
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. Some examples of CLIA-waived tests
11 include blood glucose monitoring tests, streptococcal
12 pharyngitis tests, cholesterol monitoring tests, and various
13 tests for respiratory illnesses including influenza and
14 respiratory syncytial virus, and, recently, SARS-CoV-2 (COVID-
15 19) point-of-care or "rapid" tests.

16 Accordingly, the purpose of this Act is to amend the
17 pharmacy scope of practice to specify that pharmacists may
18 order, perform, and report the results of certain CLIA-waived
19 tests.



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

4 "§461- CLIA-waived tests; authority; permitting and
5 education requirements; reporting. (a) Unless otherwise
6 authorized by law, a pharmacist shall only exercise the
7 authority granted under paragraph (5) of the definition of
8 "practice of pharmacy" in section 461-1 to order, perform, and
9 report the results of certain CLIA-waived tests:

10 (1) After completing appropriate training that includes
11 programs approved by the Accreditation Council for
12 Pharmacy Education, curriculum-based programs from an
13 Accreditation Council for Pharmacy Education-
14 accredited college of pharmacy, state or local health
15 department programs, or programs recognized by the
16 board, and any regulations promulgated by the federal
17 Centers for Medicare and Medicaid Services; and

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

20 (b) Any pharmacist performing a CLIA-waived test for a
21 patient shall report the results of the test to a minor



1 patient's pediatrician or an adult patient's primary care
2 provider, if such information is provided by the patient at the
3 time of testing. The pharmacist shall attempt to solicit
4 pedsiatrician or primary care provider information at the time of
5 performing the CLIA-waived test.

6 (c) For any CLIA-waived tests performed, pharmacists shall
7 follow all applicable state laws and rules regarding the
8 reporting of diseases."

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

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

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

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

18 "Practice of pharmacy" means:

19 (1) The interpretation and evaluation of prescription
20 orders; the compounding, dispensing, and labeling of
21 drugs and devices (except labeling by a manufacturer,



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

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



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

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



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

12 (E) Administering:
13 (i) Immunizations orally, by injection, or by
14 intranasal delivery, to persons eighteen
15 years of age or older by a pharmacist having
16 appropriate training that includes programs
17 approved by the ACPE, curriculum-based
18 programs from an ACPE-accredited college of
19 pharmacy, state or local health department
20 programs, or programs recognized by the
21 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, performing, and reporting the results of the
- 6 following CLIA-waived tests:
- 7 (A) Blood glucose;
- 8 (B) Hemoglobin A1C;
- 9 (C) Hepatitis C;
- 10 (D) Human immunodeficiency virus;
- 11 (E) Influenza;
- 12 (F) Respiratory syncytial virus;
- 13 (G) SARS-CoV-2; or
- 14 (H) Streptococcal pharyngitis."

15 SECTION 4. Statutory material to be repealed is bracketed
16 and stricken. New statutory material is underscored.

17 SECTION 5. This Act shall take effect upon its approval.



Report Title:

Pharmacy Scope of Practice; CLIA-Waived Tests; Pharmacists;
Permit; Education Requirements; Reporting Requirements

Description:

Authorizes pharmacists to order, perform, and report the results of certain Clinical Laboratory Improvement Amendments of 1988-waived tests. Specifies educational and permitting requirements for the ordering, performance, and reporting the results of certain CLIA-waived tests. (CD1)

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