

## **Testimony of the Board of Pharmacy**

**Before the  
Senate Committee on Health and Human Services  
Monday, February 13, 2023  
1:00 p.m.  
Conference Room 225 and Videoconference**

**On the following measure:  
S. B. 602, RELATING TO HEALTH**

Chair San Buenaventura and Members of the Committee:

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

Other States that allow pharmacists to administer CLIA-waived tests include, but are not limited to, Alabama, Arkansas, Georgia, Indiana, Kentucky, Massachusetts, Minnesota, North Carolina, North Dakota, Oregon, Rhode Island, South Carolina, Texas, Virginia, West Virginia, and Wyoming.

Testimony of the Board of Pharmacy  
S.B. 602  
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Thank you for the opportunity to testify on this bill.



**SanHi**

GOVERNMENT STRATEGIES

A LIMITED LIABILITY LAW PARTNERSHIP

DATE: February 12, 2023

TO: Senator Joy San Buenaventura  
Chair, Senate Committee on Health and Human Services

FROM: Mihoko Ito / Tiffany Yajima

RE: **S.B. 602 – Relating to Health**  
**Hearing Date: Monday, February 13, 2023 at 1:00 p.m.**  
**Conference Room: 225**

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Dear Chair San Buenaventura, Vice Chair Aquino, and members of the Committee on Health and Human Services:

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 collect 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:

(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 SB 602.



# HAWAI'I PHARMACISTS ASSOCIATION

## Legislative Testimony

Testimony Presented Before the  
Senate Health and Human Services Committee  
February 13, 2023

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

### **Support for SB 602, Relating to Health**

Honorable Chair San Buenaventura, Vice Chair Aquino and the Health and Human Services Committee,

The Hawai'i Pharmacists Organization (HPhA) stands in support of SB 602 that would allow pharmacists to sign and authorize performance of Clinical Laboratory Improvement Amendment (CLIA) waived tests. HB 602 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 for nonwaived tests.

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 tests would streamline the patient care process, expedite treatment regimens, prevent unnecessary exposures to infectious diseases and decrease the burden on an already overwhelmed healthcare system.

We strongly feel the inclusion of additional 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.

The argument will be made that interpretation of these tests can cause death. We would like to remind the committee that CLIA waived tests are intended to be utilized by the general population without a prescription due to the low risk of error and harm. The alternative perspective worth considering is that by not allowing pharmacists to provide these tests to the public, we will be removing the most accessible health providers from caring for patients that may also result in death. For example, a patient with low blood sugar could present to a pharmacy open 24/7 for immediate testing as opposed to not seeking testing at all, or seeking higher level care for a simple test within an already overwhelmed hospital system or clinic.

We strongly feel the inclusion of all CLIA waived tests falls within the training of a medical profession with a doctorate level education that is renowned for our accessibility and trusting relationships with patients. Enacting SB 602 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,

A handwritten signature in black ink that reads "Corrie Sanders". The signature is written in a cursive, flowing style.

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



# UNIVERSITY OF HAWAII SYSTEM

## ‘ŌNAEHANA KULANUI O HAWAII

### Legislative Testimony

#### Hō'ike Mana'o I Mua O Ka 'Aha'ōlelo

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Testimony Presented Before the  
Senate Committee on Health and Human Services  
Monday, February 13, 2023 at 1:00 p.m.

By

Bonnie Irwin, Chancellor

and

Miriam Mobley Smith, Interim Dean

Daniel K. Inouye College of Pharmacy

University of Hawai'i at Hilo

### SB 602 – RELATING TO HEALTH

Chair San Buenaventura, Vice Chair Aquino, and Members of the Committee:

Thank you for the opportunity to submit testimony on SB 602. The University of Hawai'i at Hilo (UH Hilo) supports SB 602, 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 SB 602.



**SB-602**

Submitted on: 2/12/2023 10:39:18 PM  
Testimony for HHS on 2/13/2023 1:00:00 PM



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

Comments:

**Testimony in Support of SB602**

Dear Chair San Buenaventura, Vice Chair Aquino, and Members of the Committee,

Times Pharmacy strongly supports SB602 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

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

COMMITTEE ON HEALTH AND HUMAN SERVICES

Monday, February 13, 2023, 2:30 p.m.  
Conference Room 225

Hawaii State Capitol  
415 South Beretania Street  
Honolulu HI, 96814



Aloha Chair Buenaventura, Vice-Chair Aquino, and members of the committee,

Clinical Laboratories of Hawaii respectfully submits testimony in **opposition to SB602**. 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 SB602 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 SB602.

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.*

February 12, 2023

Aloha Chair San Buenaventura, Vice Chair Aquino and Respected Members of the Committee on Health and Human Services,

I appreciate the time to allow me to testify in strong support of SB602. 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 SB602.

Sincerely,

Alanna Isobe, Rph

**SB-602**

Submitted on: 2/12/2023 9:10:39 AM

Testimony for HHS on 2/13/2023 1:00:00 PM

<b>Submitted By</b>	<b>Organization</b>	<b>Testifier Position</b>	<b>Testify</b>
Thaddeus Pham	Individual	Support	Written Testimony Only

Comments:

Aloha San Buenaventura, Vice Chair Aquino, and Committee Members,

As a public health professional, I write in strong support of SB602, which would establish permitting and education requirements for pharmacists performing certain diagnostic tests or tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). SB602 would also expand the definition of "practice of pharmacy" to include the performance of certain diagnostic or CLIA-waived tests.

As we have all learned (and likely experienced directly) during the early COVID-19 pandemic, pharmacists are essential components of a robust and responsive healthcare system. Not only do they dispense medications, but they also act as educators, screeners, and immunizers for people who otherwise might not engage with the healthcare system. As such, this bill would leverage this important workforce to provide approved rapid tests to help us respond to existing and future public health issues.

Please pass this bill to ensure that Hawai'i can respond in a timely and nimble way for public and economic health.

In gratitude,

Thaddeus Pham (he/him)