Testimony of the Board of Pharmacy

Before the
Senate Committee on Commerce and Consumer Protection
Tuesday, February 22, 2022
10:00 a.m.
Via Videoconference

On the following measure:
S. B. 2592, S. D. 1, RELATING TO HEALTH

Chair Baker and Members of the Committee:

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

The purposes of this bill are to: (1) define "clinical laboratory director" to include certain physicians, licensed clinical laboratory scientists, and pharmacists; and (2) amends the definition of "practice of pharmacy" to include the ordering and performing of certain Clinical Laboratory Improvement Amendments (CLIA) waived tests.

This bill amends the definition of “Practice of pharmacy” to authorize pharmacists to perform drug therapy and diagnostic related CLIA-waived tests provided it is in accordance with specific policies, procedures, or protocols developed collaboratively by health professionals.

Overtime, the pharmacist scope of practice has expanded as pharmacies are geographically dispersed throughout the community with extended hours of operation, making access to health care more convenient for patients who trust and recognize pharmacists as healthcare professionals who have established relationships with their patients and medical providers. Pharmacists possess the skills and knowledge to perform these simple tests that are non-technical and have a low risk for erroneous results. As an example, in response to the COVID-19 pandemic, pharmacists are ordering and administering COVID-19 antigen tests in pharmacies across the state.

Thank you for the opportunity to testify on this bill.

CVSHealth

1275 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004

Senator Rosalyn Baker, Chair
Senator Stanley Chang, Vice Chair
Committee on Commerce and Consumer Protection
415 South Beretania Street
Honolulu, Hawaii 96813

RE: SB 2592 SD1 Relating to Health – In Support
February 22, 2022, 10:00 a.m.

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

CVS Health is in support of SB 2592 SD1, 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 SB 2592 SD1. 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

SB-2592-SD-1
Submitted on: 2/18/2022 5:06:49 PM
Testimony for CPN on 2/22/2022 10:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Gerard Silva	Individual	Oppose	No

Comments:

All Crap that should not be allow How do we know that these people are Qualifed to do this job!!

SB-2592-SD-1
Submitted on: 2/18/2022 9:07:16 PM
Testimony for CPN on 2/22/2022 10:00:00 AM

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

Comments:

In full support of SB2592 SD1. Mahalo

I understand that there is a bill under consideration by the Hawaii State Senate, SB2592, that impacts on clinical laboratory testing in Hawaii. I'm concerned that this bill will negatively affect such testing because of inadequate controls on the quality of test performance, even for CLIA waived tests. The bill allows pharmacists to become laboratory directors and thus be responsible for all aspects of such testing and laboratory operations, but I believe there must be trained and qualified clinical laboratory professionals involved in an oversight role to ensure the quality of test results. I realize that there is a need to provide greater availability of testing, but a bad test is worse than no test at all. An incorrect test result could have severe consequences for the patient's health and welfare. Even for waived tests, there are many factors involved in quality control that must be carefully observed. These include following the test manufacturer's instructions, including acceptable sample type, precisely, otherwise the test becomes a "Laboratory Developed Test" and must undergo a very complex set of validation studies before use on patient samples. Other factors include making sure that positive and negative controls are run with each patient test and the results are acceptable, the test reagents are not expired, temperature restrictions for test kit storage are carefully and continuously monitored, testing personnel are adequately trained, etc. Thus, I believe that the bill as currently written is significantly flawed and should not be passed by the legislature.

Sincerely,

Michael Lieberman, PhD, D(ABMLI)

SB-2592-SD-1
Submitted on: 2/20/2022 9:22:54 PM
Testimony for CPN on 2/22/2022 10:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Linda Sakuda	Individual	Oppose	No

Comments:

I **oppose** SB 2592, I concur with testimony submitted by Hawaii State Department of Health on February 4, 2022.

As a recently retired Pathology Quality Manager at a medical center in Hawaii, waived testing was authorized to be performed by non-laboratory staff throughout the hospital. These testing sites were under diligent oversight by designated laboratory staff, i.e., laboratory consultant, from the main laboratory. Staff training was continuous and essential due to constant staff turnover. Review of records identified intermittently missed documentation or errors which required retraining to prevent further deviations. In addition to proper testing, lab oversight reviewed processes dealing with patient identification during sample collection and reporting of results.

Thus, I oppose SB 2592 as currently written.

Respectfully,

Linda Sakuda, MLS(ASCP)

SB-2592-SD-1
Submitted on: 2/20/2022 9:49:29 PM
Testimony for CPN on 2/22/2022 10:00:00 AM

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

Comments:

Aloha Chair Baker, Vice Chair Chang, and CPN Committee Members,

As a public health professional, I am writing in support of SB2592 SD1, 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)

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.” Examples of CLIA-waived tests include pregnancy tests, blood glucose tests, home drug tests, ovulation kits, home HIV tests, thyroid (TSH) tests, INR (Coumadin) tests, influenza A/B tests, covid-19 tests, cholesterol tests.
- Pharmacists are currently ordering and administering Covid-19 antigen tests in pharmacies across the state. There are some pharmacies in the state of Hawaii that do have CLIA waivers for these tests, but not all pharmacies have gone through the current extensive process.
- To clarify, pharmacists are already performing some of these tests, under the signature of a clinical laboratory director, but through oversight by pharmacies working in collaboration with physicians. 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 ability to recommend or provide some of these tests to patients in a pharmacy would not bypass patient physical exam by a physician, nor would it be the end-all final diagnosis for the patient. It will in fact allow patients to get information possibly sooner and increase access for patients that do not have access to a primary care physician. There are a lot of patients that do not go to a doctor regularly so some of these conditions go undiagnosed until it is too late. Pharmacists would be collaborating with physicians, providing information and referring care when warranted.
- The home pregnancy test was introduced in 1979. This was a revolutionary change that was viewed as one of the biggest changes for womens’ health. It gave patients the ability to be more active in their own healthcare, protected privacy of women who wanted to discreetly get these results prior to seeking medical care. These tests as well as other CLIA-waived tests merely increase access to information.
- Similar to mass health fairs, health care professionals provide cholesterol or glucose screenings and often times are the first time some of these patients learned of potential problems. These health care providers refer these patients to seek primary care physicians’ care and do not intend to bypass our healthcare system.
- Pharmacists refer patients to physicians regularly when needed. We are presented with various ailments, as patients seek self-care. Pharmacists are asked daily to determine if self-care is appropriate or what level of care (urgency) is warranted and advise patients accordingly. As more and more drugs are available without prescription, more and more ailments are being treated without physician intervention. Pharmacists are positioned to educate and steer patients to self-

care if safe to do so or towards the ER or physician if that is the best course. Similarly, these labs can give information to patients.

- The majority of my 25 year professional career has been in retail pharmacy which has evolved with the needs of the patients and healthcare. 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

Written Testimony Presented Before the
Senate Committee on Commerce and Consumer Protection
Hearing: February 22, 2022 @ 10:00PM
State Capitol, via Videoconference

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

SB2592, SD1 RELATING TO HEALTH

Chair Rosalyn H. Baker, Vice Chair Stanley Chang and members of the Senate Committee on Commerce and Consumer Protection, for this opportunity to provide testimony in support of SB2592, SD1 Relating to Health, with suggestions provided by the Hawai‘i State Center for Nursing.

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 step in improving access to healthcare, including testing and interpretation of CLIA waived tests. Hawai'i-ANA also recognizes the priority of the Commerce and Consumer Protection Committee in removing barriers to accessing safe and effective healthcare provided by patients' preferred healthcare providers, whomever they may be.

Today, APRNs are fulfilling the role of Lab Director for Class 1 Clinical Laboratory Permits as issued by the Department of Health for CLIA waived tests. 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 the suggestions made by the Hawai‘i State Center for Nursing, as below, to add APRNs as it appears in highlight, so that these authorities will be maintained should this bill be enacted.

Page 4, lines 8-18

(1) A physician licensed to practice medicine or osteopathy under chapter 453; or
(2) For clinical laboratory tests or examinations classified as waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a):
(A) An advanced practice registered nurse as defined in section 457-2.7; or

(B) ~~(A)~~ A duly licensed clinical laboratory scientist; ~~and~~ **or**
(C) A 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."

We respectfully request that SB2592, SD1 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 executivedirector@hawaii-ana.org
phone (808) 779-3001 500 Lunalilo Home Road, #27-E, Honolulu Hawai‘i USA 96825

February 21, 2022

Written Testimony for SB 2592 SD1
Before the Senate Committee on Commerce and Consumer Protection
By the Hawaii affiliate of the American Society for Clinical Laboratory Science (ASCLS Hawaii)
Marcella Yee, President

Chairman Rosalyn Baker, Vice-Chair Stanley Chang, and other members of the Committee on Commerce and Consumer Protection,

Thank you for the opportunity to comment on SB 2592 SD1 as it relates to Section 2 of this bill.

We are limiting our comments to the bill's new definition of clinical laboratory director to be inserted in Section 321-15.1, Hawaii Revised Statutes.

ASCLS Hawaii opposes the definition of "clinical laboratory director" as proposed in this bill. It conflicts with current federal Clinical Laboratory Improvement Amendments (CLIA) regulations (42CFR Part 493) and Hawaii Administrative Rules Title 11 Chapter 110.1 "Clinical Laboratories and Laboratory Personnel" (HAR 11-110.1). It will not expand access to clinical laboratory testing, but, on the contrary, decrease it.

The bill defines "clinical laboratory director" for non-waived testing as "(1) physician licensed to practice medicine under chapter 453" in Hawaii. This definition prevents other persons who are qualified to serve as a clinical laboratory director under CLIA and HAR 11-110.1. See Table 1. Qualified persons include physician assistants and nurse practitioners for provider-performed microscopy procedures.

In addition, a licensed physician will not qualify to serve as clinical laboratory director for clinical laboratories in hospitals such as The Queen's Medical Center, Kaiser Permanente, Pali Momi Medical Center, Kapiolani Women's and Children's Medical Center, Maui Memorial Medical Center, Hilo Medical Center and Wilcox Memorial Center as well as independent laboratories, such as Diagnostic Laboratory Services and Clinical Laboratories of Hawaii. These laboratories have more stringent requirements for a clinical laboratory director (Table 1) under CLIA and HAR 110.1 (Table 1).

Table 1. Clinical Laboratory Director for Non-Waived Testing Sites in Hawaii

SB2592 SD1	Current CLIA and HAR 11-110.1
Licensed physician	For Provider Performed Microscopy Procedures(PPMP): licensed physician, licensed physician assistants, licensed nurse practitioner For Laboratories performing non PPMP and non-waived tests: Licensed physician certified in clinical or anatomic pathology, licensed physician certified in a clinical laboratory science (microbiology, chemistry, immunology), or person holding a doctoral degree in a chemical, biological, or clinical laboratory science (i.e., microbiology, clinical chemistry, immunology)

The second part of the proposed definition of "clinical laboratory director" is for waived testing. It states a licensed clinical laboratory scientist, or a licensed pharmacist is qualified to serve as clinical laboratory director for sites performing waived tests. Current CLIA and HAR 11-110.1 does not restrict any person from serving as clinical laboratory director for waived testing. See Table 2. Hawaii has over 300 sites performing waived tests, and clinical laboratory directors for these sites include physicians, nurses, clinic administrators, and non-medical personnel. Limiting a clinical laboratory director of waived test sites to clinical laboratory scientists or pharmacists as stated in this bill is restrictive and will deny access to testing.

Table 2. Clinical Laboratory Director for Waived Testing Sites in Hawaii

SB 2592 SD1	Current CLIA and HAR 11-110.1
Licensed clinical laboratory scientist	No requirements
Licensed pharmacist	No requirements

In conclusion, we oppose the insertion of this new definition of "clinical laboratory director" to Hawaii Revised Statutes Section 321-15.1. It is in direct conflict with federal regulations and current Hawaii Administrative Rules. Passing this bill will not increase access to waived laboratory testing, but, in fact, decrease it.

The Hawaii affiliate of the American Society for Clinical Laboratory Science (ASCLS Hawaii) is the largest organization in Hawaii representing clinical laboratory professionals in our community. Our members include pathologists, clinical laboratory scientists, clinical laboratory specialists, clinical laboratory technicians, and cytotechnologists who work in all the major hospital laboratories, rural health hospitals, community clinics, and physician office laboratories.

As an affiliate of the national ASCLS, our mission is to promote patient safety through quality standards in clinical laboratory testing.

Date: February 21, 2022

To: The Honorable Rosalyn H. Baker, Chair
The Honorable Stanley Chang, Vice Chair
Members of the Senate Committee on Commerce and Consumer Protection

Re: **Support for SB2592 SD1**, Relating to Health

Hrg: Tuesday February 22, 2022 at 10:00am Conference Room 229 & Videoconference

Aloha Senate Committee on Commerce and Consumer Protection,

As a parent, community member and healthcare professional I am writing in **strong support of SB2592 SDS1,** which defines "clinical laboratory director" to include certain physicians, licensed clinical laboratory scientists, and pharmacists and amends the definition of "practice of pharmacy" to include the ordering and performing of certain Clinical Laboratory Improvement Amendments-waived tests.

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

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

Making CLIA-waived point of care tests, including those used to diagnose HIV and hepatitis C, available in local pharmacies increases access to health care, overcomes some of the barriers to obtaining care, and, increases healthcare equity.

I **strongly support SB2592 SD1**, respectfully ask you to pass it out of committee.

Many thanks for your consideration,

Forrest Batz, PharmD
Keaau, HI

SB-2592-SD-1
Submitted on: 2/21/2022 9:03:58 AM
Testimony for CPN on 2/22/2022 10:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Lynn Nakahara, MLS (ASCP)	Individual	Oppose	No

Comments:

I **oppose** SB 2592. I concur with the testimony submitted by the State of Hawaii Department of Health on February 4, 2022.

I am a Medical Laboratory Scientist (MLS) with over thirty years of experience in laboratory medicine, to include clinical and anatomic pathology, small satellite labs, and a large medical center. I have witnessed the positive changes that the Clinical Laboratory Improvement Amendments (CLIA) of 1988 accomplished to regulate and standardize the rapidly-changing laboratory field. It is dangerous to expand/lower the standards for any part of laboratory testing at this time of a myriad of Emergency Use Authorization (EUA) tests and treatments.

Thank you for this opportunity to submit testimony.

Respectfully,

Lynn Nakahara, MLS (ASCP)

CLINICAL LABS OF HAWAII

Chair Keohokalole, Vice Chair Baker and Members of the Committee:

I am a practicing pathologist with Clinical Laboratories of Hawaii, LLC. Thank you for the opportunity to comment on this bill. Whereas I am in favor of improving access to healthcare, changing the definition of a Clinical Laboratory Director as proposed in SB2592 bypasses important regulations that are in place to ensure quality patient care, and I am in opposition.

A Clinical Laboratory Director for CLIA waived tests is defined by the College of American Pathologists (CAP) as (1) an MD or DO or DPM licensed to practice in the jurisdiction where the laboratory is located, or (2) possess a doctoral degree in chemical, physical, biological, or clinical laboratory science from a accredited institution. This is in line with the current HAR 11-110 definition of the qualification of a clinical laboratory director. The reason for these recommendations, as stated by CAP, is that although waived tests are considered to be simple and easy to perform, no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect result is “risk free” or inconsequential with regard to potential harm. Pathologists and clinical laboratory scientists, who typically serve as laboratory directors, are specifically trained, experienced, and certified in the interpretation and handling of abnormal laboratory results. The current regulatory process already allows pharmacists to perform waived tests, and the PREP Act authorizes them to order and perform COVID-19 tests. Although I am in favor of improving access to care, my concern, as mentioned earlier, is that the bill bypasses important regulations that ensure access to quality care and I oppose changing these regulations.

Thank you very much,

Karen S. Thompson, MD
Pathologist, Clinical Laboratories of Hawaii
Professor and Chair, Department of Pathology, John A. Burns School of Medicine
President, Hawaii Society of Pathologists

SanHi
GOVERNMENT STRATEGIES
A LIMITED LIABILITY LAW PARTNERSHIP

DATE: February 22, 2022

TO: Senator Roz Baker
Chair, Committee on Commerce and Consumer Protection

FROM: Mihoko Ito / Tiffany Yajima

RE: **S.B. 2592, S.D.1 – Relating to Health**
Hearing Date: Tuesday, February 22, 2022 at 10:00 a.m.

Dear Chair Baker, Vice Chair Chang, and Members of the Committee on Commerce and Consumer Protection:

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 a pharmacist 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 technical 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 throughout the country are offering CLIA-waived tests to promote patient health and provide easy and convenient access to important patient health care information.

These tests are quick, simple and easy-to-use, and are by-definition excluded (waived) from the requirement that they be performed in a laboratory. Examples of CLIA-waived tests include blood glucose tests, home pregnancy 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 in any non-laboratory setting including at home or in a pharmacy setting.

Under current department of health regulations, pharmacies can already perform CLIA-waived tests, but are required to partner with a clinical laboratory director to sign-off on the application to perform these tests. This signature requirement is the only one of its kind in the country because it requires certain credentials for the type of clinical lab director used for the signature. The lab director signature is required even though the pharmacy already oversees, implements and manages compliance with CLIA-waiver protocol, and has oversight over all procedures in the pharmacy setting in collaboration

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with a physician. A pharmacist performing these routine tests would provide the information to the patient and recommend further consultation with their medical provider. Therefore, this measure would complement care provided for by a medical professional and would not bypass any patient safety measures that already exist in the healthcare system.

Hawaii is the only state that has additional credentialling requirements for the type of physician that can sign an application as a clinical laboratory director.[1] This signatory requirement creates regulatory barriers to testing that do not exist elsewhere in the nation at a time when there is already significant strain on our state's health care system. In fact, this measure would increase patient care because pharmacists are front line workers in the health care system and are positioned to educate and steer patients to seek additional care from their medical providers.

In addition, this measure also clarifies that pharmacists may order and perform drug therapy and diagnostic-related CLIA-waived tests by amending the practice of pharmacy statute under Chapter 461. 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 are trained by the Accreditation Council for Pharmacy Education (ACPE) to do all types of CLIA-waived tests. This measure would enable broader community access to other CLIA-waived tests because of the accessibility of pharmacies in the community.

For these reasons, Walgreens is in strong support of this measure. We appreciate the amendments made in the S.D.1 of this measure and request 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)

We note that we are in continued discussions with the Department of Health who we understand has expressed concerns about this measure. In addition, we are also supportive of amendments to the bill to include other licensed healthcare providers who can already serve in this capacity.

We respectfully ask that the committee pass this measure with amendments to allow discussions with all stakeholders to continue. Thank you for the opportunity to submit this testimony in strong support of S.B. 2592, S.D.1.

[1] There are nine states that require a physician 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.

CLINICAL LABS OF HAWAII

Dear Chair Keohokalole, Vice Chair Baker and committee members:

I am a practicing pathologist with over 20 years of experience in the field of laboratory medicine. I humbly offer this testimony to express some concerns I have over SB 2592; a bill I oppose. While I do recognize that the organization and delivery of health care must dynamically evolve to ever changing unique circumstances over time, I believe we must thoughtfully and respectfully work together as these changes affect scope of practice throughout all areas of healthcare delivery.

My concerns include the following points:

1. Ordering of laboratory tests by personnel who are not trained to recognize and treat the wide variety of possible medical conditions is dangerous.

2. Providers with continuity of care with a given patient (such as primary care providers) will inevitably be left out of the loop with testing done on their patients.

3. Concern that this will drive up the overall cost of healthcare because commercial pharmacy businesses will be incentivized to increase testing (some component of which may be not necessary), and many of these results will also need to be repeated on more accurate analyzers to verify and have greater confidence in results.

4. I also reference the official position statement of the College of American Pathology regarding scope of practice for pharmacists with the ordering of lab tests (see Appendix A).

Respectfully,

Stephen M. Smith, MD
Pathologist, Lab Director, Division Chair, Department of Pathology, Hilo Medical Center
Clinical Labs of Hawaii

APPENDIX A:

Pharmacist Scope of Practice and Laboratory Testing Responsibility **Policy Synopsis**

The College of American Pathologists believes that the interpretation of laboratory tests constitutes the practice of medicine, for which pharmacists should not be licensed. The College also believes that no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect test result is “risk free” or inconsequential with regard to potential harm. **Policy** The College believes that the interpretation of laboratory tests, used for the diagnosis, prevention, treatment, or assessment of human disease, or for purposes of drug therapy management, constitutes the practice of medicine, for which pharmacists should not be licensed. The College also believes that no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect test result is “risk free” or inconsequential with regard to potential harm. The College, therefore, recommends that any legislation or regulation addressing the ability of pharmacists to order, perform or evaluate laboratory tests should be based on the following principles: Except for individuals requesting a test for themselves as authorized by state law, the ordering of clinical laboratory tests should be limited to licensed physicians, licensed dentists, or licensed health care practitioners under the

supervision of a licensed physician or licensed dentist who is providing treatment for the patient. Diagnostic laboratory testing should only be performed by those individuals who possess appropriate clinical education and training, and under the supervision of licensed physicians, or consistent with moderate and high complexity testing requirements under CLIA 88. The interpretation of clinical laboratory tests is the practice of medicine and should, therefore, be done solely by licensed physicians. All clinical laboratory testing used for the diagnosis, prevention, treatment or assessment of human disease, and laboratory testing for purposes of drug therapy management should be subject to quality control and proficiency testing. When individuals perform any test on a person other than themselves, it should be construed as the practice of laboratory medicine, subject to all of the above listed principles, unless such test is approved by the Food and Drug Administration as an “over-the-counter” test that is available for use to the general public without a prescription and used by a home health care attendant or caregiver under the supervision of a licensed physician. The College of American Pathologists offers this policy for consideration by any government agency or legislature and for use by state pathology societies for legislative or regulatory advocacy.

Document ID: Pharmacist Scope of Practice and Laboratory Testing Responsibility Document type: Public Policy Responsible: Council on Government and Professional Affairs Approve: Board of Governors Consult: None Inform: CAP Policy Manual Adopted May 2002 Revised November 2002 Reaffirmed December 2013 Reaffirmed December 2016

WRITTEN 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
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LATE

Testimony in OPPOSITION to S.B. 2592, SD1
RELATING TO HEALTH.

SENATOR ROSALYN H. BAKER, CHAIR
SENATE COMMITTEE ON COMMERCE AND CONSUMER PROTECTION

Hearing Date: Tuesday, February 22, 2022 Room Number: Video Conf.

Fiscal Implications: None identified at this time.

Department Testimony: Thank you for the opportunity to testify in OPPOSITION to this bill. The Department changed its position to OPPOSE from COMMENTS due to further consideration of the potential negative impacts on quality of care services and based on the changes contained in SD1.

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

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

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

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

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

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

Offered Amendments: None.

LATE

Feb. 21, 2022 Testimony for SB 2592 S.D.1

Chair Baker, Vice Chair Keohokalole, and Members of the Senate CPC Committee

My name is Carolyn Ma, PharmD, and I am the newly retired Dean for the University of Hawai'i at Hilo, Daniel K. Inouye College of Pharmacy and a Registered Pharmacist. I **strongly support** bill SB 2592 S.D.1 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 performed by pharmacists increases the opportunity and convenience for our patients to access care. Pharmacists would also be collaborating with primary care providers given the results of these tests to improve patient care especially in regards to various diseases such as diabetes and cardiovascular disease. 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.

Mahalo for this opportunity to submit testimony for this bill.

HAWAI'I PHARMACISTS ASSOCIATION

Legislative Testimony

LATE

Testimony Presented Before the
Senate Committee on Commerce and
Consumer Protection
Tuesday, February 22, 2022
10 am, 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 Baker, Vice Chair Chang, 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. SB 2592 also amends pharmacist scope of practice to include the ability to order and perform 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 thorough 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 allowing for pharmacists to perform select CLIA waived tests 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.

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. The pharmacy itself ensures compliance with safety and regulatory policies despite a laboratory director signature being required. The pharmacy also serves as the point of contact and counsels the patient while assuming full responsibility for test performance.

Hawai'i is one of only nine states that requires a physician specifically to serve as a laboratory director. Throughout the rest of the country, a pharmacist can fulfill this role on a CLIA waived test application. While we understand the concerns stated by the Department of Health, we urge you to weigh the overall benefit versus risk considering the potential treatment delays in the setting of a test intended to be performed by any member of the general public. We are supportive of additional amendments allowing other healthcare professionals already serving in this capacity to continue doing so.

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.

LATE

SB-2592-SD-1
Submitted on: 2/22/2022 10:13:27 AM
Testimony for CPN on 2/22/2022 10:00:00 AM

Submitted By	Organization	Testifier Position	Remote Testimony Requested
Tami Whitney	Individual	Support	No

Comments:

Dear Chair, Vice-Chair, and the Commerce and Consumer Protection committee,

I STRONGLY support SB2592 SD1 and agree that pharmacies are a vital part of our healthcare system – especially because of the ease of access in the community.

I support this measure 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 increases access to care and addresses some of the barriers to care.

Thank you for the opportunity to testify.

Tami Whitney