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HOUSE BILL NO. 2245

Offered January 9, 2019

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A BILL to amend and reenact §§ 3.2-4112, 18.2-247, 54.1-3401, as it is currently effective and as it shall become effective, 54.1-3442.5, 54.1-3442.6, 54.1-3442.7, and 54.1-3446 of the Code of Virginia, relating to products containing tetrahydrocannabinol; permits to process and dispense cannabidiol oil and THC-A oil.

Patrons—Davis and Peace

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.2-4112, 18.2-247, 54.1-3401, as it is currently effective and as it shall become effective, 54.1-3442.5, 54.1-3442.6, 54.1-3442.7, and 54.1-3446 of the Code of Virginia are amended and reenacted as follows:

§ 3.2-4112. Definitions.

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

"Grow" means to plant, cultivate, or harvest a plant or crop.

"Grower" means any person registered pursuant to subsection A of § 3.2-4115 to grow industrial hemp.

"Hemp product" means a product made from industrial hemp.

"Higher education industrial hemp research program" means a research program established pursuant to subsection A of § 3.2-4114.1.

"Industrial hemp" means all parts and varieties of the plant Cannabis sativa, whether growing or not, *and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin,* that contain a concentration of tetrahydrocannabinol that is no greater than that allowed by federal law.

"Process" means to convert industrial hemp into a marketable form.

"Processor" means a person registered pursuant to subsection A of § 3.2-4115 to process industrial hemp.

"Process site" means the location at which a processor processes or intends to process industrial hemp.

"Production field" means the land or area on which a grower is growing or intends to grow industrial hemp.

"Virginia industrial hemp research program" means the research program established pursuant to subsection B of § 3.2-4114.1.

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

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

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

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

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

C. In determining whether a pill, capsule, tablet, or substance in any other form whatsoever, is an "imitation controlled substance," there shall be considered, in addition to all other relevant factors, comparisons with accepted methods of marketing for legitimate nonprescription drugs for medicinal purposes rather than for drug abuse or any similar nonmedicinal use, including consideration of the packaging of the drug and its appearance in overall finished dosage form, promotional materials or

representations, oral or written, concerning the drug, and the methods of distribution of the drug and where and how it is sold to the public.

D. The term "marijuana" when used in this article means any part of a plant of the genus Cannabis, whether growing or not, its seeds or resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include *(i)* any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, or the mature stalks of such plant, fiber produced from such stalk, *or* oil or cake made from the seed of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis, *or (ii) industrial hemp as defined in § 3.2-4112*.

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

§ 54.1-3401. (Effective until July 1, 2020) Definitions.

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

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

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

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

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by

a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

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

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

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

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

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

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

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

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

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

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

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

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

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 ~~that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent~~.

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

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer,

derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a

controlled substance or marijuana.

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

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

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

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

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

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

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

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

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

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

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

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

§ 54.1-3401. (Effective July 1, 2020) Definitions.

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

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

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

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

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

to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

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

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

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

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as

defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

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

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

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

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

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

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

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

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

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

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

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

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

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

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

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

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 ~~that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent~~.

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

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

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

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

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

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

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under

Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 54.1-3442.5. Definitions.

As used in this article:

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

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered 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. *"Pharmaceutical processor" includes any off-site dispensing locations established by a permitted pharmaceutical processor pursuant to subsection G of § 54.1-3442.6.*

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

"THC-A oil" has the same meaning as specified in § 54.1-3408.3.

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

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

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to ~~one~~ *two* for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil to a registered 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; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains; ~~and~~ (xi) a process for registering a cannabidiol oil and THC-A oil product*; (xii) operation of off-site dispensing locations pursuant to subsection G; and (xiii) the secure transportation of cannabidiol oil and THC-A oil between the premises at which a pharmaceutical processor processes such cannabidiol oil and THC-A oil and any off-site dispensing location established by the pharmaceutical processor*.

D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor.

E. The Board shall require an applicant for a pharmaceutical processor 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.

F. No person who has been convicted of a felony or of 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 shall be employed by or act as an agent of a pharmaceutical processor.

G. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to two off-site dispensing locations for the dispensing of cannabidiol oil and THC-A oil cultivated and produced on the premises of the pharmaceutical processor. Each off-site dispensing location shall (i) be located within the same health service area as the pharmaceutical processor, (ii) operate under the supervision and control of the pharmaceutical processor, (iii) dispense only cannabidiol oil and THC-A oil cultivated and produced by the pharmaceutical processor, and (iv) comply with all regulations of the Board related to health, safety, and security for pharmaceutical processors. The pharmaceutical processor shall submit the address of each off-site dispensing location to the Board, and the Board shall include the address of each off-site dispensing location on the permit issued to the pharmaceutical processor. Off-site dispensing locations shall operate under the permit issued to the pharmaceutical processor and shall not be required to obtain a separate permit.

§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.

A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board 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 shall make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view a current photo identification of the patient, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, parent, or legal guardian. Prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification; a current photo identification of the patient, parent, or legal guardian; and the current board registration issued to the patient, parent, or legal guardian. No pharmaceutical processor shall dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of such pharmaceutical processor.

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the Board, including *(i)* the number of practitioners, patients, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3 *and (ii) the number and locations of all off-site dispensing locations established pursuant to subsection G of § 54.1-3442.6, together with the name of the pharmaceutical processor with which they are affiliated.*

D. A pharmaceutical processor shall ensure that the concentration of tetrahydrocannabinol in any THC-A oil on site is within 10 percent of the level of tetrahydrocannabinol measured for labeling and shall establish a stability testing schedule of THC-A oil.

§ 54.1-3446. Schedule I.

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

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

1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (other name: PEPAP);

1-methyl-4-phenyl-4-propionoxypiperidine (other name: MPPP);

2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Methoxyacetyl fentanyl);

3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700);

3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921);

Acetyl fentanyl (other name: desmethyl fentanyl);

Acetylmethadol;

Allylprodine;

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

Alphameprodine;

Alphamethadol;
Benzethidine;
Betacetylmethadol;
Betameprodine;
Betamethadol;
Betaprodine;
Clonitazene;
Dextromoramide;
Diampromide;
Diethylthiambutene;
Difenoxin;
Dimenoxadol;
Dimepheptanol;
Dimethylthiambutene;
Dioxaphetylbutyrate;
Dipipanone;
Ethylmethylthiambutene;
Etonitazene;
Etoxeridine;
Furethidine;
Hydroxypethidine;
Ketobemidone;
Levomoramide;
Levophenacylmorphan;
Morpheridine;
N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (other name: Cyclopropyl fentanyl);
N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (other name: Tetrahydrofuranyl fentanyl);
N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]-N-phenylpropanamide (other name: alpha-methylthiofentanyl);
N-[1-(1-methyl-2-phenylethyl)-4-piperidyl]-N-phenylacetamide (other name: acetyl-alpha-methylfentanyl);
N-{1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl}-N-phenylpropanamide (other name: beta-hydroxythiofentanyl);
N-[1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxyfentanyl);
N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl]propionanilide (other names: 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine, alpha-methylfentanyl);
N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl);
N-(3-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl);
N-[3-methyl-1-(2-hydroxy-2-phenylethyl)4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxy-3-methylfentanyl);
N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide (other name: 3-methylfentanyl);
N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide (other name: 3-methylthiofentanyl);
N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl] -propanamide (other name: para-fluoroisobutyryl fentanyl);
N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl);
N-(4-fluorophenyl)-N-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluorofentanyl);
Noracymethadol;
Norlevorphanol;
Normethadone;
Norpipanone;
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl);
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl);
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl);
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl);
N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide (other name: thiofentanyl);
Phenadoxone;

Phenampromide;
Phenomorphan;
Phenoperidine;
Piritramide;
Proheptazine;
Properidine;
Propiram;
Racemoramide;
Tilidine;
Trimeperidine.

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

Acetorphine;
Acetyldihydrocodeine;
Benzylmorphine;
Codeine methylbromide;
Codeine-N-Oxide;
Cyprenorphine;
Desomorphine;
Dihydromorphine;
Drotebanol;
Etorphine;
Heroin;
Hydromorphinol;
Methyldesorphine;
Methyldihydromorphine;
Morphine methylbromide;
Morphine methylsulfonate;
Morphine-N-Oxide;
Myrophine;
Nicocodeine;
Nicomorphine;
Normorphine;
Pholcodine;
Thebacon.

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

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

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

3,4-methylenedioxy amphetamine;
5-methoxy-3,4-methylenedioxy amphetamine;
3,4,5-trimethoxy amphetamine;
Alpha-methyltryptamine (other name: AMT);
Bufotenine;
Diethyltryptamine;
Dimethyltryptamine;
4-methyl-2,5-dimethoxyamphetamine;
2,5-dimethoxy-4-ethylamphetamine (DOET);
2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7);
Ibogaine;
5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT);
Lysergic acid diethylamide;
Mescaline;

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

Peyote;

N-ethyl-3-piperidyl benzilate;
N-methyl-3-piperidyl benzilate;
Psilocybin;
Psilocyn;
Salvinorin A;
Tetrahydrocannabinols, except as present in marijuana and dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration *or as present in industrial hemp as defined in § 3.2-4112*;
Hashish oil (some trade or other names: hash oil; liquid marijuana; liquid hashish);
2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA);
3,4-methylenedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts and salts of isomers;
3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);
N-hydroxy-3,4-methylenedioxyamphetamine (some other names: N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA);
4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA);
4-methoxyamphetamine (some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA);
Ethylamine analog of phencyclidine (some other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE);
Pyrrolidine analog of phencyclidine (some other names: 1-(1-phenylcyclohexyl) -pyrrolidine, PCPy, PHP);
Thiophene analog of phencyclidine (some other names: 1-[1-(2-thienyl) -cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP);
1-1-(2-thienyl)cyclohexyl]pyrrolidine (other name: TCPy);
3,4-methylenedioxypyrovalerone (other name: MDPV);
4-methylmethcathinone (other names: mephedrone, 4-MMC);
3,4-methylenedioxymethcathinone (other name: methylone);
Naphthylpyrovalerone (other name: naphyrone);
4-fluoromethcathinone (other name: flephedrone, 4-FMC);
4-methoxymethcathinone (other names: methedrone; bk-PMMA);
Ethcathinone (other name: N-ethylcathinone);
3,4-methylenedioxyethcathinone (other name: ethylone);
Beta-keto-N-methyl-3,4-benzodioxolylbutanamine (other name: butylone);
N,N-dimethylcathinone (other name: metamfepramone);
Alpha-pyrrolidinopropiophenone (other name: alpha-PPP);
4-methoxy-alpha-pyrrolidinopropiophenone (other name: MOPPP);
3,4-methylenedioxy-alpha-pyrrolidinopropiophenone (other name: MDPPP);
Alpha-pyrrolidinovalerophenone (other name: alpha-PVP);
6,7-dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (other name: MDAI);
3-fluoromethcathinone (other name: 3-FMC);
4-Ethyl-2,5-dimethoxyphenethylamine (other name: 2C-E);
4-Iodo-2,5-dimethoxyphenethylamine (other name: 2C-I);
4-Methylethcathinone (other name: 4-MEC);
4-Ethylmethcathinone (other name: 4-EMC);
N,N-diallyl-5-methoxytryptamine (other name: 5-MeO-DALT);
Beta-keto-methylbenzodioxolylpentanamine (other name: Pentylone, bk-MBDP);
Alpha-methylamino-butyrophenone (other name: Buphedrone);
Alpha-methylamino-valerophenone (other name: Pentedrone);
3,4-Dimethylmethcathinone (other name: 3.4-DMMC);
4-methyl-alpha-pyrrolidinopropiophenone (other name: MPPP);
4-Iodo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanam ine (other names: 25-I, 25I-NBOMe, 2C-I-NBOMe);
Methoxetamine (other names: MXE, 3-MeO-2-Oxo-PCE);
4-Fluoromethamphetamine (other name: 4-FMA);
4-Fluoroamphetamine (other name: 4-FA);
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (other name: 2C-D);
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (other name: 2C-C);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-2);
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-4);
2-(2,5-Dimethoxyphenyl)ethanamine (other name: 2C-H);
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (other name: 2C-N);
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (other name: 2C-P);
(2-aminopropyl)benzofuran (other name: APB);
(2-aminopropyl)-2,3-dihydrobenzofuran (other name: APDB);
4-chloro-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethan amine (other names: 2C-C-NBOMe, 25C-NBOMe, 25C);
4-bromo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethana mine (other names: 2C-B-NBOMe, 25B-NBOMe, 25B);
Acetoxydimethyltryptamine (other names: AcO-Psilocin, AcO-DMT, Psilacetin);
Benocyclidine (other names: BCP, BTCP);
Alpha-pyrrolidinobutiophenone (other name: alpha-PBP);
3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA);
4-bromomethcathinone (other name: 4-BMC);
4-chloromethcathinone (other name: 4-CMC);
4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanam ine (other name: 25I-NBOH);
Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP);
Alpha-Pyrrolidinoheptiophenone (other name: PV8);
5-methoxy-N,N-methylisopropyltryptamine (other name: 5-MeO-MIPT);
Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB);
1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone);
1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP);
1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP);
4-Chloroethcathinone (other name: 4-CEC);
3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone);
1-propionyl lysergic acid diethylamide (other name: 1P-LSD);
(2-Methylaminopropyl)benzofuran (other name: MAPB);
1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone);
1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9)
3,4-tetramethylene-alpha-pyrrolidinovalerophenone (other name: TH-PVP);
4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline);
4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25B-NBOH);
4-chloro-alpha-methylamino-valerophenone (other name: 4-chloropentedrone);
4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP);
4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8);
4-hydroxy-N,N-diisopropyltryptamine (other name: 4-OH-DIPT);
4-methyl-alpha-ethylaminopentiophenone;
4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP);
5-methoxy-N,N-dimethyltryptamine (other name: 5-MeO-DMT);
5-methoxy-N-ethyl-N-isopropyltryptamine (other name: 5-MeO-EIPT);
6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD);
6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD);
(N-methyl aminopropyl)-2,3-dihydrobenzofuran (other name: MAPDB).

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

Clonazolam;
Etizolam;
Flubromazepam;
Flubromazolam;
Gamma hydroxybutyric acid (some other names include GHB; gamma hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate);
Mecloqualone;
Methaqualone.

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

2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine);

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

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, norephedrone), and any plant material from which Cathinone may be derived;

Cis-4-methylaminorex (other name: cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Ethylamphetamine;

Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate);

Fenethylline;

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

N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine);

N,N-dimethylamphetamine (other names: N, N-alpha-trimethyl-benzeneethanamine, N, N-alpha-trimethylphenethylamine).

6. Any substance that contains one or more cannabimimetic agents or that contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of one or more cannabimimetic agents.

a. "Cannabimimetic agents" includes any substance that is within any of the following structural classes:

2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent;

3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent;

3-(1-naphthoyl)pyrrole with substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent;

1-(1-naphthylmethyl)indene with substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent;

3-phenylacetylindole or 3-benzoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent;

3-cyclopropoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the cyclopropyl ring to any extent;

3-adamantoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent;

N-(adamantyl)-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent; and

N-(adamantyl)-indazole-3-carboxamide with substitution at a nitrogen atom of the indazole ring, whether or not further substituted on the indazole ring to any extent, whether or not substituted on the adamantyl ring to any extent.

b. The term "cannabimimetic agents" includes:

5-(1,1-Dimethylheptyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497);

5-(1,1-Dimethylhexyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C6 homolog);

5-(1,1-Dimethyloctyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C8 homolog);

5-(1,1-Dimethylnonyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C9 homolog);

1-pentyl-3-(1-naphthoyl)indole (other names: JWH-018, AM-678);

1-butyl-3-(1-naphthoyl)indole (other name: JWH-073);

1-pentyl-3-(2-methoxyphenylacetyl)indole (other name: JWH-250);

1-hexyl-3-(naphthalen-1-oyl)indole (other name: JWH-019);

1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (other name: JWH-200);

(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (other name: HU-210);

1-pentyl-3-(4-methoxy-1-naphthoyl)indole (other name: JWH-081);

1-pentyl-3-(4-methyl-1-naphthoyl)indole (other name: JWH-122);

1-pentyl-3-(2-chlorophenylacetyl)indole (other name: JWH-203);
1-pentyl-3-(4-ethyl-1-naphthoyl)indole (other name: JWH-210);
1-pentyl-3-(4-chloro-1-naphthoyl)indole (other name: JWH-398);
1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (other name: AM-694);
1-((N-methylpiperidin-2-yl)methyl)-3-(1-naphthoyl)indole (other name: AM-1220);
1-(5-fluoropentyl)-3-(1-naphthoyl)indole (other name: AM-2201);
1-[(N-methylpiperidin-2-yl)methyl]-3-(2-iodobenzoyl)indole (other name: AM-2233);
Pravadoline (4-methoxyphenyl)-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-y l]methanone (other name: WIN 48,098);
1-pentyl-3-(4-methoxybenzoyl)indole (other names: RCS-4, SR-19);
1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (other names: RCS-8, SR-18);
1-pentyl-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: UR-144);
1-(5-fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)i ndole (other names: XLR-11, 5-fluoro-UR-144);
N-adamantyl-1-fluoropentylindole-3-carboxamide (other name: STS-135);
N-adamantyl-1-pentylindazole-3-carboxamide (other names: AKB48, APINACA);
1-pentyl-3-(1-adamantoyl)indole (other name: AB-001);
(8-quinolinyl)(1-pentylindol-3-yl)carboxylate (other name: PB-22);
(8-quinolinyl)(1-(5-fluoropentyl)indol-3-yl)carboxylate (other name: 5-fluoro-PB-22);
(8-quinolinyl)(1-cyclohexylmethyl-indol-3-yl)carboxylate (other name: BB-22);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxa mide (other name: AB-PINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole -3-carboxamide (other name: AB-FUBINACA);
1-(5-fluoropentyl)-3-(1-naphthoyl)indazole (other name: THJ-2201);
N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-car boxamide (other name: ADB-PINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazo le-3-carboxamide (other name: AB-CHMINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole -3-carboxamide (other name: 5-fluoro-AB-PINACA);
N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)in dazole-3-carboxa mide (other names: ADB-CHMINACA, MAB-CHMINACA);
Methyl-2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methy lbutanoate (other name: 5-fluoro-AMB);
1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201);
1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)i ndole (other name: FUB-144);
1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl)indole (other name MAM-2201);
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)met hyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA);
Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-di methylbutanoate (other name: MDMB-FUBINACA);
Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbu tanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA;
Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3- methylbutanoate (other names: AMB-FUBINACA, FUB-AMB);
N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48)
N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48);
Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole -3-carboxamide (other name: AB-CHMICA);
1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006);
Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22);
Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (other name: MMB-CHMICA);
N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carbox amide (other name: 5-fluoro-ADB-PINACA).

2. That as soon as practicable but no later than September 1, 2019, the Board of Pharmacy shall issue one additional permit to operate a pharmaceutical processor for each health service area established by the Board of Health, so that the total number of permits to operate a pharmaceutical process issued by the Board of Pharmacy equals 10, with no more than two permits issued for each health service area established by the Board of Health. Such permits shall be issued to applicants for whom an application for a permit to operate a pharmaceutical process was received, reviewed, evaluated, and scored by the Board of Pharmacy pursuant to the Board of

Pharmacy's Request for Applications No. PHR-2018-1. The Board of Pharmacy shall award such permits to the applicant that received the highest score in each health service area out of all of the applicants for that health service area to which no permit has been issued, provided that the applicant provides documentation satisfactory to the Board of Pharmacy indicating that the applicant has the existing financial, infrastructure, and technical ability to begin processing cannabidiol oil and THC-A oil product in accordance with regulations of the Board of Pharmacy.