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HOUSE BILL NO. 699

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions
on February 8, 1996)

(Patron Prior to Substitute—Delegate Morgan)

A BILL to amend and reenact §§ 54.1-3303, 54.1-3401, 54.1-3408, 54.1-3410, 54.1-3411, 54.1-3422, 54.1-3426, 54.1-3435.2, 54.1-3443, 54.1-3446, and 54.1-3463 of the Code of Virginia, relating to the Drug Control Act.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3303, 54.1-3401, 54.1-3408, 54.1-3410, 54.1-3411, 54.1-3422, 54.1-3426, 54.1-3435.2, 54.1-3443, 54.1-3446, and 54.1-3463 of the Code of Virginia are amended and reenacted as follows:

§ 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. 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 ~~physician~~ practitioner-patient relationship.

For purposes of this section, a bona fide ~~physician~~ practitioner-patient-pharmacist relationship is one in which a ~~physician~~ 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. 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. No prescription shall be filled which does not result from a bona fide ~~physician~~ practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

In order to determine whether a prescription which appears questionable to the pharmacist results from a bona fide ~~physician~~ practitioner-patient-pharmacist relationship, the pharmacist shall contact the prescribing ~~physician~~ 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.

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 for Schedule VI 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's assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions for Schedule VI 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.

§ 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.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related

60 to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth.

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

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

65 "Board" means the Board of Pharmacy.

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

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

71 "Cosmetic" means all articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into
72 or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness or altering
73 the appearance, and articles intended for use as a component of any such articles except soap.

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

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

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

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

84 "Dispenser" means a practitioner who dispenses.

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

86 "Distributor" means a person who distributes.

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

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

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

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

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

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

116 "Manufacturer" means every person who manufactures.

117 "Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds or
118 resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds,
119 or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless
120 such extract contains less than twelve percent of tetrahydrocannabinol by weight, or the mature stalks of
121 such plant, fiber produced from such stalk, oil or cake made from the seeds of such plant, any other

compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

"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, and those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment.

"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.

"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 individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

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

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician's assistant pursuant to § 54.1-2952.1, veterinarian, scientific investigator, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to, a controlled substance in the course of professional practice or research in this Commonwealth.

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

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

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

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

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

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

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

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

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

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

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

212 § 54.1-3408. Professional use by practitioners.

213 A. A practitioner of medicine, osteopathy, podiatry, or dentistry, a licensed nurse practitioner
214 pursuant to § 54.1-2957.01 or a licensed physician's assistant pursuant to § 54.1-2952.1 shall only
215 prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic
216 purposes within the course of his professional practice. The practitioner may prescribe, on a written
217 prescription or on oral prescription as authorized by this chapter, and administer drugs and devices, or
218 he may cause them to be administered by a nurse or intern under his direction and supervision, or a
219 practitioner may prescribe and cause drugs and devices to be administered to patients in state-owned or
220 state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals
221 licensed by the State Mental Health, Mental Retardation and Substance Abuse Services Board by other
222 persons who have been trained to properly administer drugs and who administer drugs only under the
223 control and supervision of the practitioner or a pharmacist.

224 A practitioner may authorize registered nurses and licensed practical nurses to possess epinephrine
225 for administration in treatment of emergency medical conditions pursuant to an oral or written order or
226 standing protocol issued by a practitioner within the course of his professional practice.

227 A dentist may cause Schedule VI topical drugs to be administered under his direction and
228 supervision by either a dental hygienist or by an authorized agent certified by the Board of Dentistry
229 who has satisfactorily completed a training program for this purpose that is approved by the Board of
230 Dentistry.

231 No written prescription order form shall include more than one prescription. This provision shall not
232 apply, however, to the entry of any order on a patient's chart in any hospital or any long-term care
233 facility, as defined in Board regulations, in Virginia or to a prescription ordered through the pharmacy
234 operated by the Department of Corrections, the central pharmacy of the Department of Health, or the
235 central outpatient pharmacy operated by the Department of Mental Health, Mental Retardation and
236 Substance Abuse Services.

237 Such a prescription shall be written, dated, and signed by the person prescribing on the day when
238 issued, and shall bear the full name and address of the patient for whom the drug is prescribed, and the
239 full name, address, and registry number under the federal laws of the person prescribing, if he is
240 required by those laws to be so registered.

241 This section shall not prevent the administration of drugs by a person who has satisfactorily
242 completed a training program for this purpose approved by the Board of Nursing and who administers
243 such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of
244 administration, when the drugs administered would be normally self-administered by (i) a resident of a

facility licensed or certified by the State Mental Health, Mental Retardation and Substance Abuse Services Board; (ii) a resident of any adult care residence which is licensed by the Department of Social Services; (iii) a resident of the Virginia Rehabilitation Center for the Blind; (iv) a resident of a facility approved by the Board or Department of Youth and Family Services for the placement of children in need of services or delinquent or alleged delinquent youth; or (v) a program participant of an adult day care center licensed by the Department of Social Services.

This section shall not interfere with any ~~practitioner~~ *prescriber* issuing prescriptions in compliance with the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such ~~practitioner~~ *prescriber* shall be deemed to be valid prescriptions. This section shall not prohibit a ~~practitioner~~ *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.

B. The written prescription referred to in subsection A of this section shall be written with ink or individually typed and each prescription shall be manually signed by the ~~practitioner~~ *prescriber*. The prescription may be prepared by an agent for his signature. The prescription shall contain the name, address, telephone number, and federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand.

C. Pursuant to § 32.1-87, the prescription form shall include two boxes, one labelled "Voluntary Formulary Permitted" and the other labelled "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 labelled "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. On and after July 1, 1993, 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."

D. ~~Practitioners'~~ *Prescriber's* 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.

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

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

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

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a ~~practitioner~~ *prescriber*, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the ~~practitioner~~ *prescriber* by whom the prescription was written; and such directions as may be stated on the prescription.

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

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

306 2. If the prescription is oral, the ~~practitioner~~ *prescriber* shall furnish the pharmacist with the same
307 information as is required by law in the case of a written prescription for drugs and devices, except for
308 the signature of the prescriber.

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

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

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

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

322 § 54.1-3411. When prescriptions may be refilled.

323 Prescriptions may be refilled as follows:

324 1. A prescription for a drug in Schedule II may not be refilled.

325 2. A prescription for a drug in Schedules III or IV may not be filled or refilled more than six months
326 after the date on which such prescription was issued and no such prescription may be authorized to be
327 refilled, nor be refilled, more than five times, except that any prescription for such a drug after six
328 months from the date of issue, or after being refilled five times, may be renewed by the ~~practitioner~~
329 *prescriber* issuing it either in writing, or orally, if promptly reduced to writing and filed by the
330 pharmacist filling it.

331 3. A prescription in Schedule VI may not be refilled, unless authorized by the ~~practitioner~~ *prescriber*
332 either on the face of the original prescription or orally by the ~~practitioner~~ *prescriber* except as provided
333 in subdivision 4 of this section. Oral instructions shall be reduced promptly to writing by the pharmacist
334 and filed on or with the original prescription.

335 4. A prescription for a drug controlled by Schedule VI may be refilled without authorization from the
336 prescriber if: reasonable effort has been made to communicate with the prescriber, and the pharmacist
337 has determined that he is not available and the patient's health would be in imminent danger without the
338 benefits of the drug. The pharmacist shall inform the patient of the prescriber's unavailability and that
339 the refill is being made without his authorization. The pharmacist shall promptly inform the prescriber of
340 such refill. The date and quantity of the refill, the prescriber's unavailability and the rationale for the
341 refill shall be noted on the reverse side of the prescription.

342 § 54.1-3422. Controlled substances registration certificate required in addition to other requirements;
343 exemptions.

344 A. Every person who manufactures, distributes or dispenses any substance which is controlled in
345 Schedules I through V or who proposes to engage in the manufacture, distribution or dispensing of any
346 such controlled substance except licensed pharmacies and those persons who are licensed pharmacists
347 shall obtain annually a controlled substances registration certificate issued by the Board. This registration
348 shall be in addition to other licensing or permitting requirements enumerated in this chapter or otherwise
349 required by law.

350 B. Registration under this section and under all other applicable registration requirements shall entitle
351 the registrant to possess, manufacture, distribute, dispense, or conduct research with those substances to
352 the extent authorized by this registration and in conformity with the other provisions of this chapter.

353 C. The following persons need not register and may possess controlled substances in Schedules I
354 through V:

355 1. An agent or employee of any holder of a controlled substance registration certificate if he is acting
356 in the usual course of his business or employment;

357 2. A common or contract carrier or warehouseman, or his employee, whose possession is in the usual
358 course of business or employment; or

359 3. An ultimate user or a person in possession of any controlled substance pursuant to a lawful order
360 of a ~~practitioner~~ *prescriber* or in lawful possession of a Schedule V substance.

361 D. A separate registration is required at each principal place of business or professional practice
362 where the applicant manufactures, distributes, or dispenses controlled substances.

363 § 54.1-3426. Regulations for special packaging.

364 A. The Board shall adopt standards for special packaging consistent with those promulgated pursuant
365 to the federal Poison Prevention Packaging Act of 1970. The Board may exempt any drug from the
366 requirements of special packaging and shall exempt any drug exempted pursuant to the Poison
367 Prevention Packaging Act of 1970.

B. A ~~practitioner~~ *prescriber* or a purchaser may direct that a drug, which is subject to being dispensed in special packaging, be dispensed in other than special packaging.

§ 54.1-3435.2. Permit to act as medical equipment supplier; storage; limitation; regulations.

A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a medical equipment supplier, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a medical equipment supplier in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on or before January 1 of each year; and remit a fee as determined by the Board.

B. Prescription drugs received, stored, and distributed by authority of this section shall be limited to those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment.

C. Distribution of any Schedule VI drug or device or of any hypodermic needle or syringe, or medicinal oxygen by authority of this section is limited to delivery to the ultimate user upon lawful order by a ~~practitioner~~ *prescriber* authorized to prescribe such drugs and devices.

D. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs, devices and controlled paraphernalia by medical equipment suppliers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices and controlled paraphernalia, and to protect the public.

§ 54.1-3443. Board to administer article.

A. The Board shall administer this article and may add substances to or ~~delete~~ *deschedule* or reschedule all substances enumerated in the schedules in this article pursuant to the procedures of the Administrative Process Act (§ 9-6.14:1 et seq.). In making a determination regarding a substance, the Board shall consider the following:

1. The actual or relative potential for abuse;
2. The scientific evidence of its pharmacological effect, if known;
3. The state of current scientific knowledge regarding the substance;
4. The history and current pattern of abuse;
5. The scope, duration, and significance of abuse;
6. The risk to the public health;
7. The potential of the substance to produce psychic or physical dependence; and
8. Whether the substance is an immediate precursor of a substance already controlled under this article.

B. After considering the factors enumerated in subsection A, the Board shall make findings and issue a regulation controlling the substance if it finds the substance has a potential for abuse.

C. If the Board designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

D. If any substance is designated, rescheduled, or ~~deleted~~ *descheduled* as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 120 days from publication in the Federal Register of the final order designating a substance as a controlled substance or rescheduling or deleting a substance without following the provisions specified in subsections A and B of this section.

E. Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 4.1.

F. The Board shall exempt any nonnarcotic substance from a schedule if such substance may, under the provisions of the federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) or state law, be lawfully sold over the counter without a prescription.

§ 54.1-3446. Schedule I.

The controlled substances listed in this section are included in Schedule I:

1. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetylmethadol;

Allylprodine;

Alphamethylfentanyl;

Alphacetylmethadol (except levo-alpha-acetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

Alphameprodine;

Alphamethadol;

Benzethidine;

429 Betacetylmethadol;
430 Betameprodine;
431 Betamethadol;
432 Betaprodine;
433 Clonitazene;
434 Dextromoramide;
435 Diampromide;
436 Diethylthiambutene;
437 Difenoxin;
438 Dimenoxadol;
439 Dimepheptanol;
440 Dimethylthiambutene;
441 Dioxaphetylbutyrate;
442 Dipipanone;
443 Ethylmethylthiambutene;
444 Etonitazene;
445 Etoxidine;
446 Furethidine;
447 Hydroxypethidine;
448 Ketobemidone;
449 Levomoramide;
450 Levophenacymorphan;
451 Morpheridine;
452 Noracymethadol;
453 Norlevorphanol;
454 Normethadone;
455 Norpipanone;
456 Phenadoxone;
457 Phenampromide;
458 Phenomorphan;
459 Phenoperidine;
460 Piritamide;
461 Proheptazine;
462 Properidine;
463 Propiram;
464 Racemoramide;
465 Trimeperidine.

466 2. Any of the following opium derivatives, their salts, isomers and salts of isomers, unless
467 specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible
468 within the specific chemical designation:

469 Acetorphine;
470 Acetyldihydrocodeine;
471 Benzylmorphine;
472 Codeine methylbromide;
473 Codeine-N-Oxide;
474 Cyprenorphine;
475 Desomorphine;
476 Dihydromorphine;
477 Drotebanol;
478 Etorphine;
479 Heroin;
480 Hydromorphanol;
481 Methyl-desomorphine;
482 Methyl-dihydromorphine;
483 Morphine methylbromide;
484 Morphine methylsulfonate;
485 Morphine-N-Oxide;
486 Myrophine;
487 Nicocodeine;
488 Nicomorphine;
489 Normorphine;
490 Phoclodine;

491 Thebacon.

492 3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture,
493 or preparation, which contains any quantity of the following hallucinogenic substances, or which
494 contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers,
495 and salts of isomers is possible within the specific chemical designation (for purposes of this subdivision
496 only, the term "isomer" includes the optical, position, and geometric isomers):

497 *Alpha-ethyltryptamine (some trade or other names: Monase; a-ethyl-1H-indole-3-ethanamine;*
498 *3-[2-aminobutyl] indole; a-ET; AET);*

499 *4-Bromo-2,5-dimethoxyphenethylamine (some trade or other names:*
500 *2-[4-bromo-2,5-dimethoxyphenyl]-1-aminoethane; alpha-desmethyl DOB; 2C-B; Nexus);*

501 3,4-methylenedioxy amphetamine;

502 5-methoxy-3,4-methylenedioxy amphetamine;

503 3,4,5-trimethoxy amphetamine;

504 Bufotenine;

505 Diethyltryptamine;

506 Dimethyltryptamine;

507 4-methyl-2,5-dimethoxyamphetamine;

508 2,5-dimethoxy-4-ethylamphetamine (DOET);

509 Ibogaine;

510 Lysergic acid diethylamide;

511 Mescaline;

512 Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10- tetrahydro-6, 6,
513 9-trimethyl-6H-dibenzo [b,d] pyran; Synhexyl);

514 Peyote;

515 N-ethyl-3-piperidyl benzilate;

516 N-methyl-3-piperidyl benzilate;

517 Psilocybin;

518 Psilocyn;

519 Tetrahydrocannabinols, except as present in marijuana and dronabinol in sesame oil and encapsulated
520 in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration;

521 Hashish oil (~~Some~~some trade or other names: hash oil; liquid marijuana; liquid hashish);

522 2,5-dimethoxyamphetamine (~~Some~~some trade or other names: 2,5-dimethoxy-a-methylphenethylamine;
523 2,5-DMA);

524 4-bromo-2,5-dimethoxyamphetamine (~~Some~~some trade or other names:
525 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA);

526 4-methoxyamphetamine (~~Some~~some trade or other names: 4-methoxy-a-methylphenethylamine;
527 paramethoxyamphetamine; PMA);

528 N-ethyl analog of phencyclidine;

529 Pyrrolidine analog of phencyclidine;

530 Thiophene analog of phencyclidine.

531 4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture
532 or preparation which contains any quantity of the following substances having a depressant effect on the
533 central nervous system, including its salts, isomers and salts of isomers whenever the existence of such
534 salts, isomers and salts of isomers is possible within the specific chemical designation:

535 Mecloqualone;

536 Methaqualone.

537 5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture
538 or preparation which contains any quantity of the following substances having a stimulant effect on the
539 central nervous system, including its salts, isomers and salts of isomers:

540 *Aminorex (some trade or other names; aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4,*
541 *5-dihydro-5-phenyl-2-oxazolamine);*

542 Fenethylamine;

543 Ethylamphetamine;

544 Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone,
545 2-aminopropiophenone, and norephedrone);

546 Methcathinone (some other names: 2-(methylamino)-propiofenone; alpha-(methylamino)
547 propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone;
548 monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR
549 1432).

550 6. Any material, compound, mixture or preparation containing any quantity of the following
551 substances:

552 3-methylfentanyl-(N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide), its optical and
553 geometric isomers, salts, and salts of isomers;
554 3,4-methylenedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts
555 and salts of isomers;
556 1-methyl-4-phenyl-4-propionoxypiperidine (MPPP), its optical isomers, salts and salts of isomers;
557 1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (PEPAP), its optical isomers, salts and salts of
558 isomers;
559 N-[1-(1-methyl-2-phenyl)ethyl-4-piperidyl]-N-phenylacetamide (acetyl-alpha-methylfentanyl), its
560 optical isomers, salts and salts of isomers;
561 N-[1-(1-methyl-2-2-thienyl)ethyl-4-piperidyl]-N-phenylpropanamide (alpha-methylthiofentanyl), its
562 optical isomers, salts and salts of isomers;
563 N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of
564 isomers;
565 N-[1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide (beta-hydroxyfentanyl), its
566 optical isomers, salts and salts of isomers;
567 N-[3-methyl-1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide
568 (beta-hydroxy-3-methylfentanyl), its optical and geometric isomers, salts and salts of isomers;
569 N-[3-methyl-1-(2-2-thienyl)ethyl-4-piperidyl]-N-phenylpropanamide (3-methylthiofentanyl), its optical
570 and geometric isomers, salts and salts of isomers;
571 N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thienylfentanyl), its optical isomers, salts
572 and salts of isomers;
573 N-[1-(2-2-thienyl)ethyl-4-piperidyl]-N-phenylpropanamide (thiofentanyl), its optical isomers, salts and
574 salts of isomers.
575 § 54.1-3463. Exemption of drugs dispensed by filling or refilling prescription.
576 A. Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed
577 by law to administer such drug prescriber shall be exempt from the requirements of § 54.1-3462 except
578 subdivisions 1, 9, and 10, and the packaging requirements of subdivision 7, if the drug bears a label
579 containing the name and address of the dispenser, the serial number and date of the prescription or of its
580 filling, the name of the prescriber and the name of the patient, and the directions for use and cautionary
581 statements, if any, contained in such prescription.
582 B. This section shall not be construed to relieve any person from any requirement prescribed by or
583 under authority of law with respect to drugs now included or which may hereafter be included within
584 the classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws
585 relating to narcotic drugs and marijuana.