

HOUSE BILL NO. 1336

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health and Human Services

on _____)

(Patron Prior to Substitute--Delegate Sickles)

A BILL to amend and reenact §§ 54.1-3401, 54.1-3423, and 54.1-3434.02 of the Code of Virginia, relating to crisis stabilization services; facilities licensed by Department of Behavioral Health and Developmental Services; nursing homes; dispensing and administration of drugs; emergency.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3423, and 54.1-3434.02 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3401. Definitions.

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

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

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

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

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

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

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

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

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

41 "Board" means the Board of Pharmacy.

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

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

54 owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's
55 charter.

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

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

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

77 "Controlled substance analog" means a substance the chemical structure of which is substantially
78 similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a
79 stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar
80 to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a

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

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

95 "Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated
96 by this chapter, whether or not there exists an agency relationship, including delivery of a Schedule VI
97 prescription device to an ultimate user or consumer on behalf of a medical equipment supplier by a
98 manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor,
99 warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics
100 provider at the direction of a medical equipment supplier in accordance with § 54.1-3415.1.

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

104 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified
105 by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1
106 et seq.) and who, under the supervision of a licensed physician, an advanced practice registered nurse, a

107 physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments
108 in a Medicare-certified renal dialysis facility.

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

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

121 "Dispenser" means a practitioner who dispenses.

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

123 "Distributor" means a person who distributes.

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

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

133 "Electronic prescription" means a written prescription that is generated on an electronic application
134 and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be
135 transmitted in accordance with 21 C.F.R. Part 1300.

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

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

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

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

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

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

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

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

160 "Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or
161 its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its
162 seeds, its resin, or any extract containing one or more cannabinoids. "Marijuana" does not include (i) the
163 mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such
164 plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis;
165 (ii) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to
166 subsection A of § 3.2-4115 or his agent; (iii) industrial hemp, as defined in § 3.2-4112, that is possessed
167 by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to
168 7 C.F.R. Part 990; (iv) a hemp product, as defined in § 3.2-4112; (v) an industrial hemp extract, as defined
169 in § 3.2-5145.1; or (vi) any substance containing a tetrahydrocannabinol isomer, ester, ether, salt, or salts
170 of such isomer, ester, or ether that has been placed by the Board of Pharmacy into one of the schedules
171 set forth in the Drug Control Act (§ 54.1-3400 et seq.) pursuant to § 54.1-3443.

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

177 "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction
178 from substances of vegetable origin, or independently by means of chemical synthesis, or by a
179 combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative,
180 or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof
181 which is chemically equivalent or identical with any of the substances referred to in clause (i), but not
182 including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; or (iv) coca leaves and
183 any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative,
184 or preparation thereof which is chemically equivalent or identical with any of these substances, but not
185 including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

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

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

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

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

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

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

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

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

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

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

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

227 "Practitioner" means a physician, dentist, licensed advanced practice registered nurse pursuant to
228 § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-
229 3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian,
230 scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense,
231 prescribe and administer, or conduct research with respect to a controlled substance in the course of
232 professional practice or research in the Commonwealth.

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

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

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

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

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

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

259 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C.
260 § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and
261 Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42
262 U.S.C. § 262(k).

263 "Remote dispensing system" means a profile-driven automated drug dispensing system that
264 performs operations or activities relative to the storage, packaging, labeling, or dispensing of medications
265 employing bidirectional audio-visual technology to facilitate pharmacist communication with a patient.

266 authorized agent of the patient, or person licensed to administer drugs, and collects, controls, and
267 maintains all information online. Drugs intended to be administered by the patient or a person not licensed
268 to administer drugs must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 and
269 Board regulations. Directions for use may only be abbreviated when drugs are administered exclusively
270 by persons licensed to administer drugs.

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

273 "Tetrahydrocannabinol" means any naturally occurring or synthetic tetrahydrocannabinol,
274 including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts
275 of isomers is possible within the specific chemical designation and any preparation, mixture, or substance
276 containing, or mixed or infused with, any detectable amount of tetrahydrocannabinol. For the purposes of
277 this definition, "isomer" means the optical, position, and geometric isomers.

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

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

288 "Total tetrahydrocannabinol" means the sum, after the application of any necessary conversion
289 factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of
290 tetrahydrocannabinolic acid.

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

292 "Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-party
293 logistics provider, engaged in the business of (i) selling or otherwise distributing prescription drugs or
294 devices to any person who is not the ultimate user or consumer and (ii) delivering Schedule VI prescription
295 devices to the ultimate user or consumer pursuant to § 54.1-3415.1. No person shall be subject to any state
296 or local tax by reason of this definition.

297 "Wholesale distribution" means (i) distribution of prescription drugs to persons other than
298 consumers or patients and (ii) delivery of Schedule VI prescription devices to the ultimate user or
299 consumer pursuant to § 54.1-3415.1, subject to the exemptions set forth in the federal Drug Supply Chain
300 Security Act.

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

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

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

309 **§ 54.1-3423. Board to issue registration unless inconsistent with public interest;**
310 **authorization to conduct research; application and fees.**

311 A. The Board shall register an applicant to manufacture or distribute controlled substances
312 included in Schedules I through V unless it determines that the issuance of that registration would be
313 inconsistent with the public interest. In determining the public interest, the Board shall consider the
314 following factors:

315 1. Maintenance of effective controls against diversion of controlled substances into other than
316 legitimate medical, scientific, or industrial channels;

317 2. Compliance with applicable state and local law;

318 3. Any convictions of the applicant under any federal and state laws relating to any controlled
319 substance;

320 4. Past experience in the manufacture or distribution of controlled substances, and the existence in
321 the applicant's establishment of effective controls against diversion;

322 5. Furnishing by the applicant of false or fraudulent material in any application filed under this
323 chapter;

324 6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or
325 dispense controlled substances as authorized by federal law; and

326 7. Any other factors relevant to and consistent with the public health and safety.

327 B. Registration under subsection A does not entitle a registrant to manufacture and distribute
328 controlled substances in Schedule I or II other than those specified in the registration.

329 C. Practitioners must be registered to conduct research or laboratory analysis with controlled
330 substances in Schedules II through VI or marijuana. Practitioners registered under federal law to conduct
331 research with Schedule I substances, other than marijuana, may conduct research with Schedule I
332 controlled substances within the Commonwealth upon furnishing the evidence of that federal registration.

333 D. The Board may register other persons or entities to possess controlled substances listed on
334 Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the
335 registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled
336 substances complies with applicable state and federal laws and regulations, and (iv) the subsequent
337 storage, use, and recordkeeping of the controlled substances will be under the general supervision of a
338 licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as
339 specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in
340 subsection A in determining whether the registration shall be issued. Notwithstanding the exceptions listed
341 in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain
342 types and quantities of Schedules II through VI controlled substances as it may specify in its regulations.
343 The Board shall promulgate regulations related to requirements or criteria for the issuance of such
344 controlled substances registration, storage, security, supervision, and recordkeeping.

345 E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase,
346 possess, and administer certain Schedule II through VI controlled substances approved by the State
347 Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and
348 animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for
349 the purpose of preventing, controlling, and treating certain communicable diseases that failure to control
350 would result in transmission to the animal population in the shelter. Controlled substances used for
351 euthanasia shall be administered only in accordance with protocols established by the State Veterinarian
352 and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule
353 VI drugs and biological products used for treatment and prevention of communicable diseases within the
354 shelter shall be determined by the supervising veterinarian of the shelter and the drugs and biological
355 products shall be administered only pursuant to written protocols established or approved by the
356 supervising veterinarian of the shelter and only by persons who have been trained in accordance with
357 instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of
358 the approved list of drugs and biological products, written protocols for administering, and training records
359 of those persons administering drugs and biological products on the premises of the shelter.

360 F. The Board may register a facility, as defined in § 37.2-100, that provides crisis stabilization-unit
361 ~~established pursuant to § 37.2-500 or 37.2-601 services and is~~ licensed by the Department of Behavioral
362 Health and Developmental Services ~~to~~. Such facility may maintain a stock of ~~Schedule Schedules II~~
363 through VI controlled substances necessary for immediate treatment of patients admitted to ~~the crisis~~
364 ~~stabilization-unit~~ such facility, which may be accessed and administered by a ~~nurse~~ person licensed to
365 administer drugs pursuant to a written or oral order of a prescriber in the absence of a prescriber. ~~Schedule~~
366 ~~II through Schedule V controlled substances shall only be maintained if so authorized by federal law and~~
367 ~~Board regulations.~~

368 G. The Board may register an entity at which a patient is treated by the use of instrumentation and
369 diagnostic equipment through which images and medical records may be transmitted electronically for the
370 purpose of establishing a bona fide practitioner-patient relationship and is prescribed ~~Schedule Schedules~~
371 II through VI controlled substances when such prescribing is in compliance with federal requirements for

372 the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with
373 the U.S. Drug Enforcement Administration. In determining whether the registration shall be issued, the
374 Board shall consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such
375 registration, and (iii) whether the issuance of the registration is consistent with the public interest.

376 H. Applications for controlled substances registration certificates and renewals thereof shall be
377 made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount
378 to be determined by the Board.

379 I. Upon (i) any change in ownership or control of a business, (ii) any change of location of the
380 controlled substances stock, (iii) the termination of authority by or of the person named as the responsible
381 party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable,
382 the registrant or responsible party shall immediately surrender the registration. The registrant shall, within
383 14 days following surrender of a registration, file a new application and, if applicable, name the new
384 responsible party or supervising practitioner.

385 **§ 54.1-3434.02. Automated drug dispensing systems and remote dispensing systems.**

386 A. Hospitals or nursing homes licensed pursuant to Title 32.1-~~07~~, state facilities as defined in §
387 37.2-100 established pursuant to Title 37.2, facilities as defined in § 37.2-100 that are licensed by the
388 Department of Behavioral Health and Developmental Services and provide site-based crisis stabilization
389 services, or other facilities authorized by the Board may use automated drug dispensing systems and
390 remote dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:

391 1. Drugs are placed in the automated drug dispensing system or remote dispensing system ~~in a~~
392 such hospital, nursing home, or facility and are under the control of a pharmacy providing services to the
393 hospital, nursing home, or facility;

394 2. The pharmacist-in-charge of the pharmacy providing services to the hospital, nursing home, or
395 facility has established procedures for ~~assuring~~ ensuring the accurate stocking and proper storage of drugs
396 in the automated drug dispensing system or remote dispensing system and for ensuring accountability for
397 and security of all drugs utilized in ~~the automated drug dispensing~~ such system until the time such drugs
398 are removed from ~~the automated drug dispensing~~ such system for administration to the patients;

399 3. Removal of drugs from any automated drug dispensing system or remote dispensing system for
400 administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;

401 4. Adequate security for automated drug dispensing systems or remote dispensing systems is
402 provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii)
403 complying with federal and state regulations on prescribing and dispensing controlled substances, (iii)
404 maintaining patient confidentiality, and (iv) ~~assuring~~ ensuring compliance with the requirements of this
405 section;

406 5. Accountability for drugs dispensed from automated drug dispensing systems or remote
407 dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital,
408 nursing home, or facility or the pharmacist-in-charge of ~~any the~~ outside pharmacy providing pharmacy
409 services to the hospital, nursing home, or facility;

410 6. Filling and stocking of all drugs in automated drug dispensing systems or remote dispensing
411 systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and
412 stocking of drugs into ~~an automated drug dispensing~~ such system shall be performed by a pharmacist or a
413 registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly
414 trained in accordance with established standards set forth in a policy and procedure manual maintained by
415 the provider pharmacy. The pharmacist stocking and filling ~~the automated drug dispensing~~ such system
416 or the pharmacist-in-charge, if ~~the automated drug dispensing~~ such system is stocked and filled by a
417 registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the
418 automated drug dispensing system or remote dispensing system; and

419 7. Except when the automated drug dispensing system is used exclusively for administration of
420 drugs for emergencies, a pharmacy located outside of the hospital, nursing home, or facility it services
421 according to this subsection shall first obtain a controlled substances registration issued in the name of the
422 pharmacy at the address of the hospital, nursing home, or facility and a registration from the Drug
423 Enforcement Administration, if required, prior to stocking controlled substances in Schedules II through
424 VI.

425 B. ~~Drugs~~ Except as authorized by the Board, drugs placed into and removed from automated drug
426 dispensing systems or remote dispensing systems for administration to patients shall be in the
427 manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the
428 pharmacy. Drugs in multi-dose packaging, ~~other than those administered orally,~~ or in a liquid, injectable,
429 or inhaled formulation may be placed in such a device if approved by the pharmacist-in-charge in
430 consultation with ~~a standing hospital committee comprised of~~ pharmacy, medical, and nursing staff of the
431 hospital, nursing home, or facility.

432 C. The pharmacist-in-charge in a pharmacy located within a hospital, nursing home, or facility or
433 the pharmacist-in-charge of any outside pharmacy providing pharmacy services to a hospital, nursing
434 home, or facility shall be responsible for establishing procedures for (i) periodically inspecting and
435 auditing automated drug dispensing systems and remote dispensing systems to ~~assure~~ ensure the proper
436 storage, security, and accountability for all drugs placed in and removed from automated drug dispensing
437 systems and remote dispensing systems; and (ii) reviewing the operation and maintenance of automated
438 drug dispensing systems and remote dispensing systems. ~~This~~ For hospitals with a pharmacy located
439 within the hospital, monitoring shall be reviewed by a pharmacist while on the premises of the hospital
440 and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.

441 D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for
442 random periodic inspections and monthly audits of automated drug dispensing systems and remote
443 dispensing systems to ~~assure~~ ensure the proper storage, security, and accountability of all drugs placed in
444 and removed from ~~automated drug dispensing such~~ systems and for reviewing the operation and
445 maintenance of ~~automated drug dispensing such~~ systems.

446 E. Notwithstanding this section, the Board shall promulgate regulations for the use of a remote
447 dispensing system to store drugs previously dispensed and labeled by the provider pharmacy in
448 compliance with current laws and regulations. Such regulations shall identify the location where such
449 system may be placed and requirements to ensure the security of the drug, confidentiality of protected
450 health information, and appropriate recordkeeping.

451 **2. That an emergency exists and this act is in force from its passage.**

452 **3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act**
453 **to be effective within 280 days of its enactment.**

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