
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 COVID-19
10 testing, in April 2020 the federal government issued an
11 emergency declaration under the Public Readiness and Emergency
12 Preparedness (PREP) Act, which, among other things, authorized
13 pharmacists to order and administer COVID-19 testing and
14 increased access to certain pharmacy-administered tests. The
15 PREP Act is in effect through the end of 2024; however, there
16 are certain provisions in the PREP Act that have not been
17 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, SARS CoV-2 (COVID-19) point-of-care or
16 "rapid" tests.

17 The legislature finds that clarifying the law to allow
18 pharmacists to order and perform certain common diagnostic-
19 related tests for respiratory illness like influenza,
20 streptococcal pharyngitis, and liver function, as well as CLIA-



1 waived tests, will improve and expand patient access to
2 necessary, but simple, health care.

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

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

10 "§461- Diagnostic and certain other non-technical
11 health assessment tests; authority; permitting and education
12 requirements. Unless otherwise authorized by law, a pharmacist
13 shall only exercise the authority granted in paragraph (5) of
14 the definition of "practice of pharmacy" under section 461-1, to
15 order and perform the collection of specimens for certain
16 diagnostic-related and CLIA-waived tests:

17 (1) After completing appropriate training that includes
18 programs approved by the Accreditation Council for
19 Pharmacy Education, curriculum-based programs from an
20 Accreditation Council for Pharmacy Education-
21 accredited college of pharmacy, state or local health



1 department programs, or programs recognized by the
2 board of pharmacy, and any regulations adopted by the
3 United States Health Care Financing Administration;
4 and

5 (2) Upon application for and receipt of a permit pursuant
6 to the requirements of section 321-13."

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

9 1. By adding a new definition to be appropriately inserted
10 and to read:

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

14 2. By amending the definition of "practice of pharmacy" to
15 read:

16 ""Practice of pharmacy" means:

17 (1) The interpretation and evaluation of prescription
18 orders; the compounding, dispensing, and labeling of
19 drugs and devices (except labeling by a manufacturer,
20 packer, or distributor of nonprescription drugs and
21 commercially legend drugs and devices); the



1 participation in drug selection and drug utilization
2 reviews; the proper and safe storage of drugs and
3 devices and the maintenance of proper records
4 therefore; the responsibility for advising when
5 necessary or where regulated, of therapeutic values,
6 content, hazards, and use of drugs and devices; and
7 the interpretation and evaluation of prescription
8 orders to adjust the supply dispensed for purposes of
9 medication synchronization pursuant to section
10 431:10A-606, 432:1-621, or 432D-30;

11 (2) Performing the following procedures or functions as
12 part of the care provided by and in concurrence with a
13 "health care facility" and "health care service" as
14 defined in section 323D-2; or a "pharmacy"; or a
15 licensed physician, a licensed physician assistant, or
16 a licensed advanced practice registered nurse with
17 prescriptive authority; or a "managed care plan" as
18 defined in section 432E-1, in accordance with
19 policies, procedures, or protocols developed
20 collaboratively by health professionals, including
21 physicians and surgeons, pharmacists, physician



1 assistants, and registered nurses, and for which a
2 pharmacist has received appropriate training required
3 by these policies, procedures, or protocols:

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



1 the order of the patient's licensed physician,
2 physician assistant, or advanced practice
3 registered nurse with prescriptive authority, by
4 a pharmacist having appropriate training that
5 includes programs approved by the ACPE,
6 curriculum-based programs from an ACPE-accredited
7 college of pharmacy, state or local health
8 department programs, or programs recognized by
9 the board of pharmacy;

10 (E) Administering:

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



- 1 (ii) Vaccines to persons between fourteen and
- 2 seventeen years of age pursuant to section
- 3 461-11.4; and
- 4 (iii) Human papillomavirus, Tdap (tetanus,
- 5 diphtheria, pertussis), meningococcal, and
- 6 influenza vaccines to persons between eleven
- 7 and seventeen years of age pursuant to
- 8 section 461-11.4;
- 9 (F) As authorized by the written instructions of a
- 10 licensed physician, physician assistant, or
- 11 advanced practice registered nurse with
- 12 prescriptive authority, initiating or adjusting
- 13 the drug regimen of a patient pursuant to an
- 14 order or authorization made by the patient's
- 15 licensed physician, physician assistant, or
- 16 advanced practice registered nurse with
- 17 prescriptive authority and related to the
- 18 condition for which the patient has been seen by
- 19 the licensed physician, physician assistant, or
- 20 advanced practice registered nurse with
- 21 prescriptive authority; provided that the



1 pharmacist shall issue written notification to
2 the patient's licensed physician, physician
3 assistant, or advanced practice registered nurse
4 with prescriptive authority or enter the
5 appropriate information in an electronic patient
6 record system shared by the licensed physician,
7 physician assistant, or advanced practice
8 registered nurse with prescriptive authority,
9 within twenty-four hours;

10 (G) Transmitting a valid prescription to another
11 pharmacist for the purpose of filling or
12 dispensing;

13 (H) Providing consultation, information, or education
14 to patients and health care professionals based
15 on the pharmacist's training and for which no
16 other licensure is required; or

17 (I) Prescribing and dispensing an opioid antagonist
18 pursuant to section 461-11.8;

19 (3) The offering or performing of those acts, services,
20 operations, or transactions necessary in the conduct,
21 operation, management, and control of pharmacy; [~~and~~]



- 1 (4) Prescribing and dispensing contraceptive supplies
2 pursuant to section 461-11.6[-]; and
- 3 (5) Notwithstanding any other law to the contrary, and in
4 accordance with the requirements of section 461- ,
5 ordering tests and performing the collection of
6 specimens authorized or approved by the United States
7 Food and Drug Administration that are:
- 8 (A) Diagnostic-related laboratory tests used to
9 detect or screen for SARS-CoV-2, respiratory
10 illnesses including influenza infection,
11 streptococcal pharyngitis, or liver function
12 issues or infections; provided that no test shall
13 require the use of specimens collected by vaginal
14 swab, venipuncture, or the collection of seminal
15 fluid; or
- 16 (B) CLIA-waived tests."

17 SECTION 4. Statutory material to be repealed is bracketed
18 and stricken. New statutory material is underscored.

19 SECTION 5. This Act shall take effect on June 30, 3000.

20



Report Title:

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

Description:

Establishes permitting and education requirements for pharmacists performing 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 and collection of specimens for certain diagnostic-related or CLIA-waived tests. Effective 6/30/3000. (HD2)

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