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HOUSE BILL NO. 2218

AMENDMENT IN THE NATURE OF A SUBSTITUTE (Proposed by the House Committee on Health, Welfare and Institutions on January 28, 2021)

(Patron Prior to Substitute—Delegate Hayes)

A BILL to amend and reenact §§ 18.2-250.1, 54.1-2519, 54.1-2521, 54.1-2903, 54.1-3408.3, and

- 6 7 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia, relating to pharmaceutical processors; 8 cannabis products.
 - Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1, 54.1-2519, 54.1-2521, 54.1-2903, 54.1-3408.3, and 54.1-3442.5 through 10 54.1-3442.8 of the Code of Virginia are amended and reenacted as follows: 11 12

§ 18.2-250.1. Possession of marijuana unlawful.

13 A. It is unlawful for any person knowingly or intentionally to possess marijuana unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in 14 the course of his professional practice, or except as otherwise authorized by the Drug Control Act 15 (§ 54.1-3400 et seq.). The attorney for the Commonwealth or the county, city, or town attorney may 16 17 prosecute such a case.

18 Upon the prosecution of a person for violation of this section, ownership or occupancy of the premises or vehicle upon or in which marijuana was found shall not create a presumption that such 19 20 person either knowingly or intentionally possessed such marijuana.

21 Any person who violates this section is subject to a civil penalty of no more than \$25. A violation of 22 this section is a civil offense. Any civil penalties collected pursuant to this section shall be deposited 23 into the Drug Offender Assessment and Treatment Fund established pursuant to § 18.2-251.02.

24 B. Any violation of this section shall be charged by summons. A summons for a violation of this 25 section may be executed by a law-enforcement officer when such violation is observed by such officer. The summons used by a law-enforcement officer pursuant to this section shall be in form the same as 26

27 the uniform summons for motor vehicle law violations as prescribed pursuant to § 46.2-388. No court 28 costs shall be assessed for violations of this section. A person's criminal history record information as 29 defined in § 9.1-101 shall not include records of any charges or judgments for a violation of this section, 30 and records of such charges or judgments shall not be reported to the Central Criminal Records 31 Exchange. However, if a violation of this section occurs while an individual is operating a commercial 32 motor vehicle as defined in § 46.2-341.4, such violation shall be reported to the Department of Motor 33 Vehicles and shall be included on such individual's driving record.

34 C. The procedure for appeal and trial of any violation of this section shall be the same as provided 35 by law for misdemeanors; if requested by either party on appeal to the circuit court, trial by jury shall 36 be as provided in Article 4 (§ 19.2-260 et seq.) of Chapter 15 of Title 19.2, and the Commonwealth 37 shall be required to prove its case beyond a reasonable doubt.

38 D. The provisions of this section shall not apply to members of state, federal, county, city, or town 39 law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as 40 handlers of dogs trained in the detection of controlled substances when possession of marijuana is 41 necessary for the performance of their duties.

42 E. The provisions of this section involving marijuana in the form of cannabis oil products as that term is defined in § 54.1-3408.3 shall not apply to any person who possesses such oil cannabis product 43 pursuant to a valid written certification issued by a practitioner in the course of his professional practice 44 pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the person's diagnosed 45 condition or disease, (ii) if such person is the parent or legal guardian of a minor or of an incapacitated 46 adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition or disease, or 47 (iii) if such person has been designated as a registered agent pursuant to § 54.1-3408.3, the diagnosed **48** condition or disease of his principal or, if the principal is the parent or legal guardian of a minor or of 49 50 an incapacitated adult as defined in § 18.2-369, such minor's or incapacitated adult's diagnosed condition 51 or disease.

§ 54.1-2519. Definitions.

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

54 "Administer" means the direct application of a controlled substance, whether by injection, inhalation, 55 ingestion or any other means, to the body of a patient or research subject by (i) a practitioner or, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and 56 57 in the presence of the practitioner.

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug 58 59 Diversion Unit.

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"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of 60 the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title. 61

"Covered substance" means all controlled substances included in Schedules II, III, and IV; controlled 62 63 substances included in Schedule V for which a prescription is required; naloxone; and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. 64 65 "Covered substance" also includes cannabis oil products dispensed by a pharmaceutical processor in 66 Virginia.

"Department" means the Virginia Department of Health Professions.

"Director" means the Director of the Virginia Department of Health Professions.

"Dispense" means to deliver a controlled substance to an ultimate user, research subject, or owner of 69 an animal patient by or pursuant to the lawful order of a practitioner, including the prescribing and 70 administering, packaging, labeling or compounding necessary to prepare the substance for that delivery. 71

"Dispenser" means a person or entity that (i) is authorized by law to dispense a covered substance or 72 to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered 73 substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who 74 75 dispenses such covered substance from a location in Virginia regardless of the location of the recipient.

76 "Drug of concern" means any drug or substance, including any controlled substance or other drug or 77 substance, where there has been or there is the potential for abuse and that has been identified by the 78 Board of Pharmacy pursuant to § 54.1-3456.1.

79 "Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in 80 another state to so issue a prescription for a covered substance. 81

"Recipient" means a person who receives a covered substance from a dispenser and includes the 82 83 owner of an animal patient.

"Relevant health regulatory board" means any such board that licenses persons or entities with the 84 85 authority to prescribe or dispense covered substances, including the Board of Dentistry, the Board of Medicine, the Board of Veterinary Medicine, and the Board of Pharmacy. 86 87

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the 88 89 Department's regulations to report the dispensing of covered substances shall constitute grounds for 90 disciplinary action by the relevant health regulatory board.

91 B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the 92 following information:

93 1. The recipient's name and address.

2. The recipient's date of birth. 94

95 3. The covered substance that was dispensed to the recipient.

96 4. The quantity of the covered substance that was dispensed.

97 5. The date of the dispensing.

6. The prescriber's identifier number and, in cases in which the covered substance is a cannabis oil 98 99 product, the expiration date of the written certification.

7. The dispenser's identifier number. 100

8. The method of payment for the prescription. 101

102 9. Any other non-clinical information that is designated by the Director as necessary for the 103 implementation of this chapter in accordance with the Department's regulations.

104 10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds. 105

C. Except as provided in subdivision 7 of § 54.1-2522, in cases where the ultimate user of a covered 106 substance is an animal, the dispenser shall report the relevant information required by subsection B for 107 108 the owner of the animal.

109 D. The reports required herein shall be made to the Department or its agent within 24 hours or the 110 dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations. 111 112

§ 54.1-2903. What constitutes practice; advertising in connection with medical practice.

A. Any person shall be regarded as practicing the healing arts who actually engages in such practice 113 114 as defined in this chapter, or who opens an office for such purpose, or who advertises or announces to the public in any manner a readiness to practice or who uses in connection with his name the words or letters "Doctor," "Dr.," "M.D.," "D.O.," "D.P.M.," "D.C.," "Healer," "N.P.," or any other title, word, letter or designation intending to designate or imply that he is a practitioner of the healing arts or that 115 116 117 he is able to heal, cure or relieve those suffering from any injury, deformity or disease. 118

Signing a birth or death certificate, or signing any statement certifying that the person so signing has rendered professional service to the sick or injured, or signing or issuing a prescription for drugs or 119 120 other remedial agents, shall be prima facie evidence that the person signing or issuing such writing is 121

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practicing the healing arts within the meaning of this chapter except where persons other than physiciansare required to sign birth certificates.

124 B. No person regulated under this chapter shall use the title "Doctor" or the abbreviation "Dr." in 125 writing or in advertising in connection with his practice unless he simultaneously uses words, initials, an 126 abbreviation or designation, or other language that identifies the type of practice for which he is 127 licensed. No person regulated under this chapter shall include in any advertisement a reference to 128 marijuana, as defined in § 18.2-247, unless such advertisement is for the treatment of addiction or 129 substance abuse. However, nothing in this subsection shall prevent a person from including in any 130 advertisement that such person is registered with the Board of Pharmacy to issue written certifications for the use of cannabis oil products, as defined in § 54.1-3408.3. 131

132 § 54.1-3408.3. Certification for use of cannabis products for treatment.

133 A. As used in this section:

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

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

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

146 "Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a
147 physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the
148 Board of Medicine and the Board of Nursing.

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

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

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis oil *products* for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V controlled substances.

162 C. The written certification shall be on a form provided by the Office of the Executive Secretary of 163 the Supreme Court developed in consultation with the Board of Medicine. Such written certification 164 shall contain the name, address, and telephone number of the practitioner, the name and address of the 165 patient issued the written certification, the date on which the written certification was made, and the 166 signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no 167 later than one year after its issuance unless the practitioner provides in such written certification an 168 earlier expiration.

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

E. A practitioner who issues a written certification to a patient pursuant to this section shall register
with the Board. The Board shall, in consultation with the Board of Medicine, set a limit on the number
of patients to whom a practitioner may issue a written certification.

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

181 G. A patient, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian, may designate an individual to act as his registered agent for the

183 purposes of receiving cannabis oil products pursuant to a valid written certification. Such designated 184 individual shall register with the Board. The Board may set a limit on the number of patients for whom 185 any individual is authorized to act as a registered agent.

186 H. The Board shall promulgate regulations to implement the registration process. Such regulations 187 shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification, 188 the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an 189 incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for 190 ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a 191 prohibition for the patient to be issued a written certification by more than one practitioner during any 192 given time period.

193 I. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, 194 195 reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee 196 for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local 197 law enforcement for the purpose of investigating or prosecuting a specific individual for a specific 198 violation of law, (iii) licensed practitioners or pharmacists for the purpose of providing patient care and 199 drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a 200 pharmaceutical processor or cannabis dispensing facility involved in the treatment of a registered patient, 201 or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as 202 defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related 203 to such registered patient.

204 § 54.1-3442.5. Definitions.

As used in this article:

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206 "Cannabis oil" has "Botanical cannabis," "cannabis oil," "cannabis product," and "usable cannabis" 207 have the same meaning meanings as specified in § 54.1-3408.3.

"Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant 208 to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses 209 210 cannabis oil*products* produced by a pharmaceutical processor to a registered patient, his registered agent, 211 or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or 212 legal guardian.

213 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to 214 § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil, 215 botanical cannabis, and usable cannabis, produces cannabis oil products, and dispenses cannabis oil 216 products to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated 217 adult as defined in § 18.2-369, such patient's parent or legal guardian. 218

"Practitioner" has the same meaning as specified in § 54.1-3408.3.

"Registered agent" has the same meaning as specified in § 54.1-3408.3.

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

221 A. No person shall operate a pharmaceutical processor or a cannabis dispensing facility without first 222 obtaining a permit from the Board. The application for such permit shall be made on a form provided 223 by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical 224 processor or cannabis dispensing facility. The Board shall establish an application fee and other general 225 requirements for such application.

226 B. Each permit shall expire annually on a date determined by the Board in regulation. The number of 227 permits that the Board may issue or renew in any year is limited to one pharmaceutical processor and 228 up to five cannabis dispensing facilities for each health service area established by the Board of Health. 229 Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and 230 cannabis dispensing facility.

231 C. The Board shall adopt regulations establishing health, safety, and security requirements for 232 pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements 233 for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum 234 equipment and resources; (v) recordkeeping; (vi) labeling, including the potency of each botanical 235 cannabis product, and packaging; (vii) quarterly inspections; (viii) processes for safely and securely 236 dispensing and delivering in person cannabis oil *products* to a registered patient, his registered agent, or, 237 if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or 238 legal guardian; (ix) dosage limitations, which shall for cannabis oil that provide that each dispensed 239 dose of cannabis oil not exceed 10 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the 240 wholesale distribution of and the transfer of usable cannabis, botanical cannabis, cannabis oil, and 241 cannabis products between pharmaceutical processors and between a pharmaceutical processor and a 242 cannabis dispensing facility; (xi) an allowance for the sale of devices for administration of dispensed 243 cannabis products; (xii) an allowance for the use and distribution of inert product samples containing no 244 cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis

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dispensing facility, and not for further distribution or sale, without the need for a written certification; and (xiii) a process for acquiring oil from industrial hemp extract and formulating such oil extract with Cannabis plant extract into allowable dosages of cannabis oil. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis oil *products*; (b) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (c) (b) the secure disposal of plant remains; and (d) (c) a process for registering cannabis oil products.

252 D. The Board shall require that, after processing and before dispensing any cannabis oil products, a 253 pharmaceutical processor shall make a sample available from each homogenized batch of *cannabis* 254 product for testing by an independent laboratory located in Virginia meeting Board requirements. A 255 valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, 256 analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of 257 individual units for dispensing or distribution from each homogenized batch of cannabis oil is required 258 to achieve a representative cannabis oil sample for analysis. A minimum sample size, to be determined 259 by the certified testing laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis sample for analysis. Botanical cannabis products shall only be tested 260 261 for the following: total cannabidiol (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide 262 chemical residue; heavy metals; mycotoxins; moisture; and microbiological contaminants. Testing 263 thresholds shall be consistent with generally accepted cannabis industry thresholds. If a sample from a 264 batch of botanical cannabis fails testing requirements, the processor may remediate the batch and 265 submit a sample for retesting. If the batch fails retesting, it shall be considered usable cannabis and 266 may be processed into cannabis oil. This oil must comply with all applicable testing standards.

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

F. Every pharmaceutical processor or cannabis dispensing facility shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or cannabis dispensing facility. A pharmacist in charge of a pharmaceutical processor may authorize certain employee access to secured areas designated for cultivation and other areas approved by the Board. No pharmacist shall be required to be on the premises during such authorized access. The pharmacist-in-charge shall ensure security measures are adequate to protect the cannabis from diversion at all times.

G. The Board shall require an applicant for a pharmaceutical processor or cannabis dispensing
facility permit to submit to fingerprinting and provide personal descriptive information to be forwarded
along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of
Investigation for the purpose of obtaining criminal history record information regarding the applicant.
The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The
Central Criminal Records Exchange shall forward the results of the criminal history background check to
the Board or its designee, which shall be a governmental entity.

H. In addition to other employees authorized by the Board, a pharmaceutical processor may employ
individuals who may have less than two years of experience (i) to perform cultivation-related duties
under the supervision of an individual who has received a degree in horticulture or a certification
recognized by the Board or who has at least two years of experience cultivating plants and (ii) to
perform extraction-related duties under the supervision of an individual who has a degree in chemistry
or pharmacology or at least two years of experience extracting chemicals from plants.

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

J. No person who has been convicted of (i) a felony under the laws of the Commonwealth or another
jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or
Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the
laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor or
cannabis dispensing facility.

300 K. Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for 301 pre-employment drug screening and regular, ongoing, random drug screening of employees.

302 L. A pharmacist at the pharmaceutical processor and the cannabis dispensing facility shall determine
 303 the number of pharmacy interns, pharmacy technicians and pharmacy technician trainees who can be
 304 safely and competently supervised at one time; however, no pharmacist shall supervise more than six
 305 persons performing the duties of a pharmacy technician at one time.

306 M. Any person who proposes to use an automated process or procedure during the production of cannabis oil products that is not otherwise authorized in law or regulation or at a time when a 307 308 pharmacist will not be on site on site may apply to the Board for approval to use such process or 309 procedure pursuant to subsections B through E of § 54.1-3307.2.

310 N. A pharmaceutical processor may acquire oil from industrial hemp extract processed in Virginia, 311 and in compliance with state or federal law, from a registered industrial hemp dealer or processor. A 312 pharmaceutical processor may process and formulate such oil extract with cannabis plant extract into an 313 allowable dosage of cannabis oil. Oil from industrial hemp acquired by a pharmaceutical processor is 314 subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing 315 shall be performed by a laboratory located in Virginia and in compliance with state law. The industrial 316 hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before oil from industrial hemp may be acquired. 317

318 O. The Board shall register all cannabis products that meet testing, labeling, and packaging 319 standards. 320

§ 54.1-3442.7. Dispensing cannabis products; report.

321 A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis oil 322 *products* only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia as 323 made evident to the Board, has been issued a valid written certification, and is registered with the Board 324 pursuant to § 54.1-3408.3; (ii) such patient's registered agent; or (iii) if such patient is a minor or an 325 incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident or temporarily resides in Virginia as made evident to the Board and is registered with the Board 326 327 pursuant to § 54.1-3408.3. Prior to the initial dispensing of each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall 328 make and maintain for two years a paper or electronic copy of the written certification that provides an 329 exact image of the document that is clearly legible; shall view a current photo identification of the 330 patient, registered agent, parent, or legal guardian; and shall verify current board registration of the 331 332 practitioner and the corresponding patient, registered agent, parent, or legal guardian. Prior to any 333 subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery 334 agent shall view the current written certification; a current photo identification of the patient, registered 335 agent, parent, or legal guardian; and the current board registration issued to the patient, registered agent, 336 parent, or legal guardian. No pharmaceutical processor or cannabis dispensing facility shall dispense 337 more than a 90-day supply for any patient during any 90-day period. The Board shall establish in 338 regulation an amount of cannabis oil that constitutes a 90-day supply to treat or alleviate the symptoms 339 of a patient's diagnosed condition or disease. The supply for botanical cannabis products may not exceed 340 four ounces of botanical cannabis per 30-day period. In determining the appropriate supply, the 341 pharmacist shall consider all cannabis products dispensed to the patient and adjust the dispensing 342 accordingly.

343 B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis oil that 344 has been cultivated and products produced on the premises of a pharmaceutical processor permitted by 345 the Board or cannabis oil that has been formulated with oil from industrial hemp acquired by a pharmaceutical processor from a registered industrial hemp dealer or processor pursuant to 346 347 § 54.1-3442.6. A pharmaceutical processor may begin cultivation upon being issued a permit by the 348 Board.

349 C. The Board shall report annually by December 1 to the Chairmen of the House Committee for Courts of Justice and the Senate Committee on the Judiciary on the operation of pharmaceutical 350 351 processors and cannabis dispensing facilities issued a permit by the Board, including the number of 352 practitioners, patients, registered agents, and parents or legal guardians of patients who have registered 353 with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

354 D. The concentration of delta-9-tetrahydrocannabinol in any cannabis oil on site may be up to 10 355 percent greater than or less than the level of delta-9-tetrahydrocannabinol measured for labeling. A 356 pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any cannabis oil on site is within such range. A pharmaceutical processor producing cannabis oil shall 357 358 establish a stability testing schedule of cannabis oil. 359

§ 54.1-3442.8. Criminal liability; exceptions.

360 No agent or employee of a pharmaceutical processor or cannabis dispensing facility shall be prosecuted under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of 361 362 marijuana or for possession, manufacture, or distribution of cannabis oil products, subject to any civil 363 penalty, denied any right or privilege, or subject to any disciplinary action by a professional licensing 364 board if such agent or employee (i) possessed or manufactured such marijuana for the purposes of 365 producing cannabis oil *products* in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such cannabis oil products that are consistent with 366 367 generally accepted cannabis industry standards in accordance with the provisions of this article and **368** Board regulations.

- 369 2. That the Board of Pharmacy shall establish testing standards for botanical cannabis and 370 botanical cannabis products consistent with generally accepted cannabis industry standards.
- 371 3. That the Board of Pharmacy shall promulgate regulations implementing the provisions of this
- 372 act including its enactment clauses. The Board's adoption of regulations shall be exempt from the
- 373 Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board shall
- 374 provide an opportunity for public comment on the regulations prior to adoption. The Board shall 375 complete work on such regulations in order that they will be implemented no later than
- 376 September 1, 2021.
- 377 4. That the Board of Pharmacy may assess and collect a one-time botanical cannabis regulatory
- 378 fee from each pharmaceutical processor in an amount sufficient to implement the first, second,
- 379 and third enactments of this act, not to exceed \$75,000, including without limitation costs for new
- 380 personnel, training, promulgation of regulations and guidance documents, and information
- 381 technology.

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