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HOUSE BILL NO. 1277

Offered January 14, 2015

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A BILL to amend and reenact §§ 3.2-801 and 54.1-3401 of the Code of Virginia and to amend the Code of Virginia by adding in Title 3.2 a chapter numbered 41.1, consisting of sections numbered 3.2-4112 through 3.2-4121, relating to industrial hemp production and manufacturing.

Patron—Yost

Committee Referral Pending

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.2-801 and 54.1-3401 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Title 3.2 a chapter numbered 41.1, consisting of sections numbered 3.2-4112 through 3.2-4121, as follows:

§ 3.2-801. Powers and duties of Commissioner.

The Commissioner shall exercise or perform the powers and duties imposed upon him by this chapter. The Commissioner shall make surveys for noxious weeds and when the Commissioner determines that an infestation exists within the Commonwealth, he may request the Board to declare the weed to be noxious under this chapter and the Board shall proceed as specified in § 3.2-802.

The Commissioner in coordination with the Department of Game and Inland Fisheries shall develop a plan for the identification and control of noxious weeds in the surface waters and lakes of the Commonwealth.

The Commissioner may cooperate with any person or any agency of the federal government in carrying out the provisions of this chapter.

Expenses incurred on property owned or controlled by the federal government shall be reimbursed and refunded to the appropriation from which they were expended.

The Commissioner may, upon request, cooperate with federal, other state agencies, or political subdivisions in the enforcement of the narcotics laws to the extent of preventing the spread of and destroying marijuana or hemp, ~~Cannabis species~~, hemp grown without authorization under this chapter, or other plants that produce drugs that have been condemned for destruction under the narcotics laws, and the expenses incurred shall be reimbursed and shall be refunded to the appropriation from which they were expended. Such drug producing plants are hereby declared noxious and subject to all provisions of this chapter pertaining to eradication and spread subject to the above conditions.

CHAPTER 41.1.

INDUSTRIAL HEMP PRODUCTION AND MANUFACTURING.

§ 3.2-4112. Definitions.

As used in this chapter:

"Certified seed" means industrial hemp seed that has been certified as containing a concentration of THC that is no greater than that allowed by federal law.

"Fund" means the Virginia Industrial Hemp Program Fund established pursuant to § 3.2-4119.

"Grower" means any person licensed pursuant to § 3.2-4115 to grow industrial hemp.

"Hemp products" means all products made from industrial hemp, including cloth, cordage, fiber, food, fuel, paint, paper, particleboard, plastics, seed, seed meal and seed oil for consumption, and seed for cultivation.

"Industrial hemp" means all parts and varieties of the plant *Cannabis sativa*, cultivated or possessed by a licensed grower, whether growing or not, that contain a concentration of THC that is no greater than that allowed by federal law. Industrial hemp as defined and applied in this chapter is excluded from the definition of marijuana as found in § 54.1-3401.

"Seed research" means research conducted to develop or re-create better varieties of industrial hemp, particularly for the purposes of seed production. In conducting this research, varieties of industrial hemp with higher THC concentrations may be grown to provide breeding varieties to revitalize the production of a Virginia variety of industrial hemp. However, in no case shall the THC level exceed one percent.

"Tetrahydrocannabinol" or "THC" means the natural or synthetic equivalents of the substances contained in the plant, or in the resinous extractives, of the genus *Cannabis*, or any synthetic substances, compounds, salts, or derivatives of the plant or chemicals and their isomers with similar chemical structure and pharmacological activity.

§ 3.2-4113. Production of industrial hemp lawful.

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59 A. It is lawful for a person licensed pursuant to § 3.2-4115 to cultivate, produce, or otherwise grow
60 industrial hemp in the Commonwealth for any lawful purpose, including the manufacture of industrial
61 hemp products or scientific, agricultural, or other research related to other lawful applications for
62 industrial hemp. No person shall be prosecuted under § 18.2-247, 18.2-248, 18.1-248.1, 18.2-248.01,
63 18.2-250, or 18.2-250.1 for the possession, cultivation, or manufacture of industrial hemp plant material
64 and seeds or industrial hemp products.

65 B. Nothing in this chapter shall be construed to authorize any person to violate any federal law or
66 regulation. If any part of this chapter conflicts with a provision of federal law relating to industrial
67 hemp that has been adopted in Virginia under this section, the federal provision shall control to the
68 extent of the conflict.

69 **§ 3.2-4114. Regulations.**

70 The Board shall adopt regulations pursuant to this chapter as necessary to (i) license persons to
71 grow industrial hemp, (ii) establish industrial hemp testing criteria and protocols, and (iii) administer
72 the industrial hemp research program. The Board shall adopt as regulations the current federal
73 regulations regarding industrial hemp and any subsequent changes thereto.

74 **§ 3.2-4115. Issuance of licenses.**

75 A. The Commissioner shall establish a program of licensure to allow persons to grow industrial
76 hemp in the Commonwealth. The program shall include two separate forms of license:

77 1. An industrial hemp research program grower license, to allow a person to grow industrial hemp
78 in the Commonwealth in a controlled fashion solely and exclusively as part of the industrial hemp
79 research program overseen by the Commissioner. This form of licensure shall only be allowed subject to
80 a grant of necessary permissions, waivers, or other form of valid legal status by the U.S. Drug
81 Enforcement Administration or other appropriate federal agency pursuant to applicable federal laws
82 relating to industrial hemp; and

83 2. An industrial hemp grower license, to allow a person to grow industrial hemp in the
84 Commonwealth for any purpose. This form of licensure shall only be allowed subject to the
85 authorization of legal industrial hemp growth and production in the United States under applicable
86 federal laws relating to industrial hemp.

87 B. Any person seeking to grow industrial hemp shall apply to the Commissioner for the appropriate
88 license on a form provided by the Commissioner. At a minimum, the application shall include:

89 1. The name and mailing address of the applicant;

90 2. The legal description and geographic data sufficient for locating the production fields to be used
91 to grow industrial hemp. A license shall authorize industrial hemp propagation only on the land areas
92 specified in the license;

93 3. A signed statement indicating whether the applicant has ever been convicted of a felony. A person
94 with a prior felony drug conviction within 10 years of applying for a license under this section shall not
95 be eligible for the license;

96 4. Written consent allowing the Department of State Police, if a license is ultimately issued to the
97 applicant, to enter the premises on which the industrial hemp is grown to conduct physical inspections
98 of industrial hemp planted and grown by the applicant and to ensure compliance with the requirements
99 of this chapter. No more than two physical inspections shall be conducted under this subdivision per
100 year, unless a valid search warrant for an inspection has been issued by a court of competent
101 jurisdiction. All testing for THC levels shall be performed as provided in subsection K;

102 5. Any other information required by the Commissioner; and

103 6. The payment of a nonrefundable application fee, in an amount set by the Commissioner, not to
104 exceed \$100, and used to offset the cost of administering the licensure program.

105 C. The Commissioner shall require a state or national criminal history background check by the
106 Department of State Police on any person applying for licensure. The Department of State Police may
107 charge a fee, as established by the Department of State Police, to be paid by the applicant for the
108 actual cost of processing the background check. A copy of the results of the background check shall be
109 sent to the Commissioner.

110 D. All license applications shall be processed as follows:

111 1. Upon receipt of a license application, the Commissioner shall forward a copy of the application to
112 the Department of State Police, which shall initiate its review thereof;

113 2. The Department of State Police shall, within 60 days, perform the required state or national
114 criminal history background check of the applicant; approve the application, if it is determined that the
115 requirements relating to prior criminal convictions have been met; and return all applications to the
116 Commissioner together with its findings and a copy of the state or national criminal history background
117 check; and

118 3. The Commissioner shall review all license applications returned from the Department of State
119 Police. If the Commissioner determines that all requirements have been met and that a license should be
120 granted to the applicant, taking into consideration any prior convictions of the applicant, the

121 Commissioner shall approve the application for issuance of a license.

122 E. In the case of industrial hemp research program grower licenses, the provisions of subsection D
123 shall apply, except that the Commissioner may approve licenses for only those selected growers whose
124 demonstration plots will, in the discretion of the Commissioner, advance the goals of the industrial
125 hemp research program to the furthest extent possible based on location, soil type, growing conditions,
126 varieties of industrial hemp and their suitability for particular hemp products, and other relevant
127 factors. The location and acreage of each demonstration plot to be grown by a license holder, as well
128 as the total number of plots to be grown by a license holder, shall be determined at the discretion of
129 the Commissioner.

130 F. A minimum of one acre of land shall be planted under each industrial hemp grower license. An
131 industrial hemp research program grower license shall not be subject to a minimum acreage.

132 G. Each license shall be valid for a period of one year from the date of issuance and may be
133 renewed in successive years. Each annual renewal shall require the payment of a license renewal fee
134 not to exceed \$100.

135 H. The Commissioner shall, by regulation, establish the fee amounts, not to exceed \$100, required
136 for license applications and license renewals allowed under this section. All application and license
137 renewal fees collected by the Commissioner shall be deposited in the fund established in § 3.2-4119.

138 I. A copy or appropriate electronic record of each license issued by the Commissioner under this
139 section shall be forwarded immediately to the chief law-enforcement officer of each county or city where
140 the industrial hemp is licensed to be planted, grown, and harvested.

141 J. All records, data, and information filed in support of a license application shall be considered
142 proprietary and excluded from the provisions of the provisions of the Virginia Freedom of Information
143 Act (§ 2.2-3700 et seq.).

144 K. The Commissioner shall be responsible for monitoring the industrial hemp grown by any license
145 holder and shall provide for random testing of the industrial hemp for compliance with THC levels and
146 for other appropriate purposes established pursuant to § 3.2-4114 at the cost of the license holder, not
147 to exceed \$100.

148 **§ 3.2-4116. Industrial hemp grower license conditions.**

149 A. A person shall obtain either type of industrial hemp grower license pursuant to § 3.2-4115 prior
150 to planting or growing any industrial hemp in the Commonwealth. A holder of an industrial hemp
151 grower license who has planted and grown industrial hemp pursuant to a valid grower license may sell
152 industrial hemp produced by the grower to any person engaged in manufacturing for the purpose of
153 processing or manufacturing that industrial hemp into hemp products.

154 B. A person granted an industrial hemp grower license pursuant to § 3.2-4115 shall:

155 1. Maintain records that reflect compliance with this chapter and with all other state laws regulating
156 the planting and cultivation of industrial hemp;

157 2. Retain all industrial hemp production records for at least three years;

158 3. Allow industrial hemp crops, throughout sowing, growing, and harvesting, to be inspected by and
159 at the discretion of the Commissioner or his designee, the Department of State Police, or the chief
160 law-enforcement officer of the locality; however the Commissioner, the Department of State Police, or
161 the chief law-enforcement officer of the locality shall provide notification to the person holding the
162 license at least 48 hours prior to conducting the inspection;

163 4. File with the Commissioner documentation indicating that the industrial hemp seeds planted are of
164 a type and variety certified to contain a concentration of tetrahydrocannabinol that is no greater than
165 that allowed by federal law;

166 C. The Commissioner shall assist the grower with his compliance with the requirements of this
167 chapter.

168 D. Any person licensed to grow industrial hemp under this chapter may import and resell to another
169 licensed grower industrial hemp seed that has been certified as containing a concentration of
170 tetrahydrocannabinol that is no greater than that allowed by federal law.

171 **§ 3.2-4117. Forfeiture of industrial hemp grower license.**

172 A. The Commissioner shall deny the application, or suspend or revoke the license, of any industrial
173 hemp grower if the grower violates any provision of this chapter. The Commissioner shall provide
174 reasonable notice of an informal fact-finding conference pursuant to § 2.2-4019 to any industrial hemp
175 grower in connection with the denial, suspension, or revocation of the grower's license.

176 B. If a license is revoked as the result of an informal hearing, the decision may be appealed, and
177 upon appeal an administrative hearing shall be conducted before the Board in accordance with the
178 Administrative Process Act (§ 2.2-4000 et seq.). The grower may appeal the final order of the Board to
179 the circuit court in accordance with the Administrative Process Act.

180 C. The Commissioner may revoke any license of any person who has pled guilty to, or been
181 convicted of, a felony.

182 **§ 3.2-4118. Eligibility to receive tobacco settlement funds.**

183 *Industrial hemp growers licensed under this chapter may be eligible to receive funds from the*
184 *Tobacco Indemnification and Community Revitalization Fund established pursuant to § 3.2-3106.*

185 **§ 3.2-4119. Virginia Industrial Hemp Program Fund established.**

186 *There is hereby created in the state treasury a special nonreverting fund to be known as the Virginia*
187 *Industrial Hemp Program Fund, hereinafter referred to as "the Fund." The Fund shall be established on*
188 *the books of the Comptroller. All moneys levied and collected pursuant to this chapter shall be paid into*
189 *the state treasury and credited to the Fund. Interest earned on moneys in the Fund shall remain in the*
190 *Fund and be credited to it. Any moneys remaining in the Fund, including interest thereon, at the end of*
191 *each fiscal year shall not revert to the general fund but shall remain in the Fund. Moneys in the Fund*
192 *shall be used solely for the purposes set forth in this chapter. Expenditures and disbursements from the*
193 *Fund shall be made by the Board on warrants issued by the Comptroller upon written request signed by*
194 *the duly authorized officer of the Board. The Auditor of Public Accounts shall audit all the accounts of*
195 *the Board as is provided for in § 30-133.*

196 **§ 3.2-4120. Industrial hemp promotion.**

197 *The Commissioner shall promote research into and the development of industrial hemp, and*
198 *commercial markets for Virginia industrial hemp and hemp products, to the extent that adequate funds*
199 *are available and are approved by the Commissioner for these purposes from the Fund established*
200 *pursuant to § 3.2-4119.*

201 **§ 3.2-4121. Industrial hemp research program.**

202 *A. To the extent that adequate funds are available for the program from the Fund established*
203 *pursuant to § 3.2-4119, the Commissioner shall undertake research of industrial hemp production*
204 *through the establishment and oversight of a five-year industrial hemp research program to be directly*
205 *managed by public institutions of higher education or research institutes. This research program shall*
206 *consist primarily of demonstration plots planted and cultivated in Virginia by selected growers. The*
207 *growers shall be licensed pursuant to subsection A of § 3.2-4115 prior to planting any industrial hemp.*

208 *B. As part of the industrial hemp research program the Commissioner shall:*

209 *1. Oversee and analyze the growth of industrial hemp by selected and licensed growers, for*
210 *agronomy research and analysis of required soils, growing conditions, and harvest methods relating to*
211 *the production of various varieties of industrial hemp that may be suitable for various commercial hemp*
212 *products;*

213 *2. Conduct seed research on various types of industrial hemp that are best suited to be grown in*
214 *Virginia, including seed availability, creation of Virginia hybrid types, and in-the-ground variety trials*
215 *and seed production, and shall establish a program to recognize certain industrial hemp seeds as being*
216 *Virginia varieties of hemp seed;*

217 *3. Study the economic feasibility of developing an industrial hemp market in various types of*
218 *industrial hemp that can be grown in the Commonwealth;*

219 *4. Report on the estimated value-added benefits, including environmental benefits, to Virginia*
220 *businesses of an industrial hemp market of Virginia-grown industrial hemp varieties;*

221 *5. Study the agronomy research being conducted worldwide relating to industrial hemp varieties,*
222 *production, and use;*

223 *6. Research and promote on the world market industrial hemp and hemp seed that can be grown on*
224 *farms in the Commonwealth; and*

225 *7. Study the feasibility of attracting federal or private funding for the Virginia industrial hemp*
226 *research program.*

227 *C. In addition to the research and analysis outlined in subsection B, the Commissioner shall:*

228 *1. Coordinate with public institutions of higher education or research institutes to study the use of*
229 *industrial hemp in new energy technologies, including electricity generation, biofuels, or other forms of*
230 *energy resources; the growth of industrial hemp on reclaimed mine sites; the use of hemp seed oil in*
231 *the production of fuels; and the production costs, environmental issues, and costs and benefits involved*
232 *with the use of industrial hemp for energy; and*

233 *2. Coordinate with the Governor's Development Opportunity Fund to diversify the agricultural*
234 *economy of the Commonwealth, attract new businesses to the state, create new job opportunities for*
235 *Virginia residents, and create a commercial market for industrial hemp.*

236 *D. The research activities outlined in subsections B and C shall not:*

237 *1. Subject the industrial hemp research program to any criminal liability under the controlled*
238 *substances laws of the Commonwealth. This exemption from criminal liability is a limited exemption that*
239 *shall be strictly construed and that shall not apply to any activities of the industrial hemp research*
240 *program that are not authorized; or*

241 *2. Alter, amend, or repeal by implication any provision of this Code relating to controlled*
242 *substances.*

243 *E. The Commissioner shall pursue any permits or waivers from the U.S. Drug Enforcement*

244 Administration or appropriate federal agency that are necessary for the advancement of the industrial
245 hemp research program.

246 F. The Commissioner shall notify the Commissioner of State Police and all local law-enforcement
247 agencies of the duration, size, and location of all industrial hemp demonstration plots.

248 G. The Commissioner is permitted to cooperatively seek funds from public and private sources to
249 implement the industrial hemp research program. The funds shall be deposited into the Fund established
250 pursuant to § 3.2-4119.

251 H. By November 1, 2015, and annually thereafter, the Commissioner shall report on the status and
252 progress of the industrial hemp research program to the Governor and to the General Assembly.

253 **§ 54.1-3401. Definitions.**

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

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

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

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

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

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

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

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

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

282 "Board" means the Board of Pharmacy.

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

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

297 "Compounding" means the combining of two or more ingredients to fabricate such ingredients into a
298 single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by
299 a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or
300 therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in
301 expectation of receiving a valid prescription based on observed historical patterns of prescribing and
302 dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as
303 an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the
304 course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or

305 chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a
306 manufacturer's product drugs for the purpose of administration to a patient, when performed by a
307 practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person
308 supervised by such practitioner pursuant to subdivision A 6 or A 19 of § 54.1-2901, or a person
309 supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to
310 subdivision A 4 of § 54.1-2901 shall not be considered compounding.

311 "Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of
312 this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms
313 are defined or used in Title 3.2 or Title 4.1.

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

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

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

321 "Dialysis care technician" or "dialysis patient care technician" means an individual who is certified
322 by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§
323 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician
324 assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a
325 Medicare-certified renal dialysis facility.

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

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

338 "Dispenser" means a practitioner who dispenses.

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

340 "Distributor" means a person who distributes.

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

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

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

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

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

358 "Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any
359 such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

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

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

366 "Label" means a display of written, printed, or graphic matter upon the immediate container of any

367 article. A requirement made by or under authority of this chapter that any word, statement, or other
 368 information appear on the label shall not be considered to be complied with unless such word,
 369 statement, or other information also appears on the outside container or wrapper, if any, of the retail
 370 package of such article or is easily legible through the outside container or wrapper.

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

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

378 "Manufacturer" means every person who manufactures.

379 "Marijuana" means any part of a plant of the genus *Cannabis* whether growing or not, its seeds, or
 380 its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its
 381 seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids
 382 unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana
 383 include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the
 384 seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the
 385 genus *Cannabis*. *Marijuana shall not include industrial hemp as defined in § 3.2-4112.*

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

391 "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction
 392 from substances of vegetable origin, or independently by means of chemical synthesis, or by a
 393 combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative,
 394 or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof
 395 which is chemically equivalent or identical with any of the substances referred to in clause (i), but not
 396 including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and
 397 any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer,
 398 derivative, or preparation thereof which is chemically equivalent or identical with any of these
 399 substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain
 400 cocaine or ecgonine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

471 "Reference biological product" means the single biological product licensed pursuant to 42 U.S.C.
472 § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food
473 and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to
474 42 U.S.C. § 262(k).

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

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

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

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

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

489 "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs

490 including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors;
491 jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug
492 warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale
493 drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any
494 state or local tax as a wholesale merchant by reason of this definition.

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

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