

A Bill for an Act Relating to Health.

*Be It Enacted by the Legislature of the State of Hawaii:*

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

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

In addition to COVID-19 tests, the legislature further finds that pharmacists in the State are currently permitted to perform certain drug therapy-related tests under the definition of "practice of pharmacy" in section 461-1, Hawaii Revised Statutes. However, there are differing interpretations under state law as to whether pharmacists can explicitly perform tests that are classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA-waived tests are 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, streptococcal pharyngitis tests, cholesterol monitoring tests, and various tests for respiratory illnesses including influenza and respiratory syncytial virus, and, recently, SARS-CoV-2 (COVID-19) point-of-care or "rapid" tests.

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

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

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

- (1) After completing appropriate training that includes programs approved by the Accreditation Council for Pharmacy Education, curriculum-based programs from an Accreditation Council for Pharmacy Education-accredited college of pharmacy, state or local health department programs, or programs recognized by the board, and any regulations promulgated by the federal Centers for Medicare and Medicaid Services; and
- (2) Upon application for and receipt of a permit pursuant to the requirements of section 321-13.

(b) Any pharmacist performing a CLIA-waived test for a patient shall report the results of the test to a minor patient's pediatrician or an adult patient's primary care provider, if such information is provided by the patient at the time

of testing. The pharmacist shall attempt to solicit pediatrician or primary care provider information at the time of performing the CLIA-waived test.

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

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

1. By adding a new definition to be appropriately inserted and to read: ““CLIA-waived tests” means any test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a).”

2. By amending the definition of “practice of pharmacy” to read: ““Practice of pharmacy” means:

- (1) The interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices (except labeling by a manufacturer, packer, or distributor of non-prescription drugs and commercially legend drugs and devices); the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records therefor; the responsibility for advising when necessary or where regulated, of therapeutic values, content, hazards, and use of drugs and devices; and the interpretation and evaluation of prescription orders to adjust the supply dispensed for purposes of medication synchronization pursuant to section 431:10A-606, 432:1-621, or 432D-30;
- (2) Performing the following procedures or functions as part of the care provided by and in concurrence with a “health care facility” and “health care service” as defined in section 323D-2; or a “pharmacy”; or a licensed physician, a licensed physician assistant, or a licensed advanced practice registered nurse with prescriptive authority; or a “managed care plan” as defined in section 432E-1, in accordance with policies, procedures, or protocols developed collaboratively by health professionals, including physicians and surgeons, pharmacists, physician assistants, and registered nurses, and for which a pharmacist has received appropriate training required by these policies, procedures, or protocols:
  - (A) Ordering or performing routine drug therapy related patient assessment procedures;
  - (B) Ordering drug therapy related laboratory tests;
  - (C) Initiating emergency contraception oral drug therapy in accordance with a written collaborative agreement approved by the board, between a licensed physician, physician assistant, or advanced practice registered nurse with prescriptive authority and a pharmacist who has received appropriate training that includes programs approved by the Accreditation Council for Pharmacy Education (ACPE), curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board ~~[of pharmacy]~~;
  - (D) Administering drugs orally, topically, by intranasal delivery, or by injection, pursuant to the order of the patient’s licensed physician, physician assistant, or advanced practice registered nurse with prescriptive authority, by a pharmacist having appropriate training that includes programs approved by the

ACPE, curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board [~~of pharmacy~~];

- (E) Administering:
    - (i) Immunizations orally, by injection, or by intranasal delivery, to persons eighteen years of age or older by a pharmacist having appropriate training that includes programs approved by the ACPE, curriculum-based programs from an ACPE-accredited college of pharmacy, state or local health department programs, or programs recognized by the board [~~of pharmacy~~];
    - (ii) Vaccines to persons between fourteen and seventeen years of age pursuant to section 461-11.4; and
    - (iii) Human papillomavirus, Tdap (tetanus, diphtheria, pertussis), meningococcal, and influenza vaccines to persons between eleven and seventeen years of age pursuant to section 461-11.4;
  - (F) As authorized by the written instructions of a licensed physician, physician assistant, or advanced practice registered nurse with prescriptive authority, initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's licensed physician, physician assistant, or advanced practice registered nurse with prescriptive authority and related to the condition for which the patient has been seen by the licensed physician, physician assistant, or advanced practice registered nurse with prescriptive authority; provided that the pharmacist shall issue written notification to the patient's licensed physician, physician assistant, or advanced practice registered nurse with prescriptive authority or enter the appropriate information in an electronic patient record system shared by the licensed physician, physician assistant, or advanced practice registered nurse with prescriptive authority, within twenty-four hours;
  - (G) Transmitting a valid prescription to another pharmacist for the purpose of filling or dispensing;
  - (H) Providing consultation, information, or education to patients and health care professionals based on the pharmacist's training and for which no other licensure is required; or
  - (I) Prescribing and dispensing an opioid antagonist pursuant to section 461-11.8;
- (3) The offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of pharmacy; [~~and~~]
- (4) Prescribing and dispensing contraceptive supplies pursuant to section 461-11.6[-]; and
- (5) Notwithstanding any other law to the contrary, and in accordance with the requirements of section 461- ordering, performing, and reporting the results of the following CLIA-waived tests:
- (A) Blood glucose;
  - (B) Hemoglobin A1C;
  - (C) Hepatitis C;
  - (D) Human immunodeficiency virus;
  - (E) Influenza;
  - (F) Respiratory syncytial virus;

(G) SARS-CoV-2; or  
(H) Streptococcal pharyngitis.”

SECTION 4. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.<sup>1</sup>

SECTION 5. This Act shall take effect upon its approval.  
(Approved June 22, 2023.)

**Note**

1. Edited pursuant to HRS §23G-16.5.