THE SENATE
THIRTY-SECOND LEGISLATURE, 2023
STATE OF HAWAII

S.B. NO. 602 S.D. 1

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 the administration of COVID-19 tests, 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. Most CLIA-waived tests are approved by the federal Food and Drug Administration for home use and pose very little reasonable risk of harm to the patient if performed incorrectly. Some examples of CLIA-waived tests include blood glucose monitoring tests, cholesterol monitoring tests, and, recently, COVID-19 point-of-care or "rapid" tests.

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

Accordingly, the purpose of this Act is to amend the scope of practice for pharmacists to clarify that pharmacists may order certain tests and perform the collection of specimens for certain diagnostic-related and 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- Diagnostic and certain other non-technical health assessment tests; authority; permitting and education requirements.** (a) Unless otherwise authorized by law, no pharmacist shall order, or perform the collection of specimens for, certain diagnostic-related and CLIA-waived tests without first obtaining a permit pursuant to rules adopted in accordance with section 321-13.

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

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

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 nonprescription 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 tests and performing the collection of

specimens authorized or approved by the United States Food and Drug Administration, that are:

(A) Diagnostic-related laboratory tests used to detect or screen for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and respiratory illnesses including influenza infection, streptococcal pharyngitis, or liver function issues or infections; provided that no test shall require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid; or

(B) CLIA-waived tests."

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

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

S.B. NO. 602 S.D. 1

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. (SD1)

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