

**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'OKELE

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April 1, 2025

To: COMMITTEE ON WAYS AND MEANS

Senator Donovan M. Dela Cruz, Chair Senator Sharon Y. Moriwaki, Vice Chair
COMMITTEE ON JUDICIARY Senator Karl Rhoads, Chair Senator Mike Gabbard,
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.

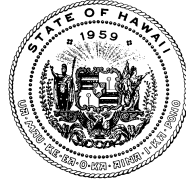
The 340B program helps stretch limited resources, allowing hospitals to reinvest savings into essential community benefits. These benefits include financial assistance for low-income patients, free wellness visits, screenings, vaccinations, transportation to appointments, health education classes, and 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.



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KENNETH S. FINK, M.D., M.G.A., M.P.H.
DIRECTOR OF HEALTH
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**Testimony COMMENTING on HB712 HD2 SD1
RELATING TO HEALTH.**

SEN. DONOVAN M. DELA CRUZ, CHAIR
SENATE COMMITTEE ON WAYS AND MEANS

SEN. KARL RHOADS, CHAIR
SENATE COMMITTEE ON JUDICIARY

Hearing Date: April 1, 2025

Room Number: 211

1 **Department Testimony:** The Department of Health (DOH) supports this measure with
2 amendments.

3 This program is vital for Hawaii's overall health care system and for DOH, which depends on
4 340B pricing to deliver services to some of the most vulnerable populations, such as through the
5 department's Sexually Transmitted Infection clinic and HIV Drug Assistance Program.

6 Hawaii's not-for-profit health care system is caught up in a larger national struggle to maximize
7 profits for for-profit pharmaceutical companies by targeting contract pharmacies. Rural
8 communities are unable to support more robust health care infrastructure and must rely on
9 contract pharmacies and other health care providers who make the conscious decision to practice
10 in underserved areas. Those providers deserve support and the proposed amendments strike a
11 balance between the pharmaceutical industry's concerns about fraudulent program participation
12 and assuring access to care in rural and underserved patients.

13 Thank you for the opportunity to testify.

14 **Offered Amendments:** Strike from page 6, line 16 through page 11, line 12, "Covered entity
15 transparency to increase accountability to safeguard benefit" and replace with:

1
2 § -6 Reporting by 340B Covered Entities. Each 340B
3 covered entity participating in the federal 340B Drug Pricing
4 Program pursuant to section 340B of the Public Health Service
5 Act (42 U.S.C. § 256b) shall annually submit to the department
6 of health an attestation that it is compliant with all federal
7 requirements of the program. The department may prescribe the
8 form and manner of submission and may adopt rules pursuant to
9 chapter 91 to effectuate the purposes of this section.

10
11 Add in a severability clause as a new Bill Section:
12

13 If any provision of this Act or the application thereof to
14 any person or circumstance is held invalid, the invalidity does
15 not affect other provisions or applications of the Act that can
16 be given effect without the invalid provision or application,
17 and to this end the provisions of this Act are severable.



HAWAII' I HEALTH &
HARM REDUCTION CENTER

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*"Reducing harm,
promoting health,
creating wellness, and
fighting stigma
in Hawai'i and
the Pacific."*

TESTIMONY IN SUPPORT OF HB 712, HD 2, SD 1

TO: Chair Dela Cruz, Vice Chair Moriwaki, & WAM Committee
Chair Rhoads, Vice Chair Gabbard, & JDC Committee

FROM: Nikos Leverenz, Policy & Advancement Manager

DATE: April 1, 2025 (10:00 AM)

Hawai'i Health & Harm Reduction Center (HHHRC) **strongly supports** HB 712, HD 2, SD 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.

Thank you for the opportunity to testify on this measure.



**Testimony to the Senate Joint Committee on Ways and Means and
Judiciary
Tuesday, April 1, 2025; 10:00 a.m.
State Capitol, Conference Room 211
Via Videoconference**

RE: HOUSE BILL NO. 0712, HOUSE DRAFT 2, SENATE DRAFT 1, RELATING TO HEALTH.

Chair Dela Cruz, Chair Rhoads, 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 2, Senate Draft 1, RELATING TO HEALTH.

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. The measure further clarifies that the prohibition against certain discriminatory acts does not deny, restrict, or prohibit a manufacturer from requiring a 340B covered entity to provide claims information for the manufacturer's 340B drugs, and requires the Department of Health to compile claims data and to report this information annually to the Legislature

This measure would take effect on December 31, 2050.

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 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.

Accordingly, 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@hawaiiipca.net.



April 1, 2025 at 10:00 am
Conference Room 211

Senate Committee on Ways and Means

To: Chair Donovan M. Dela Cruz
Vice Chair Sharon Y. Moriwaki

Senate Committee on Judiciary

To: Chair Karl Rhoads
Vice Chair Mike Gabbard

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

Re: Support with Amendments
HB 712 HD 2 SD 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 **support with amendments** to 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. This year alone, nearly 30 states are moving legislation 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 states join the seven states that have already passed legislation on this.) While we support this bill moving forward, **critical amendments are required to ensure the integrity of this program and allow resource-strapped, safety-net providers to continue to participate.**

If this bill does not pass, Hawaii's safety net hospitals stand to lose an estimated **\$30 million every year**—funds that are critical to sustaining basic care and services in underserved communities. This loss would come at a time when these providers are already facing the

threat of deep federal funding cuts, compounding financial pressure and jeopardizing access to care for thousands of Hawaii residents.

The question before many legislatures is simple: should critical funding remain with local hospitals and clinics that care for our communities, or be redirected to the profits for multinational pharmaceutical corporations? More than 20 states have answered this question by supporting their healthcare systems and acting to preserve the integrity of this program and allowing essential providers to continue serving and investing in their communities.

340B Transparency and Oversight Requirements

There have been many accusations over this session that hospitals and health centers lack oversight. When pressed, none of these accusations can be backed up and no examples have been provided of fraud and abuse in either public or private settings.

That is because hospitals and health centers participating in the 340B program are subject to strict federal oversight. They must maintain detailed records showing that each 340B-purchased drug was dispensed to an eligible patient, in accordance with the program's eligibility criteria. These records are regularly audited by the Health Resources and Services Administration (HRSA), and providers found to be noncompliant may face repayment demands and removal from the program. Drug manufacturers are also able to request access to these records so that they may complete their own review if they suspect fraud.

The requirements for reporting in this bill are not designed to actually improve any transparency or oversight of the program—in fact, the requirements fall short of what is already required to be submitted to the federal government for verification by 340B covered entities. Instead, these amendments are designed entirely to make it more onerous for small, safety-net providers to participate in the program. This tactic is consistent with the past 30 years of work that drug manufacturers have done to chip away at the benefits of this program in order to grow their own bottom lines. We suggest an amendment to attest to the Department of Health that providers meet federal standards, which are already stringent and come with penalties, including termination from the program entirely.

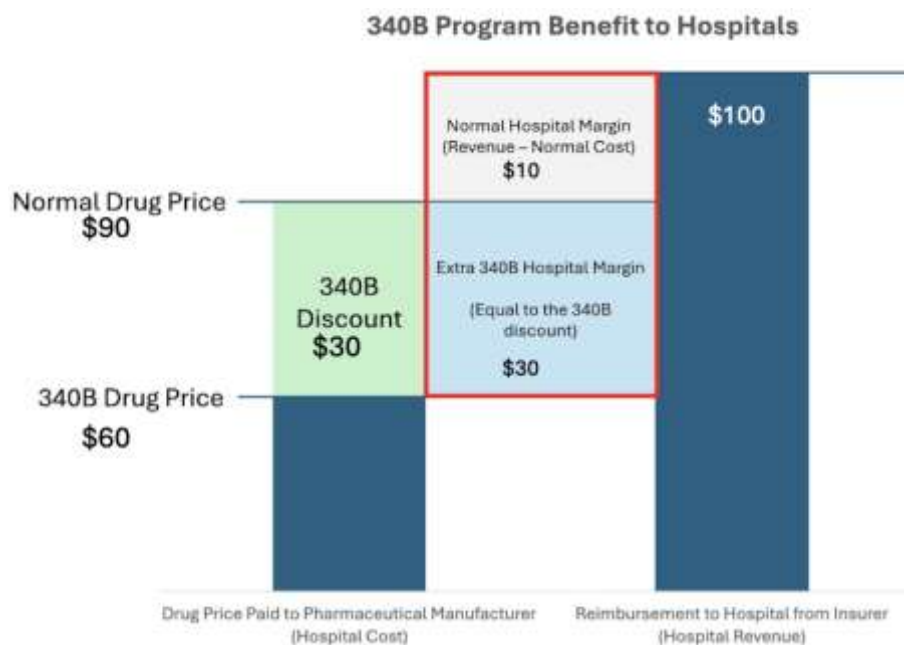
Further, hospitals provide detailed reports of their community benefits, noting the programs, services, and personnel supported and the dollar amounts they dedicate to these benefits. Drug manufacturers distort how safety net hospitals support their communities by focusing solely on charity care. This is misguided, since charity care is only indicative of the amount of care provided to patients who qualify for the hospital's financial assistance policy and is therefore provided to the patient free of cost. It does not account for costs that hospitals incurred for services where payment was expected but not received (bad debt) or payment shortfalls from public payers like Medicaid (underpayments).

Therefore, it is more accurate to look at a hospital's total uncompensated care (bad debt and charity care) and their total community benefits, which among other costs includes

uncompensated care costs as well as payment shortfalls. In 2020, 340B hospitals provided nearly \$85 billion in total community benefits—much more than the approximately \$46 billion they receive in discounted drugs. 340B hospitals are providing these high levels of uncompensated care and community benefits despite many of these hospitals operating on razor-thin margins.

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

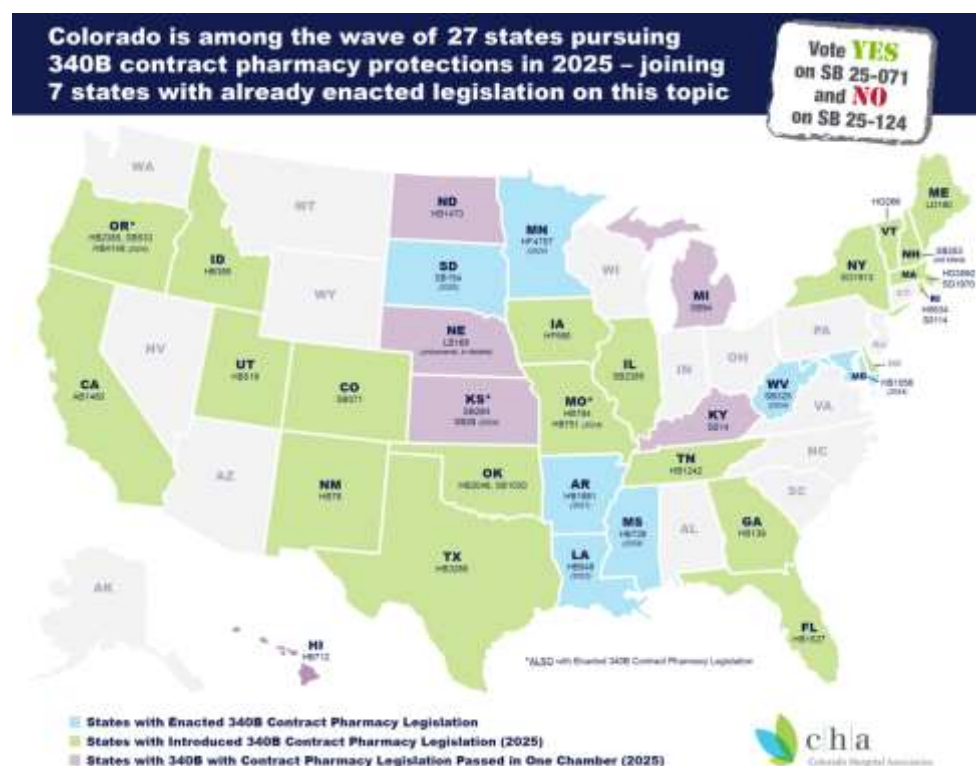
safety-net providers in the program to partner, or contract with, pharmacies in the community to ensure that providers can realize the full benefits of the program.

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 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.*

The Colorado Hospital Association has been tracking the states who have either passed or are considering similar legislation. This is a widely bipartisan issue that states are active on. Since this graphic was published, North Dakota passed its own legislation prohibiting the unfair drug manufacturer practices that we are targeting in this legislation.



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.

We respectfully request two amendments, which came about as the result of discussions between safety net providers and agency partners.

First, we request that the section titled “Covered entity transparency to increase accountability to safeguard benefit” (found on page 6, line 16 through page 11, line through 12) be struck and replaced with the following language:

§ -6 Reporting by 340B Covered Entities. Each 340B covered entity participating in the federal 340B Drug Pricing Program pursuant to section 340B of the Public Health Service Act (42 U.S.C. § 256b) shall annually submit to the department of health an attestation that it is compliant with all federal requirements of the program. The department may prescribe the form and manner of submission and may adopt rules pursuant to chapter 91 to effectuate the purposes of this section.

Second, we request that a severability clause be inserted, to read:

If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

Thank you for your continued commitment to supporting non-profit, safety net, and rural healthcare providers in Hawaii.

Wednesday, March 19, 2025 at 8:30 AM
Via Video Conference; Conference Room 229

Senate Committee on Ways and Means

To: Senator Donovan Dela Cruz, Chair
Senator Sharon Moriwaki, Vice Chair

Senate Committee on Judiciary

To: Senator Karl Rhoads, Chair
Senator Mike Gabbard, Vice Chair

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

**Re: Comments on HB 712, HD2, SD1
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 (HPH) 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 provides the following COMMENTS on HB 712, HD2, SD1. HB 712, HD2, SD1 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 measure also authorizes the Attorney General and the 340B covered entity to bring a civil action for violations of the statute. In its current form, the bill requires each covered entity, including each offsite pharmacy, to report to the Department of Health a slew of data and information, delineated by form of insurance or third-party payor type, that potentially may violate HIPPA, individual privacy interests and which may contain confidential proprietary information. Accordingly, we SUPPORT §-1 through §-5 in Section 2 at pages 3-6 which represents the consensus of the Attorney General, Department of Commerce and Consumer Affairs, Department of Health, and the Health Care Association of Hawaii. We also SUPPORT and agree with the amendments requested by the Health Care Association of Hawaii and the Department of Health to revert the bill back to the version contained in the HD2. We OPPOSE ALL OF §-6 (Covered entity transparency to increase accountability to safeguard benefit) at pages 6-11.

The federal 340B Drug Pricing Program has been 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 program provides eligible safety net hospitals access to discounted outpatient drugs; these savings help HPH offset losses its medical centers and clinics incur when caring for our state's most vulnerable and underserved individuals.

Contract pharmacies are a vital component to enable 340B-eligible hospitals the ability to create a pharmacy network to ensure patients are able to have access to the medications they need beyond where our hospitals are physically located. This ability is especially crucial in Hawai'i due to the geographic barriers including location, size, and transportation challenges experienced 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. 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.

For HPH, the 340B Drug Pricing Program plays a crucial role in funding our mission to create a healthier Hawaii. HPH invests in programming and community support efforts that exceed the savings it receives from the 340B program. As an example, in FY 22, our 340B savings of \$32.7 million was less than half that of its total Community Benefit activity for FY22 of \$78.3 million.

The 340B Drug Pricing Program allows the financial flexibility needed to invest in tailored solutions that address the unique needs of communities we serve. Were the program to be eliminated or scaled back, the 340B-eligible medical centers in the Hawaii Pacific Health system would struggle to continue providing much-needed health care to low-income and underinsured individuals. It also would jeopardize our long-standing, vital partnerships with those providers who serve isolated rural communities.

There is Extensive Oversight in the Program—including Reporting Requirements Imposed By Drug Manufacturers Themselves.

§-6 of the bill encompasses amendments requested by Pharma in the previous hearing. These amendments impose numerous additional reporting requirements on covered entities as well as contract pharmacies. These requirements create an unnecessary burden and expense on 340B-eligible medical centers and covered entities. Moreover, the data sought in §-6 is duplicative of information that is already provided to the federal Health Resources and Services Administration, the State's MedQuest division and the pharmaceutical manufacturers themselves.

HPH guarantees full compliance with the 340B program by strictly adhering to all federal requirements and maintaining comprehensive, auditable records in line with federal guidelines. We continuously conduct both external and internal audits to evaluate and enhance our processes, ensuring the prevention of diversion to ineligible patients. Additionally, our covered entities fully align with the state MedQuest division's reporting requirements, effectively preventing duplicate discounts.

Oversight and audits of hospitals participating in the 340B Drug Pricing Program are already extensive, with covered entities required to comply with strict reporting and compliance requirements. The Health Resources and Services Administration (HRSA) conducts audits to ensure that hospitals meet eligibility criteria, prevent drug diversion, and maintain proper patient eligibility records. Hospitals must also self-audit and maintain meticulous documentation to demonstrate compliance, making the assertion that the program lacks oversight misleading. Despite these existing governmental safeguards, drug manufacturers have imposed additional burdens on hospitals, particularly those using contract pharmacies, by requiring participation in a third-party data submission platform known as 340B ESP.

Manufacturers have made assertions that they have doubts over whether 340B discounts are being used appropriately. *This is curious, since they have already imposed their own solution by mandating that hospitals report detailed claims data through 340B ESP as a condition of receiving discounted drugs at contract pharmacies.* **Drug manufacturers admit, however, that they are unaware of any violations of the program in Hawai'i.** The drug manufacturers' current reporting requirement already places additional financial and administrative burdens on hospitals, many of which are operating with limited resources. Hospitals must absorb the cost of using this third-party vendor while navigating the complex and frequently changing manufacturer restrictions on contract pharmacy arrangements. Rather than ensuring appropriate use of the program, these requirements function as an unnecessary barrier to access, undermining the very intent of 340B of supporting hospitals serving vulnerable patient populations. Based on all the information hospitals must already provide to the drug manufacturers, the drug manufacturers are potentially in a position to use reconstruction techniques to re-identify data. For example, they may apply some of the techniques listed below to do so:

1. ****Small Group Analysis:**** If the aggregated data is broken down into small groups (e.g., by region or type of provider or in our case by Medicare, Medicaid, commercial insurance), it becomes easier to reverse-engineer specific details. For instance, if only one hospital in a region participates in the 340B program, the aggregated data might effectively represent that hospital alone.
2. ****Auxiliary Information:**** Pharmaceutical companies often have access to other datasets, such as sales records or prescribing patterns. By cross-referencing these with the aggregated data, they could infer which providers are using specific drugs and in what quantities.

3. **Trends and Patterns:** Advanced analytics, like machine learning, can identify patterns in the aggregated data. For example, if a certain drug's utilization spikes in a specific state, it might indicate which providers are prescribing it and for what conditions.

4. **Profit Margins:** Aggregated profit data could reveal how much providers are saving through the 340B program. By comparing this with known drug prices and reimbursement rates, companies might deduce which providers are benefiting the most.

In order to comply with the new reporting mandates in HB 712, HD2, SD1, the covered entities and contract pharmacies would be required to engineer a process that would safeguard patient privacy and confidentiality, along with protecting confidential proprietary information without compromising the data. As such, financial resources would be diverted to comply with these new reporting requirements to the detriment of patient care.

Passage in Other States & Failed Legal Challenges

Furthermore, it is worth noting that there are currently at least eight states that have passed similar legislation to HB 712 HD2 preventing manufacturer restrictions on 340B contract pharmacies in Arkansas (2021), Maryland (2022), Louisiana (2023), West Virginia (2024), Missouri (2024), Kansas (2024), Minnesota (2024), and Mississippi (2024). We are unaware of legislation in any other state mandating reporting of the kind of information outlined in §-6 of the SD2.

The language adopted in the original version of HB 712 has survived legal scrutiny in other states where it has been determined that State action to preserve 340B savings are not preempted by the Federal 340B program. For example, Arkansas passed a drug pricing law (Act 1103) - a law similar to what is proposed in HB 712 - which protects contract pharmacies from pharmaceutical company policies from restricting dispensing of 340B drugs to community and specialty pharmacy partners. Despite the law being challenged in Arkansas, the U.S. Court of Appeals for the Eighth Circuit's ruled that Section 340B of the Public Health Services Act does not preempt Arkansas' law. The Eighth Circuit's ruling was further affirmed when the U.S. Supreme Court refused to hear an appeal of the lower court's ruling challenging Arkansas' drug pricing law in December 2024.

Finally, HPH continues to support the conversations with the Department of the Attorney General, Department of Commerce and Consumer Affairs, the Department of Health and the Health Care Association of Hawai'i (HAH) on this measure in order to craft a law that implements the intent of the Federal 340B Drug Program and which is acceptable to the state agencies concerned. HB 712, HD2 which was drafted with the assistance of the Attorney General is the product of this collaboration.

By prohibiting drug manufacturers from engaging in conduct that limits or denies access to 340B drugs, this measure would ensure that patients, especially low-income individuals and those residing in rural areas of the state, are able to have access to health care and obtain the medications they need. We urge your committees to delete §-6 of the bill, and

revert back to the version contained in the HD2 as recommended by the HAH and DOH so that hospitals, covered entities and contract pharmacies can fulfill their mission of providing health care to Hawai'i's citizens without compromising care.

Thank you for the opportunity to testify.



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March 31st, 2025

Senate Committee on Ways and Means

Chair Donovan M. Dela Cruz

Vice Chair Sharon Y. Moriwaki

Senate Committee on Judiciary

Chair Karl Rhoads

Vice Chair Mike Gabbard

RE: SUPPORT FOR BILL HB-712, RELATING TO HEALTH (340B DRUG ACCESS), WITH NECESSARY AMENDMENTS TO VERSION HB-712 (HD-2, SD-1).

On behalf of the Hawai'i Island Community Health Center (HICHC), we strongly support the original intent of HB-712 to prohibit drug manufacturers from restricting access to 340B medications at contract pharmacies. This critical legislation will help ensure that community health centers and other safety-net providers continue to offer affordable medications and essential healthcare services to our most vulnerable patients. However, we are deeply concerned that the recently introduced amendments to HB-712 version (HD-2, SD-1) will significantly weaken the bill and fundamentally undermine the original intent for the following reasons:

- **Increased Administrative Burdens:** Community health centers and other 340B-covered entities operate with limited resources. The additional requirement to compile and submit claim-level data and annual information to the Department of Health diverts staff time and funding away from patient care.
- **Patient Privacy Concerns:** Sharing detailed claims-level data raises serious concerns about patient privacy and data security. Protecting sensitive health information should remain a priority, and this amendment introduces potential risks.
- **Barrier to Affordable Medications:** Contract pharmacies are critical in ensuring that patients have access to 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. While it is true that patients can obtain medications from the pharmacy of their choice, 340B-priced medications, and the associated savings for uninsured and underinsured patients, can only be accessed at pharmacies affiliated with a covered entity, as described by the 340B statute.
- **Reduced 340B Savings and Negative Impact on Patient Care:** The 340B Program was intended to allow safety-net providers to reinvest savings into expanding access to care, supporting essential services, and reducing costs for uninsured and underinsured patients. If health centers lose 340B savings due to manufacturers limiting contract pharmacy access, the direct result will be fewer resources for primary care, behavioral health, substance use treatment, and other critical services. Patients who rely on these programs will face greater barriers to receiving the care they need.

- **Loopholes for Continued Restrictions:** The amendment that added Section 2(b) will allow manufacturers to continue restricting 340B medications at contract pharmacies—the very practice this bill was designed to prohibit.

Urgent consideration is necessary for addressing the recent amendments to HB-712 version (HD-2, SD-1). Please consider the following solution to restore HB-712:

Amend HB-712 version (HD-2, SD-1) to explicitly restore the original intent of the bill, prohibiting drug manufacturers from imposing any restrictions on 340B pricing at contract pharmacies as below:

- Strike line 2(b) ~~Nothing in this section shall deny, restrict, or prohibit a manufacturer from requiring a 340B covered entity to provide claims information for the manufacturer's 340B drugs~~
- Section 6 titled “Covered entity transparency to increase accountability to safeguard benefit” to be struck in its entirety and replaced with the following language:

“Reporting by 340B Covered Entities. Each 340B covered entity participating in the federal 340B Drug Pricing Program pursuant to section 340B of the Public Health Service Act (42 U.S.C. § 256b) shall annually submit to the department of health an attestation that it is compliant with all federal requirements of the program...” (Healthcare Association of Hawai’i)

We respectfully request your support in ensuring that this vital legislation is enacted, without the amendments that oppose HB-712’s original intent, to safeguard access to affordable medications for our most vulnerable populations.

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 'Melni Bg', with a long horizontal flourish extending to the right.

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

mabumgardner@hicomunityhealthcenter.org



To: The Honorable Donovan M. Dela Cruz, Chair
The Honorable Sharon Y. Moriwaki, Vice Chair
Senate Committee on Ways and Means

The Honorable Karl Rhoads, Chair
The Honorable Mike Gabbard, Vice Chair
Senate Committee on Judiciary

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

Hearing: Tuesday, April 1, 2025, 10:00 AM, Conference Room 211

RE: **HB712 HD2 SD1 Relating to Health**

AlohaCare appreciates the opportunity to provide testimony in **support with comments on HB712 HD2 SD1**. 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; authorizes the 340B covered entity and Attorney General to bring a civil action for enforcement; specifies a four-year limitations period for bringing an action; requires each covered entity to report certain information annually to the Department of Health; requires the Department of Health to prepare annual reports detailing the information received from covered entities, submit the reports to the Legislature, and make the reports publicly available; and defines covered entity.

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 protects the integrity of the 340B program and ensures that patients continue to receive the care and medications they need.

Consistent with our support of safety net providers, we are concerned that recent amendments requiring additional, duplicative reporting from 340B entities, particularly smaller community health centers, will make administering the program more administratively burdensome. We would respectfully ask your committees to consider reverting the bill language to the HD2 version.

Mahalo for this opportunity to testify in **support with comments** on **HB712 HD2 SD1**.



**WAIANAE COAST
COMPREHENSIVE
HEALTH CENTER**

Tuesday, April 1, 2025 at 10:00 AM
State Capitol, Conference Room 211 & Videoconference

SENATE COMMITTEE ON WAYS AND MEANS & SENATE COMMITTEE ON JUDICIARY

To **Chair Donovan Dela Cruz** **Chair Karl Rhoads**
 Vice Chair Sharon Moriwaki **Vice Chair Mike Gabbard**

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

RE: TESTIMONY IN SUPPORT OF HOUSE BILL 712 HD2 SD1 - RELATING TO HEALTH

Aloha Chair Dela Cruz, Chair Rhoads, Vice Chairs Moriwaki and Gabbard, and Members of the Committees,

The Waianae Coast Comprehensive Health Center (WCCHC) **strongly supports HB712 HD2 SD1 with amendments**. This measure protects the integrity of the federal 340B Drug Pricing Program by prohibiting discriminatory practices by drug manufacturers.

Waianae Coast Comprehensive Health Center (WCCHC) is a Federally Qualified Health Center (FQHC) dedicated to improving the health and well-being of the West O'ahu community through accessible and affordable medical and traditional healing services, outreach to vulnerable populations including people experiencing homelessness, supporting our community's wellbeing. With 52 years of service, WCCHC is committed to providing comprehensive healthcare by addressing individual's unique needs. We have relied on the 340B program for decades to deliver critical care that our community could not otherwise afford. These savings allow us to sustain outreach, behavioral health, and pharmacy assistance programs that directly benefit our most vulnerable patients.

The stakes for Hawai'i's safety net system are extremely high. Without this legislation, safety-net hospitals and health centers could lose tens of millions of dollars annually. At WCCHC, the loss of 340B revenue would force difficult decisions that might affect care for patients with the fewest resources. These funds are not theoretical, they help fund important services.

Across the country, more than 30 states are pursuing similar legislation to defend the 340B program against predatory restrictions by pharmaceutical manufacturers. Hawai'i should act now to prevent local savings from being siphoned into pharmaceutical profits. The language in HB712 mirrors successful legislation passed in other states and has withstood legal challenges. It is both practical and will benefit Hawai'i.

We also believe it's important to respond to concerns about transparency. FQHCs like WCCHC are already held to high federal standards, including strict HRSA audits to ensure that 340B medications are dispensed only to eligible patients. The new reporting requirements in this bill do not improve transparency; rather, they replicate existing obligations and impose unnecessary administrative burden on safety-net providers.



**WAIANAЕ COAST
COMPREHENSIVE
HEALTH CENTER**

We respectfully request two amendments.

First, we request that the section titled “Covered entity transparency to increase accountability to safeguard benefit” (found on page 6, line 16 through page 11, line through 12) be struck and replaced with the following language:

§ -6 Reporting by 340B Covered Entities. Each 340B covered entity participating in the federal 340B Drug Pricing Program pursuant to section 340B of the Public Health Service Act (42 U.S.C. § 256b) shall annually submit to the department of health an attestation that it is compliant with all federal requirements of the program. The department may prescribe the form and manner of submission and may adopt rules pursuant to chapter 91 to effectuate the purposes of this section.

Second, we request that a severability clause be inserted, to read:

If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

Thank you for your continued commitment to supporting safety net and rural healthcare providers in Hawai'i.

To: Senator Donovan M. Dela Cruz, Chair
Senator Sharon Y. Moriwaki, Vice Chair
Senate Committee on Ways and Means

Senator Karl Rhoads, Chair
Senator Mike Gabbard, Vice Chair
Senate Committee on Judiciary

From: Chevelle Davis, MPH - Director of Early Childhood & Health Policy
Hawai'i Children's Action Network Speaks!

Subject: Measure H.B. No. 712, H.D. 2, S.D. 1 – Relating to Health

Hearing: Tuesday, April 1, 2025, at 10:00 AM, Conference Room 211

POSITION: STRONG SUPPORT

Aloha e Chairs Dela Cruz and Rhoads, Vice Chairs Moriwaki and Gabbard, and Members of the Committees:

Mahalo for the opportunity to provide testimony in **strong support of H.B. No. 712, H.D. 2, S.D. 1**, which seeks to prohibit drug manufacturers and wholesale distributors from restricting or denying access to pharmacies contracted with 340B covered entities from purchasing 340B drugs at the federally mandated discounted prices. This bill is essential to upholding the integrity and intent of the federal 340B Drug Pricing Program, ensuring that safety-net providers can continue to serve vulnerable and underserved populations.

The 340B Drug Pricing Program was established by Congress in 1992 with the specific goal of enabling covered entities—such as community health centers, rural hospitals, and nonprofit clinics—to stretch scarce federal resources and provide essential healthcare services to low-income and uninsured patients. However, in recent years, drug manufacturers and distributors have increasingly engaged in restrictive practices that limit access to these discounted drugs. These actions not only undermine the purpose of the 340B program but also jeopardize the ability of safety-net providers to deliver affordable medications and critical healthcare services to those most in need.

By prohibiting these unfair and deceptive practices, H.B. No. 712 will:

1. **Ensure Patient Access to Affordable Medications** – The restrictions imposed by drug manufacturers and distributors have led to increased costs for 340B covered entities, which ultimately impact patients who rely on these discounted medications. This bill will help restore fair pricing and protect patient access to necessary treatments.

2. **Support Safety-Net Providers** – Community health centers, rural hospitals, and nonprofit healthcare organizations depend on 340B savings to fund vital programs, including uncompensated care, substance use treatment, and preventive health services. Ensuring that 340B entities can access discounted drugs without restriction is critical to maintaining these services.
3. **Hold Manufacturers and Distributors Accountable** – The bill imposes civil penalties for engaging in unfair or deceptive trade practices, creating a deterrent against exploitative pricing policies and reinforcing the obligation of drug manufacturers and distributors to comply with the 340B program's requirements.
4. **Promote Health Equity** – Many 340B covered entities serve populations that experience significant health disparities. Protecting the ability of these providers to access affordable medications is a crucial step in reducing barriers to care and addressing healthcare access and outcomes inequities.

Without legislative action, restrictive practices by drug manufacturers and distributors will continue to threaten the viability of the 340B program and the essential healthcare services it supports. This bill is a necessary safeguard to ensure that covered entities can continue their mission of providing care to the most underserved members of our communities.

For these reasons, I **strongly urge the committee to pass H.B. No. 712, H.D. 2, S.D. 1**, and protect the integrity of the 340B Drug Pricing Program.

Mahalo for the opportunity to provide testimony on this important measure.

HB-712-SD-1

Submitted on: 3/27/2025 4:42:51 PM

Testimony for WAM on 4/1/2025 10:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Aaron Ruddick	Individual	Support	Written Testimony Only

Comments:

Dear Chair Dela Cruz , Vice Chair Morikawa and members of the WAM committee

Dear Chair Rhoads, Vice Chair Gabbard and members of the JDC committee

We **support HB 712 HD2 SD1**. 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 such things as 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. Four out of ten health centers rely solely on contract pharmacies and nine out of ten 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.

HB-712-SD-1

Submitted on: 3/28/2025 9:29:34 AM

Testimony for WAM on 4/1/2025 10:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Jean Crowder	Individual	Support	Written Testimony Only

Comments:

Dear Chair Dela Cruz , Vice Chair Morikawa and members of the WAM committee

Dear Chair Rhoads, Vice Chair Gabbard and members of the JDC committee

I support HB 712 HD2 SD1. 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 such things as 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. Four out of ten health centers rely solely on contract pharmacies and nine out of ten 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.

Dear Chair Dela Cruz , Vice Chair Morikawa and members of the WAM committee

Dear Chair Rhoads, Vice Chair Gabbard and members of the JDC committee

I support HB 712 HD2 SD1. 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 such things as 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. Four out of ten health centers rely solely on contract pharmacies and nine out of ten 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.

HB-712-SD-1

Submitted on: 3/28/2025 3:48:50 PM

Testimony for WAM on 4/1/2025 10:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Jason Yaris	Individual	Support	Written Testimony Only

Comments:

Dear Chair Dela Cruz , Vice Chair Morikawa and members of the WAM committee

Dear Chair Rhoads, Vice Chair Gabbard and members of the JDC committee

I support HB 712 HD2 SD1. 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 such things as 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. Four out of ten health centers rely solely on contract pharmacies and nine out of ten 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.

HB-712-SD-1

Submitted on: 3/28/2025 11:26:00 PM

Testimony for WAM on 4/1/2025 10:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Ronald Taniguchi, Pharm.D., MBA	Individual	Support	Written Testimony Only

Comments:

I fully support HB712 HD2 SD1. Mahalo

To: The Honorable Donovan M. Dela Cruz, Chair
The Honorable Sharon Moriwaki, Vice Chair
Members, Senate Committee on Ways and Means

The Honorable Karl Rhoads, Chair
The Honorable Mike Gabbard, Vice Chair
Members, Senate Committee on Judiciary

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

Date: April 1, 2025

Re: Support for HB712 HD2 SD1: 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 HD2 SD1, which 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 and authorizes the 340B covered entity and Attorney General to bring a civil action for enforcement.

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

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.

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 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, neighbor island, and critical access hospitals are asked to do more with less and are ceasing to exist with greater frequency; the result is creating 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 centers millions in excess drug cost and lost revenue from their contract pharmacies; revenue that Queen's relies on to reinvest in programs that directly improve health outcomes for our patients. We implore you to take action to hold these companies accountable and protect the hospital and healthcare safety net that our communities depend on.

We support the suggested amendment provide by Healthcare Association of Hawai'i, adding a severability clause.

We respectfully request two amendments, which came about as the result of discussions between safety net providers and agency partners.

First, we request that the section titled "Covered entity transparency to increase accountability to safeguard benefit" (found on page 6, line 16 through page 11, line through 12) be struck and replaced with the following language:

§ -6 Reporting by 340B Covered Entities. Each 340B covered entity participating in the federal 340B Drug Pricing Program pursuant to section 340B of the Public Health Service Act (42 U.S.C. § 256b) shall annually submit to the department of health an attestation that it is compliant with all federal requirements of the program. The department may prescribe the form and manner of submission and may adopt rules pursuant to chapter 91 to effectuate the purposes of this section.

Second, we request that a severability clause be inserted, to read:

If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

Thank you for the opportunity to testify in support of HB712 HD2 SD1.

March 31, 2025

TO: Chair Donovan M. Dela Cruz
Vice Chair Sharon Y. Moriwaki
Members of the Senate Committee on Ways and Means

Chair Karl Rhoads
Vice Chair Mike Gabbard
Members of the Senate Committee on Judiciary

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

RE: **HB 712, HD2, SD1** - Relating to Health
Hearing Date: April 1, 2025
Time: 10:00 am

PhRMA opposes in part **HB 712, HD2, SD1**. Attached is PhRMA's testimony.

Thank you for considering this testimony.

In Opposition to Hawaii HB 712, HD2, SD1

Position: The Pharmaceutical Research and Manufacturers of America (“PhRMA”) respectfully opposes HB 712, HD2, SD1 to the extent that it 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. PhRMA supports the amendments incorporated in the SD1 relating to transparency and reporting requirements and opposes the Healthcare Association of Hawaii’s (“HAH”) proposed amendment seeking to replace the transparency provisions by the submission of an attestation to the Department of Health of compliance with the requirements of the 340B program. PhRMA also responds to certain statements made by proponents of the original bill and to answer questions raised by Senators at the HHS/CPN hearing.

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. 340B hospitals collect 7 times as much as independent physician offices for the sale of medicines administered to commercially insured patients¹ 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.²

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.^{3,4} 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 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.⁵

Use of 340B displaces manufacturer rebates on the same drug, raising costs for everyone. This displacement caused a combined \$5.2 billion increase in health care costs for self-insured employers and workers in 2021. That is because drug costs were estimated to be 4.2% higher under the 340B program than they otherwise would have been had rebates been paid to PBMs and employers.⁶ Based on additional analysis by IQVIA, a leading global provider of advanced analytics, technology solutions and clinical research services to the life services industry in which includes pharmaceutical and biotech firms employers in Hawaii pay an estimated \$21.9 million more in health care costs due to foregone rebates as a result of the 340B program.⁸ The same

analysis by IQVIA showed that proposed contract pharmacy legislation in Hawaii is estimated to increase health care costs for employers by \$6.8 million and state and local governments by \$1 million due to additional foregone rebates.⁹

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.⁶ 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,⁷ 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, HD2, SD1 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.⁸ 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.⁸ 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.⁹ Today, the program stands at \$66.3 billion, a 23% growth increase from the previous year.¹⁰

In 2023, the Minnesota Legislature passed legislation¹¹ 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.¹²

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 net¹³ 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.¹⁴ Most entities did not report data for office administered drugs, which are estimated to account for 80% of all 340B drug spending.¹⁵

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.¹⁶

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.

In response to the proponents of the shipping mandate's continued claims that they are losing \$30 million a year, it should be noted that the 340B program continues to grow at incredibly high rate. Recent data from the federal regulator, HRSA, found that 340B purchases grew by 23.4% despite contract pharmacy restrictions being in place. This means that no covered entity is losing money from contract pharmacy restrictions, they just are not seeing their revenue grow as quickly from year to year.

Proponents of the shipping mandate claim that 340B is not costing the state money. However, the growth of the program comes at the expense of health insurers, businesses and the State. As set forth earlier, IQVIA recently found that the 340B program costs \$21.9 million to Hawaii employers and the state due to forgone rebates. Without the oversight that HB 712, HD2, SD1 will allow, the revenue loss to employers, insurers and the State will grow, with profits being diverted to corporations such as CVS and Walmart and patients continuing to pay inflated 340B prescription drug prices.

The transparency provisions of the SD1 will help ensure that funds going to contract pharmacies can be monitored and scrutinized by manufacturers, covered entities and, most importantly, the State. It will also allow the State to address some of the program integrity findings that have been demonstrated through several audits and the United States Government Accountability Office ("GAO") report on 340B contract pharmacies. Specifically, the GAO found weaknesses in the oversight of the program. They concluded that the weak oversight impedes HRSA's ability to ensure compliance with 340B Program requirements at contract pharmacies. The GAO found, among other things, that:

- HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. HRSA audits of Hawaii covered entities have noted this exact finding on multiple occasions.
- HRSA does not require all covered entities to provide evidence that they have taken corrective action and are in compliance with program requirements prior to closing the audit. Instead, HRSA generally relies on each covered entity to self-attest that all audit findings have been addressed, and that the entity came into compliance with 340B Program requirements.

The GAO report which consist of 68 pages is available upon request.

Notwithstanding testimony by the Healthcare Association of Hawaii ("HAH") that there is already federal oversight in place, current audit and reporting provisions do not provide adequate information as to whether 340B discounted drugs being dispensed by contract pharmacies are going to the intended and qualified beneficiaries. Section 6 of the SD1 will provide more pertinent and relevant information with regard to contract pharmacies and should be left in place.

HAH's proposed amendment as to Section 6 "Reporting by 340B Covered Entities" which seeks to replace the transparency provisions relating to contract pharmacies by having covered entities submit an attestation to the Department of Health that they are compliant with the requirements of the 340B program is perfunctory because federal law is silent on contract pharmacies under the 340B program which is the subject of this bill. Further, the transparency requirements do not change the covered entities' claims to these funds; however, the providing of 340B drugs should come with some reporting and accountability requirements to help ensure that they are being provided to intended and qualified beneficiaries under the program.

For the above reasons, PhRMA opposes Section 2 of SD1 which would blanketedly require biopharmaceutical manufacturers to ship 340B drugs to all contract pharmacies. It supports the transparency and reporting provisions in the SD1 and opposes the removal of those provisions as requested by the HAH in its proposed amendment. PhRMA also requests that the original language of its proposed amendment as to the effective date of the prohibition against manufacturers of January 1, 2030 be restored to allow time to consider the annual reports submitted by the Department of Health. Thank you for your consideration of the foregoing.

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.

¹ 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)

² 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

³ 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>

⁴ 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>

⁵ 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>

⁶ 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>.

⁷ 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.

⁸ Government Accountability Office, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," GAO-18-480, June 2018.

⁹ Berkeley Research Group. For-Profit Pharmacy Participation in the 340B Program. October 2020.

¹⁰ 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>

¹¹ 2023 Minnesota Statutes, Section 62J.312

¹² Minnesota Department of Public Health, "340B Covered Entity Report," Nov. 25, 2024. <https://www.health.state.mn.us/data/340b/docs/2024report.pdf>

¹³ 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)

¹⁴ 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

¹⁵ Spending in the 340B Drug Pricing Program, 2010 to 2021 (<https://www.cbo.gov/system/files/2024-06/60339-340B-DrugPricing-Program.pdf>)

¹⁶ Minnesota Department of Public Health, "340B Covered Entity Report," Nov. 25, 2024. <https://www.health.state.mn.us/data/340b/docs/2024report.pdf>

HB-712-SD-1

Submitted on: 3/31/2025 1:23:20 PM

Testimony for WAM on 4/1/2025 10:00:00 AM

Submitted By	Organization	Testifier Position	Testify
Andrea Staley	Individual	Support	Written Testimony Only

Comments:

Dear Chair Dela Cruz, Vice Chair Morikawa, and members of the WAM committee

Dear Chair Rhoads, Vice Chair Gabbard, and members of the JDC committee

I support HB 712 HD2 SD1. 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, thereby increasing patient access by reducing geographic and financial barriers to care. Four out of ten health centers rely solely on contract pharmacies, and nine out of ten 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, with 39 manufacturers now imposing limitations on shipments of their medications that vary by covered entity type. This has resulted in significant decreases in the financial resources required to support these otherwise unfunded patient access programs. Patient access to care and clinical outcomes suffer as a result.

Mahalo for the opportunity to provide testimony.