

SENATE BILL NO. 591

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee on Rehabilitation and Social Services

on _____)

(Patron Prior to Substitute--Senator Hanger)

A BILL to amend and reenact §§ 3.2-4113, 3.2-4118, 4.1-600, 4.1-606, 18.2-247, 18.2-251.1, 19.2-188.1, 54.1-3401, 54.1-3408.3, 54.1-3423, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to marijuana; shape prohibitions; definitions of marijuana and tetrahydrocannabinol.

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.2-4113, 3.2-4118, 4.1-600, 4.1-606, 18.2-247, 18.2-251.1, 19.2-188.1, 54.1-3401, 54.1-3408.3, 54.1-3423, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 3.2-4113. Production of industrial hemp lawful.

A. It is lawful for a grower, his agent, or a federally licensed hemp producer to grow, a dealer or his agent to deal in, or a processor or his agent to process industrial hemp in the Commonwealth for any lawful purpose. No federally licensed hemp producer or grower or his agent shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1 or § 18.2-247, 18.2-248, 18.2-248.01, 18.2-248.1, or 18.2-250 for the possession or growing of industrial hemp or any Cannabis sativa with a tetrahydrocannabinol concentration that does not exceed the total ~~delta-9~~ tetrahydrocannabinol concentration percentage established in federal regulations applicable to negligent violations located at 7 C.F.R. 990.6(b)(3). No dealer or his agent or processor or his agent shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1 or § 18.2-247, 18.2-248, 18.2-248.01, 18.2-248.1, or 18.2-250 or issued a summons or judgment for the possession, dealing, or processing of industrial hemp. In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provision of Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2 or the Drug Control Act (§ 54.1-3400 et seq.), it shall not be necessary to

26 negate any exception, excuse, proviso, or exemption contained in this chapter or the Drug Control Act,
27 and the burden of proof of any such exception, excuse, proviso, or exemption shall be on the defendant.

28 B. Nothing in this chapter shall be construed to authorize any person to violate any federal law or
29 regulation.

30 C. No person shall be prosecuted under Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1 or § 18.2-247,
31 18.2-248, 18.2-248.01, 18.2-248.1, or 18.2-250 for the involuntary growth of industrial hemp through the
32 inadvertent natural spread of seeds or pollen as a result of proximity to a production field, dealership, or
33 process site.

34 **§ 3.2-4118. Forfeiture of industrial hemp grower, dealer, or processor registration;**
35 **violations.**

36 A. The Commissioner shall deny the application, or suspend or revoke the registration, of any
37 person who, with a culpable mental state greater than negligence, violates any provision of this chapter.
38 The Commissioner shall provide reasonable notice of an informal fact-finding conference pursuant to §
39 2.2-4019 to any person in connection with the denial, suspension, or revocation of a registration.

40 B. If a registration is revoked as the result of an informal hearing, the decision may be appealed,
41 and upon appeal an administrative hearing shall be conducted in accordance with the Administrative
42 Process Act (§ 2.2-4000 et seq.). The grower, dealer, or processor may appeal a final order to the circuit
43 court in accordance with the Administrative Process Act.

44 C. A person issued a registration pursuant to subsection A of § 3.2-4115 who negligently (i) fails
45 to provide a description and geographic data sufficient for locating his production field, dealership, or
46 process site; (ii) grows, deals in, or processes Cannabis sativa with a tetrahydrocannabinol concentration
47 greater than that allowed by federal law; or (iii) produces a Cannabis sativa product shall comply with any
48 corrective action plan established by the Commissioner in accordance with the provisions of subsection

49 E. The Commissioner shall not deem a grower negligent if such grower makes reasonable efforts to grow
50 industrial hemp and grows Cannabis sativa with a tetrahydrocannabinol concentration that does not exceed
51 the total—delta-9 tetrahydrocannabinol concentration percentage established in federal regulations
52 applicable to negligent violations located at 7 C.F.R. 990.6(b)(3).

53 D. A person who grows, deals in, or processes industrial hemp and who negligently fails to register
54 pursuant to subsection A of § 3.2-4115 shall comply with any corrective action plan established by the
55 Commissioner in accordance with the provisions of subsection E.

56 E. A corrective action plan established by the Commissioner in response to a negligent violation
57 of a provision of this chapter shall identify a reasonable date by which the person who is the subject of the
58 plan shall correct the negligent violation and shall require such person to report periodically for not less
59 than two calendar years to the Commissioner on the person's compliance with the provisions of this
60 chapter.

61 F. No person who negligently violates the provisions of this chapter three times in a five-year
62 period shall be eligible to grow, deal in, or process industrial hemp for a period of five years beginning on
63 the date of the third violation.

64 **§ 4.1-600. Definitions.**

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

66 "Advertisement" or "advertising" means any written or verbal statement, illustration, or depiction
67 that is calculated to induce sales of retail marijuana, retail marijuana products, marijuana plants, or
68 marijuana seeds, including any written, printed, graphic, digital, electronic, or other material, billboard,
69 sign, or other outdoor display, publication, or radio or television broadcast.

70 "Authority" means the Virginia Cannabis Control Authority created pursuant to this subtitle.

71 "Board" means the Board of Directors of the Virginia Cannabis Control Authority.

72 "Cannabis Control Act" means Subtitle II (§ 4.1-600 et seq.).

73 "Child-resistant" means, with respect to packaging or a container, (i) specially designed or
74 constructed to be significantly difficult for a typical child under five years of age to open and not to be
75 significantly difficult for a typical adult to open and reseal and (ii) for any product intended for more than
76 a single use or that contains multiple servings, resealable.

77 "Cultivation" or "cultivate" means the planting, propagation, growing, harvesting, drying, curing,
78 grading, trimming, or other similar processing of marijuana for use or sale. "Cultivation" or "cultivate"
79 does not include manufacturing or testing.

80 "Edible marijuana product" means a marijuana product intended to be consumed orally, including
81 marijuana intended to be consumed orally or marijuana concentrate intended to be consumed orally.

82 "Immature plant" means a nonflowering marijuana plant that is no taller than eight inches and no
83 wider than eight inches, is produced from a cutting, clipping, or seedling, and is growing in a container.

84 "Licensed" means the holding of a valid license granted by the Authority.

85 "Licensee" means any person to whom a license has been granted by the Authority.

86 "Manufacturing" or "manufacture" means the production of marijuana products or the blending,
87 infusing, compounding, or other preparation of marijuana and marijuana products, including marijuana
88 extraction or preparation by means of chemical synthesis. "Manufacturing" or "manufacture" does not
89 include cultivation or testing.

90 "Marijuana" means (i) any part of a plant of the genus Cannabis, whether growing or not, its seeds
91 or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its
92 seeds, its resin, or any extract containing one or more cannabinoids or (ii) any substance containing a total
93 tetrahydrocannabinol concentration that exceeds 0.3 percent, including a hemp product, as defined in §
94 3.2-4112, or an industrial hemp extract, as defined in § 3.2-5145.1. "Marijuana" does not include (a) the
95 mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seed of such
96 plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis-
97 ~~"Marijuana" does not include (i);~~ (b) industrial hemp, as defined in § 3.2-4112, that is possessed by a
98 person registered pursuant to subsection A of § 3.2-4115 or his agent or (ii); (c) industrial hemp, as defined
99 in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S.
100 Department of Agriculture pursuant to 7 C.F.R. Part 990 or his agent; (d) a hemp product, as defined in §
101 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived
102 from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state
103 or federal law; (e) an industrial hemp extract, as defined in § 3.2-5145.1, containing a
104 tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as
105 defined in § 3.2-4112, grown, dealt, or processed in compliance with state or federal law; or (f) a substance
106 containing a tetrahydrocannabinol isomer or salts of a tetrahydrocannabinol isomer listed as a scheduled

107 substance in the Drug Control Act (§ 54.1-3400 et seq.) by the Board of Pharmacy pursuant to § 54.1-
108 3443.

109 "Marijuana concentrate" means marijuana that has undergone a process to concentrate one or more
110 active cannabinoids, thereby increasing the product's potency. Resin from granular trichomes from a
111 marijuana plant is a concentrate for purposes of this subtitle.

112 "Marijuana cultivation facility" means a facility licensed under this subtitle to cultivate, label, and
113 package retail marijuana; to purchase or take possession of marijuana plants and seeds from other
114 marijuana cultivation facilities; to transfer possession of and sell retail marijuana, immature marijuana
115 plants, and marijuana seeds to marijuana wholesalers and retail marijuana stores; to transfer possession of
116 and sell retail marijuana, marijuana plants, and marijuana seeds to other marijuana cultivation facilities;
117 to transfer possession of and sell retail marijuana to marijuana manufacturing facilities; and to sell
118 immature marijuana plants and marijuana seeds to consumers for the purpose of cultivating marijuana at
119 home for personal use.

120 "Marijuana establishment" means a marijuana cultivation facility, a marijuana testing facility, a
121 marijuana manufacturing facility, a marijuana wholesaler, or a retail marijuana store.

122 "Marijuana manufacturing facility" means a facility licensed under this subtitle to manufacture,
123 label, and package retail marijuana and retail marijuana products; to purchase or take possession of retail
124 marijuana from a marijuana cultivation facility or another marijuana manufacturing facility; and to transfer
125 possession of and sell retail marijuana and retail marijuana products to marijuana wholesalers, retail
126 marijuana stores, or other marijuana manufacturing facilities.

127 "Marijuana paraphernalia" means all equipment, products, and materials of any kind that are either
128 designed for use or are intended for use in planting, propagating, cultivating, growing, harvesting,
129 manufacturing, compounding, converting, producing, processing, preparing, strength testing, analyzing,
130 packaging, repackaging, storing, containing, concealing, ingesting, inhaling, or otherwise introducing into
131 the human body marijuana.

132 "Marijuana products" means (i) products that are composed of marijuana and other ingredients and
133 are intended for use or consumption, ointments, and tinctures or (ii) marijuana concentrate.

134 "Marijuana testing facility" means a facility licensed under this subtitle to develop, research, or
135 test marijuana, marijuana products, and other substances.

136 "Marijuana wholesaler" means a facility licensed under this subtitle to purchase or take possession
137 of retail marijuana, retail marijuana products, immature marijuana plants, and marijuana seeds from a
138 marijuana cultivation facility, a marijuana manufacturing facility, or another marijuana wholesaler and to
139 transfer possession and sell or resell retail marijuana, retail marijuana products, immature marijuana
140 plants, and marijuana seeds to a marijuana cultivation facility, marijuana manufacturing facility, retail
141 marijuana store, or another marijuana wholesaler.

142 "Non-retail marijuana" means marijuana that is not cultivated, manufactured, or sold by a licensed
143 marijuana establishment.

144 "Non-retail marijuana products" means marijuana products that are not manufactured and sold by
145 a licensed marijuana establishment.

146 "Place or premises" means the real estate, together with any buildings or other improvements
147 thereon, designated in the application for a license as the place at which the cultivation, manufacture, sale,
148 or testing of retail marijuana or retail marijuana products shall be performed, except that portion of any
149 such building or other improvement actually and exclusively used as a private residence.

150 "Public place" means any place, building, or conveyance to which the public has, or is permitted
151 to have, access, including restaurants, soda fountains, hotel dining areas, lobbies and corridors of hotels,
152 and any park, place of public resort or amusement, highway, street, lane, or sidewalk adjoining any
153 highway, street, or lane.

154 "Residence" means any building or part of a building or structure where a person resides, but does
155 not include any part of a building that is not actually and exclusively used as a private residence, nor any
156 part of a hotel or club other than a private guest room thereof.

157 "Retail marijuana" means marijuana that is cultivated, manufactured, or sold by a licensed
158 marijuana establishment.

159 "Retail marijuana products" means marijuana products that are manufactured and sold by a
160 licensed marijuana establishment.

161 "Retail marijuana store" means a facility licensed under this subtitle to purchase or take possession
162 of retail marijuana, retail marijuana products, immature marijuana plants, or marijuana seeds from a
163 marijuana cultivation facility, marijuana manufacturing facility, or marijuana wholesaler and to sell retail
164 marijuana, retail marijuana products, immature marijuana plants, or marijuana seeds to consumers.

165 "Sale" and "sell" includes soliciting or receiving an order for; keeping, offering, or exposing for
166 sale; peddling, exchanging, or bartering; or delivering otherwise than gratuitously, by any means, retail
167 marijuana or retail marijuana products.

168 "Special agent" means an employee of the Virginia Cannabis Control Authority whom the Board
169 has designated as a law-enforcement officer pursuant to this subtitle.

170 "Testing" or "test" means the research and analysis of marijuana, marijuana products, or other
171 substances for contaminants, safety, or potency. "Testing" or "test" does not include cultivation or
172 manufacturing.

173 "Tetrahydrocannabinol" or "THC" includes (i) delta-6a(10a), delta-7, delta-8, delta-9, and delta-
174 10 tetrahydrocannabinol and (ii) any substance (a) containing a detectable amount of tetrahydrocannabinol
175 or (b) in which the existence of tetrahydrocannabinol salts, isomers, or salts of isomers is possible within
176 the specific chemical designation.

177 "Total tetrahydrocannabinol concentration" means the sum, after the application of any necessary
178 conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of
179 tetrahydrocannabinolic acid in a substance.

180 **§ 4.1-606. Regulations of the Board.**

181 A. The Board may promulgate reasonable regulations, not inconsistent with this subtitle or the
182 general laws of the Commonwealth, that it deems necessary to carry out the provisions of this subtitle and
183 to prevent the illegal cultivation, manufacture, sale, and testing of marijuana and marijuana products. The
184 Board may amend or repeal such regulations. Such regulations shall be promulgated, amended, or repealed
185 in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) and shall have the effect of law.

186 B. The Board shall promulgate regulations that:

- 187 1. Govern the outdoor cultivation of marijuana by a marijuana cultivation facility licensee,
188 including security requirements to include lighting, physical security, and alarm requirements, provided
189 that such requirements do not prohibit the cultivation of marijuana outdoors or in a greenhouse;
- 190 2. Establish requirements for securely transporting marijuana between marijuana establishments;
- 191 3. Establish sanitary standards for retail marijuana product preparation;
- 192 4. Establish a testing program for retail marijuana and retail marijuana products pursuant to
193 Chapter 14 (§ 4.1-1400 et seq.);
- 194 5. Establish an application process for licensure as a marijuana establishment pursuant to this
195 subtitle in a way that, when possible, prevents disparate impacts on historically disadvantaged
196 communities;
- 197 6. Establish requirements for health and safety warning labels to be placed on retail marijuana and
198 retail marijuana products to be sold or offered for sale by a licensee to a consumer in accordance with the
199 provisions of this subtitle;
- 200 7. Establish a maximum tetrahydrocannabinol level for retail marijuana products, which shall not
201 exceed (i) five milligrams per serving for edible marijuana products and where practicable an equivalent
202 amount for other marijuana products or (ii) 50 milligrams per package for edible marijuana products and
203 where practicable an equivalent amount for other marijuana products. Such regulations may include other
204 product and dispensing limitations on tetrahydrocannabinol;
- 205 8. Establish requirements for the form, content, and retention of all records and accounts by all
206 licensees;
- 207 9. Provide alternative methods for licensees to maintain and store business records that are subject
208 to Board inspection, including methods for Board-approved electronic and offsite storage;
- 209 10. Establish (i) criteria by which to evaluate new licensees based on the density of retail marijuana
210 stores in the community and (ii) metrics that have similarly shown an association with negative
211 community-level health outcomes or health disparities. In promulgating such regulations, the Board shall
212 coordinate with the Cannabis Public Health Advisory Council established pursuant to § 4.1-603;

213 11. Require retail licensees to file an appeal from any hearing decision rendered by a hearing
214 officer within 30 days of the date the notice of the decision is sent. The notice shall be sent to the licensee
215 at the address on record with the Board by certified mail, return receipt requested, and by regular mail;

216 12. Prescribe the schedule of proration for refunded license fees to licensees who qualify pursuant
217 to subsection C of § 4.1-1002;

218 13. Establish criteria by which to evaluate social equity license applicants, which shall be an
219 applicant who has lived or been domiciled for at least 12 months in the Commonwealth and is either (i)
220 an applicant with at least 66 percent ownership by a person or persons who have been convicted of or
221 adjudicated delinquent for any misdemeanor violation of § 18.2-248.1, former § 18.2-250.1, or subsection
222 A of § 18.2-265.3 as it relates to marijuana; (ii) an applicant with at least 66 percent ownership by a person
223 or persons who is the parent, child, sibling, or spouse of a person who has been convicted of or adjudicated
224 delinquent for any misdemeanor violation of § 18.2-248.1, former § 18.2-250.1, or subsection A of § 18.2-
225 265.3 as it relates to marijuana; (iii) an applicant with at least 66 percent ownership by a person or persons
226 who have resided for at least three of the past five years in a jurisdiction that is determined by the Board
227 after utilizing census tract data made available by the United States Census Bureau to have been
228 disproportionately policed for marijuana crimes; (iv) an applicant with at least 66 percent ownership by a
229 person or persons who have resided for at least three of the last five years in a jurisdiction determined by
230 the Board after utilizing census tract data made available by the United States Census Bureau to be
231 economically distressed; or (v) an applicant with at least 66 percent ownership by a person or persons who
232 graduated from a historically black college or university located in the Commonwealth;

233 14. For the purposes of establishing criteria by which to evaluate social equity license applicants,
234 establish standards by which to determine (i) which jurisdictions have been disproportionately policed for
235 marijuana crimes and (ii) which jurisdictions are economically distressed;

236 15. Establish standards and requirements for (i) any preference in the licensing process for
237 qualified social equity applicants, (ii) what percentage of application or license fees are waived for a
238 qualified social equity applicant, and (iii) a low-interest business loan program for qualified social equity
239 applicants;

240 16. Establish guidelines, in addition to requirements set forth in this subtitle, for the personal
241 cultivation of marijuana that promote personal and public safety, including child protection, and
242 discourage personal cultivation practices that create a nuisance, including a nuisance caused by odor;

243 17. Establish reasonable time, place, and manner restrictions on outdoor advertising of retail
244 marijuana or retail marijuana products, not inconsistent with the provisions of this chapter, so that such
245 advertising displaces the illicit market and notifies the public of the location of marijuana establishments.
246 Such regulations shall be promulgated in accordance with § 4.1-1404;

247 18. Establish restrictions on the number of licenses that a person may be granted to operate a
248 marijuana establishment in single locality or region;~~and~~

249 19. Establish restrictions on pharmaceutical processors and industrial hemp processors that have
250 been granted a license in more than one license category pursuant to subsection C of § 4.1-805 that ensure
251 all licensees have an equal and meaningful opportunity to participate in the market. Such regulations may
252 limit the amount of products cultivated or manufactured by the pharmaceutical processor or industrial
253 hemp processor that such processor may offer for sale in its retail marijuana stores; and

254 20. Prohibit the production and sale of retail marijuana and retail marijuana products that depict or
255 are in the shape of a human, animal, vehicle, or fruit.

256 C. The Board may promulgate regulations that:

257 1. Limit the number of licenses issued by type or class to operate a marijuana establishment;
258 however, the number of licenses issued shall not exceed the following limits:

- 259 a. Retail marijuana stores, 400;
- 260 b. Marijuana wholesalers, 25;
- 261 c. Marijuana manufacturing facilities, 60; and
- 262 d. Marijuana cultivation facilities, 450.

263 In determining the number of licenses issued pursuant to this subdivision, the Board shall not
264 consider any license granted pursuant to subsection C of § 4.1-805 to (i) a pharmaceutical processor that
265 has been issued a permit by the Board of Pharmacy pursuant to Article 4.2 (§ 54.1-3442.5 et seq.) of the

266 Drug Control Act or (ii) an industrial hemp processor registered with the Commissioner of Agriculture
267 and Consumer Services pursuant to Chapter 41.1 (§ 3.2-4112 et seq.) of Title 3.2.

268 2. Prescribe any requirements deemed appropriate for the administration of taxes under §§ 4.1-
269 1003 and 4.1-1004, including method of filing a return, information required on a return, and form of
270 payment.

271 3. Limit the allowable square footage of a retail marijuana store, which shall not exceed 1,500
272 square feet.

273 4. Allow certain persons to be granted or have interest in a license in more than one of the following
274 license categories: marijuana cultivation facility license, marijuana manufacturing facility license,
275 marijuana wholesaler license, or retail marijuana store license. Such regulations shall be drawn narrowly
276 to limit vertical integration to small businesses and ensure that all licensees have an equal and meaningful
277 opportunity to participate in the market.

278 D. Board regulations shall be uniform in their application, except those relating to hours of sale
279 for licensees.

280 E. Courts shall take judicial notice of Board regulations.

281 F. The Board shall consult with the Cannabis Public Health Advisory Council in promulgating any
282 regulations relating to public health, including regulations promulgated pursuant to subdivision B 3, 4, 6,
283 7, 10, or 16, and shall not promulgate any such regulation that has not been approved by a majority of the
284 members of the Cannabis Public Health Advisory Council.

285 G. With regard to regulations governing licensees that have been issued a permit by the Board of
286 Pharmacy to operate as a pharmaceutical processor or cannabis dispensing facility pursuant to Article 4.2
287 (§ 54.1-3442.5 et seq.) of the Drug Control Act, the Board shall make reasonable efforts (i) to align such
288 regulations with any applicable regulations promulgated by the Board of Pharmacy that establish health,
289 safety, and security requirements for pharmaceutical processors and cannabis dispensing facilities and (ii)
290 to deem in compliance with applicable regulations promulgated pursuant to this subtitle such
291 pharmaceutical processors and cannabis dispensing facilities that have been found to be in compliance

292 with regulations promulgated by the Board of Pharmacy that mirror or are more extensive in scope than
293 similar regulations promulgated pursuant to this subtitle.

294 H. The Board's power to regulate shall be broadly construed.

295 § 18.2-247. Use of terms "controlled substances," "marijuana," "Schedules I, II, III, IV, V,
296 and VI," "imitation controlled substance" and "counterfeit controlled substance" in Title 18.2.

297 A. ~~Wherever the terms~~ As used in this title, "controlled-substances" substance and "Schedules I,
298 II, III, IV, V, and VI" ~~are used in Title 18.2, such terms refer to~~ means the same as those terms ~~as they~~ are
299 used or defined in the Drug Control Act (§ 54.1-3400 et seq.).

300 B. ~~The term~~ When used in this article, "imitation controlled substance" ~~when used in this article~~
301 means (i) a counterfeit controlled substance or (ii) a pill, capsule, tablet, or substance in any form
302 whatsoever ~~which~~ that is not a controlled substance subject to abuse, and:

303 1. Which by overall dosage unit appearance, including color, shape, size, marking, and packaging
304 or by representations made, would cause the likelihood that such a pill, capsule, tablet, or substance in any
305 other form whatsoever will be mistaken for a controlled substance unless such substance was introduced
306 into commerce prior to the initial introduction into commerce of the controlled substance ~~which~~ that it is
307 alleged to imitate; or

308 2. Which by express or implied representations purports to act like a controlled substance as a
309 stimulant or depressant of the central nervous system and which is not commonly used or recognized for
310 use in that particular formulation for any purpose other than for such stimulant or depressant effect, unless
311 marketed, promoted, or sold as permitted by the U.S. Food and Drug Administration.

312 C. In determining whether a pill, capsule, tablet, or substance in any other form whatsoever, is an
313 "imitation controlled substance," there shall be considered, in addition to all other relevant factors,
314 comparisons with accepted methods of marketing for legitimate nonprescription drugs for medicinal
315 purposes rather than for drug abuse or any similar nonmedicinal use, including consideration of the
316 packaging of the drug and its appearance in overall finished dosage form, promotional materials or
317 representations, oral or written, concerning the drug, and the methods of distribution of the drug and where
318 and how it is sold to the public.

319 D. ~~The term "marijuana" when~~ As used in this article:

320 "Counterfeit controlled substance" means a controlled substance that, without authorization, bears,
321 is packaged in a container or wrapper that bears, or is otherwise labeled to bear the trademark, trade name,
322 or other identifying mark, imprint, or device or any likeness thereof of a drug manufacturer, processor,
323 packer, or distributor other than the manufacturer, processor, packer, or distributor that did in fact so
324 manufacture, process, pack, or distribute such drug.

325 "Marijuana" means (i) any part of a plant of the genus Cannabis, whether growing or not, its seeds
326 or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its
327 seeds, its resin, or any extract containing one or more cannabinoids or (ii) any substance, including a hemp
328 product as defined in § 3.2-4112 or an industrial hemp extract as defined in § 3.2-5145.1, with a total
329 tetrahydrocannabinol concentration in excess of 0.3 percent. "Marijuana" does not include (a) the mature
330 stalks of such plant, fiber produced from such stalk, oil or cake made from the seed of such plant, unless
331 such stalks, fiber, oil or cake is combined with other parts of plants of the genus Cannabis. ~~Marijuana does~~
332 ~~not include (i);~~ (b) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered
333 pursuant to subsection A of § 3.2-4115 or his agent; ~~(ii);~~ (c) industrial hemp, as defined in § 3.2-4112, that
334 is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture
335 pursuant to 7 C.F.R. Part 990; ~~or (iii);~~ (d) a hemp product, as defined in § 3.2-4112, containing a
336 tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as
337 defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law; (e) an
338 industrial hemp extract, as defined in § 3.2-5145.1, containing a tetrahydrocannabinol concentration of no
339 greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112, grown, dealt, or
340 processed in compliance with state or federal law; or (f) a substance containing a tetrahydrocannabinol
341 isomer or salts of a tetrahydrocannabinol isomer listed as a scheduled substance in the Drug Control Act
342 (§ 54.1-3400 et seq.) by the Board of Pharmacy pursuant to § 54.1-3443.

343 "Tetrahydrocannabinol" or "THC" includes (i) delta-6a(10a), delta-7, delta-8, delta-9, and delta-
344 10 tetrahydrocannabinol and (ii) any substance (a) containing a detectable amount of tetrahydrocannabinol

345 or (b) in which the existence of tetrahydrocannabinol salts, isomers, or salts of isomers is possible within
346 the specific chemical designation.

347 "Total tetrahydrocannabinol concentration" means the sum, after the application of any necessary
348 conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of
349 tetrahydrocannabinolic acid in a substance.

350 ~~E. The term "counterfeit controlled substance" means a controlled substance that, without~~
351 ~~authorization, bears, is packaged in a container or wrapper that bears, or is otherwise labeled to bear, the~~
352 ~~trademark, trade name, or other identifying mark, imprint or device or any likeness thereof, of a drug~~
353 ~~manufacturer, processor, packer, or distributor other than the manufacturer, processor, packer, or~~
354 ~~distributor who did in fact so manufacture, process, pack or distribute such drug.~~

355 F. The Department of Forensic Science shall determine the proper methods for detecting the
356 concentration of ~~delta-9 tetrahydrocannabinol (THC)~~ tetrahydrocannabinol in substances for the purposes
357 of this title, Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1, and §§ § 54.1-3401 and 54.1-3446. The testing
358 methodology shall use post-decarboxylation testing or other equivalent method and shall consider the
359 potential conversion of ~~delta-9 tetrahydrocannabinol~~ tetrahydrocannabinolic acid (THC-A) into THC. ~~The~~
360 ~~test result shall include the total available THC derived from the sum of the THC and THC-A content.~~

361 **§ 18.2-251.1. Possession or distribution of marijuana for medical purposes permitted.**

362 A. No person shall be prosecuted under § 18.2-250 or ~~§ 18.2-250.1~~ for the possession of marijuana
363 ~~or tetrahydrocannabinol~~ when that possession occurs pursuant to a valid prescription issued by a medical
364 doctor in the course of his professional practice for treatment of cancer or glaucoma.

365 B. No medical doctor shall be prosecuted under § 18.2-248 or ~~§ 18.2-248.1~~ for dispensing or
366 distributing marijuana ~~or tetrahydrocannabinol~~ for medical purposes when such action occurs in the course
367 of his professional practice for treatment of cancer or glaucoma.

368 C. No pharmacist shall be prosecuted under §§ 18.2-248 to 18.2-248.1 for dispensing or
369 distributing marijuana ~~or tetrahydrocannabinol~~ to any person who holds a valid prescription of a medical
370 doctor for such substance issued in the course of such doctor's professional practice for treatment of cancer
371 or glaucoma.

372 **§ 19.2-188.1. Testimony regarding identification of controlled substances.**

373 ~~A. In any preliminary hearing on a violation of Chapter 11 (§ 4.1-1100 et seq.) of Title 4.1, Article~~
374 ~~1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2, or subdivision 6 of § 53.1-203, any law-enforcement~~
375 ~~officer shall be permitted to testify as to the results of field tests that have been approved by the Department~~
376 ~~of Forensic Science pursuant to regulations adopted in accordance with the Administrative Process Act (§~~
377 ~~2.2-4000 et seq.), regarding whether or not any substance the identity of which is at issue in such hearing~~
378 ~~is a controlled substance, imitation controlled substance, or marijuana, as defined in § 4.1-600 or 18.2-~~
379 ~~247.~~

380 ~~B. In any trial for a violation of § 4.1-1105.1, any law enforcement officer shall be permitted to~~
381 ~~testify as to the results of any marijuana field test approved as accurate and reliable by the Department of~~
382 ~~Forensic Science pursuant to regulations adopted in accordance with the Administrative Process Act (§~~
383 ~~2.2-4000 et seq.), regarding whether or not any plant material, the identity of which is at issue, is marijuana~~
384 ~~provided the defendant has been given written notice of his right to request a full chemical analysis. Such~~
385 ~~notice shall be on a form approved by the Supreme Court and shall be provided to the defendant prior to~~
386 ~~trial.~~

387 ~~In any case in which the person accused of a violation of § 4.1-1105.1, or the attorney of record~~
388 ~~for the accused, desires a full chemical analysis of the alleged plant material, he may, by motion prior to~~
389 ~~trial before the court in which the charge is pending, request such a chemical analysis. Upon such motion,~~
390 ~~the court shall order that the analysis be performed by the Department of Forensic Science in accordance~~
391 ~~with the provisions of § 18.2-247 and shall prescribe in its order the method of custody, transfer, and~~
392 ~~return of evidence submitted for chemical analysis.~~

393 **§ 54.1-3401. Definitions.**

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

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

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

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

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

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

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

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

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

422 "Board" means the Board of Pharmacy.

423 "Bulk drug substance" means any substance that is represented for use, and that, when used in the
424 compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a

425 finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are
426 used in the synthesis of such substances.

427 "Change of ownership" of an existing entity permitted, registered, or licensed by the Board means
428 (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns
429 or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership,
430 or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the
431 outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a
432 wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting
433 stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the
434 merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary
435 owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's
436 charter.

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

439 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into
440 a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by
441 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or
442 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in
443 expectation of receiving a valid prescription based on observed historical patterns of prescribing and
444 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an
445 incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course
446 of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical
447 analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's
448 product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine
449 or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner
450 pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed

451 nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered
452 compounding.

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

458 "Controlled substance analog" means a substance the chemical structure of which is substantially
459 similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a
460 stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar
461 to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a
462 controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person
463 represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous
464 system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on
465 the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog"
466 does not include (a) any substance for which there is an approved new drug application as defined under
467 § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as
468 safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21
469 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance
470 for which an exemption is in effect for investigational use for that person under § 505 of the federal Food,
471 Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such
472 exemption; or (c) any substance to the extent not intended for human consumption before such an
473 exemption takes effect with respect to that substance.

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

476 "Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated
477 by this chapter, whether or not there exists an agency relationship, including delivery of a Schedule VI

478 prescription device to an ultimate user or consumer on behalf of a medical equipment supplier by a
479 manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor,
480 warehouse, nonresident warehouse, third-party logistics provider, or nonresident third-party logistics
481 provider at the direction of a medical equipment supplier in accordance with § 54.1-3415.1.

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

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

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

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

502 "Dispenser" means a practitioner who dispenses.

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

504 "Distributor" means a person who distributes.

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

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

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

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

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

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

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

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

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

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

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

541 "Marijuana" means (i) any part of a plant of the genus Cannabis whether growing or not, its seeds,
542 or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its
543 seeds, its resin, or any extract containing one or more cannabinoids or (ii) any substance, including a hemp
544 product as defined in § 3.2-4112 or an industrial hemp extract as defined in § 3.2-5145.1, with a total
545 tetrahydrocannabinol concentration in excess of 0.3 percent. Marijuana does not include (a) the mature
546 stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant,
547 unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis-
548 ~~Marijuana does not include (i);~~ (b) industrial hemp, as defined in § 3.2-4112, that is possessed by a person
549 registered pursuant to subsection A of § 3.2-4115 or his agent, ~~(ii);~~ (c) industrial hemp, as defined in §
550 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department
551 of Agriculture pursuant to 7 C.F.R. Part 990, ~~or (iii);~~ (d) a hemp product, as defined in § 3.2-4112,
552 containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from
553 industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or
554 federal law; (e) an industrial hemp extract, as defined in § 3.2-5145.1, containing a tetrahydrocannabinol
555 concentration of no greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112,
556 grown, dealt, or processed in compliance with state or federal law; or (f) a substance containing a
557 tetrahydrocannabinol isomer or salts of a tetrahydrocannabinol isomer listed as a scheduled controlled

558 substance in the Drug Control Act (§ 54.1-3400 et seq.) by the Board of Pharmacy pursuant to § 54.1-
559 3443.

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

565 "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction
566 from substances of vegetable origin, or independently by means of chemical synthesis, or by a
567 combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative,
568 or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof
569 which is chemically equivalent or identical with any of the substances referred to in clause (i), but not
570 including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and
571 any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative,
572 or preparation thereof which is chemically equivalent or identical with any of these substances, but not
573 including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

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

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

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

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

594 "Opiate" means any substance having an addiction-forming or addiction-sustaining liability
595 similar to morphine or being capable of conversion into a drug having such addiction-forming or
596 addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article
597 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts
598 (dextromethorphan). It does include its racemic and levorotatory forms.

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

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

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

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

609 "Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the
610 application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant
611 pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale

612 and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the
613 pharmacy and the pharmacy's personnel as required by § 54.1-3432.

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

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

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

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

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

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

632 "Proprietary medicine" means a completely compounded nonprescription drug in its unbroken,
633 original package which does not contain any controlled substance or marijuana as defined in this chapter
634 and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general
635 public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name,
636 or other trade symbol privately owned, and the labeling of which conforms to the requirements of this
637 chapter and applicable federal law. However, this definition shall not include a drug that is only advertised
638 or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that

639 may be dispensed only upon prescription or the label of which bears substantially the statement "Warning
640 — may be habit-forming," or a drug intended for injection.

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

647 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C.
648 § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and
649 Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42
650 U.S.C. § 262(k).

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

653 "Tetrahydrocannabinol" or "THC" includes (i) delta-6a(10a), delta-7, delta-8, delta-9, and delta-
654 10 tetrahydrocannabinol and (ii) any substance (a) containing a detectable amount of tetrahydrocannabinol
655 or (b) in which the existence of tetrahydrocannabinol salts, isomers, or salts of isomers is possible within
656 the specific chemical designation.

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

663 "Third-party logistics provider" means a person that provides or coordinates warehousing of or
664 other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale

665 distributor, or dispenser of the drug or device but does not take ownership of the product or have
666 responsibility for directing the sale or disposition of the product.

667 "Total tetrahydrocannabinol concentration" means the sum, after the application of any necessary
668 conversion factor, of the percentage by weight of tetrahydrocannabinol and the percentage by weight of
669 tetrahydrocannabinolic acid in a substance.

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

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

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

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

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

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

687 **§ 54.1-3408.3. Certification for use of cannabis oil for treatment.**

688 A. As used in this section:

689 "Botanical cannabis" means cannabis that is composed wholly of usable cannabis from the same
690 parts of the same chemovar of cannabis plant.

691 "Cannabis oil" means any formulation of processed Cannabis plant extract, which may include oil
692 from industrial hemp extract acquired by a pharmaceutical processor pursuant to § 54.1-3442.6, or a
693 dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or
694 tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of ~~delta-9-tetrahydrocannabinol~~
695 tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112,
696 that is grown, dealt, or processed in compliance with state or federal law, unless it has been acquired and
697 formulated with cannabis plant extract by a pharmaceutical processor.

698 "Cannabis product" means a product that is (i) produced by a pharmaceutical processor, registered
699 with the Board, and compliant with testing requirements and (ii) composed of cannabis oil or botanical
700 cannabis.

701 "Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-
702 162.3, or home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home
703 health services, private provider licensed by the Department of Behavioral Health and Developmental
704 Services pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2, assisted living facility
705 licensed pursuant to § 63.2-1701, or adult day care center licensed pursuant to § 63.2-1701.

706 "Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine,
707 a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the
708 Board of Medicine and the Board of Nursing.

709 "Registered agent" means an individual designated by a patient who has been issued a written
710 certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated
711 by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

712 "Usable cannabis" means any cannabis plant material, including seeds, but not (i) resin that has
713 been extracted from any part of the cannabis plant, its seeds, or its resin; (ii) the mature stalks, fiber
714 produced from the stalks, or any other compound, manufacture, salt, or derivative, mixture, or preparation
715 of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

716 B. A practitioner in the course of his professional practice may issue a written certification for the
717 use of cannabis products for treatment or to alleviate the symptoms of any diagnosed condition or disease

718 determined by the practitioner to benefit from such use. The practitioner shall use his professional
719 judgment to determine the manner and frequency of patient care and evaluation and may employ the use
720 of telemedicine, provided that the use of telemedicine includes the delivery of patient care through real-
721 time interactive audio-visual technology. If a practitioner determines it is consistent with the standard of
722 care to dispense botanical cannabis to a minor, the written certification shall specifically authorize such
723 dispensing. If not specifically included on the initial written certification, authorization for botanical
724 cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.

725 C. The written certification shall be on a form provided by the Office of the Executive Secretary
726 of the Supreme Court developed in consultation with the Board of Medicine. Such written certification
727 shall contain the name, address, and telephone number of the practitioner, the name and address of the
728 patient issued the written certification, the date on which the written certification was made, and the
729 signature or authentic electronic signature of the practitioner. Such written certification issued pursuant to
730 subsection B shall expire no later than one year after its issuance unless the practitioner provides in such
731 written certification an earlier expiration.

732 D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for the issuance of a
733 certification for the use of cannabis products for the treatment or to alleviate the symptoms of a patient's
734 diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing
735 in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly
736 evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for
737 evaluating or treating medical conditions.

738 E. A practitioner who issues a written certification to a patient pursuant to this section shall register
739 with the Board and shall hold sufficient education and training to exercise appropriate professional
740 judgment in the certification of patients. The Board shall not limit the number of patients to whom a
741 practitioner may issue a written certification. The Board may report information to the applicable licensing
742 board on unusual patterns of certifications issued by a practitioner.

743 F. A patient who has been issued a written certification shall register with the Board or, if such
744 patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian

745 shall register and shall register such patient with the Board. No patient shall be required to physically
746 present the written certification after the initial dispensing by any pharmaceutical processor or cannabis
747 dispensing facility under each written certification, provided that the pharmaceutical processor or cannabis
748 dispensing facility maintains an electronic copy of the written certification.

749 G. A patient, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such
750 patient's parent or legal guardian, may designate an individual to act as his registered agent for the purposes
751 of receiving cannabis products pursuant to a valid written certification. Such designated individual shall
752 register with the Board. The Board may set a limit on the number of patients for whom any individual is
753 authorized to act as a registered agent.

754 H. Upon delivery of cannabis oil by a pharmaceutical processor or cannabis dispensing facility to
755 a designated caregiver facility, any employee or contractor of a designated caregiver facility, who is
756 licensed or registered by a health regulatory board and who is authorized to possess, distribute, or
757 administer medications, may accept delivery of the cannabis oil on behalf of a patient or resident for
758 subsequent delivery to the patient or resident and may assist in the administration of the cannabis oil to
759 the patient or resident as necessary.

760 I. The Board shall promulgate regulations to implement the registration process. Such regulations
761 shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification,
762 the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an
763 incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for
764 ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a
765 prohibition for the patient to be issued a written certification by more than one practitioner during any
766 given time period.

767 J. Information obtained under the registration process shall be confidential and shall not be subject
768 to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However,
769 reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee
770 for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local
771 law enforcement for the purpose of investigating or prosecuting a specific individual for a specific

772 violation of law, (iii) licensed practitioners or pharmacists, or their agents, for the purpose of providing
773 patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv)
774 a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a registered patient,
775 or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as
776 defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related
777 to such registered patient.

778 **§ 54.1-3423. Board to issue registration unless inconsistent with public interest;**
779 **authorization to conduct research; application and fees.**

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

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

786 2. Compliance with applicable state and local law;

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

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

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

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

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

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

798 C. Practitioners must be registered to conduct research or laboratory analysis with controlled
799 substances in Schedules II through VI, ~~tetrahydrocannabinol~~, or marijuana. Practitioners registered under
800 federal law to conduct research with Schedule I substances, other than ~~tetrahydrocannabinol~~ marijuana,
801 may conduct research with Schedule I substances within this Commonwealth upon furnishing the evidence
802 of that federal registration.

803 D. The Board may register other persons or entities to possess controlled substances listed on
804 Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the
805 registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled
806 substances complies with applicable state and federal laws and regulations, and (iv) the subsequent
807 storage, use, and recordkeeping of the controlled substances will be under the general supervision of a
808 licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as
809 specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in
810 subsection A ~~of this section~~ in determining whether the registration shall be issued. Notwithstanding the
811 exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites
812 maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify
813 in its regulations. The Board shall promulgate regulations related to requirements or criteria for the
814 issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.

815 E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase,
816 possess, and administer certain Schedule II through VI controlled substances approved by the State
817 Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and
818 animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for
819 the purpose of preventing, controlling, and treating certain communicable diseases that failure to control
820 would result in transmission to the animal population in the shelter. Controlled substances used for
821 euthanasia shall be administered only in accordance with protocols established by the State Veterinarian
822 and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule
823 VI drugs and biological products used for treatment and prevention of communicable diseases within the
824 shelter shall be determined by the supervising veterinarian of the shelter and the drugs and biological

825 products shall be administered only pursuant to written protocols established or approved by the
826 supervising veterinarian of the shelter and only by persons who have been trained in accordance with
827 instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of
828 the approved list of drugs and biological products, written protocols for administering, and training records
829 of those persons administering drugs and biological products on the premises of the shelter.

830 F. The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601
831 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of
832 Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis
833 stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order
834 of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall
835 only be maintained if so authorized by federal law and Board regulations.

836 G. The Board may register an entity at which a patient is treated by the use of instrumentation and
837 diagnostic equipment through which images and medical records may be transmitted electronically for the
838 purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through
839 VI controlled substances when such prescribing is in compliance with federal requirements for the practice
840 of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S.
841 Drug Enforcement Administration. In determining whether the registration shall be issued, the Board shall
842 consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such registration,
843 and (iii) whether the issuance of the registration is consistent with the public interest.

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

847 I. Upon (i) any change in ownership or control of a business, (ii) any change of location of the
848 controlled substances stock, (iii) the termination of authority by or of the person named as the responsible
849 party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable,
850 the registrant or responsible party shall immediately surrender the registration. The registrant shall, within

851 14 days following surrender of a registration, file a new application and, if applicable, name the new
852 responsible party or supervising practitioner.

853 **§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.**

854 A. No person shall operate a pharmaceutical processor or a cannabis dispensing facility without
855 first obtaining a permit from the Board. The application for such permit shall be made on a form provided
856 by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical
857 processor's dispensing area or cannabis dispensing facility. The Board shall establish an application fee
858 and other general requirements for such application.

859 B. Each permit shall expire annually on a date determined by the Board in regulation. The number
860 of permits that the Board may issue or renew in any year is limited to one pharmaceutical processor and
861 up to five cannabis dispensing facilities for each health service area established by the Board of Health.
862 Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and
863 cannabis dispensing facility.

864 C. The Board shall adopt regulations establishing health, safety, and security requirements for
865 pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements
866 for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum
867 equipment and resources; (v) recordkeeping; (vi) labeling, including the potency of each botanical
868 cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and
869 packaging; (vii) routine inspections no more frequently than once annually; (viii) processes for safely and
870 securely dispensing and delivering in person cannabis products to a registered patient, his registered agent,
871 or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or
872 legal guardian; (ix) dosage limitations for cannabis oil that provide that each dispensed dose of cannabis
873 oil not exceed 10 milligrams of ~~delta-9-tetrahydrocannabinol~~ tetrahydrocannabinol; (x) a process for the
874 wholesale distribution of and the transfer of usable cannabis, botanical cannabis, cannabis oil, and
875 cannabis products between pharmaceutical processors, between a pharmaceutical processor and a
876 cannabis dispensing facility, and between cannabis dispensing facilities; (xi) an allowance for the sale of
877 devices for administration of dispensed cannabis products and hemp-based CBD products that meet the

878 applicable standards set forth in state and federal law, including the laboratory testing standards set forth
879 in subsection M; (xii) an allowance for the use and distribution of inert product samples containing no
880 cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing
881 facility, and not for further distribution or sale, without the need for a written certification; (xiii) a process
882 for acquiring oil from industrial hemp extract and formulating such oil extract with Cannabis plant extract
883 into allowable dosages of cannabis oil; and (xiv) an allowance for the advertising and promotion of the
884 pharmaceutical processor's products and operations, which shall not limit the pharmaceutical processor
885 from the provision of educational material to practitioners who issue written certifications and registered
886 patients. The Board shall also adopt regulations for pharmaceutical processors that include requirements
887 for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis
888 products, (b) the secure disposal of agricultural waste, and (c) a process for registering cannabis oil
889 products.

890 D. The Board shall require that, after processing and before dispensing any cannabis products, a
891 pharmaceutical processor shall make a sample available from each batch of cannabis product for testing
892 by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for
893 testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and
894 laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing
895 or distribution from each homogenized batch of cannabis oil is required to achieve a representative
896 cannabis oil sample for analysis. A minimum sample size, to be determined by the certified testing
897 laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis
898 sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol
899 (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals;
900 mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with
901 generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate cannabis
902 oil that fails any quality testing standard. Following remediation, all remediated cannabis oil shall be
903 subject to laboratory testing and approved upon satisfaction of testing standards applied to cannabis oil
904 generally. If the batch fails retesting, it shall be considered usable cannabis and may be processed into

905 cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be
906 considered usable cannabis and shall not be processed into cannabis oil. Stability testing shall not be
907 required for any cannabis oil product with an expiration date assigned by the pharmaceutical processor of
908 six months or less from the date of packaging.

909 E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances
910 registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the
911 Board in regulation.

912 F. Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under
913 the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or
914 cannabis dispensing facility. The pharmaceutical processor shall ensure that security measures are
915 adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have
916 concurrent responsibility for preventing diversion from the dispensing area.

917 Every pharmaceutical processor shall designate a person who shall have oversight of the
918 cultivation and production areas of the pharmaceutical processor and shall provide such information to
919 the Board. The Board shall direct all communications related to enforcement of requirements related to
920 cultivation and production of cannabis oil products by the pharmaceutical processor to such designated
921 person.

922 G. The Board shall require the material owners of an applicant for a pharmaceutical processor or
923 cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive
924 information to be forwarded along with his fingerprints through the Central Criminal Records Exchange
925 to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information
926 regarding the applicant's material owners. The cost of fingerprinting and the criminal history record search
927 shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the
928 criminal history background check to the Board or its designee, which shall be a governmental entity. A
929 pharmaceutical processor shall maintain evidence of criminal background checks for all employees and
930 delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery
931 agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.

932 H. In addition to other employees authorized by the Board, a pharmaceutical processor may
933 employ individuals who may have less than two years of experience (i) to perform cultivation-related
934 duties under the supervision of an individual who has received a degree in a field related to the cultivation
935 of plants or a certification recognized by the Board or who has at least two years of experience cultivating
936 plants, (ii) to perform extraction-related duties under the supervision of an individual who has a degree in
937 chemistry or pharmacology or at least two years of experience extracting chemicals from plants, and (iii)
938 to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a
939 pharmacy technician.

940 I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to
941 five cannabis dispensing facilities for the dispensing of cannabis products that have been cultivated and
942 produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing
943 facility shall be located within the same health service area as the pharmaceutical processor.

944 J. No person who has been convicted of a felony under the laws of the Commonwealth or another
945 jurisdiction within the last five years shall be employed by or act as an agent of a pharmaceutical processor
946 or cannabis dispensing facility.

947 K. Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for pre-
948 employment drug screening and regular, ongoing, random drug screening of employees.

949 L. A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing
950 facility shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician
951 trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise
952 more than six persons performing the duties of a pharmacy technician at one time in the pharmaceutical
953 processor's dispensing area or cannabis dispensing facility.

954 M. A pharmaceutical processor may acquire industrial hemp extract processed in Virginia, and in
955 compliance with state or federal law, from a registered industrial hemp dealer or processor. A
956 pharmaceutical processor may process and formulate such extract with cannabis plant extract into an
957 allowable dosage of cannabis oil. Industrial hemp extract acquired by a pharmaceutical processor is
958 subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall

959 be performed by a laboratory located in Virginia and in compliance with state law. The industrial hemp
960 dealer or processor shall provide such third-party testing results to the pharmaceutical processor before
961 industrial hemp extract may be acquired.

962 N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§
963 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption
964 of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the
965 Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of
966 Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to
967 comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation;
968 and (iii) the name, address, and telephone number of the agency contact person responsible for receiving
969 public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such
970 notice for submittals of public comment. The legislative review provisions of subsections A and B of §
971 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section.
972 The Board of Pharmacy shall consider and keep on file all public comments received for any regulation
973 adopted pursuant to this section.

974 O. The Board shall register all cannabis products that meet testing, labeling, and packaging
975 standards.

976 **§ 54.1-3442.7. Dispensing cannabis products; report.**

977 A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis
978 products only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia as
979 made evident to the Board, has been issued a valid written certification, and is registered with the Board
980 pursuant to § 54.1-3408.3; (ii) such patient's registered agent; or (iii) if such patient is a minor or an
981 incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia
982 resident or temporarily resides in Virginia as made evident to the Board and is registered with the Board
983 pursuant to § 54.1-3408.3. A companion may accompany a registered patient into a pharmaceutical
984 processor's dispensing area or cannabis dispensing facility. Prior to the initial dispensing of cannabis oil
985 pursuant to each written certification, a pharmacist or pharmacy technician employed by the

986 pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or remotely by
987 electronic means, for two years a paper or electronic copy of the written certification that provides an
988 exact image of the document that is clearly legible; shall view, in person or by audiovisual means, a current
989 photo identification of the patient, registered agent, parent, or legal guardian; and shall verify current board
990 registration of the practitioner and the corresponding patient, registered agent, parent, or legal guardian.
991 Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal guardian,
992 or designated caregiver facility. Prior to any subsequent dispensing of cannabis oil pursuant to each written
993 certification, an employee or delivery agent shall view a current photo identification of the patient,
994 registered agent, or legal guardian and the current board registration issued to the patient, registered agent,
995 parent, or legal guardian. No pharmaceutical processor or cannabis dispensing facility shall dispense more
996 than a 90-day supply of a cannabis product, as determined by the dispensing pharmacist or certifying
997 practitioner, for any patient during any 90-day period; however, a pharmaceutical processor or cannabis
998 dispensing facility may dispense more than one cannabis product to a patient at one time. No more than
999 four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis
1000 is dispensed. A pharmaceutical processor or cannabis dispensing facility may dispense less than a 90-day
1001 supply. In determining the appropriate amount of a cannabis product to be dispensed to a patient, a
1002 pharmaceutical processor or cannabis dispensing facility shall consider all cannabis products dispensed to
1003 the patient and adjust the amount dispensed accordingly.

1004 B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis
1005 products produced on the premises of a pharmaceutical processor permitted by the Board or cannabis oil
1006 that has been formulated with oil from industrial hemp acquired by a pharmaceutical processor from a
1007 registered industrial hemp dealer or processor pursuant to § 54.1-3442.6. A pharmaceutical processor may
1008 begin cultivation upon being issued a permit by the Board.

1009 C. The Board shall report annually by December 1 to the Chairmen of the House Committee for
1010 Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of
1011 pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board, including the

1012 number of practitioners, patients, registered agents, and parents or legal guardians of patients who have
1013 registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

1014 D. The concentration of ~~delta-9-tetrahydrocannabinol~~ tetrahydrocannabinol in any cannabis
1015 product on site may be up to 10 percent greater than or less than the level of ~~delta-9-tetrahydrocannabinol~~
1016 tetrahydrocannabinol measured for labeling. A pharmaceutical processor and cannabis dispensing facility
1017 shall ensure that such concentration in any cannabis product on site is within such range. A pharmaceutical
1018 processor producing cannabis products shall establish a stability testing schedule of cannabis products.

1019 **2. That the provisions of this act amending §§ 54.1-3408.3, 54.1-3442.6, and 54.1-3442.7 of the Code**
1020 **of Virginia shall become effective on the date that persons are allowed to apply for, obtain, and fully**
1021 **utilize a license from the Virginia Cannabis Control Authority to sell retail marijuana, retail**
1022 **marijuana products, immature marijuana plants, and marijuana seeds to the public.**

1023 #