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2021 SPECIAL SESSION I

CHAPTER 214

An Act to amend and reenact Sections 54.1-3300 and 54.1-3303.1 of the Code of Virginia, relating to pharmacists; initiation of treatment; certain drugs and devices.

[H 2079]

Approved March 18, 2021

Be it enacted by the General Assembly of Virginia:

1. That Sections 54.1-3300 and 54.1-3303.1 of the Code of Virginia are amended and reenacted as follows:

Section 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in Section 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of Section 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of Section 54.1-3321.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper records; (iii) the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; (iv) the management of patient care under the terms of a collaborative agreement as defined in this section; and (v) the initiating of treatment with or dispensing or administering of certain drugs, devices, or controlled paraphernalia in accordance with the provisions of Section 54.1-3303.1.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (Section 54.1-3400 et seq.) unless the context requires a different meaning.

Section 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of Section 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs ~~and~~ , devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in Section 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; ~~and~~

6. ~~Medications~~ Drugs as defined in Section 54.1-3401, devices as defined in Section 54.1-3401, controlled paraphernalia as defined in Section 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention or that have a current emergency use authorization from the U.S. Food and Drug Administration;

8. Tuberculin purified protein derivative for tuberculosis testing; and

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention.

B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

C. A pharmacist who administers a vaccination pursuant to subdivision A 7 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of Section 32.1-46.01.

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with Section 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2021. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to recommend protocols to the Board of Pharmacy for review and implementation. No pharmacist shall initiate treatment with or dispense or administer such drug, device, controlled paraphernalia, or supply or equipment until such protocols have been adopted. Such protocols shall address training and continuing education for pharmacists regarding the initiation of

treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment pursuant to Section 54.1-3303.1 of the Code of Virginia, as amended by this act.

3. That the Board of Pharmacy, in collaboration with the Board of Medicine, shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulation shall include authorization for a pharmacist to initiate treatment with or dispense or administer drugs, devices, controlled paraphernalia, and supplies and equipment described in Section 54.1-3303.1 of the Code of Virginia, as amended by this act, in accordance with protocols adopted by the Board of Pharmacy. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to develop recommendations and propose language for inclusion in such regulations.

4. That the Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine as well as representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board of Pharmacy may deem appropriate to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment for the treatment of diseases or conditions for which clinical decision-making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety and report its recommendations to the Governor and the Chairmen of the Joint Commission on Health Care, the House Committee on Health, Welfare and Institutions, and the Senate Committee on Education and Health by November 1, 2021.

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