SUBCOMMITTEE: SUBCOMMITTEE #2

SENATE BILL NO. 330

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on _____

on _____)

(Patron Prior to Substitute--Senator Dunnavant)

A BILL to amend and reenact §§ 54.1-2519, 54.1-2521, 54.1-2522.1, as it is currently effective and as it shall become effective, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to dispensing of THC-A oil; tetrahydrocannabinol levels and stability testing.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2519, 54.1-2521, 54.1-2522.1, as it is currently effective and as it shall become effective, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-2519. 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, under the practitioner's direction, his authorized agent or (ii) the patient or research subject at the direction and in the presence of the practitioner.

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

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

"Covered substance" means all controlled substances included in Schedules II, III, and IV and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. <u>"Covered substance" also includes cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia.</u>

"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 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.

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

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

"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 another state to so issue a prescription for a covered substance.

"Recipient" means a person who receives a covered substance from a dispenser.

"Relevant health regulatory board" means any such board that licenses persons or entities with the authority to prescribe or dispense covered substances, including, but not limited to, the Board of Dentistry, the Board of Medicine, and the Board of Pharmacy.

§ 54.1-2521. Reporting requirements.

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

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

1. The recipient's name and address.

2. The recipient's date of birth.

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

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

5. The date of the dispensing.

6. The prescriber's identifier number and, in cases in which the covered substance is cannabidiol oil or THC-A oil, the expiration date of the written certification.

7. The dispenser's identifier number.

8. The method of payment for the prescription.

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

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.

C. The reports required herein shall be made to the Department or its agent within 24 hours or the 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.

§ 54.1-2522.1. (Effective until July 1, 2022) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. A prescriber registered with the Prescription Monitoring Program or a person to whom he has delegated authority to access information in the possession of the Prescription Monitoring Program pursuant to § 54.1-2523.2 shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than seven consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of

determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. A prescriber shall not be required to meet the provisions of subsection B if:

1. The opioid is prescribed to a patient currently receiving hospice or palliative care;

2. The opioid is prescribed to a patient as part of treatment for a surgical or invasive procedure and such prescription is for no more than 14 consecutive days;

3. The opioid is prescribed to a patient during an inpatient hospital admission or at discharge;

4. The opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy;

5. The Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or

6. The prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record.

D. Prior to issuing a written certification for the use of cannabidiol oil or THC-A oil in accordance with § 54.1-3408.3, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 54.1-2522.1. (Effective July 1, 2022) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in

opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. The Secretary of Health and Human Resources may identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients. Prescribers who prescribe such identified benzodiazepines or opiates shall not be required to meet the provisions of subsection B. In addition, a prescriber shall not be required to meet the provisions of subsection B if the course of treatment arises from pain management relating to dialysis or cancer treatments.

D. Prior to issuing a written certification for the use of cannabidiol oil or THC-A oil in accordance with § 54.1-3408.3, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 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 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; ~~and~~ (x) the secure disposal of plant remains; (xi) a process for registering a cannabidiol oil and THC-A oil product; and (xii) a requirement for an applicant for a pharmaceutical processor permit to have a criminal background check through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining a criminal history record information check regarding the applicant.

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

E. 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.

§ 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 ~~verify that the practitioner issuing the written certification, the patient, and, if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board~~ 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 30-day supply for any patient during any 30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.

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 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.

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.

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

3. That an emergency exists and this act is in force from its passage.

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