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**SENATE BILL NO. 1026**

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Education and Health on February 6, 2020)

(Patron Prior to Substitute—Senator Dunnavant)

*A BILL to amend and reenact §§ 38.2-3408, 54.1-3300, and 54.1-3300.1 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3303.1, relating to pharmacists; initiating treatment, dispensing, and administering of controlled substances.*

**Be it enacted by the General Assembly of Virginia:**

**1. That §§ 38.2-3408, 54.1-3300, and 54.1-3300.1 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3303.1 as follows:**

**§ 38.2-3408. Policy providing for reimbursement for services that may be performed by certain practitioners other than physicians.**

A. If an accident and sickness insurance policy provides reimbursement for any service that may be legally performed by a person licensed in this Commonwealth as a chiropractor, optometrist, optician, professional counselor, psychologist, clinical social worker, podiatrist, physical therapist, chiropodist, clinical nurse specialist who renders mental health services, audiologist, speech pathologist, certified nurse midwife or other nurse practitioner, marriage and family therapist, or licensed acupuncturist, reimbursement under the policy shall not be denied because the service is rendered by the licensed practitioner.

B. If an accident and sickness insurance policy provides reimbursement for a service that may be legally performed by a licensed pharmacist, reimbursement under the policy shall not be denied because the service is rendered by the licensed pharmacist, provided that (i) the service is performed for an insured for a condition under the terms of a collaborative agreement, as defined in § 54.1-3300, ~~between a pharmacist and the physician with whom the insured is undergoing a course of treatment~~ *provided in accordance with § 54.1-3303.1* or (ii) the service is for the administration of vaccines for immunization. Notwithstanding the provisions of § 38.2-3407, the insurer may require the pharmacist, any pharmacy or provider that may employ such pharmacist, or the collaborating physician to enter into a written agreement with the insurer as a condition for reimbursement for such services. In addition, reimbursement to pharmacists acting under the terms of a collaborative agreement under this subsection shall not be subject to the provisions of § 38.2-3407.7.

C. This section shall not apply to Medicaid, or any state fund.

**§ 54.1-3300. Definitions.**

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

*"Approved test" means a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. § 263a).*

"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 § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative ~~practice~~ 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 § 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.

*"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. "Controlled substance" does not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. "Controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.*

"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.

"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; ~~and~~ *(iv)* the management of patient care under the terms of a collaborative agreement as defined in this section*; and (v) the initiation of treatment, dispensing, or administering of certain drugs in accordance with the provisions of § 54.1-3303.1*.

*"Prescribe" means to issue an order for drugs or medical supplies for medicinal or therapeutic purposes.*

"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 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

**§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.**

*A.* A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (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 § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative ~~practice~~ 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 § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes *for patients who meet the criteria set forth in the collaborative agreement*. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

~~No patient shall be required to participate in a collaborative procedure without such patient's consent.~~

*B.* A patient who *meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and* chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

*C.* Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for

disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

*D.* Collaborative agreements may only be used for conditions ~~which~~ *that* have protocols that are clinically accepted as the standard of care~~,~~ or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy *and the Department of Health* shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

*E.* Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

***§ 54.1-3303.1. Initiating treatment, dispensing, and administering of controlled substances by pharmacists.***

*A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment, dispense, and administer in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and Department of Health and set forth in regulations of the Board as follows:*

*1. Vaccines, as approved by the federal Food and Drug Administration or recommended by the federal Advisory Committee on Immunization Practices (ACIP) and published by the federal Centers for Disease Control and Prevention (CDC);*

*2. 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;*

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

*4. Epinephrine, subject to the following conditions: (i) dispensing for school for stock in school clinics pursuant to a standing order or (ii) to patients who the pharmacist confirms has been dispensed epinephrine in the prior 12 months, a pharmacist may dispense no more than four additional doses during the succeeding 24 months following the initiating of treatment;*

*5. Nicotine replacement therapies, other than controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), together with providing appropriate patient counseling on tobacco cessation therapies;*

*6. Tuberculin purified protein derivative for tuberculosis testing, provided that the pharmacist makes arrangements to read the test results or informs the patient how to read the test results if the patient agrees to not have the pharmacist read the test results;*

*7. Injectable or self-administered hormonal contraceptives, subject to the following conditions: (i) the patient completes a self-screening assessment as developed by the Boards of Medicine and Pharmacy; (ii) if the patient does not have a provider of obstetrics and gynecology services, the pharmacist provides the patient a list of providers, free clinics, federally qualified health centers, or public health departments in the geographic area where such services can be obtained; (iii) the pharmacist confirms the patient has had a wellness and preventative care visit within the previous 12 months; and (iv) the dispensing by the pharmacist under this section shall not exceed 36 months. If the patient has not had a wellness and preventative care visit within the previous 12 months before the pharmacist initiates treatment or dispenses, such treatment or dispensing shall not exceed 12 months unless the patient obtains a wellness and preventative visit;*

*8. Controlled substances for the treatment of diseases or conditions caused by infection with influenza virus and group A Streptococcus bacteria if (i) an evaluation and assessment of the patient is performed and (ii) such infection is confirmed by a positive result on an approved test administered by the pharmacist. If an approved test administered by the pharmacist is negative, the pharmacist shall not initiate treatment, dispense, or administer controlled substances and shall refer the patient to a health care provider for evaluation, diagnosis, and treatment. No pharmacist shall initiate treatment, dispense, or administer to a patient for the same or similar medical condition, referenced in this subdivision, more than two times within a 14-day period;*

*9. Prenatal vitamins; and*

*10. Medications 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.*

*B. A pharmacist who administers a vaccination pursuant to subdivision A 1 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.*

*C. A pharmacist who initiates treatment pursuant to this section other than a vaccination described in subdivision A 1 shall notify the patient's primary health care provider or other health care provider the patient requests that such controlled substance 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 in the area, including the contact information for any free clinics, federally qualified health centers, or local public health departments in the geographic area.*

*D. A pharmacist shall not initiate treatment, dispense, or administer to a patient who is not an adult.*

**2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act within 280 days of the effective date of this act. Such regulations shall include processes and procedures for the following: (i) a means for pharmacists to verify with primary health care providers that patients presenting for treatment have a provider-patient relationship and what controlled substances have been prescribed; (ii) a means for pharmacists to notify the primary health care provider of the treatment initiated or controlled substances dispensed; (iii) a means for pharmacists who have initiated treatment or dispensed controlled substances to provide patients information about the health care rendered and any side effects or complications that may occur and what follow up is recommended if the side effects present; and (iv) a means to ensure that all physical settings for the initiation of treatment under this section shall be in compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq. The Board shall report to the Chairman of the Senate Committee on Education and Health and the Chairman of the House Committee on Health, Welfare and Institutions by November 1, 2020, on the status of the regulations.**

**3. That the provisions of this act shall become effective on July 1, 2021.**