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## HOUSE BILL NO. 2204

Offered January 8, 2003

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A BILL to amend and reenact § 54.1-3401 of the Code of Virginia, to amend the Code of Virginia by adding sections numbered 54.1-3410.2 and 54.1-3435.02, and to repeal § 54.1-3402 of the Code of Virginia, relating to the practice of pharmacy; compounding of drug products.

Patron—Jones, S.C.

Referred to Committee on Health, Welfare and Institutions

**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 sections numbered 54.1-3410.2 and 54.1-3435.02 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, and corticosteroids, that promotes muscle growth.

"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 fifty 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.

"Compound" means the taking of two or more ingredients and fabricating them into a single preparation, usually referred to as a dosage form.

"Compounding" means the combining of 2 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 professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing.

INTRODUCED

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

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

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

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

69 "Dialysis care technician" means an unlicensed individual who, under the supervision of a licensed  
70 practitioner of medicine or a registered nurse, assists in the care of patients undergoing renal dialysis  
71 treatments in a Medicare-certified renal dialysis facility.

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

76 "Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the  
77 lawful order of a practitioner, including the prescribing and administering, packaging, labeling or  
78 compounding necessary to prepare the substance for that delivery.

79 "Dispenser" means a practitioner who dispenses.

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

81 "Distributor" means a person who distributes.

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

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

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

96 "*FDA means the United States Food and Drug Administration.*"

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

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

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

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

110 "Manufacture" means the production, preparation, propagation, ~~compounding~~, conversion or  
111 processing of any item regulated by this chapter, either directly or indirectly by extraction from  
112 substances of natural origin, or independently by means of chemical synthesis, or by a combination of  
113 extraction and chemical synthesis, and includes any packaging or repackaging of the substance or  
114 labeling or relabeling of its container. This term does not include ~~the preparing~~, compounding,  
115 ~~packaging or labeling of a controlled substance by a practitioner as an incident to his administering or~~  
116 ~~dispensing of a controlled substance or marijuana in the course of his professional practice, or by a~~  
117 ~~practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to,~~  
118 ~~research, teaching, or chemical analysis and not for sale.~~

119 "Manufacturer" means every person who manufactures.

120 "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 twelve 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 § 1-13.19, 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 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.

"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,

182 licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified  
183 optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title, veterinarian, scientific  
184 investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe  
185 and administer, or conduct research with respect to, a controlled substance in the course of professional  
186 practice or research in this Commonwealth.

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

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

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

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

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

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

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

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

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

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

221 "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs  
222 including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors;  
223 jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug  
224 warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale  
225 drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any  
226 state or local tax as a wholesale merchant by reason of this definition.

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

230 The terms "pharmacist," "pharmacy" and "practice of pharmacy" as used in this chapter shall be  
231 defined as provided in Chapter 33 of this title unless the context requires a different meaning.

232 § 54.1-3410.2. *Compounding; pharmacists' authority to compound under certain conditions; labeling  
233 and record maintenance requirements.*

234 A. A pharmacist may engage in compounding of drug products when the dispensing of such  
235 compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with  
236 the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

237 Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription  
238 in accordance with this chapter and the Board's regulations, and shall include on the labeling an  
239 appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for  
240 pharmacy compounding.

241 B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of  
242 prescriptions based on a routine, regularly observed prescribing pattern.

243 Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength

of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision.

Pharmacists shall label all compounded products distributed to practitioners for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall maintain and comply with a policy and procedure manual when engaging in the levels of compounding of drug products associated with any of the following: (i) higher risk from contamination in compounding, such as the compounding of sterile injectable products, sterile ophthalmic or otic products, total parenteral nutrition products, chemotherapy injectable products and implants; (ii) radiopharmaceuticals; or (iii) preparation of dosage forms that are dose-critical or are specialized preparations, such as slow-release products or transdermal patches.

Such manual shall (i) be consistent with USP-NF standards and guidance for compounding; (ii) describe all significant procedures in compounding; and (iii) establish a quality assurance program to ensure accountability, accuracy, quality, safety, and uniformity.

A policy and procedure manual shall not be required for nonsterile compounding that only involves the mixing of 2 or more commercially available preparations, the mixing or reconstitution of a commercially available product in accordance with the manufacturer's instructions, preparation of injections for immediate administration using commercially available sterile products, preparation of other nonsterile dosage forms that are not dose-critical or specialized products, and the addition of flavoring.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

2. Are manufactured by an establishment that is registered by the FDA; or

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal; or

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, or (iii) the mixing of 2 or more commercially available products regardless of whether the end product is a commercially available product.

- I. Pharmacists shall maintain records of all compounded drug products as part of the prescription,

305 formula record, formula book, or other log or record. Records may be maintained electronically,  
306 manually, in a combination of both, or by any other readily retrievable method. All compounding  
307 records shall include: (i) the date of the preparation; (ii) the generic name and the name of the  
308 manufacturer of the raw materials or the brand name of the raw materials; (iii) the manufacturer's lot  
309 number and expiration date for each component, and, when the original manufacturer's lot number and  
310 expiration date are unknown, the source of acquisition of the component; (iv) the prescription number  
311 or the assigned lot number when compounding in anticipation of receiving a prescription; (v) the  
312 signature or initials of the pharmacist or other authorized person performing the compounding; (vi) the  
313 signature or initials of the pharmacist responsible for supervising support personnel and conducting  
314 in-process and final checks of compounded products when other authorized personnel perform the  
315 compounding function; (vii) the quantity in units of finished products or quantity of raw materials used  
316 in compounding the product; (viii) the package size and the number of units prepared; (ix) the  
317 beyond-use date and the criteria used for determining this date; (x) for the levels of compounding  
318 described in subsection E, requiring the maintenance and compliance with a policy and procedure  
319 manual, a complete formula with compounding procedures, including, when appropriate, complete  
320 mixing instructions with the order of mixing, mixing temperatures or other environmental controls,  
321 duration of mixing, equipment needed, and other factors necessary to replicate the preparation as  
322 compounded; and (xi) documentation for the levels of compounding described in subsection E of any  
323 tests conducted on compounded products in accordance with the required policy and procedure manual.

324 J. Practitioners who may lawfully compound drugs for administering or dispensing to their own  
325 patients pursuant to §§ 54.1-3301, 54.1-3304 and 54.1-3304.1 shall comply with all provisions of this  
326 section and the relevant Board regulations.

327 § 54.1-3435.02. Certain permitted pharmacies exempted.

328 A permitted pharmacy may engage in wholesale distributions of small quantities of prescription  
329 drugs without being licensed as wholesale distributors when such wholesale distributions are in  
330 compliance with federal law as follows: such wholesale distributions of controlled substances do not  
331 exceed 5 percent of the gross annual sales of prescription drugs by the relevant permitted pharmacy or  
332 such wholesale distributions of Schedules II through V controlled substances do not exceed 5 percent of  
333 the total dosage units of the Schedule II through V controlled substances dispensed annually by the  
334 relevant permitted pharmacy.

335 2. That § 54.1-3402 of the Code of Virginia is repealed.