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**HOUSE BILL NO. 2452**

Offered January 14, 2009

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*A BILL to amend and reenact § 54.1-3401 of the Code of Virginia, and to amend the Code of Virginia by adding a section numbered 54.1-3408.04, relating to confidentiality of prescription information.*

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Patron—Sickles

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Referred to Committee on Health, Welfare and Institutions

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

**1. That § 54.1-3401 of the Code of Virginia is amended and reenacted, and that the Code of Virginia is amended by adding a section numbered 54.1-3408.04 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.

"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.

"Commercial purpose" means advertising, marketing, promotion, or any activity that is intended to be used or is used (i) to influence sales or the market share of a pharmaceutical product, (ii) to influence or evaluate the prescribing behavior of an individual health care professional, (iii) to market prescription drugs to patients, or (iv) to evaluate the effectiveness of a professional pharmaceutical detailing sales force.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed prescribing patterns; (ii) by or for a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his

59 professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical  
60 analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's  
61 product drugs for the purpose of administration to a patient, when performed by a practitioner of  
62 medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.) or a person supervised by such  
63 practitioner pursuant to subdivisions 4, 6, or 19 of § 54.1-2901, shall not be considered compounding.

64 "Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of  
65 this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms  
66 are defined or used in Title 3.1 or Title 4.1.

67 "DEA" means the Drug Enforcement Administration, United States Department of Justice, or its  
68 successor agency.

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

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

74 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified  
75 by an organization approved by the Board of Health Professions pursuant to Chapter 27.01  
76 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner,  
77 physician assistant or a registered nurse, assists in the care of patients undergoing renal dialysis  
78 treatments in a Medicare-certified renal dialysis facility.

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

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

91 "Dispenser" means a practitioner who dispenses.

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

93 "Distributor" means a person who distributes.

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

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

103 *"Electronic transmission intermediary" means an entity that provides the infrastructure that connects  
104 the computer systems or other electronic devices used by practitioners, pharmacies, health care  
105 facilities, health insurers, third-party administrators, and agents and contractors of those persons in  
106 order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization  
107 request, claim, payment, or other prescription drug information.*

108 "Electronic transmission prescription" means any prescription, other than an oral or written  
109 prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly  
110 to a pharmacy without interception or intervention from a third party from a practitioner authorized to  
111 prescribe or from one pharmacy to another pharmacy.

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

115 "FDA" means the United States Food and Drug Administration.

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

118 "Immediate precursor" means a substance which the Board of Pharmacy has found to be and by  
119 regulation designates as being the principal compound commonly used or produced primarily for use,  
120 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.

"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.

"Marijuana" means any part of a plant of the genus *Cannabis* whether growing or not, its seeds or 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, 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*.

"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 which are used for the operation and cleaning of medical equipment and solutions for peritoneal dialysis.

"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 United States 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.) of this chapter, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and

182 levorotatory forms.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

239 "Wholesale distribution" means distribution of prescription drugs to persons other than consumers or  
240 patients, subject to the exceptions set forth in § 54.1-3401.1.

241 "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs  
242 including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors;  
243 jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug

warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

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 unless the context requires a different meaning.

*§ 54.1-3408.04. Confidentiality of prescription information.*

*A. No health insurer, self-insured employer, electronic transmission intermediary, pharmacy or other similar entity shall license, transfer, use, or sell records that include prescription information containing patient-identifiable or prescriber-identifiable data for any commercial purpose.*

*B. The provisions of this section shall not apply to:*

*1. The license, transfer, use, or sale of prescription records for the limited purposes of pharmacy reimbursement, prescription drug formulary compliance, patient care management, utilization review by a health care provider or insurance provider, health care research, or as otherwise provided by law;*

*2. The dispensing of prescription medications to a patient or the patient's authorized representative;*

*3. The transition of prescription information between an authorized prescriber and a licensed pharmacy, between licensed pharmacies, or that may occur if a pharmacy's ownership is changed or transferred;*

*4. Communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy, and other information related to the drug being dispensed, treatment options, or clinical trials;*

*5. The use or disclosure of prescription information as otherwise authorized by this title; and*

*6. The collection, use, transfer, or sale of patient and prescriber data for commercial purposes if the data do not identify a person, and there is no reasonable basis to believe that the data provided could be used to identify a person.*