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HOUSE BILL NO. 1506**AMENDMENT IN THE NATURE OF A SUBSTITUTE**(Proposed by the House Committee on Health, Welfare and Institutions
on February 6, 2020)

(Patron Prior to Substitute—Delegate Sickles)

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 with and 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 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 provided in accordance with § 54.1-3303.1.

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:

"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.

"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.

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

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

65 "Practice of pharmacy" means the personal health service that is concerned with the art and science
66 of selecting, procuring, recommending, administering, preparing, compounding, packaging, and
67 dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease,
68 whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and
69 shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper
70 records; (iii) the responsibility of providing information concerning drugs and medicines and their
71 therapeutic values and uses in the treatment and prevention of disease; and (iv) the management of
72 patient care under the terms of a collaborative agreement as defined in this section; and (v) *the initiating*
73 *of treatment with or dispensing or administering of certain drugs in accordance with the provisions of*
74 *§ 54.1-3303.1.*

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

80 Other terms used in the context of this chapter shall be defined as provided in Chapter 34
81 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

82 **§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the**
83 **Boards of Medicine and Pharmacy.**

84 A. A pharmacist and his designated alternate pharmacists involved directly in patient care may
85 participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any
86 person licensed, registered, or certified by a health regulatory board of the Department of Health
87 Professions who provides health care services to patients of such person licensed to practice medicine,
88 osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such
89 collaborative agreement is signed by each physician participating in the collaborative practice agreement;
90 (iii) any licensed physician assistant working under the supervision of a person licensed to practice
91 medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the
92 provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize
93 cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices,
94 under defined conditions or limitations, for the purpose of improving patient outcomes *for patients who*
95 *meet the criteria set forth in the collaborative agreement.* However, no person licensed to practice
96 medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a
97 pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity
98 on behalf of which the person is authorized to act enters into a collaborative agreement with a
99 pharmacist and his designated alternate pharmacists.

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

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

106 C. Collaborative agreements may include the implementation, modification, continuation, or
107 discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of
108 drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other
109 patient care management measures related to monitoring or improving the outcomes of drug or device
110 therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties.
111 Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a
112 collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for
113 disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

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

E. Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.
§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense or administer the following drugs and devices 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 § 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 as recommended by the American College of Obstetrics and Gynecology;

4. Prenatal vitamins for which a prescription is required; and

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.

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 in the area. Such pharmacist may also provide information about any federally qualified health centers or free clinics serving the area in which the patient is located.

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiating of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as created by this act, by November 1, 2020.

3. That the Board of Pharmacy (the Board) shall establish a work group consisting of representatives of the Board of Medicine, the Departments of Health and Medical Assistance Services, schools of medicine and pharmacy located in the Commonwealth, the Medical Society of Virginia, the Virginia Pharmacists Association, the American College of Obstetrics and Gynecology, the Virginia Association of Chain Drug Stores, and such other stakeholders as the Board may deem appropriate to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering to persons 18 years of age or older by pharmacists of drugs and devices including: (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy; (iii) tuberculin purified protein derivative for tuberculosis testing; (iv) controlled substances or devices 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, *Helicobacter pylori* bacteria, urinary tract infection, and group A *Streptococcus* bacteria; (v) 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; and (vi) drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription. The work group shall report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2021.