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# A BILL FOR AN ACT

RELATING TO HEALTH.

**BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:**

1           SECTION 1. The legislature finds that pharmacies are vital  
2 to the State's health care system because of their convenient  
3 points of access in their communities. Pharmacists are trusted  
4 health care professionals who have established relationships  
5 with their patients, medical providers, and hospitals.

6           The legislature further finds that the coronavirus disease  
7 2019 (COVID-19) pandemic highlighted the critical need to  
8 address health care testing accessibility and streamline  
9 unnecessary administrative regulations. To increase the  
10 administration of COVID-19 tests, in April 2020, the federal  
11 government issued an emergency declaration under the Public  
12 Readiness and Emergency Preparedness (PREP) Act, which, among  
13 other things, authorized pharmacists to order and administer  
14 COVID-19 testing and increased access to certain pharmacy-  
15 administered tests. The PREP Act is in effect through the end  
16 of 2024; however, there are certain provisions in the PREP Act  
17 that have not been codified in state law.



1           In addition to COVID-19 tests, the legislature further  
2 finds that pharmacists in the State are currently permitted to  
3 perform certain drug therapy-related tests under the definition  
4 of "practice of pharmacy" in section 461-1, Hawaii Revised  
5 Statutes. However, there are differing interpretations under  
6 state law as to whether pharmacists can explicitly perform tests  
7 that are classified as waived under the federal Clinical  
8 Laboratory Improvement Amendments of 1988 (CLIA). CLIA-waived  
9 tests are simple tests that are non-technical and have a low  
10 risk for erroneous results. Most CLIA-waived tests are approved  
11 by the federal Food and Drug Administration for home use and  
12 pose very little reasonable risk of harm to the patient if  
13 performed incorrectly. Some examples of CLIA-waived tests  
14 include blood glucose monitoring tests, cholesterol monitoring  
15 tests, and, recently, COVID-19 point-of-care or "rapid" tests.

16           The legislature further finds that clarifying the law to  
17 allow pharmacists to order certain tests and collect specimens  
18 for certain common diagnostic-related tests for respiratory  
19 illness like influenza, streptococcal pharyngitis, and liver  
20 function, as well as CLIA-waived tests, will improve and expand  
21 patient access to necessary, but simple, health care.



1           Accordingly, the purpose of this Act is to amend the scope  
2 of practice for pharmacists to clarify that pharmacists may  
3 order certain tests and perform the collection of specimens for  
4 certain diagnostic-related and CLIA-waived tests.

5           SECTION 2. Chapter 461, Hawaii Revised Statutes, is  
6 amended by adding a new section to be appropriately designated  
7 and to read as follows:

8           "§461-       Diagnostic and other certain non-technical health  
9 assessment tests; authority; permitting and education  
10 requirements. (a) Unless otherwise authorized by law, no  
11 pharmacist shall order, or perform the collection of specimens  
12 for, certain diagnostic-related and CLIA-waived tests without  
13 first obtaining a permit pursuant to rules adopted in accordance  
14 with section 321-13.

15           (b) Before ordering, or performing the collection of  
16 specimens for, certain diagnostic-related and CLIA-waived tests,  
17 the pharmacist shall have completed appropriate training that  
18 includes programs approved by the Accreditation Council for  
19 Pharmacy Education, curriculum-based programs from an ACPE-  
20 accredited college of pharmacy, state or local health department  
21 programs, or programs recognized by the board of pharmacy, and



1 any regulations adopted by the United States Health Care  
2 Financing Administration."

3 SECTION 3. Section 461-1, Hawaii Revised Statutes, is  
4 amended as follows:

5 1. By adding a new definition to be appropriately inserted  
6 and to read:

7 "CLIA-waived tests" means any test that is classified as  
8 waived under the federal Clinical Laboratory Improvement  
9 Amendments of 1988 (42 U.S.C. 263a)."

10 2. By amending the definition of "practice of pharmacy" to  
11 read:

12 "'Practice of pharmacy" means:

- 13 (1) The interpretation and evaluation of prescription
- 14 orders; the compounding, dispensing, and labeling of
- 15 drugs and devices (except labeling by a manufacturer,
- 16 packer, or distributor of nonprescription drugs and
- 17 commercially legend drugs and devices); the
- 18 participation in drug selection and drug utilization
- 19 reviews; the proper and safe storage of drugs and
- 20 devices and the maintenance of proper records
- 21 therefor; the responsibility for advising when



1 necessary or where regulated, of therapeutic values,  
2 content, hazards, and use of drugs and devices; and  
3 the interpretation and evaluation of prescription  
4 orders to adjust the supply dispensed for purposes of  
5 medication synchronization pursuant to section  
6 431:10A-606, 432:1-621, or 432D-30;

7 (2) Performing the following procedures or functions as  
8 part of the care provided by and in concurrence with a  
9 "health care facility" and "health care service" as  
10 defined in section 323D-2; or a "pharmacy"; or a  
11 licensed physician, a licensed physician assistant, or  
12 a licensed advanced practice registered nurse with  
13 prescriptive authority; or a "managed care plan" as  
14 defined in section 432E-1; in accordance with  
15 policies, procedures, or protocols developed  
16 collaboratively by health professionals, including  
17 physicians and surgeons, pharmacists, physician  
18 assistants, and registered nurses, and for which a  
19 pharmacist has received appropriate training required  
20 by these policies; procedures, or protocols:



- 1 (A) Ordering or performing routine drug therapy
- 2 related patient assessment procedures;
- 3 (B) Ordering drug therapy related laboratory tests;
- 4 (C) Initiating emergency contraception oral drug
- 5 therapy in accordance with a written
- 6 collaborative agreement approved by the board,
- 7 between a licensed physician, physician
- 8 assistant, or advanced practice registered nurse
- 9 with prescriptive authority and a pharmacist who
- 10 has received appropriate training that includes
- 11 programs approved by the Accreditation Council
- 12 for Pharmacy Education (ACPE), curriculum-based
- 13 programs from an ACPE-accredited college of
- 14 pharmacy; state or local health department
- 15 programs, or programs recognized by the board of
- 16 pharmacy;
- 17 (D) Administering drugs orally, topically, by
- 18 intranasal delivery, or by injection, pursuant to
- 19 the order of the patient's licensed physician,
- 20 physician assistant, or advanced practice
- 21 registered nurse with prescriptive authority, by



1 a pharmacist having appropriate training that  
2 includes programs approved by the ACPE,  
3 curriculum-based programs from an ACPE-accredited  
4 college of pharmacy, state or local health  
5 department programs, or programs recognized by  
6 the board of pharmacy;

7 (E) Administering:

8 (i) Immunizations orally, by injection, or by  
9 intranasal delivery, to persons eighteen  
10 years of age or older by a pharmacist having  
11 appropriate training that includes programs  
12 approved by the ACPE, curriculum-based  
13 programs from an ACPE-accredited college of  
14 pharmacy, state or local health department  
15 programs, or programs recognized by the  
16 board of pharmacy;

17 (ii) Vaccines to persons between fourteen and  
18 seventeen years of age pursuant to section  
19 461-11.4; and

20 (iii) Human papillomavirus, Tdap (tetanus,  
21 diphtheria, pertussis), meningococcal, and



1                   influenza vaccines to persons between eleven  
2                   and seventeen years of age pursuant to  
3                   section 461-11.4;

4           (F) As authorized by the written instructions of a  
5           licensed physician, physician assistant, or  
6           advanced practice registered nurse with  
7           prescriptive authority, initiating or adjusting  
8           the drug regimen of a patient pursuant to an  
9           order or authorization made by the patient's  
10          licensed physician, physician assistant, or  
11          advanced practice registered nurse with  
12          prescriptive authority and related to the  
13          condition for which the patient has been seen by  
14          the licensed physician, physician assistant, or  
15          advanced practice registered nurse with  
16          prescriptive authority; provided that the  
17          pharmacist shall issue written notification to  
18          the patient's licensed physician, physician  
19          assistant, or advanced practice registered nurse  
20          with prescriptive authority or enter the  
21          appropriate information in an electronic patient





- 1 record system shared by the licensed physician,  
2 physician assistant, or advanced practice  
3 registered nurse with prescriptive authority,  
4 within twenty-four hours;
- 5 (G) Transmitting a valid prescription to another  
6 pharmacist for the purpose of filling or  
7 dispensing;
- 8 (H) Providing consultation, information, or education  
9 to patients and health care professionals based  
10 on the pharmacist's training and for which no  
11 other licensure is required; or
- 12 (I) Prescribing and dispensing an opioid antagonist  
13 pursuant to section 461-11.8;
- 14 (3) The offering or performing of those acts, services,  
15 operations, or transactions necessary in the conduct,  
16 operation, management, and control of pharmacy; [and]
- 17 (4) Prescribing and dispensing contraceptive supplies  
18 pursuant to section 461-11.6 [-]; and
- 19 (5) Notwithstanding any other law to the contrary, and in  
20 accordance with the requirements of section 461-,  
21 ordering, or performing the collection of specimens



1           for, tests authorized or approved by the United States  
2           Food and Drug Administration, that are:  
3           (A) Diagnostic-related laboratory tests used to  
4           detect or screen for severe acute respiratory  
5           syndrome coronavirus 2 (SARS-CoV-2) and  
6           respiratory illnesses including influenza  
7           infection, streptococcal pharyngitis, or liver  
8           function issues or infections; provided that no  
9           test shall require the use of specimens collected  
10           by vaginal swab, venipuncture, or the collection  
11           of seminal fluid; or  
12           (B) CLIA-waived tests."

13           SECTION 4. Statutory material to be repealed is bracketed  
14 and stricken. New statutory material is underscored.

15           SECTION 5. This Act shall take effect on December 31,  
16 2050.



**Report Title:**

Diagnostic Testing; CLIA-Waived Tests; Pharmacists; Permit;  
Education Requirements

**Description:**

Establishes permitting and education requirements for pharmacists ordering or collecting specimens for certain diagnostic tests or tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Expands the definition of "practice of pharmacy" to include the ordering of certain tests and collecting specimens for certain diagnostic or CLIA-waived tests. Effective 12/31/2050. (SD2)

*The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.*

