
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 COVID-19 pandemic
7 highlighted the critical need address health care testing
8 accessibility and streamline unnecessary administrative
9 regulations. To increase COVID-19 testing, in April 2020 the
10 federal government issued an emergency declaration under the
11 Public Readiness and Emergency Preparedness (PREP) Act, which,
12 among other things, authorized pharmacists to order and
13 administer COVID-19 testing and increased access to certain
14 pharmacy-administered tests. The PREP Act is in effect through
15 the end of 2024; however, there are certain provisions in the
16 PREP Act 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, 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. (a) Unless otherwise authorized by law,
13 pharmacist shall only exercise the authority granted in
14 paragraph (5) of the definition of "practice of pharmacy" under
15 section 461-1, to order and perform the collection of specimens
16 for certain diagnostic-related and CLIA-waived tests, upon
17 application for and receipt of a permit pursuant to the
18 requirements of section 321-13.

19 (b) Before a pharmacist may exercise the authority granted
20 in paragraph (5) of the definition of "practice of pharmacy"
21 under section 461-1 to order and perform the collection of



1 specimens for certain diagnostic-related and CLIA-waived tests,
2 the pharmacist shall have completed appropriate training that
3 includes programs approved by the Accreditation Council for
4 Pharmacy Education, curriculum-based programs from an
5 Accreditation Council for Pharmacy Education-accredited college
6 of pharmacy, state or local health department programs, or
7 programs recognized by the board of pharmacy, and any
8 regulations adopted by the United States Health Care Financing
9 Administration."

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

12 1. By adding a new definition to be appropriately inserted
13 and to read:

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

17 2. By amending the definition of "practice of pharmacy" to
18 read:

19 "'Practice of pharmacy" means:

20 (1) The interpretation and evaluation of prescription
21 orders; the compounding, dispensing, and labeling of



1 drugs and devices (except labeling by a manufacturer,
2 packer, or distributor of nonprescription drugs and
3 commercially legend drugs and devices); the
4 participation in drug selection and drug utilization
5 reviews; the proper and safe storage of drugs and
6 devices and the maintenance of proper records
7 therefore; the responsibility for advising when
8 necessary or where regulated, of therapeutic values,
9 content, hazards, and use of drugs and devices; and
10 the interpretation and evaluation of prescription
11 orders to adjust the supply dispensed for purposes of
12 medication synchronization pursuant to section
13 431:10A-606, 432:1-621, or 432D-30;

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



1 policies, procedures, or protocols developed
2 collaboratively by health professionals, including
3 physicians and surgeons, pharmacists, physician
4 assistants, and registered nurses, and for which a
5 pharmacist has received appropriate training required
6 by these policies, procedures, or protocols:

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



1 programs, or programs recognized by the board of
2 pharmacy;

3 (D) Administering drugs orally, topically, by
4 intranasal delivery, or by injection, pursuant to
5 the order of the patient's licensed physician,
6 physician assistant, or advanced practice
7 registered nurse with prescriptive authority, by
8 a pharmacist having appropriate training that
9 includes programs approved by the ACPE,
10 curriculum-based programs from an ACPE-accredited
11 college of pharmacy, state or local health
12 department programs, or programs recognized by
13 the board of pharmacy;

14 (E) Administering:

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



1 programs, or programs recognized by the
2 board of pharmacy;

3 (ii) Vaccines to persons between fourteen and
4 seventeen years of age pursuant to section
5 461-11.4; and

6 (iii) Human papillomavirus, Tdap (tetanus,
7 diphtheria, pertussis), meningococcal, and
8 influenza vaccines to persons between eleven
9 and seventeen years of age pursuant to
10 section 461-11.4;

11 (F) As authorized by the written instructions of a
12 licensed physician, physician assistant, or
13 advanced practice registered nurse with
14 prescriptive authority, initiating or adjusting
15 the drug regimen of a patient pursuant to an
16 order or authorization made by the patient's
17 licensed physician, physician assistant, or
18 advanced practice registered nurse with
19 prescriptive authority and related to the
20 condition for which the patient has been seen by
21 the licensed physician, physician assistant, or



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

12 (G) Transmitting a valid prescription to another
13 pharmacist for the purpose of filling or
14 dispensing;
15 (H) Providing consultation, information, or education
16 to patients and health care professionals based
17 on the pharmacist's training and for which no
18 other licensure is required; or

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



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

20 SECTION 4. Statutory material to be repealed is bracketed
 21 and stricken. New statutory material is underscored.



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

2



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 of and the collection of specimens for certain diagnostic or CLIA-waived tests. Effective 6/30/3000. (HD1)

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