

Honolulu, Hawaii

FEB 18 2022

RE: S.B. No. 2592  
S.D. 1

Honorable Ronald D. Kouchi  
President of the Senate  
Thirty-First State Legislature  
Regular Session of 2022  
State of Hawaii

Sir:

Your Committee on Health, to which was referred S.B. No. 2592 entitled:

"A BILL FOR AN ACT RELATING TO HEALTH,"

begs leave to report as follows:

The purpose and intent of this measure is to:

- (1) Define "clinical laboratory director" to include certain physicians, licensed clinical laboratory scientists, and pharmacists-in-charge of pharmacies; and
- (2) Amend the definition of "practice of pharmacy" to include the ordering and performing of certain Clinical Laboratory Improvement Amendments-waived tests.

Your Committee received testimony in support of this measure from Hawai'i Pharmacists Association, Walgreens, Times Pharmacy, Hawai'i--American Nurses Association, and four individuals. Your Committee received comments on this measure from the Department of Health, Board of Pharmacy, and Hawai'i State Center for Nursing.

Your Committee finds that the Clinical Laboratory Improvement Amendments of 1988, P.L. 100-578 (CLIA), regulates all facilities that perform laboratory testing on human specimens for health assessment. The CLIA provides waivers for certain tests, such as simple tests that are non-technical and have a low risk for



erroneous results. Some examples of CLIA-waived tests include blood glucose monitoring tests, cholesterol monitoring tests, and, recently, coronavirus disease 2019 tests. 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 CLIA-waived tests. This measure defines "clinical laboratory director" to include pharmacists-in-charge of pharmacies and specifies that ordering and performing certain CLIA-waived tests is included in the "practice of pharmacy."

Your Committee heard from various stakeholders, which recommended that pharmacists, rather than pharmacists-in-charge of pharmacies, be included as clinical laboratory directors authorized to sign applications to perform CLIA-waived tests. Furthermore, the measure as currently drafted lists specific CLIA-waived tests that are included within the "practice of pharmacy." Your Committee finds that this enumeration is unnecessary, as tests may be included or removed from the list of CLIA-waived tests in the future.

Therefore, your Committee has amended this measure by:

- (1) Replacing pharmacists-in-charge with pharmacists in the definition of "clinical laboratory directors";
- (2) Removing the enumerated list of CLIA-waived tests included in the definition of "practice of pharmacy";
- (3) Inserting an effective date of July 1, 2050, to encourage further discussion; and
- (4) Making technical, nonsubstantive amendments for the purposes of clarity and consistency.

As affirmed by the record of votes of the members of your Committee on Health that is attached to this report, your Committee is in accord with the intent and purpose of S.B. No. 2592, as amended herein, and recommends that it pass Second Reading in the form attached hereto as S.B. No. 2592, S.D. 1, and be referred to your Committee on Commerce and Consumer Protection.



Respectfully submitted on  
behalf of the members of the  
Committee on Health,



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JARRETT KEOHOKALOLE, Chair



The Senate  
Thirty-First Legislature  
State of Hawai'i

**Record of Votes  
Committee on Health  
HTH**

Bill / Resolution No.:*	Committee Referral:	Date:		
<b>SB2092</b>	<b>HTH, CPN</b>	<b>2-11-2022</b>		
<input type="checkbox"/> The Committee is reconsidering its previous decision on this measure. If so, then the previous decision was to: _____				
The Recommendation is: <input type="checkbox"/> Pass, unamended 2312 <input checked="" type="checkbox"/> Pass, with amendments 2311 <input type="checkbox"/> Hold 2310 <input type="checkbox"/> Recommit 2313				
Members	Aye	Aye (WR)	Nay	Excused
KEOHOKALOLE, Jarrett (C)	✓			
BAKER, Rosalyn H. (VC)	✓			
MORIWAKI, Sharon Y.	✓			
SAN BUENAVENTURA, Joy A.	✓			
FEVELLA, Kurt	✓			
<b>TOTAL</b>	<b>5</b>	<b>-</b>	<b>-</b>	<b>-</b>
Recommendation: <input checked="" type="checkbox"/> Adopted <input type="checkbox"/> Not Adopted				
Chair's or Designee's Signature: <i>Rosalyn H Baker</i>				
<b>Distribution:</b> Original                      Yellow                      Pink                      Goldenrod File with Committee Report    Clerk's Office            Drafting Agency            Committee File Copy				

\*Only one measure per Record of Votes