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HOUSE BILL NO. 1823**AMENDMENT IN THE NATURE OF A SUBSTITUTE**(Proposed by the House Committee on Health, Welfare and Institutions
on January 23, 2003)

(Patron Prior to Substitute—Delegate Morgan)

A BILL to amend and reenact §§ 2.2-4002, 54.1-3303, 54.1-3401, 54.1-3408.01, and 54.1-3457 of the Code of Virginia, to amend the Code of Virginia by adding a section numbered 54.1-3408.03, and to repeal Article 3 (§§ 32.1-79 through 32.1-88) of Chapter 3 of Title 32.1 of the Code of Virginia, relating to voluntary formulary; therapeutically equivalent (generic) substitutions.

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.2-4002, 54.1-3303, 54.1-3401, 54.1-3408.01, and 54.1-3457 of the Code of Virginia are amended and reenacted, and that the Code of Virginia is amended by adding a section numbered 54.1-3408.03 as follows:

§ 2.2-4002. Exemptions from chapter generally.

A. Although required to comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 et seq.), the following agencies shall be exempted from the provisions of this chapter, except to the extent that they are specifically made subject to §§ 2.2-4024, 2.2-4030 and 2.2-4031:

1. The General Assembly.

2. Courts, any agency of the Supreme Court, and any agency that by the Constitution is expressly granted any of the powers of a court of record.

3. The Department of Game and Inland Fisheries in promulgating regulations regarding the management of wildlife and for all case decisions rendered pursuant to any provisions of Chapters 2 (§ 29.1-200 et seq.), 3 (§ 29.1-300 et seq.), 4 (§ 29.1-400 et seq.), 5 (§ 29.1-500 et seq.), and 7 (§ 29.1-700 et seq.) of Title 29.1.

4. The Virginia Housing Development Authority.

5. Municipal corporations, counties, and all local, regional or multijurisdictional authorities created under this Code, including those with federal authorities.

6. Educational institutions operated by the Commonwealth, provided that, with respect to § 2.2-4031, such educational institutions shall be exempt from the publication requirements only with respect to regulations that pertain to (i) their academic affairs; (ii) the selection, tenure, promotion and disciplining of faculty and employees; (iii) the selection of students; and (iv) rules of conduct and disciplining of students.

7. The Milk Commission in promulgating regulations regarding (i) producers' licenses and bases, (ii) classification and allocation of milk, computation of sales and shrinkage, and (iii) class prices for producers' milk, time and method of payment, butterfat testing and differential.

8. The Virginia Resources Authority.

9. Agencies expressly exempted by any other provision of this Code.

10. ~~The Virginia Voluntary Formulary Board in formulating recommendations regarding amendments to the Formulary pursuant to § 32.1-81.~~

~~11. The Department of General Services in promulgating standards for the inspection of buildings for asbestos pursuant to § 2.2-1164.~~

~~12. The State Council of Higher Education for Virginia, in developing, issuing, and revising guidelines pursuant to § 23-9.6:2.~~

~~13. The Commissioner of Agriculture and Consumer Services in adopting regulations pursuant to subsection B of § 3.1-726.~~

~~14. The Commissioner of Agriculture and Consumer Services and the Board of Agriculture and Consumer Services in promulgating regulations pursuant to subsections B and C of § 3.1-106.4, subsection B of §§ 3.1-126.12:1, 3.1-271.1, 3.1-530.1, and 3.1-398, subsections B and C of § 3.1-828.4, and subsection A of § 3.1-884.21:1.~~

~~15. The Board of Optometry when specifying therapeutic pharmaceutical agents, treatment guidelines, and diseases and abnormal conditions of the human eye and its adnexa for TPA-certification of optometrists pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of Title 54.1.~~

~~16. [Repealed.]~~

~~17. The Virginia War Memorial Foundation.~~

~~18. The Virginia Medicaid Prior Authorization Advisory Committee in making recommendations to the Board of Medical Assistance Services regarding prior authorization for prescription drug coverage pursuant to Article 4 (§ 32.1-331.12 et seq.) of Chapter 10 of Title 32.1.~~

~~19. The State Board of Education, in developing, issuing, and revising guidelines pursuant to § 22.1-203.2.~~

2018. The Virginia Racing Commission, (i) when acting by and through its duly appointed stewards or in matters related to any specific race meeting or (ii) in promulgating technical rules regulating actual live horse racing at race meetings licensed by the Commission.

2119. The Virginia Small Business Financing Authority.

2220. The Virginia Economic Development Partnership Authority.

2321. The Board of Agriculture and Consumer Services in adopting, amending or repealing regulations pursuant to subsection A (ii) of § 59.1-156.

2422. The Insurance Continuing Education Board pursuant to § 38.2-1867.

2523. The Board of Health in promulgating the list of diseases that shall be reported to the Department of Health pursuant to § 32.1-35.

B. Agency action relating to the following subjects shall be exempted from the provisions of this chapter:

1. Money or damage claims against the Commonwealth or agencies thereof.

2. The award or denial of state contracts, as well as decisions regarding compliance therewith.

3. The location, design, specifications or construction of public buildings or other facilities.

4. Grants of state or federal funds or property.

5. The chartering of corporations.

6. Customary military, naval or police functions.

7. The selection, tenure, dismissal, direction or control of any officer or employee of an agency of the Commonwealth.

8. The conduct of elections or eligibility to vote.

9. Inmates of prisons or other such facilities or parolees therefrom.

10. The custody of persons in, or sought to be placed in, mental, penal or other state institutions as well as the treatment, supervision, or discharge of such persons.

11. Traffic signs, markers or control devices.

12. Instructions for application or renewal of a license, certificate, or registration required by law.

13. Content of, or rules for the conduct of, any examination required by law.

14. The administration of pools authorized by Chapter 47 (§ 2.2-4700 et seq.) of this title.

15. Any rules for the conduct of specific lottery games, so long as such rules are not inconsistent with duly adopted regulations of the State Lottery Board, and provided that such regulations are published and posted.

16. Orders condemning or closing any shellfish, finfish, or crustacea growing area and the shellfish, finfish or crustacea located thereon pursuant to Article 2 (§ 28.2-803 et seq.) of Chapter 8 of Title 28.2.

17. Any operating procedures for review of child deaths developed by the State Child Fatality Review Team pursuant to § 32.1-283.1.

18. The regulations for the implementation of the Health Practitioners' Intervention Program and the activities of the Intervention Program Committee pursuant to Chapter 25.1 (§ 54.1-2515 et seq.) of Title 54.1.

19. The process of reviewing and ranking grant applications submitted to the Commonwealth Neurotrauma Initiative Advisory Board pursuant to Chapter 3.1 (§ 51.5-12.1 et seq.) of Title 51.5.

20. Loans from the Small Business Environmental Compliance Assistance Fund pursuant to Article 4 (§ 10.1-1197.1 et seq.) of Chapter 11.1 of Title 10.1.

21. The Virginia Breeders Fund created pursuant to § 59.1-372.

22. The types of pari-mutuel wagering pools available for live or simulcast horse racing.

23. The administration of medication or other substances foreign to the natural horse.

C. Minor changes to regulations published in the Virginia Administrative Code under the Virginia Register Act, Chapter 41 (§ 2.2-4100 et seq.) of this title, made by the Virginia Code Commission pursuant to § 30-150, shall be exempt from the provisions of this chapter.

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being

prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

B. In order to determine whether a prescription which appears questionable to the pharmacist results from a bona fide practitioner-patient relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.

No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

C. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine authorized to issue such prescription if the prescription complies with the requirements of this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title, known as the "Drug Control Act," except that out-of-state prescriptions are not required to comply with the provisions of subsection A of § 32.1-87 and subsection C of § 54.1-3408 which establish a prescription blank format accommodating the Virginia Voluntary Formulary.

D. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in Chapter 34 of this title in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

E. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in Chapter 34 of this title in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

F. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 of this title may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to oral analgesics included in Schedules III and VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), when appropriate to relieve ocular pain, and topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act.

§ 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.

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

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

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

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

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

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

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

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

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

215 "Dispenser" means a practitioner who dispenses.

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

217 "Distributor" means a person who distributes.

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

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

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

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

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

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

240 "Label" means a display of written, printed or graphic matter upon the immediate container of any
241 article. A requirement made by or under authority of this chapter that any word, statement or other
242 information appear on the label shall not be considered to be complied with unless such word, statement
243 or other information also appears on the outside container or wrapper, if any, of the retail package of
244 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, compounding, 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 the preparing, compounding, packaging or labeling of a controlled substance by a practitioner as an incident to his administering or dispensing of a controlled substance or marijuana in the course of his professional practice, or by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

"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 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

363 "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs
364 including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors;
365 jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug
366 warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale
367 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.) of this title 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 of this title unless the context requires a different meaning.

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

No written prescription order form shall include more than one prescription. However, this provision shall not apply to prescriptions written as chart orders for patients in hospitals and long-term-care facilities, patients receiving home infusion services or hospice patients, or to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Mental Health, Mental Retardation and Substance Abuse Services.

B. Pursuant to § 32.1-87, any prescription form shall include two boxes, one labeled "Voluntary Formulary Permitted" and the other labeled "Dispense As Written." A prescriber may indicate his permission for the dispensing of a drug product included in the Formulary upon signing a prescription form and marking the box labeled "Voluntary Formulary Permitted." A Voluntary Formulary product shall be dispensed if the prescriber fails to indicate his preference. If no Voluntary Formulary product is immediately available or if the patient objects to the dispensing of a generic drug, the pharmacist may dispense a brand name drug. Printed prescription forms shall provide:

~~"[] Dispense As Written~~

~~— [] Voluntary Formulary Permitted~~

~~.....~~

~~—Signature of prescriber~~

If neither box is marked, a Voluntary Formulary product must be dispensed."

C. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

DC. The oral prescription referred to in subsection A of this section § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

§ 54.1-3408.03. Dispensing of therapeutically equivalent drug product permitted.

A. A pharmacist may dispense a therapeutically equivalent drug product for a prescription that is written for a brand-name drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on

429 *the dispensing of the brand-name drug product.*

430 *In the case of an oral prescription, the prescriber's oral dispensing instructions regarding*
431 *substitution shall be followed.*

432 *B. Prescribers using prescription blanks printed in compliance with Virginia law in effect on June*
433 *30, 2003, having 2 check boxes and referencing the Virginia Voluntary Formulary, may indicate, until*
434 *July 1, 2006, that substitution is not authorized by checking the "Dispense as Written" box. If the*
435 *"Voluntary Formulary Permitted" box is checked on such prescription blanks or if neither box is*
436 *checked, a pharmacist may dispense a therapeutically equivalent drug product pursuant to such*
437 *prescriptions.*

438 *C. If the pharmacist dispenses a drug product other than the brand name prescribed, he shall so*
439 *inform the purchaser and shall indicate, unless otherwise directed by the prescriber, on both his*
440 *permanent record and the prescription label, the brand name or, in the case of a therapeutically*
441 *equivalent drug product, the name of the manufacturer or the distributor. Whenever a pharmacist*
442 *dispenses a therapeutically equivalent drug product pursuant to a prescription written for a brand-name*
443 *product, the pharmacist shall label the drug with the name of the therapeutically equivalent drug*
444 *product followed by the words "generic for" and the brand name of the drug for which the prescription*
445 *was written.*

446 *D. When a pharmacist dispenses a drug product other than the drug product prescribed, the*
447 *dispensed drug product shall be at a lower retail price than that of the drug product prescribed. Such*
448 *retail price shall not exceed the usual and customary retail price charged by the pharmacist for the*
449 *dispensed therapeutically equivalent drug product.*

450 § 54.1-3457. Prohibited acts.

451 The following acts shall be prohibited:

452 1. The manufacture, sale, or delivery, holding or offering for sale of any drug, device, or cosmetic
453 that is adulterated or misbranded.

454 2. The adulteration or misbranding of any drug, device, or cosmetic.

455 3. The receipt in commerce of any drug, device, or cosmetic that is adulterated or misbranded, and
456 the delivery or proffered delivery thereof for pay or otherwise.

457 4. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of
458 § 54.1-3421.

459 5. The dissemination of any false advertisement.

460 6. The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access
461 to or copying of any record.

462 7. The giving of a false guaranty or undertaking.

463 8. The removal or disposal of a detained article in violation of § 54.1-3459.

464 9. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the
465 labeling of, or the doing of any other act with respect to a drug, device, or cosmetic, if such act is done
466 while such article is held for sale and results in such article being adulterated or misbranded.

467 10. The forging, counterfeiting, simulating, or falsely representing, or without proper authority using
468 any mark, stamp, tag, label, or other identification device authorized or required by regulations
469 promulgated under the provisions of this chapter or of the federal act.

470 11. The using by any person to his own advantage, or revealing, other than to the Board or its
471 authorized representative or to the courts when relevant in any judicial proceeding under this chapter of
472 any information acquired under authority of this chapter concerning any method or process which as a
473 trade secret is entitled to protection.

474 12. The using, on the labeling of any drug or in any advertisement relating to such drug, of any
475 representation or suggestion that an application with respect to such drug is effective under § 54.1-3421,
476 or that such drug complies with the provisions of such section.

477 13. In the case of a drug distributed or offered for sale in this Commonwealth, the failure of the
478 manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner
479 licensed by applicable law to administer such drug who makes written request for information as to such
480 drug, true and correct copies of all printed matter which is required to be included in any package in
481 which that drug is distributed or sold, or such other printed matter as is approved under the federal act.
482 This subdivision shall not be construed to exempt any person from any labeling requirement imposed by
483 or under other provisions of this chapter.

484 14. Placing or causing to be placed upon any drug or device or container, with intent to defraud, the
485 trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or
486 selling, dispensing, disposing of or causing to be sold, dispensed or disposed of, or concealing or
487 keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or
488 any container thereof, with knowledge that the trade name or other identifying mark or imprint of
489 another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by this
490 section or making, selling, disposing of, or causing to be made, sold or disposed of, or keeping in

possession, control or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

15. The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

16. Dispensing or causing to be dispensed; ~~except as provided in § 32.1-87 relating to the Virginia Voluntary Formulary~~, a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the permission of the person ordering or prescribing, *except as provided in § 54.1-3408.03 relating to dispensing of therapeutically equivalent drugs.*

2. That Article 3 (§§ 32.1-79 through 32.1-88) of Chapter 3 of Title 32.1 of the Code of Virginia is repealed.