JOSH GREEN, M.D. GOVERNOR OF HAWAI'I KE KIA'ĂINA O KA MOKU'ĂINA 'O HAWAI'I



KENNETH S. FINK, M.D., M.G.A., M.P.H. DIRECTOR OF HEALTH KA LUNA HO'OKELE

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

Testimony COMMENTING on HB659 RELATING TO HEALTH.

REP. DELLA BELATTI, CHAIR HOUSE COMMITTEE ON HEALTH & HOMELESSNESS

Hearing Date: February 1, 2023

Room Number: 329

1 Fiscal Implications: N/A.

2 Department Testimony: The Department of Health (DOH) acknowledges the scope of practice

3 discussion prompted by the proposed amendments to chapter 461, Hawaii Revised Statutes.

4 Further clarification is required to distinguish pharmacist scope of practice issues, i.e., the

5 ordering and interpreting of test result, with diagnostic laboratory quality control issues that are

6 the purview of the Department of Health.

7 DOH looks forward to ongoing discussions with stakeholders to assure that the continuity of

8 diagnostic and clinical care, community standards and practices, and healthcare infrastructure are

9 maintained; and that unnecessary fragmentation of health be avoided.

10 Offered Amendments:

11



UNIVERSITY OF HAWAI'I SYSTEM 'ÕNAEHANA KULANUI O HAWAI'I

Legislative Testimony Hōʻike Manaʻo I Mua O Ka ʻAhaʻōlelo

> Testimony Presented Before the House Committee on Health and Homelessness Wednesday, February 1, 2023 at 8:30 a.m. By Bonnie Irwin, Chancellor and Miriam Mobley Smith, Interim Dean Daniel K. Inouye College of Pharmacy University of Hawai'i at Hilo

HB 659 - RELATING TO HEALTH

Chair Belatti, Vice Chair Takenouchi, and Members of the Committee:

Thank you for the opportunity to submit testimony on HB 659. The University of Hawai'i at Hilo (UH Hilo) supports HB 659, which establishes permitting and education requirements for pharmacists performing certain diagnostic tests or tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This bill expands the definition of "practice of pharmacy" to include the performance of certain diagnostic or CLIA-waived tests.

Pharmacists in the State of Hawai'i are currently permitted to perform certain drug therapy-related tests under the definition of "practice of Pharmacy" in section 461-1, Hawai'i Revised Statutes. CLIA-waived tests are simple and non-technical. They are FDA-approved, apply methods that are accurate and intuitive, the likelihood of error is negligible and, if performed incorrectly poses no reasonable risk of patient harm. New developments in point of care testing technology have significantly broadened the number of available CLIA-waived tests. Subsequently, expanding pharmacists' performance of any aspect of CLIA-waived tests can contribute to improving patient care outcomes.

Offering CLIA-waived testing for multiple services including medication management, health wellness and disease prevention, infectious disease screening, chronic illness screening, chronic care management can increase access to health care and improve public health. Based on test findings, pharmacists can help patients avoid adverse drug interactions, refer patients to their primary care providers or health care centers, educate patients about chronic disease risk factors and preventive health measures, and assist patients to undertake risk reduction strategies.

As the only College of Pharmacy in the State of Hawai'i, our mission is to educate pharmacy practitioners and leaders who will improve health in Hawai'i and throughout the Pacific through education, research and service. We prepare our student pharmacists to serve patients in pharmacies and as members of inter-professional health care teams. As their role has evolved to encompass a greater focus on the provision of services, pharmacists should be permitted to perform CLIA-waived tests that enhance their contribution to patient care.

Thank you for the opportunity to testify in support of HB 659.

Testimony of the Board of Pharmacy

Before the House Committee on Health and Homelessness Wednesday, February 1, 2023 8:30 a.m. Conference Room 329 and Videoconference

On the following measure: H. B. 659, RELATING TO HEALTH

Chair Belatti and Members of the Committee:

My name is James Skizewski, and I am the Executive Officer of the Board of Pharmacy (Board). The Board appreciates the intent of and offers comments on this bill.

The purposes of this bill are to: (1) establish permitting and education requirements for pharmacists performing certain diagnostic tests or tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA); and (2) expand the definition of "practice of pharmacy" to include the performance of certain diagnostic or CLIA-waived tests.

This bill amends the definition of "Practice of pharmacy" to authorize pharmacists to order or perform diagnostic and CLIA-waived tests provided it is in accordance with permit and education requirements.

Pharmacies are geographically dispersed throughout the community with extended hours of operation, making access to health care provided through pharmacies convenient for patients in each locality. Patients have established relationships of trust with and recognize pharmacists as healthcare professionals. As a result, the pharmacist scope of practice has expanded over time. Pharmacists possess the skills and knowledge necessary to perform diagnostic and CLIA-waived tests, which are non-technical and have a low risk for erroneous results. For example, in response to the COVID-19 pandemic, pharmacists order and administer COVID-19 tests in pharmacies across the State, safely expanding patient access to care

Thank you for the opportunity to testify on this bill.



HAWAI'I PHARMACISTS ASSOCIATION

Legislative Testimony

Testimony Presented Before the House Health and Homelessness Committee Wednesday February 1, 2022

Corrie L. Sanders, PharmD. on behalf of The Hawai'i Pharmacists Association (HPhA)

Support for HB 659, Relating to Health

To the Honorable Chair Belatti, Vice Chair Takenouchi and members of the Committee,

The Hawai'i Pharmacists Organization (HPhA) stands in support of HB 659 that would allow pharmacists to sign and authorize performance of Clinical Laboratory Improvement Amendment (CLIA) waived tests. HB 659 adds an additional responsibility to pharmacist scope of practice to include the ability to order and perform CLIA waived tests and requires pharmacy registration as a collection facility.

Per the CLIA law, waived tests are tests determined by CDC or FDA to be so simple that there is little risk of error when utilized by the general population. Some testing methods for glucose and cholesterol are waived along with pregnancy tests, fecal occult blood tests, some urine tests, select infectious disease tests, etc. CLIA waived tests can provide time-sensitive, live saving information that has the potential to impact population health.

Community pharmacies in Hawai'i provide the most accessible point of care, specifically during evening, holiday, overnight and weekend hours. All pharmacists are fully capable of ordering and administering CLIA waived tests and should be granted permission to utilize professional judgement, as they would for any other function. Awaiting for additional parties to sign off on a CLIA waived test continues to serve as a barrier to care, specifically on our neighbor islands where access to care faces additional obstacles and logistical challenges.

Pharmacists play an integral role in patient care amid a growing shortage of primary care providers in Hawai'i. Our value has become exceedingly evident throughout the COVID-19 pandemic where pharmacists served as cornerstones of care and were integral in the successful distribution of COVID-19 testing and vaccinations. As the most accessible health care providers, allowing pharmacists to authorize CLIA waived tests would streamline the patient care process, expedite treatment regimens, prevent unnecessary exposures to infectious diseases and decrease the burden on an overwhelmed healthcare system.

We strongly feel the inclusion of third parties in administering CLIA waived tests that are intended for general population use serves as an administrative barrier that prevents expedited patient care. Regardless of additional registration processes, the patient safety and training responsibilities still fully fall on the pharmacist.

Enacting HB 165 will align the responsibility of Hawai'i pharmacists with the education we receive to perform CLIA waived tests and decrease time sensitive care barriers across all Hawaiian islands. Please consider allowing us to leverage our training and accessibility to benefit the health and safety of our community at large.

Oh behalf of The Hawai'i Pharmacists Association, mahalo for this opportunity to testify.

Very Respectfully,

Corrie L. Sanders, PharmD., BCACP, CPGx President, Hawai'i Pharmacists Association



To: Committee on Health and Homelessness

Hearing Date/Time: Wednesday February 1, 2021 8:30AM

Re: Testimony in Support of HB 659

From: Hep Free Hawaii

Dear Chair Belatti, Vice Chair Takenouchi and members of the committee

The Hep Free Hawai'i supports HB659 which would clarify HRS to allow pharmacists to order and perform certain common diagnostic-related tests such as influenza as well as CLIA-waived tests such as hepatitis and HIV point-of-care tests. Pharmacists are an important part of our healthcare continuum of care and for many people, accessing their pharmacy is much easier than access their primary care provider. Allowing pharmacists, who already are allowed to provide vaccinations and other services, would make it much easier for people to access these basic health services.

We hope you will consider passing HB659 – we need more access to services that pharmacists can provide under their practice of pharmacy.

Thank you for the opportunity to testify.

Aaron Ruddick, Policy Chair, Hep Free Hawaii



To: Committee on Health and Homelessness

Hearing Date/Time: Wednesday February 1, 2021 8:30AM

Re: Testimony in Support of HB 659

From: Heather Lusk, Hawaii Health and Harm Reduction Center

Dear Chair Belatti, Vice Chair Takenouchi and members of the committee

The Hawaii Health & Harm Reduction Center (HHHRC) supports HB659 which would clarify HRS to allow pharmacists to order and perform certain common diagnostic-related tests such as influenza as well as CLIA-waited tests such as hepatitis and HIV point-of-care tests. Pharmacists are an important part of our healthcare continuum of care and for many people, accessing their pharmacy is much easier than access their primary care provider. Allowing pharmacists, who already are allowed to provide vaccinations and other services, would make it much easier for people to access these basic health services.

HHHRC's mission is to reduce harm, promote health, create wellness and fight stigma in Hawaii and the Pacific. We focus our efforts on those disproportionately affected by social determinants of health, including but not limited to: people living with and/or affected by HIV, hepatitis, substance use, and the transgender, LGBQ and the Native Hawaiian communities.

HHHRC provides CLIA-waived HIV and hepatitis C testing and know that our community would also access them if their local pharmacist was able to provide in a variety of locations throughout the islands. We hope you will consider passing HB659 – we need more access to services that pharmacists can provide under their practice of pharmacy.

Thank you for the opportunity to testify.

Heather Lusk, Executive Director, Hawaii Health and Harm Reduction Center



February 1, 2023

- TO: Chair Della Au Belatti Members of the House Committee on Health & Homelessness
- FR: Kevin Loscotoff Director, Public and Government Affairs

RE: HB659 Relating to Health. - Support

On behalf of Walmart Inc., I appreciate the opportunity to submit testimony in favor of HB 659. Community-based pharmacists, pharmacy technicians, and pharmacy interns are integral members of the community that bring significant value to the individuals they serve. The role of pharmacists is expanding in many locations, and pharmacists are in a unique position to provide a variety of clinical services intended to improve patient health outcomes while at the same time serve racially diverse communities. This can include not only delivering effective and tailored pharmaceutical care, counseling, and education about medications, diet, health, and wellness, but also establishing meaningful, personal connections and building positive relationships. Pharmacists are trusted healthcare professionals and, as the role of pharmacists expands, we could be a first stop on a patient's healthcare journey, most frequently due to availability, affordability, and/or geography. Nearly 90 percent of Americans live within 5 miles of a community pharmacy.¹ Walmart and Sam's Club operate 10 pharmacies and 2 pharmacies, respectively, in Hawaii.

Pharmacists are available to provide valuable healthcare services to communities that have limited access to care. In Hawaii, Hawaii County, Kauai County, Maui County, and City and County of Honolulu are designated as primary care health professional shortage areas.² According to the Bureau of Labor Statistics (BLS), in Hawaii there are approximately 300 family medicine physicians and 350 general internal medicine physicians, and 900 pharmacists and 1,470 pharmacy technicians.³

Doctors have historically had primary responsibility for providing care to patients, and we expect that to continue, but pharmacists can play a critical and complimentary role in providing essential clinical care to the public, particularly in rural and medically underserved areas. As the healthcare system places a greater emphasis on prevention and management of acute and chronic disease and pharmacists' clinical roles and responsibilities evolve to include more direct patient care, laws must be modified to better recognize the significant role that pharmacists can play in mitigating the burden on communities. Providing communities with direct pharmacy access to preventive services, educational counseling, medication therapy management, and more has the potential to contribute to better outcomes and support broader health and wellness in the population. Because of our local accessibility, pharmacies can help to advance health equity among patients, many of whom are medically or socially vulnerable.

I encourage this committee to support HB 659. Allowing pharmacists to order and perform certain common diagnostic-related laboratory tests promotes greater accessibility to and affordability of healthcare. Passage of HB 659 will better enable pharmacists to care for Hawaii's population and is a critical step towards advancing health equity in the state.

Chair Au Belatti, members of the Committee, thank you for this opportunity to submit testimony on this important topic.

¹ <u>https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf</u>

² https://health.hawaii.gov/opcrh/

³ <u>https://www.bls.gov/oes/tables.htm</u>



DATE: January 31, 2023

- TO: Representative Della Au Belatti Chair, House Committee on Health & Homelessness
- FROM: Mihoko Ito / Tiffany Yajima

RE: H.B. 659 – Relating to Health Hearing Date: Wednesday, February 1, 2023 at 8:30 a.m. Conference Room: 329

Dear Chair Belatti, Vice Chair Takenouchi, and members of the Committee on Health & Homelessness:

We submit this testimony on behalf of Walgreen Co. ("Walgreens"). Walgreens operates stores at more than 9,000 locations in all 50 states, the District of Columbia, and Puerto Rico. In Hawaii, Walgreens has 17 stores on the islands of Oahu and Maui.

Walgreens is in **strong support** of this measure which amends the practice of pharmacy statute under Chapter 461 to allow pharmacists to order and perform certain diagnostic related laboratory tests and CLIA-waived tests as part of the practice of pharmacy. We also respectfully request an amendment.

As a result of the COVID-19 pandemic, the federal Public Readiness and Emergency Preparedness (PREP) Act granted pharmacists the independent authority to order and perform CLIA-waived tests and certain diagnostic related tests such as PCR tests for COVID-19 testing. Pharmacists have been performing these tests pursuant to the PREP Act, and as a result they have the skill, experience and training to perform these tests. The purpose of this measure is to clarify their independent authority to do so.

Clinical Laboratory Improvement Amendments ("CLIA") waived tests are simple, easy to use tests that are non-technical in nature and are meant to be performed by lay persons in a non-clinical setting. Examples of CLIA-waived tests include blood glucose tests, cholesterol monitoring tests, and most recently, COVID-19 tests. In fact, throughout the pandemic, pharmacies have served as crucial points of access for COVID-19 testing. There is little to no risk to patients experiencing adverse health effects from these tests and they can easily be performed at home or in a pharmacy setting. When done in the pharmacy, the pharmacy itself oversees, implements and manages compliance with CLIA-waiver protocol, and has oversight over all procedures within the pharmacy.

This bill also clarifies that pharmacists may order and perform diagnostic-related laboratory tests used to detect or screen for COVID-19, influenza, streptococcal pharyngitis, or liver function issues or infections. To clarify the intent of this language, we would respectfully request an amendment on page 10, at lines 3-7, as follows:

First Hawaiian CenterT999 Bishop Street, Suite 1400FHonolulu, HI 96813

(5) Notwithstanding any other law to the contrary, and in accordance with the requirements of section 461- the ordering or performing of certain tests ordering tests and performing the collection of specimens authorized or approved by the United States Food and Drug Administration, that are:

This amendment would make clear that pharmacists may only order tests and perform the collection of specimens but may not process these tests.

Thank you for the opportunity to submit this testimony in strong support of HB 659.

HB-659 Submitted on: 1/30/2023 10:40:34 PM Testimony for HLT on 2/1/2023 8:30:00 AM

Submitted By	Organization	Testifier Position	Testify
Patrick Uyemoto	Times Pharmacy	Support	Written Testimony Only

Comments:

Testimony in Support of HB659

Dear Chair Belatti, Vice Chair Takenouchi, and Members of the Committee,

Times Pharmacy strongly supports HB659 which would help clarify the law to allow pharmacists to order and perform certain common diagnostic-related tests as well as CLIA-waived tests.

Pharmacies and pharmacists play an integral role in our healthcare system and are considered one of the most accessible healthcare providers in the nation. By allowing pharmacists to order and perform CLIA-waived tests, it would help expand services to many rural and underserved communities.

The PREP Act allowed pharmacists to order and administer COVID tests which aided in the increased identification of COVID positive cases and resulted in preventative measures to reduce further transmission. CLIA-waived tests exist for Hemoglobin A1c, Cholesterol, Influenza, Hepatitis C, and HIV just to name a few. Early detection of unbeknownst disease state markers could drastically change the course of disease progression and improve therapeutic outcomes. Proactive and preventative care is needed to decrease overall healthcare spend and improve quality of life.

Thank you for the opportunity to testify,

Patrick Uyemoto, Pharm.D.

Director of Pharmacy

Times Pharmacy

January 30, 2023

Aloha Chair Belatti and Respected Members of the Committee onHealth and Homelessness:

I appreciate the time to allow me to testify in strong support of HB659. This may be redundant testimony, but I think it is important for people unfamiliar with pharmacists and pharmacy practice to understand some key points.

- Pharmacists are the most accessible health care professionals and have the most frequent encounters with patients. Pharmacists have the skill and knowledge to perform these tests.
- Pharmacies are geographically dispersed throughout the community with extended hours of operation, so access for patients is convenient.
- These tests are quick and easy tests that by definition are "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." Some examples of other common CLIA waived tests are urine pregnancy and ovulation tests, fecal occult blood tests, blood glucose home monitoring, various dipstick urine tests for drug use or bacterial infection, and influenza or covid nasal swabs.
- Pharmacists have been essential to ordering and administering Covid-19 antigen tests in pharmacies across the state and nation through the pandemic, and this bill is needed to clarify their authority to continue as the PREP act expires in 2024 by adding specific language to Chapter 461, Practice of pharmacy.

We need to proactively clarify Chapter 461 before the expiration of the PREP act so the services that were expanded can continue to fill gaps in healthcare, especially in underserved populations. As a pharmacist, I feel these tests will arm me with more information to make better recommendations and referrals for care when self-care is not appropriate. Pharmacists are the first line or stop when people want to self-treat ailments or contemplate seeing a doctor.

Thank you for the opportunity to testify in strong support of HB 659.

Sincerely,

Alanna Isobe, Rph

HB-659 Submitted on: 1/30/2023 9:05:12 PM Testimony for HLT on 2/1/2023 8:30:00 AM

Submitted By	Organization	Testifier Position	Testify
Leilani Maxera	Individual	Support	Written Testimony Only

Comments:

HB659 would allow pharmicists to do certain diagnostic tests, inlcuding CLIA-waived hepatitic C antibody tests. This would increase access to testing as pharmacies are often easier to access than getting in to see a doctor. As we face a huge shortage of health care workers, expansion of this testing to include pharmacists would greatly serve our community. Please support HB659!

Date: January 30, 2023

- To: The Honorable Della Au Belatti, Chair The Honorable Jenna Takenouchi, Vice Chair Members of the House Committee on Health & Homelessness
- Re: **Support for HB659**, Relating to Health

Hrg: Wednesday February 1, 2023 at 8:30am Conference Room 329 & Videoconference

Aloha House Committee on Health & Homelessness,

As a parent, community member and healthcare professional I am writing in **strong support of HB659**, which establishes permitting and education requirements for pharmacists performing certain diagnostic tests or tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and expands the definition of "practice of pharmacy" to include the performance of certain diagnostic or CLIA-waived tests.

Pharmacies are a vital part of our healthcare system, offering ease of access in both urban and rural communities.

Pharmacists are well-trained in administering, interpreting, following-up and documenting CLIA-waived tests as an integral part of our pharmacy school education.

Making tests, including those used to diagnose HIV and hepatitis C, available in local pharmacies increases access and overcomes some of the barriers to testing, and promotes health equity.

I strongly support HB659, respectfully ask you to pass it out of committee.

Many thanks for your consideration,

Forrest Batz, PharmD Keaau, HI

<u>HB-659</u>

Submitted on: 1/27/2023 10:25:16 PM Testimony for HLT on 2/1/2023 8:30:00 AM

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

Comments:

I support legal and regulatory measures required to enable qualified pharmacists to perform certain diagnostic tests and CLIA-waived lab tests. Mahalo

HB-659 Submitted on: 1/30/2023 5:36:49 PM Testimony for HLT on 2/1/2023 8:30:00 AM

Submitted By	Organization	Testifier Position	Testify
Wendy Wink	Individual	Support	Written Testimony Only

Comments:

Dear Chair Belatti, Vice Chair Takenouchi and members of the committee

I strongly **support HB659** allowing pharmacists to perform diagnostic-related CLIA-waived tests such as Hepatitis and HIV rapid tests. Pharmacists are an important part of our healthcare workforce and they can be much more easily accessed to a wider range of community members. They are already allowed to provide vaccinations (and by the second Covid booster, have gotten really good at it), this would just make it much easier for people to access a wider range of basic healthcare needs. Although we have some amazing programs that offer these services, we are still falling short. We need better access to care and pharmacists across the islands can provide some of that, given the opportunity.

Thank you for the opportunity to testify.

With Gratitude,

Wendy Wink

LATE *Testimony submitted late may not be considered by the Committee for decision making purposes.

<u>HB-659</u>

Submitted on: 1/31/2023 2:43:16 PM Testimony for HLT on 2/1/2023 8:30:00 AM

Submitted By	Organization	Testifier Position	Testify
Kerri Okamura	Individual	Support	Written Testimony Only

Comments:

Clinical Laboratories of Hawaii 99-193 Aiea Heights Dr Aiea, HI 96701

House Committee on Health and Homelessness Wednesday, February 1, 2023, 8:30 AM Conference Room 329

Hawaii State Capitol 415 South Beretania Street Honolulu HI, 96814

Aloha Chair Belatti, Vice-Chair Takenouchi, and members of the committee,

Clinical Laboratories of Hawaii respectfully submits testimony in **opposition to HB659**. This measure will unnecessarily expand a pharmacist's power to order and perform waived tests.

Waived testing is approved through certification; current practice necessitates that oversight be done by a clinical laboratory director and the use of a laboratory consultant to ensure quality control and quality assurance. Expanding waived testing powers will require the use of State assets to fund the newly necessitated enforcement by CLIA, including in-person and more frequent visits to waived testing sites. While we respect the work of all health care professionals, pharmacists do not have the education and/or training to serve as clinical laboratory directors and should not be the final authority on a waived laboratory.

The primary concern regarding this measure is that it will allow pharmacists to "order and perform" all available waived tests.

Currently, HRA 11-110.1-2 an "authorized person" who can order test includes "a pharmacist licensed pursuant to HRS Chapter 461 in collaboration with a licensed physician...pursuant to HRS Chapter 442 and can only "order, receive and interpret laboratory test results within the scope of their practice." The "scope of their practice" for pharmacists only includes "routine drug therapy" per HRS Chapter 461, and only in accordance with a physician order or a protocol developed collaboratively with a physician and under which a pharmacist must receive appropriate training. Bill HB659 wants pharmacists to be able to order ALL waived tests (currently around 120), most if not almost all, outside the "scope of their practice."

To expand from a narrative perspective, a physician will examine the patient, take vital statistics, and explore family history to evaluate a patient's well-being to parse out the lab tests needed to refine a diagnosis. A physician can determine the gravity of the results and then refine a treatment plan for the patient, which may include prescriptions. A pharmacist does not have the education or experience to do any of those things. Moreover, under the law, pharmacists can't prescribe drugs to a customer without a physician order – since while they understand drugs, they do not have the medical background to diagnose and treat.

This measure gives pharmacists unwarranted authority in the field of medicine by allowing them to order tests without the appropriate education, certification, training, or experience. It is for this and the other aforementioned reasons that we request you to vote against HB659.

If you have any questions, please contact me at your convenience. Mahalo for your time and consideration.

Respectfully,

Ally Park

President, Clinical Laboratories of Hawaii

Clinical Labs of Hawaii is proud to celebrate 52 years of caring for Hawai'i. Clinical Labs of Hawaii (CLH) and Pan Pacific Pathologists were founded in 1971, by Dr. Moon S. Park. Upon completion of his pathology training at the Mayo Clinic, Dr. Park brought his vision of providing quality laboratory testing to the healthcare providers and patients of Hawai'i to reality by opening his first laboratory in Hilo. Today, Clinical Labs of Hawaii has more than 850 employees and 50+ locations throughout the Hawaiian Islands. The focus and vision have remained the same, quality patient care with best-in-class technology and service.