



STATE OF HAWAII
DEPARTMENT OF HEALTH
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Testimony COMMENTING on S.B. 2592
RELATING TO HEALTH.

SENATOR JARRETT KEOHOKALOOLE, CHAIR
SENATE COMMITTEE ON HEALTH

Hearing Date: Friday, February 4, 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 Department's COMMENTS are on Section 2 of the bill; the Department defers to the
4 Department of Commerce and Consumer Affairs (DCCA) on Section 3 on revising the statutory
5 definition of "practice of pharmacy."

6 The bill attempts to improve access to care but in a way that could jeopardize quality of
7 care. It would bypass current regulatory processes that are aimed at optimizing the quality of
8 care for patients and appears to be using the COVID-19 pandemic as leverage to gain
9 authorization for pharmacies to perform additional CLIA waived tests and to allow the public to
10 access pharmacies for those tests in perpetuity following the pandemic. However, pharmacies
11 can already conduct waived testing and all major pharmacies and most smaller pharmacies in
12 Hawaii currently possess CLIA certificates and state permits to perform waived tests. The
13 current regulatory process permits pharmacies to perform any waived tests by contracting with a
14 laboratory consultant who is certified by education, experience, and pass a national certifying
15 exam to ensure quality of care.

1 The Department is concerned that this bill would allow pharmacies to bypass the
2 regulatory requirement by redefining a "clinical laboratory director" to include a pharmacist.
3 The new definition would place the pharmacist on the same level as a clinical laboratory scientist
4 who, as stated earlier, is the laboratory consultant who is certified by education, experience, and
5 passing a national certifying exam to ensure quality of care. The bill could also allow bypassing
6 other important features of the current healthcare system, namely: 1. Patient physical exam for
7 physical findings and obtaining patient and family history to determine a preliminary diagnosis;
8 2. Final diagnosis based on lab testing, physical findings and patient and family history; and 3.
9 Creating an objective treatment plan beyond ordering of pharmaceuticals.

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

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

13 **Offered Amendments:** None.

Testimony of the Board of Pharmacy

**Before the
Senate Committee on Health
Friday, February 4, 2022
1:00 p.m.
Via Videoconference**

**On the following measure:
S.B. 2592, RELATING TO HEALTH**

Chair Keohokalole 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 S.B. 2592, 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
Senate Committee on Health
Friday, February 04, 2022 at 1:00 PM.
via Videoconference**

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

Comments on SB 2592

Chair Keohokalole, Vice Chair Baker, and members of the Senate Committee on Health, thank you for the opportunity to provide comments on SB 2592 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 the Health 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 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, the Center 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."

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.

The Center defers to the Department of Health's Office of Health Care Assurance as it relates to the full impact and implementation of these safety and quality assurance processes. The Center also 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.



Testimony Presented Before the
House Committee on Health, Human Services and Homelessness
Friday, February 4
1 pm, Via Videoconference

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

Support for SB 2592, Relating to Health

To the:
Honorable Chair Keohokalole, Vice Chair Baker 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 SB 2592 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, live 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. SB 2592 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 SB 2592 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.



SanHi

GOVERNMENT STRATEGIES

A LIMITED LIABILITY LAW PARTNERSHIP

DATE: February 3, 2022

TO: Senator Jarrett Keohokalole
Chair, Committee on Health

FROM: Mihoko Ito / Tiffany Yajima

RE: **S.B. 2592 – Relating to Health**
Hearing Date: Friday, February 4, 2022 at 1:00 p.m.

Dear Chair Keohokalole, Vice Chair Baker, and Members of the Committee on Health:

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 submits this testimony in **strong support** of this measure that would: 1) allow the 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 some clarifying amendments 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. 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 S.B. 2592. We respectfully ask that the committee pass this measure with amendments.

SB-2592

Submitted on: 2/3/2022 8:54:58 AM

Testimony for HTH on 2/4/2022 1:00:00 PM

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

Comments:

Times Pharmacy Strongly Supports SB2592

Aloha Chair Keohokalole, Vice Chair Baker, and Members of the Committee on Health,

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.

SB-2592

Submitted on: 2/1/2022 7:39:55 PM

Testimony for HTH on 2/4/2022 1:00:00 PM

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

Comments:

I am providing written testimony in favor of SB2592

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.
- To clarify, pharmacists are already performing these tests, under the clinical laboratory director's oversight. This is not a new skill set. Pharmacists in all but a few states allow pharmacists to act in this capacity, so this would align us with the rest of the nation. Pharmacists would not be prescribing treatments or bypassing medical care anymore than a home pregnancy or at home covid test currently does. In fact, this would allow pharmacists to order tests that are necessary and push patients to seek medical care if needed, as opposed to patients not getting the tests at all and delaying care.

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

SB-2592

Submitted on: 2/1/2022 1:49:36 PM

Testimony for HTH on 2/4/2022 1:00:00 PM

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

Comments:

In support as written. Mahalo.

SB-2592

Submitted on: 2/2/2022 8:20:33 PM

Testimony for HTH on 2/4/2022 1:00:00 PM

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

Comments:

Aloha Chair Keohokalole, Vice Chair Baker, and HTH Committee Members,

As a public health professional, I am writing in support of SB2592, 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)

Chair Keohokalole, Vice Chair Baker and Members of the Committee

As the newly retired Dean for the University of Hawai'i at Hilo, Daniel K. Inouye College of Pharmacy and as a Registered Pharmacist, I support bill SB 2592 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 in order to provide CLIA waived testing for patients. 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. Pharmacies hold these types of events on a routine 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 upon entering the workforce. These skills must be maintained by earning continuing education credits earned for as long as they hold a license as a registered pharmacist (RPh).

Specific to the bill language, under Part II, Section 2. Section 321-15.1, I support the change of the “Clinical Laboratory Director: section 1 and 2.A and B, and respectfully suggest that the language of “A pharmacist-in-charge” be changed to “registered pharmacist”. Permits for CLIA waivers are held by most schools of pharmacy and the term ‘pharmacist-in-charge’ is not relevant in the academic setting.

Pharmacists are the most accessible health care professional in our communities. The availability of CLIA waived testing by pharmacists increases the opportunity and convenience for our patients to access care. In regards to the concern regarding continuity of care, pharmacists and health science students are trained to refer patients back to their primary care provider or advanced nurse practitioner for diagnostic follow up.

Passage of this bill will put Hawaii 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 programs that perform 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 this opportunity to submit testimony for this bill.

**Written Testimony Presented Before the
Senate Committee on Health
Hearing: February 4, 2022 @ 1:00PM
State Capitol, via Videoconference**

LATE

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



SB2592 RELATING TO HEALTH

Chair Jarrett Keohokalole, Vice Chair Rosalyn H. Baker and members of the Senate Committee on Health, for this opportunity to provide testimony in support of SB2592 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 SB2592 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
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phone (808) 779-3001 500 Lunalilo Home Road, #27-E, Honolulu Hawai'i USA 96825