THE SENATE
THIRTY-FIRST LEGISLATURE, 2022
STATE OF HAWAII

S.B. NO. 2592 S.D. 2

A BILL FOR AN ACT

RELATING TO HEALTH.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

PART I

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

The Clinical Laboratory Improvement Amendments of 1988, P.L. 100-578 (CLIA), regulates all facilities that perform laboratory testing on human specimens for health assessment. The CLIA also provide waivers for certain tests, such as simple tests that are non-technical and have a low risk for erroneous results. Most CLIA-waived tests are approved by the Federal Drug Administration for home use; employ simple methodologies that are so accurate as to render the likelihood of erroneous results negligible; use unprocessed specimens, including blood or oral fluids; 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, coronavirus disease 2019 (COVID-19) tests.

The legislature further finds that pharmacists in the State are permitted to order and perform drug therapy related tests under section 461-1, Hawaii Revised Statutes. One interpretation of this provision is that these assessment procedures include tests waived in accordance with the CLIA. Notwithstanding the existing authority for pharmacists to perform assessment procedures, under current department of health regulations, pharmacies that perform CLIA-waived tests are required to partner with a clinical laboratory director to sign off on the application to perform the tests. This requirement places Hawaii in a minority of states that still require a laboratory director to sign off on CLIA waiver applications. Most states instead allow certain pharmacists to sign applications for the purpose of authorizing CLIA-waived testing.

The legislature further finds that the COVID-19 pandemic has highlighted the need to address health care accessibility and streamline unnecessary administrative regulation. The

federal government addressed pharmacy-administered CLIA-waived tests specifically in an April 2020 emergency declaration under the Public Readiness and Emergency Preparedness Act, which, among other things, authorized pharmacists to order and administer COVID-19 testing utilizing a CLIA-waived device.

Accordingly, the purpose of this Act is to:

(1) Clarify who is authorized to sign an application to perform CLIA-waived tests; and

(2) Amend the pharmacist scope of practice to include the ordering and performing of certain CLIA-waived tests.

PART II

SECTION 2. Section 321-15.1, Hawaii Revised Statutes, is amended by adding a new definition to be appropriately inserted and to read as follows:

""Clinical laboratory director" means a person who is responsible for the administrative, technical, and scientific operation of a clinical laboratory, including the supervision of procedures for testing and the reporting of the test results. "Clinical laboratory director" includes the following:

(1) A physician licensed to practice medicine or osteopathy under chapter 453; or

(2) For clinical laboratory tests or examinations classified as waived pursuant to the Clinical Laboratory Improvement Amendments of 1998 (title 42 United States Code section 263a):

(A) An advanced practice registered nurse, as identified in section 457-2.7;

(B) A duly licensed clinical laboratory scientist; or

(c) A pharmacist serving as the director of a laboratory that only performs tests waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 (title 42 United States Code section 263a) or that performs the collection of a specimen that is processed by a clinical laboratory."

SECTION 3. Section 461-1, Hawaii Revised Statutes, is amended by amending the definition of "practice of pharmacy" to read as follows:

""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 performance of 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 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, 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 or performing drug therapy and diagnostic related laboratory and Clinical Laboratory Improvement Amendments of 1988 (title 42 United States Code section 263a)-waived tests[~~.~~], including performing any United States Food and Drug Administration-approved or United States Food and Drug Administration-authorized test that is classified as waived pursuant to the Clinical Laboratory Improvement Amendments of 1988 by a pharmacist having 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, and any regulations adopted thereunder by the United States Health Care Financing Administration; provided that no test shall require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid;

(C) Initiating emergency contraception oral drug therapy in accordance with a written collaborative agreement approved by the board, between a licensed physician 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 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 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 or advanced practice registered nurse with prescriptive authority and related to the condition for which the patient has been seen by the licensed physician or advanced practice registered nurse with prescriptive authority; provided that the pharmacist shall issue written notification to the patient's licensed physician or advanced practice registered nurse with prescriptive authority or enter the appropriate information in an electronic patient record

system shared by the licensed physician 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."

SECTION 4. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun before its effective date.

SECTION 5. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 6. This Act shall take effect on January 1, 2050.

S.B. NO. 2592 S.D. 2

Report Title:
Clinical Laboratory Directors; Pharmacies; Pharmacists; Clinical Laboratory Improvement Amendments Waived Tests

Description:
Defines "clinical laboratory director" to include certain physicians, or advanced practice registered nurses, licensed clinical laboratory scientists, or pharmacists for the purpose of certain tests or examinations. Amends the definition of "practice of pharmacy" to include the ordering and performing of certain Clinical Laboratory Improvement Amendments-waived tests. Effective 1/1/2050. (SD2)

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