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SENATE BILL NO. 1230

Offered January 11, 2017

Prefiled January 10, 2017

A BILL to amend and reenact §§ 54.1-3401, 54.1-3408.02, and 54.1-3410 of the Code of Virginia, relating to prescriptions for controlled substances containing opiates; electronic prescription.

Patrons—Dunnavant, Ebbin, Howell, Mason and McPike

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3408.02, and 54.1-3410 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3401. Definitions.

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

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

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59 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a
60 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by
61 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or
62 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in
63 expectation of receiving a valid prescription based on observed historical patterns of prescribing and
64 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as
65 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the
66 course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or
67 chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a
68 manufacturer's product drugs for the purpose of administration to a patient, when performed by a
69 practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person
70 supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person
71 supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to
72 subdivision A 4 of § 54.1-2901 shall not be considered compounding.

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

78 "Controlled substance analog" means a substance the chemical structure of which is substantially
79 similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a
80 stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar
81 to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a
82 controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person
83 represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous
84 system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect
85 on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance
86 analog" does not include (a) any substance for which there is an approved new drug application as
87 defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally
88 recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and
89 Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular
90 person, any substance for which an exemption is in effect for investigational use for that person under
91 § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that
92 substance is pursuant to such exemption; or (c) any substance to the extent not intended for human
93 consumption before such an exemption takes effect with respect to that substance.

94 "DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor
95 agency.

96 "Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by
97 this chapter, whether or not there exists an agency relationship.

98 "Device" means instruments, apparatus, and contrivances, including their components, parts, and
99 accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in
100 man or animals or to affect the structure or any function of the body of man or animals.

101 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified
102 by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§
103 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician
104 assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a
105 Medicare-certified renal dialysis facility.

106 "Dialysis solution" means either the commercially available, unopened, sterile solutions whose
107 purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal
108 dialysis, or commercially available solutions whose purpose is to be used in the performance of
109 hemodialysis not to include any solutions administered to the patient intravenously.

110 "Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the
111 lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or
112 compounding necessary to prepare the substance for that delivery. However, dispensing shall not include
113 the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites
114 operated by such practitioner or that practitioner's medical practice for the purpose of administration of
115 such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For
116 practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a
117 practitioner to patients to take with them away from the practitioner's place of practice.

118 "Dispenser" means a practitioner who dispenses.

119 "Distribute" means to deliver other than by administering or dispensing a controlled substance.

120 "Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

~~"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy a written prescription that is generated on an electronic application in accordance with 21 C.F.R. Part 1300 and is transmitted to a pharmacy as an electronic data file.~~

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures, a manufacturer's co-licensed partner, or a repackager.

"Marijuana" means any part of a plant of the genus *Cannabis* whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus *Cannabis*. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer,

derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species *Papaver somniferum* L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning — may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party logistics provider, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

§ 54.1-3408.02. Transmission of prescriptions.

A. Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy ~~by~~ *as an electronic transmission prescription* or by facsimile machine and shall be treated as valid original prescriptions.

B. Any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription.

§ 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in

305 accordance with the Board's regulations;

306 3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a
307 prescriber, he shall affix to the container in which such drug is dispensed, a label showing the
308 prescription serial number or name of the drug; the date of initial filling; his name and address, or the
309 name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of
310 the owner of the animal and the species of the animal; the name of the prescriber by whom the
311 prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart
312 order; and such directions as may be stated on the prescription.

313 B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be
314 dispensed upon receipt of a written or oral prescription as follows:

315 1. If the prescription is written, it shall be properly executed, dated and signed by the person
316 prescribing on the day when issued and bear the full name and address of the patient for whom, or of
317 the owner of the animal for which, the drug is dispensed, and the full name and address of the person
318 prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is
319 prescribed.

320 2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as
321 is required by law in the case of a written prescription for drugs and devices, except for the signature of
322 the prescriber.

323 A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device
324 as required in subdivision A 3 of this section.

325 C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if,
326 after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available
327 and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be
328 made in compliance with the provisions of § 54.1-3411.

329 If the written or oral prescription is for a Schedule VI drug or device and does not contain the
330 address or registry number of the prescriber, or the address of the patient, the pharmacist need not
331 reduce such information to writing if such information is readily retrievable within the pharmacy.

332 D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally
333 transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written
334 record of the prescription required by this subsection specifies the full name of the agent of the
335 prescriber transmitting the prescription.

336 *E. No pharmacist shall dispense a controlled substance that contains an opiate unless the*
337 *prescription for such controlled substance is issued as an electronic prescription.*

338 **2. That the provisions of the first enactment of this act shall become effective on July 1, 2020.**

339 **3. That the Secretary of Health and Human Resources shall convene a work group to review**
340 **actions necessary for the implementation of the provisions of this act and shall make an interim**
341 **progress report to the Chairmen of the House Committee on Health, Welfare and Institutions and**
342 **the Senate Committee on Education and Health by November 1, 2017 and shall make a final**
343 **report to such Chairmen by November 1, 2018.**