 Amplifieds



Biotechnology Innovation Organization
1201 New York Ave, NW, Suite 1300
Washington, DC, 20005
202-962-9200

LATE

February 11, 2025

The Honorable Scot Matayoshi
Chair, House Committee on Consumer Protection & Commerce
Hawai'i House of Representatives
415 S Beretania St.
Honolulu, HI 96813

Dear Representative Matayoshi and Members of the Committee:

The Biotechnology Innovation Organization (BIO) has an **oppose** position on **HB 712**, which is currently before your committee. This bill would prohibit biopharmaceutical manufacturers participating in the federal 340B Drug Discount Program ("340B Program") from establishing requirements or standards intended to ensure compliance with federal laws. BIO has very serious concerns with these provisions, which would enact state requirements in an exclusively federal program and would preclude legitimate efforts to ensure transparency and integrity in the 340B Program.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life- saving medicines and vaccines for all individuals.

The 340B Program was enacted in 1992 to provide steeply discounted drugs to certain qualified hospitals and clinics, collectively referred to as "covered entities," intended to support these facilities' care to uninsured and underinsured patients. Covered entities are able dispense discounted drugs to patients and receive reimbursement by commercial payers at the full price, keeping the difference and providing a revenue stream for the covered entity. However, under federal law, 340B drugs cannot be subject to Medicaid rebates when dispensed to Medicaid beneficiaries ("duplicate discounts"). Additionally, 340B drugs may only be dispensed to patients of a covered entity; dispensing 340B drugs to ineligible patients is prohibited and referred to as "diversion" from the 340B program.

The 340B program has grown exponentially in volume over the past decade. the 340B program has expanded in ways that no one could have foreseen. From 2015 to 2021, purchases under

the program grew at an average rate of 24% per year and as of 2023 totaled \$66.3 billion.^{1, 2} 340B is now the second largest pharmaceutical program in the nation behind Medicare Part D.³ An October 2020 study found that from April 2010 to April 2020, contract pharmacy arrangements in the program grew by 4,228% from 2,321 in 2010 to 101,469 today.⁴ Because of this explosive growth in the 340B Program, it is important to ensure all appropriate federal laws are being followed and all steps are taken to prevent fraud, waste, and abuse.

In addition to 340B covered entities dispensing drugs directly to patients, the Health Resources and Services Administration (HRSA), which implements the program, has issued sub-regulatory guidance to allow covered entities to contract with outside pharmacies to dispense drugs to covered entities' patients. However, a heightened risk for duplicate discounts and diversion at contract pharmacies exists because, unlike at covered entities' in-house pharmacies, most of the patients visiting contract pharmacies are not eligible for 340B drugs. The federal Government Accountability Office (GAO) reports that contract pharmacies are a significant source of diversion and duplicate discounts, in part, because they often do not identify patients as 340B-eligible until after the prescription has been dispensed.⁵ In fact, the GAO also notes, "66 percent of the 380 diversion findings in HRSA audits involved drugs distributed at contract pharmacies."⁶

HRSA's main mode of enforcing the 340B program is through random audits. They audit 200 covered entities per year, and problems with duplicate discounts and diversion are common findings in audits, as well as working with "contract pharmacies" without any actual contract in place. Idaho facilities are found to have compliance issues approximately on par with the rest of the country. A report by the federal GAO in 2018 found that 72 percent of audits had findings of noncompliance.⁷ Unfortunately, the HRSA audit program has limitations, as indicated in the title of GAO's 2018 report: "Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement."

Adding further concern to compliance concerns with contract pharmacies, HRSA does not even cite audit findings of noncompliance if the noncompliance is by a contract pharmacy. In another report in 2021, GAO states "HRSA officials told GAO that, beginning in fall 2019, the agency started issuing findings only when audit information presents a clear and direct violation of the requirements outlined in the 340B Program statute. HRSA officials explained that guidance, which is used to interpret provisions of the 340B statute for the purposes of promoting program compliance among covered entities, does not provide the agency with appropriate enforcement capability. For example, *HRSA officials reported that there were instances among fiscal year 2019 audits in which the agency did not issue findings for a failure to comply with guidance related to contract pharmacies in part because the 340B statute does not address contract pharmacy use and, therefore, there may not have been a clear statutory violation*" (emphasis added).⁸

¹ Fein, Adam, "What I (and Others) Told the Senate about the 340B Drug Pricing Program." Drug Channels, August 8, 2023. Accessed September 14, 2023. <https://www.drugchannels.net/2023/08/what-i-and-others-told-senate-about.html>

² Fein, Adam, The 340B Program Reached \$66 Billion in 2023- Up 23% vs 2022: Analyzing the Numbers and HRSA's Curious Actions." Drug Channels. October 22, 2024. Accessed December 10, 2024.

³ Blalock, Eleanor. Measuring the Relative Size of the 340B Program, BGR Group, June 2022.

⁴ Vandervelde, Aaron, et al., For-Profit Pharmacy Participation in the 340B Program, BRG Group, October 2020.

⁵ *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO Report, June 2018.

⁶ Ibid.

⁷ Ibid.

⁸ *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, GAO Report, December 2020.

We strongly oppose this bill's provisions intended to prohibit biopharmaceutical manufacturers participating in the 340B Program from establishing requirements or standards to ensure compliance with federal laws. The use of contract pharmacies in the 340B Program simply has not been adequately policed by HRSA. It is for this reason that some manufacturers have put in place requirements for covered entities that use multiple contract pharmacies. This particular issue is currently being litigated in several federal courts, as there is no statutory requirement for manufacturers to extend 340B prices to contract pharmacies. Contract pharmacy was created through sub-regulatory federal guidance (guidance that HRSA itself has acknowledged is legally unenforceable⁹). This bill's provisions are nearly identical to bills in nearly *two dozen* other states this year, which are part of an effort by covered entities to inappropriately enshrine *their* interpretation of federal law into state statutes. Yet the belief that manufacturers have no ability to establish standards and must provide discounted 340B drugs to all contract pharmacies, regardless of a history of noncompliance, has been rejected by multiple courts.

Even beyond the exclusive federal jurisdiction of the 340B program and the multiple pending federal lawsuits, the policy contained in these provisions is flawed. Biopharmaceutical manufacturers have participated in the 340B Program for 30 years and, in doing so, provided hundreds of billions of dollars in financial support to covered entities. However, when evidence exists that certain arrangements (i.e., contract pharmacies) result in increased rates of illegal duplicate discounts and diversion of 340B drugs, it is untenable to preclude manufacturers from implementing *any* standards. In doing so, the state would be facilitating contract pharmacies' noncompliance with federal statute.

For these reasons, we respectfully oppose HB 712 and urge your NO vote on this measure. If you have any questions, please do not hesitate to contact me at bwarren@bio.org.

Sincerely,



Brian Warren
Vice President, State Government Affairs

⁹ "HRSA Urges Pharma to Continue 340B Discounts at Contract Pharmacies," *Inside Health Policy*, August 20, 2020.



ALOHA CARE

LATE

To: The Honorable Scot Z. Matayoshi, Chair
The Honorable Cory M. Chun, Vice Chair
House Committee on Consumer Protection and Commerce

From: Paula Arcena, External Affairs Vice President
Mike Nguyen, Public Policy Manager
Sarielyn Curtis, External Affairs Specialist

Hearing: Tuesday, February 11, 2025, 2:00PM, Conference Room 329

RE: **HB712 HD1 Relating to Health**

AlohaCare appreciates the opportunity to provide testimony in **support** of **HB712 HD1**. This measure prohibits drug manufacturers from denying, restricting, or prohibiting the acquisition, shipping, or delivery of a 340B drug to pharmacies contracted with 340B covered entities under the federal 340B Drug Pricing Program.

Founded in 1994 by Hawai'i's community health centers, AlohaCare is a community-rooted, non-profit health plan serving over 70,000 Medicaid and dual-eligible health plan members on all islands. Approximately 37 percent of our members are keiki. We are Hawai'i's only health plan exclusively dedicated to serving Medicaid and Medicaid-Medicare dually-eligible beneficiaries. Our mission is to serve individuals and communities in the true spirit of aloha by ensuring and advocating for access to quality, whole-person care for all.

AlohaCare is committed to improving access to affordable, comprehensive care, especially for underserved and vulnerable low-income populations. This measure ensures that 340B covered entities—such as community health centers, Native Hawaiian Health Systems, hospitals, and other safety net providers—are able to stretch scarce financial resources as far as possible, reaching more eligible patients and providing more comprehensive services. Under the 340B program, drug manufacturers participating in Medicaid agree to provide outpatient drugs to covered entities at significantly reduced prices. These safety net providers reinvest 340B savings into a range of essential community benefits, such as social services, free wellness visits, vaccinations, health education classes, and workforce development programs.

It's our understanding that in recent years, drug manufacturers have implemented restrictive policies that limit covered entities' access 340B pricing through contract pharmacies, threatening access to affordable medications and other critical programs. This measure addresses these practices and protects the integrity of the 340B program and ensures that patients continue to receive the care and medications they need.

Mahalo for this opportunity to testify in **support** of **HB712 HD1**.

HB-712-HD-1

Submitted on: 2/9/2025 12:53:13 PM

Testimony for CPC on 2/11/2025 2:00:00 PM

Submitted By	Organization	Testifier Position	Testify
Rev. Dr. Robert W. Nelson	Individual	Support	Written Testimony Only

Comments:

I support this measure to increase access to affordable child care for Hawai'i's families.

HB-712-HD-1

Submitted on: 2/10/2025 1:52:46 PM

Testimony for CPC on 2/11/2025 2:00:00 PM

Submitted By	Organization	Testifier Position	Testify
Kelsey Kaku	Individual	Support	Remotely Via Zoom

Comments:

I strongly support the bill that prohibits drug manufacturers or any agents or affiliates from restricting or denying access to 340B drugs at discounted prices for pharmacies contracted with 340B covered entities. The 340B Drug Pricing Program was established to support safety-net providers, such as critical access hospitals and federally qualified health centers, in their mission to serve vulnerable populations. The savings generated by the program are reinvested back into the communities, expanding access to vital services like adult dental care, clinical pharmacy programs, and affordable medications. Contract pharmacies play a critical role in increasing access by overcoming geographic and financial barriers. Yet, since 2020, drug manufacturers have increasingly restricted 340B drug access at these pharmacies, severely limiting the resources needed to sustain essential services. This has had a direct impact on patient care and clinical outcomes. This bill is vital to protect the integrity of the 340B program and ensure continued access to care for those who need it most.