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HOUSE BILL NO. 910

Offered January 8, 2020
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A BILL to amend and reenact §§ 32.1-5, 32.1-11.3, 32.1-14, 53.1-234, 54.1-3307, and 54.1-3308 of the Code of Virginia, relating to practice of pharmacy; compounding; regulation by Board of Pharmacy.

Patron—Simon

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-5, 32.1-11.3, 32.1-14, 53.1-234, 54.1-3307, and 54.1-3308 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-5. Appointment of members; terms and vacancies.

There shall be a State Board of Health ~~which~~ *that* shall consist of 15 residents of the Commonwealth appointed by the Governor for terms of four years each. Two members of the Board shall be members of the Medical Society of Virginia, one member shall be a member of the Virginia Pharmaceutical Association, one member shall be a member of the State Dental Association, one member shall be a member of the Virginia Nurses' Association, one member shall be a member of the Virginia Veterinary Medical Association, one member shall be a representative of local government, one member shall be a representative of the hospital industry, one member shall be a representative of the nursing home industry, one member shall be a representative of the licensed health carriers responsible under Title 38.2 for a managed care health insurance plan, one member shall be a corporate purchaser of health care, ~~two members~~ *one member* shall be ~~consumers~~ *a consumer*, one member shall have public environmental health expertise, ~~and~~ one member shall be a representative of the emergency medical services community recommended by the State Emergency Medical Services Advisory Board, *and one member shall be a pharmacist with expertise in compounding recommended by the Board of Pharmacy*. A vacancy other than by expiration of term shall be filled by the Governor for the unexpired term.

No person shall be eligible to serve more than two full consecutive four-year terms.

§ 32.1-11.3. Patient and community health education services.

The Board shall formulate a program of patient and community health education services to be provided by the Department on a regional, district, or local basis. The program shall include services addressing health promotion and disease prevention and shall encourage the coordination of local and private sector health education services. This program shall include information on *(i)* the causes, prevention, early detection, and treatment of osteoporosis *and (ii) the safe use of compounded drugs*.

§ 32.1-14. Annual report.

The Board shall submit an annual report to the Governor and General Assembly. Such report shall contain information on the Commonwealth's vital records and health statistics and an analysis and summary of health care issues affecting the citizens of Virginia, including but not limited to, health status indicators, the effectiveness of delivery of health care, progress toward meeting standards and goals, the financial and geographic accessibility of health care, and the distribution of health care resources, with particular attention to health care access for those Virginia citizens in rural areas, inner cities, and with greatest economic need. Such report shall also contain statistics and analysis regarding the health status and conditions of minority populations in the Commonwealth by age, gender, and locality.

The Board shall report annually by December 1 to the Governor and the General Assembly on actions taken by the Board (i) to ensure the safety and quality of compounded drugs produced by compounding pharmacies and outsourcing facilities located in the Commonwealth and compounding pharmacies and outsourcing facilities located outside the Commonwealth that provide compounded drugs to patients in the Commonwealth; (ii) to reduce illegal use of opioids and opioid abuse in the Commonwealth; and (iii) to implement provisions of and ensure compliance with the requirements of Title II of the federal Drug Supply Chain Security Act of 2013, P.L. 113-54, related to prescription drug identification, tracing, and verification.

§ 53.1-234. Transfer of prisoner; how death sentence executed; who to be present.

The clerk of the circuit court in which is pronounced the sentence of death against any person shall, after such judgment becomes final in the circuit court, deliver a certified copy thereof to the Director. Such person so sentenced to death shall be confined prior to the execution of the sentence in a state correctional facility designated by the Director. Prior to the time fixed in the judgment of the court for the execution of the sentence, the Director shall cause the condemned prisoner to be conveyed to the

state correctional facility housing the death chamber.

The Director, or the assistants appointed by him, shall at the time named in the sentence, unless a suspension of execution is ordered, cause the prisoner under sentence of death to be electrocuted or injected with a lethal substance, until he is dead. The method of execution shall be chosen by the prisoner. In the event the prisoner refuses to make a choice at least 15 days prior to the scheduled execution, the method of execution shall be by lethal injection. Execution by lethal injection shall be permitted in accordance with procedures developed by the Department. At the execution there shall be present the Director or an assistant, a physician employed by the Department or his assistant, such other employees of the Department as may be required by the Director and, in addition thereto, at least six citizens who shall not be employees of the Department. In addition, the counsel for the prisoner and a clergyman may be present.

The Director may make and enter into contracts with ~~a pharmacy, as defined in § 54.1-3300, or~~ *an* outsourcing facility, as defined in § 54.1-3401, for the compounding of drugs necessary to carry out an execution by lethal injection. Any such drugs provided to the Department pursuant to the terms of such a contract shall be used only for the purpose of carrying out an execution by lethal injection. ~~The compounding of such drugs pursuant to the terms of such a contract (i) shall not constitute the practice of pharmacy as defined in § 54.1-3300; (ii) is not subject to the jurisdiction of the Board of Pharmacy, the Board of Medicine, or the Department of Health Professions; and (iii) is exempt from the provisions of Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 and the Drug Control Act (§ 54.1-3400 et seq.).~~ The ~~pharmacy or~~ outsourcing facility providing such drugs to the Department pursuant to the terms of such a contract shall label each such drug with the drug name, its quantity, a projected expiration date for the drug, and a statement that the drug shall be used only by the Department for the purpose of carrying out an execution by lethal injection.

The ~~identities~~ *identity* of any ~~pharmacy or~~ outsourcing facility that enters into a contract with the Department for the compounding of drugs necessary to carry out an execution by lethal injection, any officer or employee of such ~~pharmacy or~~ outsourcing facility, and any person or entity used by such ~~pharmacy or~~ outsourcing facility to obtain equipment or substances to facilitate the compounding of such drugs ~~and any information reasonably calculated to lead to the identities of such persons or entities, including their names,~~ *shall not be confidential, shall be subject to the Virginia Freedom of Information Act (§ 2.2-3700 et seq.), and may be subject to discovery or introduction as evidence in any civil proceeding. However, the* residential and office addresses, residential and office telephone numbers, social security numbers, and tax identification numbers~~,~~ *of officers and employees of the outsourcing facility and any person or entity used by the outsourcing facility to obtain equipment or substances to facilitate the compounding of such drugs* shall be confidential~~, shall be~~ *and* exempt from the *Virginia* Freedom of Information Act (§ 2.2-3700 et seq.)~~, and shall not be subject to discovery or introduction as evidence in any civil proceeding unless good cause is shown~~.

§ 54.1-3307. Specific powers and duties of Board.

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

B. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

C. The Board shall report annually by December 1 to the Governor and the General Assembly on actions taken by the Board to (i) ensure the safety and quality of compounded drugs produced by compounding pharmacies and outsourcing facilities located in the Commonwealth and compounding pharmacies and outsourcing facilities located outside the Commonwealth that provide compounded drugs to patients in the Commonwealth; (ii) reduce illegal use of opioids and opioid abuse in the Commonwealth; and (iii) implement provisions of and ensure compliance with the requirements of Title II of the federal Drug Supply Chain Security Act of 2013, P.L. 113-54, related to prescription drug identification, tracing, and verification.

§ 54.1-3308. Power of inspection.

The members of the Board and their duly authorized agents shall have the power to inspect in a lawful manner the drugs, cosmetics, and devices ~~which~~ *that* are manufactured, stored, or dispensed in the Commonwealth. For this purpose, the Board shall have the right to enter and inspect during business hours any pharmacy, or any other place in Virginia where drugs, cosmetics, or devices are manufactured, stored, or dispensed. *Such inspections may be made in response to complaints received by the Board, in any case in which the Board has reason to believe that the pharmacy or other place where drugs, cosmetics, or devices are manufactured, stored, or dispensed has violated any state or federal law or as otherwise deemed necessary by the Board to protect the health and safety of the public.* The Board shall report any evidence of violation of the provisions of this chapter or Chapter 34 (§ 54.1-3400 et seq.) ~~of this title~~ by practitioners for action to the appropriate licensing board. The report shall constitute a pending complaint upon which the appropriate licensing board shall initiate action within ~~thirty~~ *30* days.