

**Testimony of the Board of Pharmacy**

**Before the  
House Committee on Consumer Protection and Commerce  
Friday, February 11, 2022  
2:00 p.m.  
Via Videoconference**

**On the following measure:  
H.B. 1667, H.D. 1, RELATING TO HEALTH**

Chair Johanson and Members of the Committee:

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

The purposes of this bill are to: (1) define “clinical laboratory director” to include certain physicians, licensed clinical laboratory scientists, and pharmacists-in-charge; (2) 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, H.D. 1, 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.



**Written Testimony Presented Before the  
House Committee on Consumer Protection & Commerce  
Friday, February 11, 2022 at 2:00 P.M.  
via Videoconference**

**by  
Laura Reichhardt, APRN, AGPCNP-BC  
Director, Hawai'i State Center for Nursing  
University of Hawai'i at Mānoa**

**Comments on HB 1667, HD1**

Chair Johanson Vice Chair Kitagawa, and members of the House Committee on Consumer Protection & Commerce, thank you for the opportunity for the Hawai'i State Center for Nursing to provide comments on HB 1667, HD1 as it relates to Section 2 only.

The Hawai'i State Center for Nursing thanks the Legislature for identifying this issue as a critical step in improving access to healthcare, including testing and interpretation of CLIA waived tests. The Center also recognizes the priority of this Committee in removing barriers to accessing healthcare by patients' preferred healthcare providers, whomever they may be.

Further, the Center notes that according to the Joint Commission, "For waived testing, there are no federally defined qualifications for the Laboratory Director in the Clinical Laboratory Improvement Amendments (CLIA). The individual should have the technical knowledge and experience required to oversee the specific laboratory testing performed."

[\(https://www.jointcommission.org/standards/standard-faqs/home-care/waived-testing-wt/000001789/\)](https://www.jointcommission.org/standards/standard-faqs/home-care/waived-testing-wt/000001789/).

The Center for Nursing respectfully requests that the Committee consider adding "licensed healthcare provider" to enable a breadth of qualified healthcare providers to seek CLIA waivers for labs in their offices. Page 4, lines 12-13:

- (1) A physician licensed to practice medicine or osteopathy under chapter 453; and
- (2) For clinical laboratory tests or examinations classified as waived:
  - (A) A duly licensed clinical laboratory scientist; and [or]
  - (B) A pharmacist-in-charge of a pharmacy serving [or licensed healthcare provider] 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."

The Hawai'i State Center for Nursing acknowledges the longstanding commitment of the Hawai'i State Legislature in supporting the people of Hawai'i in accessing healthcare and your support of the healthcare field. Thank you for the opportunity to share comments on this measure.

*The mission of the Hawai'i State Center for Nursing is that through collaborative partnerships, the Center provides accurate nursing workforce data for planning, disseminates nursing knowledge to support excellence in practice and leadership development; promotes a diverse workforce; and advocates for sound health policy to serve the changing health care needs of the people of Hawai'i.*



SanHi

GOVERNMENT STRATEGIES

A LIMITED LIABILITY LAW PARTNERSHIP

DATE: February 10, 2022

TO: Representative Aaron Johanson  
Chair, Committee on Consumer Protection & Commerce

FROM: Mihoko Ito / Tiffany Yajima

RE: **H.B. 1667, H.D.1 – Relating to Health**  
**Hearing Date: Friday, February 11, 2022 at 2:00 p.m.**

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Dear Chair Johanson, Vice Chair Kitagawa, and Members of the Committee on Consumer Protection and Commerce:

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 15 stores on the islands of Oahu and Maui.

Walgreens submits this testimony in **strong support** of this measure that would: 1) 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 and 2) clarify that pharmacists may order and perform diagnostic related laboratory tests and CLIA-waived tests. **We would also request that a clarifying amendment be incorporated into the bill, as outlined below.**

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. There are only nine states that require a physician only to serve as the laboratory director, whereas in all other states pharmacists in addition to physicians can serve as the laboratory director on a CLIA-waiver application. Hawaii is the only state that has additional requirements for the type of physician that can serve as a clinical laboratory director.

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 a technical amendment on page 4, line 7 to change the word “and” with “or” as follows:

“Clinical laboratory director” includes the following:

(1) A physician licensed to practice medicine or osteopathy under chapter 453;  
~~and~~ **or**

(2) For clinical laboratory tests or examinations classified as waived pursuant to the Clinical Laboratory Improvement. Amendments of 1988 (42 U.S.C. 11 263a)

Thank you for the opportunity to submit this testimony in strong support of H.B. 1667, H.D.1. We respectfully ask that the committee pass this measure with amendments.

Representative Aaron Ling Johanson, Chair  
Representative Lisa Kitagawa, Vice Chair  
Committee on Consumer Protection and Commerce  
415 South Beretania Street  
Honolulu, Hawaii 96813

**RE: HB 1667 HD1 Relating to Health – In Support**

February 11, 2022, 2:00 p.m.

Aloha Chair Johanson, Vice Chair Kitagawa and members of the committee:

CVS Health is in support of House Bill 1667 (“HB 1667 HD1”), which defines “clinical laboratory director” to include certain physicians, licensed clinical laboratory scientists, and pharmacists. It also amends the definition of “practice of pharmacy” to include the ordering and performing of certain Clinical Laboratory Improvement Amendments (CLIA) waived tests.

Providing increased access to diagnostic testing will support Hawaii’s patients 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 HD1. The bill will enable the pharmacist to serve as a laboratory director for the purposes of authorizing CLIA-waived 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, thank you for allowing us to provide our comments of support and we ask for your favorable consideration in passing this measure.

Respectfully,



Shannon Butler  
Executive Director of State Government Affairs  
CVS Health

**Written Testimony Presented Before the  
House Committee on Consumer Protection and Commerce  
Hearing: February 11, 2022 @ 2:00PM  
State Capitol, via Videoconference**

By Hawai'i – American Nurses Association (Hawai'i-ANA)



**HB1667, HD1 RELATING TO HEALTH**

Chair Aaron Ling Johanson, Vice Chair Lisa Kitagawa and members of the House Committee on Consumer Protection and Commerce, for this opportunity to provide testimony in support of HB1667, HD1 Relating to Health.

Hawai'i - American Nurses Association (Hawai'i-ANA) speaks for over 15,000 Registered Nurses in Hawai'i. Our mission is to “empower nurses to advocate for the improvement of the healthcare system in the communities where we live and work”. We thank the Legislature for identifying this issue as a critical step in improving access to healthcare, including testing and interpretation of CLIA waived tests. Hawai'i-ANA also recognizes the priority of the Health Committee in removing barriers to accessing healthcare by patients' preferred healthcare providers, whomever they may be.

Hawai'i-ANA has concerns that by omitting other licensed healthcare professionals who may be qualified to be CLIA waived laboratory directors, this measure will inadvertently prohibit providers, including Advanced Practice Registered Nurses (APRNs), from maintaining or becoming CLIA lab directors. Therefore, Hawai'i-ANA respectfully requests that the Committee consider adding “licensed healthcare provider”, as it appears in highlight, to enable the breadth of qualified healthcare providers to seek CLIA waivers for labs in their offices. Page 4, lines 12-13:

- (1) A physician licensed to practice medicine or osteopathy under chapter 453; and
- (2) For clinical laboratory tests or examinations classified as waived:
  - (A) A duly licensed clinical laboratory scientist; and [or]
  - (B) A pharmacist-in-charge of a pharmacy [or licensed healthcare provider] 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."

We respectfully request that HB1667, HD1 be passed out of this committee, with this friendly amendment that will improve access to healthcare. Thank you for your continuing careful consideration of measures that address the healthcare needs of our community.

Contact information for Hawai'i – American Nurses Association  
President: Katie Kemp, BAN, RN-BC    Executive Director: Dr. Linda Beechinor, APRN, FNP  
[president@hawaii-ana.org](mailto:president@hawaii-ana.org)                      [executivedirector@hawaii-ana.org](mailto:executivedirector@hawaii-ana.org)  
phone (808) 779-3001              500 Lunalilo Home Road, #27-E, Honolulu Hawai'i USA 96825

**HB-1667-HD-1**

Submitted on: 2/9/2022 5:49:25 PM

Testimony for CPC on 2/11/2022 2:00:00 PM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Remote Testimony Requested</b>
Gerard Silva	Individual	Oppose	No

Comments:

They are not Doctors there forthey have no Athority!!

**HB-1667-HD-1**

Submitted on: 2/9/2022 9:39:16 PM

Testimony for CPC on 2/11/2022 2:00:00 PM

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

Comments:

In support as written. Mahalo



**HB-1667-HD-1**

Submitted on: 2/10/2022 8:46:33 AM

Testimony for CPC on 2/11/2022 2:00:00 PM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Remote Testimony Requested</b>
Tami Whitney	Individual	Support	No

Comments:

Dear Chair Johanson, Vice-Chair Kitagawa, and members of the Consumer Protection & Commerce Committee,

I am writing to support HB1667 HD1, which would allow pharmacists to order and perform CLIA-waived tests.

Thank you,

Tami Whitney (she/her)

## **Testimony in Support for HB 1667**

Dear Chair Johanson, Vice Chair Kitagawa, and Respected Members of the Committee,

My name is Derek Tengan and I am a pharmacist and 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.

## **Testimony in Support for HB 1667**

Dear Chair Johanson, Vice Chair Kitagawa, and Respected Members of the Committee,

My name is Tiffany Bihis and I am a community pharmacist for an independent pharmacy here on 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 to 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. Additionally, it has relieved healthcare clinics to further aid those who require medical attention. This bill will continue this effort as well as expand it.

Other aspects of this bill will also allow pharmacists to utilize their pharmacotherapeutic knowledge 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 Johanson, Vice Chair Kitagawa, and Respected Members of the Committee,

My name is Keri Oyadomari and I am a community pharmacist for an independent pharmacy here on 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 to 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. Additionally, it has relieved healthcare clinics to further aid those who require medical attention. This bill will continue this effort as well as expand it.

Other aspects of this bill will also allow pharmacists to utilize their pharmacotherapeutic knowledge 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 Johanson, Vice Chair Kitagawa, and Respected Members of the Committee,

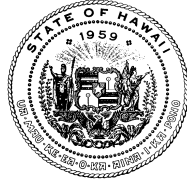
My name is Joo Kim and I am a community pharmacist technician for an independent pharmacy here on Oahu. I am writing to testify my support for HB 1667 Relating to Health.

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 to 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. Additionally, it has relieved healthcare clinics to further aid those who require medical attention. This bill will continue this effort as well as expand it.

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

Thank you for the opportunity to submit testimony.

DAVID Y. IGE  
GOVERNOR OF HAWAII



ELIZABETH A. CHAR, M.D.  
DIRECTOR OF HEALTH

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

**LATE**

**Testimony in OPPOSITION to H.B. 1667, HD1  
RELATING TO HEALTH.**

REPRESENTATIVE AARON LING JOHANSON, CHAIR  
HOUSE COMMITTEE ON CONSUMER PROTECTION & COMMERCE

Hearing Date: Friday, February 11, 2022

Room Number: Video Conf.

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

2 **Department Testimony:** Thank you for the opportunity to testify in OPPOSITION to this bill.

3 The Department changed its position to OPPOSE from COMMENTS due to further  
4 consideration of the potential negative impacts on quality of care services and based on the  
5 changes contained in HD1.

6 The Department's OPPOSITION is on Section 2 of the bill; the Department defers to the  
7 Department of Commerce and Consumer Affairs (DCCA) on Section 3 on revising the statutory  
8 definition of "practice of pharmacy."

9 The bill attempts to streamline the current regulatory process by allowing any pharmacist  
10 to serve as the director of a laboratory without a clinical laboratory consultant to order and  
11 perform waived tests at pharmacies. It would bypass current regulatory processes that are aimed  
12 at optimizing the quality of care for consumers and this bill appears to be using the COVID-19  
13 pandemic as leverage to gain authorization for pharmacies to perform additional CLIA waived  
14 tests in perpetuity following the pandemic. The current regulatory process permits pharmacies to

1 perform waived tests after contracting with a laboratory consultant who is certified by education,  
2 experience, and passed a national certifying exam to ensure quality of care.

3           This bill would redefine a clinical laboratory director to include a pharmacist but without  
4 a laboratory consultant. The laboratory consultant acts as an objective third-party clinical  
5 professional to help ensure quality of care. The bill could also allow bypassing important  
6 features of the current healthcare system, namely: 1. patient physical exam for physical findings  
7 and obtaining patient and family history to determine a preliminary diagnosis; 2. final diagnosis  
8 based on lab testing; and 3. creating an objective treatment plan beyond ordering of  
9 pharmaceuticals.

10           In summary, while the Department supports easy access to care, it supports access to  
11 quality care which is what the current regulatory process helps to ensure.

12           Thank you for the opportunity to testify in OPPOSITION of this measure. The  
13 Department requests this bill be DEFERRED.

14   **Offered Amendments:** None.

**LATE**

February 10, 2022

Aloha Chair Johanson and members of the committee:

I appreciate the time to allow me to testify in strong support of HB1667 again. 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.”
- Pharmacists are currently ordering and administering Covid-19 antigen tests in pharmacies across the state.

HB1667 would allow pharmacists to act as the laboratory director. This pharmacist would attest to quality and policies and procedures that the current laboratory director is attesting to. This would ensure the same qualities are being measured and expected as the current standard of care. There are several pharmacies that are currently performing these tests. This bill should streamline the application process and puts the responsibility of the laboratory director on the pharmacist applicant.

Pharmacies would still be required to work collaboratively with physicians and Pharmacists will still be required to have appropriate training. This is similar to their current practice in 461-1 “Practice of pharmacy” that allows collaboration with physicians so that pharmacists can initiate emergency contraception, administer drugs, and administer vaccines.

Thank you for the opportunity to testify in strong support of HB 1667.

Sincerely,

Alanna Isobe, Rph





Hawaii Pharmacists  
Association

## HAWAI'I PHARMACISTS ASSOCIATION

### Legislative Testimony

Testimony Presented Before the  
House Consumer Protection Committee  
Friday February 10, 2022  
2 pm, Via Videoconference

**LATE**

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

### **Support for HB 1667, Relating to Health**

To the:  
Honorable Chair 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.

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.

Furthermore, we feel the inclusion of the laboratory manager in this process serves as an administrative barrier that prevents expedited patient care. Although there is a pharmacy registration process through the Department of Health, the patient safety and training responsibilities still fully fall on the pharmacist even in the presence of these contracts. The simplicity of CLIA waived tests should not require a third party signature when adequately trained healthcare providers are available and already assuming responsibility for safety in the formalized process.

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.