

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

Testimony COMMENTING on H.B. 1667
RELATING TO HEALTH.

REPRESENTATIVE RYAN I. YAMANE, CHAIR
HOUSE COMMITTEE ON HEALTH, HUMAN SERVICES, & HOMELESSNESS

Hearing Date: Tuesday, February 1, 2022

Room Number: Video Conf.

1 **Fiscal Implications:** None identified at this time.

2 **Department Testimony:** Thank you for the opportunity to provide COMMENTS on this bill.

3 The bill attempts to improve access to care but in a way that could jeopardize quality of
4 care. It would bypass current regulatory processes that are aimed at optimizing the quality of
5 care for patients and appears to be using the COVID-19 pandemic as leverage to gain
6 authorization for pharmacies to perform certain CLIA waived tests and to allow the public to
7 access pharmacies for those tests in perpetuity following the pandemic. As a result, this bill
8 would extend the authority contained in the Public Readiness and Emergency Preparedness
9 (PREP) Act for pharmacists to order and perform tests on a variety of medical conditions.

10 The Department is concerned that this would bypass other important and regular features
11 of the current healthcare system, namely: 1. Patient physical exam for physical findings and
12 obtaining patient and family history to determine a preliminary diagnosis; 2. Final diagnosis
13 based on lab testing, physical findings and patient and family history; and 3. Creating an
14 objective treatment plan beyond ordering of pharmaceuticals.

1 While the Department supports easy access to care, it supports access to quality care
2 which is what the current regulatory process helps to ensure.

3 Thank you for the opportunity to offer COMMENTS on this measure.

4 **Offered Amendments:** None.

Testimony of the Board of Pharmacy

**Before the
House Committee on Health, Human Services, & Homelessness
Tuesday, February 1, 2022
9:00 a.m.
Via Videoconference**

**On the following measure:
H.B. 1667, RELATING TO HEALTH**

Chair Yamane and Members of the Committee:

My name is James Skizewski, and I am the Executive Officer of the Board of Pharmacy (Board).

The purpose of this bill is to define “clinical laboratory director” to include certain physicians, licensed clinical laboratory scientists, and pharmacists-in-charge, and amend the definition of “practice of pharmacy” to include the ordering and performing of certain tests classified as waived pursuant to the Clinical Laboratory Improvement Amendments of 1988.

The Board will review and take a position on H.B. 1667, Relating to Health, at its next meeting, currently scheduled for Thursday, February 10, 2022. The Board will provide the Committee with updated information about its position following the meeting.

Thank you for the opportunity to testify on this bill.



To: Committee on Health, Human Services & Homelessness

Hearing Date/Time: Tuesday, February 1, 2022

Re: Testimony in Support of HB 1667

From: Heather Lusk, Hawaii Health and Harm Reduction Center

Dear Chair Yamane, Vice Chair Tam and members of the committee

The Hawaii Health & Harm Reduction Center (HHRC) supports 1667 and agrees that pharmacies are vital part of our healthcare system – especially because of the ease of access in the community. HHRC supports this measure in order to allow CLIA-waived point of care tests such as those used to diagnose HIV and hepatitis C as there is evidence that supporting these and other types of tests at the pharmacy level increase access to care and address some of the barriers to care.

HHRC'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, LGBTQ and the Native Hawaiian communities. While not a “traditional” homeless service agency, more than half of our clients/patients struggle with homelessness and we have been very active in providing housing services.

Thank you for the opportunity to testify.

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

HB-1667

Submitted on: 1/30/2022 8:58:46 PM

Testimony for HHH on 2/1/2022 9:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Patrick Uyemoto	Times Pharmacy	Support	No

Comments:

Times Pharmacy Strongly Supports HB1667

Aloha Chair Yamane, Vice Chair Tam, and Members of the Committee on Health, Human Services, and Homelessness

CLIA waived tests are categorized as “simple laboratory examinations and procedures that have an insignificant risk of an erroneous result” and the FDA determines which tests meet these criteria. Allowing pharmacists to order and perform CLIA waived tests has not only been a great experience and opportunity for the pharmacy profession but has also benefited the health of our communities. Most recently with the COVID pandemic, allowing pharmacists to order and perform CLIA waived COVID testing has dramatically increased its convenience and accessibility for the general public. This aspect is even more important on neighbor islands where there is a shortage of healthcare resources and primary care providers.



Testimony Presented Before the
House Committee on Health, Human Services and Homelessness
Tuesday, Feb. 1, 2022
9 am, Via Videoconference

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

Support for HB 1667, Relating to Health

To the:
Honorable Chair Yamane, Vice Chair Tam and members of the Committee

My name is Corrie Sanders and I serve as the President for the Hawai'i Pharmacists Association. Our organization stands in support of HB 1667 that would allow pharmacists to sign and authorize performance of Clinical Laboratory Improvement Amendment (CLIA) waived tests. HB 1667 also amends pharmacist scope of practice to include the ability to order and perform predefined CLIA waived tests.

As one of the most trusted and accessible members of the healthcare team, pharmacists play an integral role in patient care amid a growing shortage of primary care providers. By nature, CLIA waived tests have low risk for error and can provide time-sensitive, life saving information that has the potential to impact population health. Pharmacy school curriculums specifically include substantial training under supervised settings to equip pharmacists to perform these tests upon graduation.

Our value has become exceedingly evident throughout the COVID-19 pandemic. In the midst of constantly changing guidelines and regulations, pharmacists have served as cornerstones of care and been integral in the successful distribution of COVID-19 testing and vaccinations as granted through the Public Readiness and Emergency Preparedness (PREP) Act. 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 potentially overwhelmed healthcare systems.

I fear where the health of our state would be today without the enactment of the PREP Act and encourage you to consider how pharmacies across Hawai'i are successfully filling gaps in the continuum of care. HB 1667 would allow for care continuity past the expiration of the PREP Act and permit pharmacists to respond quickly to any future state of emergency.

Specific to the proposed bill, under Part II, Section 2. Section 321-15.1, HPhA supports the change of the "Clinical Laboratory Director," but respectfully requests that the language of "A pharmacist-in-charge" be changed to "pharmacist".

With the accessible night and weekend hours that many community pharmacies provide, the pharmacist-in-charge is not always present. During such times, the pharmacist on duty fills that role in their absence. Thus, 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. Furthermore, finding a clinical laboratory director 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.

Enacting HB 1667 will align the responsibility of Hawai'i pharmacists with the rest of the country to perform CLIA waived tests. 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.

January 31, 2022

Senator Jarrett Keohokalole, Chair
Senator Rosalyn Baker, Vice Chair
Senate Committee on Health
415 South Beretania Street
Honolulu, Hawaii 96813

RE: HB 1667 Relating to CLIA-waived testing and specimen collection
Hearing date: February 1, 2022

Aloha Chair Keohokalole, Vice Chair Baker, and members of the committee:

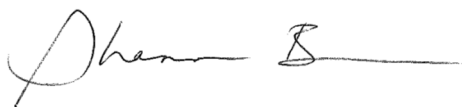
CVS Health is writing to share with you our support regarding House Bill 1667 (“HB 1667”), relating to Health. The amendments within will provide increased and equitable access to diagnostic testing by enabling a pharmacist to serve as a clinical laboratory director authorizing CLIA-waived testing and specimen collection. Providing increased access to diagnostic testing will support the patients of Hawaii with early detection of chronic conditions, management of their current disease states, and aid in determining if an acute malady requires further medical intervention.

Pharmacists’ clinical ability and current scope of practice in the state enables them to order and administer the testing encompassed within HB 1667. The amendments within the bill will enable the pharmacist-in-charge of a pharmacy to serve as a laboratory director for the purposes of authorizing testing and specimen collection at their pharmacy location. This measure will increase patient access to covered testing while removing the administrative burden of contracting with a clinical laboratory before ordering and performing this key patient service.

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

On behalf of CVS Health, I thank you for allowing us to provide our comments of support for consideration.

Respectfully,





Shannon Butler
Executive Director of State Government Affairs
CVS Health



To: Committee on Health, Human Services & Homelessness

Hearing Date/Time: Tuesday, February 1, 2022

Re: Testimony in Support of HB 1667

From: Hep Free Hawai`i

Dear Chair Yamane, Vice Chair Tam and members of the committee

Hep Free Hawai`i (HFH) supports 1667 and agrees that pharmacies are vital part of our healthcare system – especially because of the ease of access in the community. HFH supports this measure in order to allow CLIA-waived point of care tests such as those used to diagnose HIV and hepatitis C as there is evidence that supporting these and other types of tests at the pharmacy level increase access to care and address some of the barriers to care.

Hep Free Hawai`i (HFH) is a community-based coalition of over 100 local, national, and global partner agencies and over 1800 individual partners dedicated to increasing viral hepatitis awareness and access to viral hepatitis services throughout Hawai`i (www.hepfreehawaii.org). HFH is a program under the fiscal sponsorship of the Hawai`i Health and Harm Reduction Center (HHHRC), a 501c(3) nonprofit organization.

Thank you for the opportunity to testify.

Aaron Ruddick

Hepatitis Care Coordinator, Hep Free Hawaii



SanHi

GOVERNMENT STRATEGIES

A LIMITED LIABILITY LAW PARTNERSHIP

DATE: January 30, 2022

TO: Representative Ryan Yamane
Chair, Committee on Health, Human Services, and Homelessness

FROM: Mihoko Ito / Tiffany Yajima

RE: **H.B. 1667 – Relating to Health**
Hearing Date: Tuesday, February 1, 2022 at 9:00 a.m.

Dear Chair Yamane, Vice Chair Tam, and Members of the Committee on Health, Human Services, and 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 now has 19 stores on the islands of Oahu, Maui, and Hawaii.

Walgreens submits this testimony in **strong support** of this measure that would allow pharmacist-in-charge of a pharmacy to sign-off on applications for the purpose of authorizing Clinical Laboratory Improvement Amendments waived testing at pharmacies. Walgreens also supports this measure which clarifies that pharmacists may order and perform diagnostic related laboratory tests and CLIA-waived tests.

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. Pharmacies are increasingly offering CLIA-waived tests to promote patient health. 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.

Under current department of health regulations, pharmacies that perform CLIA-waived tests are required to partner with a clinical laboratory director to sign-off on the application to perform these tests. The pharmacy itself oversees, implements and manages compliance with CLIA-waiver protocol, and has oversight over all procedures in the pharmacy setting. For that reason, the signatory requirement is unnecessary and creates barriers to testing at a time when there is a significant strain on our state’s health care system. Hawaii is in the minority of states that have barriers to CLIA-waived testing, and this measure would put Hawaii in line with the majority of other states that have opened access to CLIA-waived testing in pharmacies.

In addition, this measure also amends the practice of pharmacy statute under Chapter 461 to clarify that pharmacists may order and perform drug therapy and diagnostic-

related CLIA-waived tests. Pharmacists are already performing COVID-19 tests pursuant to the April 2020 emergency declaration under the federal Public Readiness and Emergency Preparedness Act (PREP Act) and receive appropriate training by the Accreditation Council for Pharmacy Education (ACPE). This measure would enable broader community access to other CLIA-waived tests because of the accessibility of pharmacies in the community.

Walgreens requests an amendment on page 4, line 12 as follows:

(B) A ~~pharmacist in charge of a pharmacy~~ pharmacist serving as the director of a laboratory that only performs tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. §263a) or that performs the collection of a specimen that is processed by a clinical laboratory.

This amendment would allow any pharmacist, not just the pharmacist in charge of a pharmacy, to serve as the clinical laboratory director. In many pharmacy operations, a pharmacist other than the pharmacist in charge would oversee this program and serve as the signatory on clinical laboratory applications.

Additionally, Walgreens also requests an amendment to remove the language in paragraph (B)(ii) on page 7 at lines 9-17 as follows:

~~Used to detect or screen for SARS-CoV-2 or 10 other respiratory illness, condition, or 11 disease; mononucleosis; a sexually 12 transmitted infection; strep throat; anemia; 13 cardiovascular health issues; 14 conjunctivitis; a urinary tract infection; 15 liver or kidney function issues, liver or 16 kidney infection; thyroid function issues; a 17 substance use disorder; diabetes;~~

This language specifically enumerates the tests that pharmacists are authorized to perform and removing this language would allow pharmacists to order and perform all CLIA-waived tests that are currently approved by the FDA as well as any tests that will be approved in the future.

Thank you for the opportunity to submit this testimony in strong support of H.B. 1667. We respectfully ask that the committee pass this measure with amendments.

HB-1667

Submitted on: 1/30/2022 9:59:33 PM

Testimony for HHH on 2/1/2022 9:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Alanna Isobe	Individual	Support	No

Comments:

I am providing written testimony in favor of HB 1667

RELATING TO HEALTH. Defines "clinical laboratory director" to include certain physicians, licensed clinical laboratory scientists, and pharmacists-in-charge of pharmacies. Amends the definition of "practice of pharmacy" to include the ordering and performing of certain Clinical Laboratory Improvement Amendments waived tests.

- 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.”
- Pharmacists are currently ordering and administering Covid-19 antigen tests in pharmacies across the state.

The majority of my 25 year professional career has been in retail pharmacy which has evolved with the needs of the patients and healthcare system. Pharmacist training aligns with providing much more than just filling pills as we have demonstrated with the this pandemic, as well as other health outbreaks. Patients see their pharmacists for cuts and scrapes, sniffles and coughs, measles and hepatitis outbreak questions and now definitely for their Covid vaccination and testing. Patients rely on and trust their pharmacists for information. Increasing access to these laboratory tests will arm patients with more information regarding their ailments and treatments can be initiated appropriately and sooner.

The pharmacy field is diverse. This bill is a permissive bill that would allow pharmacists to perform these tests and be designated as lab director to make the CLIA-waived tests more accessible in pharmacies that choose to add these services to their patients. This is not a requirement for all pharmacies and will give us some more tools to better service patients.

I am supportive of this bill as it allows pharmacists to expand their scope of practice and maximize their ability to serve their patients in the community.

Sincerely,

Alanna S Isobe, Rph

HB-1667

Submitted on: 1/29/2022 8:42:55 PM

Testimony for HHH on 2/1/2022 9:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Thaddeus Pham	Individual	Support	No

Comments:

Aloha Chair Yamane, Vice Chair Tam, and HHH Committee Members,

As a public health professional, I am writing in support of HB1667, which would allow for pharmacists to order and perform CLIA-waived tests.

As made clear throughout the ongoing COVID-19 pandemic, pharmacist play a vital role in our statewide health infrastructure. Expanding their capacity for testing not only makes sense for current health issues, but will also prepare Hawai'i for future public health emergencies.

Mahalo,

Thaddeus Pham (he/him)

HB-1667

Submitted on: 1/27/2022 9:29:39 PM

Testimony for HHH on 2/1/2022 9:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Ronald Taniguchi, Pharm.D.	Individual	Support	No

Comments:

Support.

HB-1667

Submitted on: 1/30/2022 8:05:06 PM

Testimony for HHH on 2/1/2022 9:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Hiromi Saito	Individual	Support	No

Comments:

Dear Chair Yamane, Vice Chair Tam and members of the HHH committee,

I support HB1667 and agree that pharmacies are vital part of our healthcare system – especially because of the ease of access in the community.

I support this measure in order to allow CLIA-waived point of care tests such as those used to diagnose HIV and hepatitis C as there is evidence that supporting these and other types of tests at the pharmacy level increase access to care and address some of the barriers to care.

Thank you for the opportunity to testify.



UNIVERSITY OF HAWAII SYSTEM

Legislative Testimony

Testimony Presented Before the
House Committee on Health, Human Services, and Homelessness
Tuesday, February 1, 2022 at 9:00 a.m.
Conference Room 329

By
Bonnie Irwin, PhD
Chancellor
and
Carolyn Ma, PharmD, BCOP
Dean, Daniel K. Inouye College of Pharmacy
University of Hawai'i at Hilo

HB 1667 – RELATING TO HEALTH

Chair Yamane, Vice Chair Tam, and members of the committee:

Thank you for the opportunity to submit testimony on HB 1667. The University of Hawai'i at Hilo (UH Hilo) supports HB 1667 that proposes clarification as to who is authorized to sign an application to perform Clinical Laboratory Improvement Amendments waived tests: and amends the pharmacist scope of practice act to include the ordering and performing of certain CLIA waived tests.

All pharmacy schools across the U.S. are accredited by the Accreditation Council of Pharmacy Education (ACPE) to award the terminal professional degree Doctor of Pharmacy (PharmD). This testimony outlines the education and training requirements that all pharmacy schools provide students pertinent to CLIA waived testing ability. First, both didactic and experiential coursework includes pathology, therapeutics and monitoring of disease and necessary testing for various types of diseases. Training for testing would include blood sugar, cholesterol and lipid levels and other types of tests.

Secondly, as mandated by ACPE, in an area referred to as Entrustable Professional Activities (EPA), these skills must be applied in a supervised practice co-curricular setting such as a health fair or clinical screenings with private or public community partnerships such as American Diabetes Association. The college holds these types of events on a routine monthly or weekly basis.

Lastly, over 30% of the PharmD curriculum consists of the clinical experiential portion. Students in Introductory Pharmacy Practice Experiences (IPPE–440 hours) and Advanced Pharmacy Practice Experiences (1500 hours) are expected to perform these types of skills on patients in the various pharmacy settings in hospitals, outpatient clinics and community pharmacy retail sites. Graduates are expected to be practice ready at graduation and upon entering the workforce. These skills must be maintained by earning continuing education credits earned throughout their career as a pharmacist and as long as they hold a license as a registered pharmacist (RPh).

In order to fulfill the above-mentioned educational requirements, the Daniel K. Inouye College of Pharmacy (DKICP) has maintained a CLIA waived permit since 2009. This permit allows both our students and practice faculty to perform these tests in the co-curricular activities and experiential rotations. Our current director is currently signed under a medical director affiliated with the DKICP.

Specific to the bill language, under Part II, Section 2. Section 321-15.1, the DKICP supports the change of the "Clinical Laboratory Director: section 1 and 2.A and B, the DKICP respectfully requests that the language of "A pharmacist-in-charge" be changed to "pharmacist". Permits for CLIA waivers are held by most schools of pharmacy and we do not have a term 'pharmacist-in-charge' in the academic setting, however, most all pharmacy practice faculty hold a pharmacist license.

Passage of this bill will put Hawai'i in line with the rest of the country in terms of allowing pharmacists to serve as the clinical lab's director for pharmacies or colleges of pharmacy, medicine or other health science professional education program who are performing these tests.

A final request would be to remove the inclusive list of tests that can be done and amend it with a language to the effect of "all CLIA-waived tests" as new types of tests are added in the future.

Mahalo for allowing UH Hilo to testify on this issue.

HB-1667

Submitted on: 1/31/2022 10:45:00 AM

Testimony for HHH on 2/1/2022 9:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Shavon Fenton	Individual	Support	No

Comments:

Dear Chair Yamane, Vice Chair Tam and members of the HHH committee,

I support HB1667 and agree that pharmacies are vital part of our healthcare system – especially because of the ease of access in the community.

I support this measure in order to allow CLIA-waived point of care tests such as those used to diagnose HIV and hepatitis C as there is evidence that supporting these and other types of tests at the pharmacy level increase access to care and address some of the barriers to care.

Thank you for the opportunity to testify.

Sincerely,

Shavon Fenton

Testimony in Support for HB 1667

Dear Chair Yamane , Vice Chair Tam and Respected Members of the Committee,

My name is Keri Oyadomari and I am a community pharmacist here on the island of Oahu. I am writing to testify my support for HB 1667 relating to Health.

Pharmacies and pharmacists are a vital part of our healthcare system, especially because of their ease of access in the community. I support this measure in order to allow CLIA-waived point of care tests be ordered and administered by pharmacists. This amended scope of practice for pharmacists will increase access to care in the community. A great example of this has been during the COVID-19 Pandemic. The PREP act allowed pharmacists to order and administer COVID tests which aided in the efforts for identifying positive cases earlier and proactively. This bill will continue this effort as well as expand it to other areas of healthcare.

Other aspects of this bill will also allow pharmacists to utilize their expertise in playing a more collaborative role in the healthcare of patients.

Thank you for the opportunity to submit testimony.

Testimony in Support for HB 1667

Dear Chair Yamane , Vice Chair Tam and Respected Members of the Committee,

My name is Derek Tengan and I am a pharmacist and a pharmacy owner of an independent pharmacy with four locations here on the island of Oahu. I am writing to testify my support for HB 1667 relating to Health.

Pharmacies and pharmacists are a vital part of our healthcare system, especially because of their ease of access in the community. I support this measure in order to allow CLIA-waived point of care tests be ordered and administered by pharmacists. This amended scope of practice for pharmacists will increase access to care in the community. A great example of this has been during the COVID-19 Pandemic. The PREP act allowed pharmacists to order and administer COVID tests which aided in the efforts for identifying positive cases earlier and proactively. This bill will continue this effort as well as expand it.

Other aspects of this bill will also allow pharmacists to utilize their expertise in playing a more collaborative role in the healthcare of patients.

Thank you for the opportunity to submit testimony.