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Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-60-10 et seq.
Regulation title(s)	Regulations Governing Pharmaceutical Processors
Action title	Replacement of emergency regulations
Date this document prepared	11/7/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Chapter 60 sets out the requirements for issuance of permits to pharmaceutical processors for the cultivation, production, and dispensing of cannabidiol oil or THC-A oil. Regulations also establish requirements for registrations of physicians for writing certification to registered patients, parents or legal guardians for possession of such oils.

Part I establishes definitions and fees to be charged to applicants, registrants, and permitted processors. As specified in the legislation, Part II of the regulations establishes requirements for issuance or denial of registration for certifying physicians, patients, parents or legal guardians. Part III sets out the application and approval process for issuing a permit to a pharmaceutical processor, including the information that must be submitted, the requirements for issuing conditional and then final approval, the rules for notification to the Board of any changes or of closure of the processor, and the causes for action against a processor.

Part IV sets out the provisions for personnel at the pharmaceutical processor, including a requirement that a pharmacist with a current, unrestricted Virginia license provide personal supervision on the premises at all times during hours of operation or whenever the processor is accessed. It includes requirements for employee training, supervision of pharmacy technicians, and the responsibilities of the pharmacist-in-charge. Part V sets out provisions for the operation of a pharmaceutical processor, including requirements for inventory, security, storage and handling, record-keeping, and reportable events.

Part VI establishes requirements for the cultivation, production, and dispensing of cannabidiol oil, including labeling, laboratory and testing standards, dispensing errors and quality assurance, and proper disposal.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

N/A

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Chapter 577 of the 2016 Acts of the Assembly required the Board to promulgate regulations governing issuance of a permit for a pharmaceutical processor to manufacture and provide cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. Chapters 246 and 567 of the 2018 Acts of the Assembly required the Board to amend its emergency regulations governing issuance of a permit for a pharmaceutical processor to manufacture and provide cannabidiol oil and THC-A oil. The 2018 Code made changes for patients who may receive a certification from a physician to possess the oil, the type of physician who may issue a certification, the change from a 30-day to a 90-day supply for dispensing the oil and the number of plants allocated, criminal background checks for applicants, allowance for delivery of the oil after the initial dispensing, and requirements for registration and labeling of the product by brand name.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any,

authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification, licensure or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.

6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate, license, permit, or multistate licensure privilege which such board has authority to issue for causes enumerated in applicable law and regulations.

The statutory authority for the Board to promulgate these regulations is found in the following sections:
§ 54.1-3408.3. Certification for use of cannabidiol oil or THC-A oil for treatment.
A. As used in this section:

"Cannabidiol oil" means a processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol per milliliter but not more than five percent tetrahydrocannabinol.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine.

"THC-A oil" means a processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of tetrahydrocannabinol acid per milliliter but not more than five percent tetrahydrocannabinol.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

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

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

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

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

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

H. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House and Senate Committees for Courts of Justice, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed physicians or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered

patient, (iv) a pharmaceutical processor involved in the treatment of a registered patient, or (v) a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

Article 4.2. Permitting of Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil.

§ 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.

"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 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.

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.

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§ 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 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.

§ 54.1-3442.8. Criminal liability; exceptions.

In any prosecution of an agent or employee of a pharmaceutical processor under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession, manufacture, or distribution of cannabidiol oil or THC-A oil, it shall be an affirmative defense that such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations. If such agent or employee files a copy of the permit issued to the pharmaceutical processor pursuant to § 54.1-3442.6 with the court at least 10 days prior to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such permit shall be

prima facie evidence that (a) such marijuana was possessed or manufactured for the purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or (b) such cannabidiol oil or THC-A oil was possessed, manufactured, or distributed in accordance with the provisions of this article and Board regulations.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The purpose of the regulatory action is compliance with Chapter 577 of the 2016 Acts of the Assembly and with Chapters 246 and 567 of the 2018 Acts of the Assembly, which mandated adoption of regulations to implement the acts. The goals of the new regulation are accessibility of cannabidiol or THC-A oil for patients with any disease or condition diagnosed by a physician licensed in the Commonwealth in compliance with the conditions and restraints imposed by the statute and in consideration of the need for security of the facility and its contents and the integrity of the dispensed product.
The law specifically requires the Board to "adopt regulations establishing health, safety, and security requirements for pharmaceutical processors." (§ 54.1-3442.6 (C)) The safeguards put in place in statute and regulations are essential to protect the health and safety of the general public and, in particular, the health of the patients to whom cannabidiol or THC-A oil is dispensed.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Chapter 60 sets out the requirements for issuance of permits to pharmaceutical processors for the cultivation, production, and dispensing of cannabidiol oil or THC-A oil. Regulations also establish requirements for registrations of physicians for writing certification to registered patients, parents or legal guardians for possession of such oils.

Part I establishes definitions and fees to be charged to applicants, registrants, and permitted processors. As specified in the legislation, Part II of the regulations establishes requirements for issuance or denial of registration for certifying physicians, patients, parents or legal guardians. Part III sets out the application and approval process for issuing a permit to a pharmaceutical processor, including the information that must be submitted, the requirements for issuing conditional and then final approval, the rules for notification to the Board of any changes or of closure of the processor, and the causes for action against a processor.

Part IV sets out the provisions for personnel at the pharmaceutical processor, including a requirement that a pharmacist with a current, unrestricted Virginia license provide personal supervision on the premises at all times during hours of operation or whenever the processor is accessed. It includes requirements for employee training, supervision of pharmacy technicians,

and the responsibilities of the pharmacist-in-charge. Part V sets out provisions for the operation of a pharmaceutical processor, including requirements for inventory, security, storage and handling, record-keeping, and reportable events.

Part VI establishes requirements for the cultivation, production, and dispensing of cannabidiol oil, including labeling, laboratory and testing standards, dispensing errors and quality assurance, and proper disposal.

Issues

Please identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) The advantages to the public include assurance of the safety and integrity of the product dispensed and security for the Cannabis and oils produced; there are no disadvantages to the public;
2) The advantage to the agency is more clarity in the rules for a permitted facility; there are no disadvantages to the agency; and
3) This is a significant new program for the Board of Pharmacy and the Department of Health Professions in an evolving environment of medical marijuana with wide variance in the policies and models adopted across the United States and in a situation in which marijuana remains an illegal substance on the federal level.

The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The limited number of pharmaceutical processors (one in each of the five health planning districts) as specified in statute created competition for permits, but the regulations promulgated by the Board do not represent any restraint on that competition. Regulations for processors are a foreseeable result of the statute requiring the Board to protect the health and safety of patients in the Commonwealth. The Board is authorized under § 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to administer effectively the regulatory system*" and has acted in accordance with a statutory mandate in § 54.1-3442.6 to "*adopt regulations establishing health, safety, and security requirements for pharmaceutical processors.*"

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.

There are no applicable federal requirements for the production and dispensing of cannabidiol or THC-A oils.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. There are on-going expenditures related to approval of permit applications, operation of a pharmaceutical processor program, routine inspections, investigations of complaint, and adjudication of disciplinary cases. The pharmaceutical processor program will have a separate budget from the Board of Pharmacy and will be expected to absorb any costs within the revenue received from application and renewal fees. In addition to allocated costs for a portion of the Pharmacy budget dedicated to the processor program, there are plans for a program manager

	and a licensing administrative assistant to be hired in the coming weeks. Training of inspectors will likely necessitate travel out-of-state to places where similar facilities are operated. There are unknown factors that may impact expenditures for this program, including issues relating to the competitive nature of issuing permits, as specified in law.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There should be no impact on other state agencies.
For all agencies: Benefits the regulatory change is designed to produce.	There are no benefits to the regulatory change for state agencies.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There is no impact on localities as a result of these regulations. Localities in which a processor is approved for operation should benefit from employment opportunities, etc.
Benefits the regulatory change is designed to produce.	There are no benefits from this regulatory change.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Patients with a diagnosed disease or condition that may benefit from the use of cannabidiol or THC-A oil are registering under the emergency regulations. Parents or guardians of minor patients are currently paying $50 to register; they will benefit from a reduction of one-half the fee in proposed regulation. Doctors of medicine or osteopathy who want to write certification for patients to possess such oils. Pharmaceutical processors who will grow Cannabis, produce (manufacture) the oils, and dispense to patients.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	As of 11/9/18, there are: 93 registered patients 0 registered parents or guardians 189 registered doctors of medicine or osteopathy There were 51 applications for initial approval for a pharmaceutical processor permit. By law, only five can be approved to receive permits. Some of the applicants were small businesses while other were large corporations that operate nationally.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to:	The costs for registration of physician, patients, parents or guardians and the costs for pharmaceutical processor permits are set in Section 20 of the chapter.

a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	Costs for recordkeeping, security, equipment, etc. are not known since no permits have been issued.
Benefits the regulatory change is designed to produce.	The proposed regulations are necessary in order to replace emergency regulations currently in effect that authorize the operation of a pharmaceutical processor and the dispensing of cannabidiol and THC-A oils for the benefit of patient suffering for a variety of diseases and conditions. While possession of such oils may be permissible with a written certification, there is currently no source for the oils in Virginia until the processors are permitted and facilities are built and become operational.

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

Initially, emergency regulations for the permitting of pharmaceutical processors and registration of physicians, patients, and parents were developed using the expertise and recommendations of a Regulatory Advisory Panel. The Panel was comprised of a broad range of interested parties with relevant experience and information. In addition to Senator David Marsden, Panel member and patron of the 2016 legislation (SB701), the Panel included:

Ryan Logan, Board of Pharmacy and Chair
Cynthia Warriner, Board of Pharmacy
Jody H. Allen, Board of Pharmacy
Svinder Toor, MD, Board of Medicine/ child neurologist
William L. Harp, MD, Board of Medicine, Executive Director
Alexander Pytlarz, Virginia Pharmacists Association
Ed McCann, former owner of cannabis facility
Regina Whitsett, Substance Abuse Free Environment, Inc. (SAFE)
Beth Collins, Americans for Safe Access
Baylor Rice, community compounding pharmacist
Jake Bergman, Surterra Holdings
Julia Whiting, MD, concerned parent/physician
Chuck Moss, concerned family member
Paul Lyons, MD, child neurologist

The Panel held three lengthy meetings, on July 1, 2016, July 26, 2016, and August 30, 3016, to receive public comment from law enforcement, advocates for accessibility of medical marijuana,

opponents of expanded access, health system pharmacists, and others. The Panel had a presentation on medical literature on intractable epilepsy, reviewed information from other states with similar regulatory schemes, responded to discussion questions, and considered draft regulatory language. After much deliberation, the Panel recommended draft regulations which were presented and adopted with only minor revisions by the Board at its meeting in September.

There are no alternatives to the adoption of regulations, which are mandated by Chapter 577 of the 2016 Acts of the Assembly and by Chapters 246 and 567 of the 2018 Acts of the Assembly.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

As a new regulatory program mandated by the General Assembly, the Board has not identified alternative regulatory method consistent with health, safety, environmental and economic welfare that will accomplish the objectives of applicable law.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

A Notice of Intended Regulatory Action was published with the original emergency regulations on August 7, 2017 with comment accepted until September 6, 2017. The emergency regulations became effective on August 7, 2017. There were no comments on the NOIRA.

The Board did not proceed with proposed regulations at that time because it was aware that there were significant changes in the law recommended for the 2018 General Assembly. With the passage of HB1251, SB330 and SB726, it was necessary to revise the emergency. Legislation passed in 2018 had emergency clauses so the provisions became effective upon signing by the Governor. Therefore, the Board adopted revised emergency regulations in June of 2018, and those regulations went into effect on October 1, 2018.

In preparation for replacing the emergency regulations, which are due to expire on February 6, 2019, the Board issued a General Notice with a 30-day comment period from July 23, 2018 to August 22, 2019. The Notice stated that the Board of Pharmacy would be adopting proposed regulations to replace emergency regulations for pharmaceutical processors at its meeting on

September 25, 2018. While it was not a comment on the NOIRA, it did provide an opportunity for interested parties to participate in the process and for the Board to consider comment prior to adoption of proposed regulations.

Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

In addition to any other comments, the Board of Pharmacy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change. Delete inapplicable tables.

If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements

10	Creates definitions for words and terms used in this chapter	§§ 54.1-3408.3 and 54.1-3442.7	To provide clarity for use of terms such as dispensing error, one-month supply, resident, qualifying patient, temperature and humidity. The definition of certification was amended in the 2nd emergency regulation to include any diagnosed condition or disease, as opposed to the previous requirement of a diagnosis of intractable epilepsy. There were amendments throughout the regulation to delete "intractable epilepsy" and insert "any diagnosed condition or disease." The definition of "one-month supply" was deleted and replaced by a definition for a "90-day supply" with the amount allowed to be dispensed changed from 20 fluid ounces to 60 fluid ounces. In sections 10, 90 and in any other sections in which there was a reference to a one-month supply, the regulation was amended to read "90-day supply."
20	Sets fees to be charged for registration of patients, parents, & guardians; for physicians who write certifications; for pharmaceutical processor applicants and permit holders	§§ 54.1-2400 (5) and 54.1-3442.6 C	Fees are proposed with the intent of covering the expenditures to be incurred by the Board and Department for registration of individuals, renewal of registration, processing of applications for a pharmaceutical processor, a permit fee, renewal of permits, and any changes that require a re-inspection of the facility. *Since this is a new activity for the Board, there was no precedence to follow in setting fees. Fees in other states were reviewed for some guidance. For example, in Maryland, the application fee for a combination grower/processor is $11,000 and the annual renewal fee is $165,000. In Connecticut, the annual fee for a producer is $25,000 and for a dispensary, it is $75,000. (In Virginia, the growing, producing, and dispensing are all housed in a single pharmaceutical processor.) The Board based its fees on estimates of additional staffing for licensing, investigations, and inspections (which are required by law to be conducted quarterly.) Specialized training and personnel will be required to conduct the regulatory and disciplinary functions relating to growing, processing and dispensing of these oils.* Chapter 567 of the 2018 General Assembly added a new requirement for registration of a cannabidiol oil and THC-A oil product, so a $25 fee was added to the fee schedule to cover costs related to the registration process by the Board.
30	Sets out requirements for practitioners	§§ 54.1-2519, 54.1-2521,54.1-2522.1,	The requirements are intended to fulfill the statutory mandate for registration of a practitioner who issues certification for the

	issuing a certification for cannabidiol or THC-A oil for treatment of any disease or condition		use of cannabidiol oil or THC-A oil. The practitioner must be personally responsible for his/her diagnosis, availability, and certification and for instruction about the use of the oils. Chapter 567of the 2018 General Assembly amended law relating to the Prescription Monitoring Program to include cannabidiol oil and THC-A oil as covered substances with dispensing reportable to the PMP. There is also a new requirement in statute for a practitioner issuing a written certification for the use of the oils to request information from the PMP to determine what covered substances a patient may be receiving. Therefore, subsection B (9) was amended in the revised emergency regulation to include such a requirement for a practitioner.
40	Lists the practices that are prohibited for a practitioner registered to issue certifications, including benefitting from such certification, providing samples or discounts, or certifying for self or family	§§ 54.1-3316 and 54.1-3408.3	The Board has statutory authority to refuse to issue or discipline a registration. The prohibitions listed in section 40 are unique to the registration of a certifying physician and are intended to protect the integrity of the process and discourage certifying irresponsibly.
50	Sets out requirements for registration of a patient, parent or legal guardian. Regulations list the information that must be submitted on a registration application. Applicants must give permission for a criminal background check and cannot be issued more than one certification at any one time.	§ 54.1-3408.3	The requirements for registration are consistent with the statute and are intended to ensure the identity of the person(s) being registered and their suitability for possession of the oils. The limitation of one certification during any given time frame is specified in the law.
60	Sets out the causes for denial of registration for a patient or parent or legal guardian	§§ 54.1-3316 and 54.1-3408.3	The Board has statutory authority to refuse to issue or discipline a registration. The causes listed in section 60 are unique to the registration of a qualifying patient, his parent or legal guardian and are intended to protect the integrity of the process and appropriate dispensing.

70	Lists the reporting requirements for registered entities as necessary to ensure current information is available and eligibility for certifying and use of the oils is maintained.	§ 54.1-3408.3	The statute requires regulations to establish "a process for ensuring that any changes in the information are reported in an appropriate timeframe." That is the intent of section 70. If, for any reason, the registrant is no longer eligible or the registration is lost or stolen, the Board must be notified within 5 business days and the initial registration must be deactivated.
80	Establishes the rules for proper storage and disposal of the oils by patients or parents or guardians	§ 54.1-3307	Disposal of unused oil is intended to prevent theft, loss or access by unauthorized persons. The methods of disposal are similar to advised methods for prescription drugs.
90	Sets out causes for revocation, suspension of a patient, parent or guardian registration	§§ 54.1-3316 and 54.1-3408.3	The Board has statutory authority to discipline a registrant. The causes listed in section 90 are unique to the specific requirements for a qualifying patient, his parent or legal guardian and for the product being dispensed.
100	Establishes the rules for publication of a notice for submission of an application	§§ 54.1-3307 and 54.1-3442.6	The application and approval of a processor is intended to be a three-part process, initiated with the publication of a notice that the board is receiving applications.
110	The process for permits is set out in this section, beginning with the initial application, followed by awarding of conditional approval, and granting of a full permit.	§§ 54.1-3307 and 54.1-3442.6	The initial application is intended to provide the Board with sufficient information to determine the financial status of the applicant, the proposed location of the facility, authorization to conduct a processing/dispensing business in the locality, graphic and blueprints of the facility, and information about expertise in agriculture and other production techniques required to produce the oils. At the initial application phase, the Board will review paper submissions to determine the viability and suitability of an applicant. The Code, as amended in 2018, specifies a criminal background check by the Board on an "applicant." The regulation was amended accordingly.
120	Requirements for conditional approval are established to include the criteria by which the Board will evaluate the initial applications, the causes for	§§ 54.1-3307 and 54.1-3442.6	At this 2nd phase of the process, an applicant will be given conditional approval to operate, which will allow construction or remodeling of a facility and employment of personnel. Since there is a statutory limitation of one processor perm health service area (5 in Virginia), it is important to grant conditional approval only to those applicants that have

	disqualification of an applicant, and the time limitation of one year for completion of all requirements necessary to operate.		been deemed suitable and viable to conduct business.
130	Sets out the process and requirements for granting a full permit as a pharmaceutical processor, including designation of a pharmacist-in-charge, criminal background checks for all employees, utilization of an electronic tracking system for all plants from seed to finished oils, and a satisfactory inspection.	§§ 54.1-3307 and 54.1-3442.6	An applicant that has not commenced operation with 180 days of granting a permit may have the permit withdrawn. Again, there can only be one per health district, so a permit holder that is not operational is denying access to the oils to patients and preventing the Board from issuing another permit in that area. Regulations restrict the growing or holding of cannabis more than 2 weeks prior to the approved opening date, which is a requirement intended to limit access to the marijuana used to produce the oils.
140	Lists the requirements for notification to the board of any changes by processors from the information provided in the initial application. The pharmacist-in-charge is responsible for maintenance of current information, and the permit holder cannot make changes to the location, structure, or security of the processor without a new inspection and payment of a fee.	§§ 54.1-3307 and 54.1-3442.6	The statute requires regulations to include requirements for physical standards, location restrictions, security systems, etc, Any substantive changes in such requirements necessitates a new inspection to ensure that safety and security continue to be met.
150	Sets out requirements for the closing, going	§§ 54.1-3434.01 and 54.1-3442.6	There are specific steps that must be followed to ensure the security and proper disposition of the contents of a processor,

	out of business or change in ownership of a processor. The board must be informed about the disposition and the public must be properly notified to mitigate the effect of a loss of access to the oils.		including the plants, dispensing records, and patient information records. The requirements are similar to those for all pharmacies in the Drug Control Act and are intended to provide for continuity of services to the extent possible.
160	Sets out the causes for disciplinary action against a pharmaceutical processor	§§ 54.1-2400 and 54.1-3316	The Board has statutory authority to take disciplinary against a permit holder. The causes listed in section 160 are unique to the specific requirements for a pharmaceutical processor.
170	Establishes the rules for employee licenses and registrations, including a requirement to have a pharmacist-in-charge and a pharmacist personally supervising in the facility whenever it is being accessed. The duties that may be performed by a pharmacy technician are specified. The qualifications of other employees, who are not pharmacists or pharmacy technicians are also set out in this section	§§ 54.1-3307, 54.1-3320 and 54.1-3442.6	While other states require all employees to be registered with the Board, there is no such authorization in the Virginia law. However, the law does grant general authority to establish requirements as may be necessary to ensure the quality and security of the dispensed product.
180	Requires training for employees, to include proper security measures, state and federal law about patient confidentiality, and procedures for responding to an emergency. The pharmacist-in-charge must	§§ 54.1-3307 and 54.1-3442.6	The intent of this section is assurance that all employees are properly trained to ensure the security of the facility and its contents and efficacy of the dispensed product.

	assure on-the-job training as necessary and the continuing competence of all employees		
190	Specifies the ratio of pharmacy technicians and the responsibility for supervision	§§ 54.1-3321, 54.1-3320 and 54.1-3442.6 18VAC110-20-111. Pharmacy Technicians 18VAC110-20-270. Dispensing of Prescriptions; Certification of Completed Prescriptions; Supervision of Pharmacy Technicians.	The requirement for registration of technicians and for work under supervision of a licensed pharmacist is set in Code in Chapter 33 of Title 54.1. The ratio is the same for processors as for pharmacy practice in general. The limitations on the practice of pharmacy technicians are necessary to ensure that they do not exceed their scope of practice.
200	Sets out the responsibilities of the pharmacist-in-charge, including a requirement that he/she: 1) only be PIC for one processor at a time and work full-time (at least 35 hours a week); 2) is in full and actual control of all aspects of the practice; 3) is responsible for compliance with all requirements for employees, security, etc. There are provisions for a transition to a new pharmacist-in-charge and for an absence of more than 30 days.	§§ 54.1-3307, 54.1-3432 and 54.1-3442.6 18VAC110-20-110. Pharmacy Permits Generally.	The Code specifies that the processor must have a pharmacist in full and actual charge. Regulations set forth in section 200 are similar to the requirements for a pharmacist-in-charge in Chapter 20 for all pharmacies.
210	Sets out the general provisions for operation of a pharmaceutical processor to include prohibitions in practice, requirement for dispensing, restrictions on	§§ 54.1-3307 and 54.1-3442.6	Provisions for operation of a processor are intended to ensure a secure environment that offers appropriate access and information to patients. Since there will be a very limited number of processors, processors have an obligation of accessibility and notification of any limitations. Regulations adopted for operation are very similar to those in other states.

	access, requirements for identification of employees and hours of operation, notification of a closure, informational materials, and work place policies.		
220	Establishes prohibitions for practice by a processor, including requirements that: 1) the facility be closed and secured if there is no pharmacist on premises; 2) no other products are sold; 3) there is no marketing or advertising except basic information on a website; 4) proper identification be worn and access to the facility limited; and 5) no oils be sold, dispensed or distributed by delivery.	§§ 54.1-3307, 54.1-3442.6 and 54.1-3442.7, ad amended by Chapter 567	The intent of prohibitions is to follow the statutory mandate to adopt regulations establishing health, safety, and security requirements, including personal supervision by a pharmacist on premises. The prohibition on delivery of the product was amended because a change in the law will allow delivery of the product after the initial dispensing, as specified in section 310.
230	Sets out requirement for a comprehensive inventory at the processor, including all plants, seeds, extracts and oils to allow the facility to detect diversion, theft or loss. When the business is operational, there must be a weekly inventory to account for all contents and dispensing, and records must be	§§ 54.1-3307 and 54.1-3442.6	Inventory control is one of the primary methods for maintaining the processor in a security manner. Processors use an electronic tracking system by which every part of the plant and the oils produced thereof can be traced. Without such a system, it would be possible for diversion to occur without detection.

	maintained for 3 years.		
240	Sets out the requirements for security of the processor to include: 1) a limitation on the number of plants; 2) locking and protection from entry to the areas; 3) a security system capable of remaining operational during a power outage and in accordance with industry standards; and 4) security of the perimeter with video recording of all access points and on-site surveillance.	§§ 54.1-3307, 54.1-3442.6 and 54.1-3442.7, as amended by Chapter 246	The Code specifies requires a limitation on the number of plants that a processor may possess at any time. Likewise, the law requires regulations for security systems and controls. Requirements adopted are similar to other states, primarily Connecticut. Since the Code was amended in 2018 to allow the processor to dispense a 90-day, rather than a one-month supply, all limitations were adjusted accordingly. A processor may cultivate only the number of plants necessary to produce the amount of oil needed for the first nine months of operation (rather than three months). The processor is not allowed to maintain more than 23 plants per patient (rather than four plants) based on dispensing data from the previous 90 days (rather than 30 days).
250	Sets out requirements for storage and handling of plants and oils to include a quarantined area for outdated, damaged or adulterated products or plant parts and compartmentalized areas based on function with restricted access between compartments. The policy and procedures for the processor must include handling recalls, crisis management, and destruction of damaged, deteriorated, etc. items.	§§ 54.1-3307 and 54.1-3442.6	Since the pharmaceutical processor in Virginia will be engaged in the activities of cultivation, production, and dispensed, rules for all of those facilities in other states were incorporated into this chapter.
260	Recordkeeping requirements are listed to include an	§§ 54.1-3307 and 54.1-3442.6	Recordkeeping is essential to accountability for processors and the persons who might seek access to the plants and/or the oils.

	electronic system for storage and retrieval of patient information and records related to cultivating, producing and dispensing of the oils. All records, including inventories, laboratory results, and dispensing must be maintained for 3 years.		
270	Sets out requirements for reporting to the board any discrepancies, diversion, theft, loss, unauthorized entry, or alteration of records.	§§ 54.1-3307 and 54.1-3442.6	The reporting requirements are consistent with the statutory mandate for regulations for the health, safety and security of processors.
280	Sets out the requirements for cultivation and production of the oils.	§§ 54.1-3307 and 54.1-3442.6	The rules for cultivation are intended to produce oils from cannabis plants that are safe for very vulnerable patients.
285	Sets out requirements for registration of the oil products	§§ 54.1-3307 and 54.1-3442.6	The registration requirements for the product are separated from the labeling of a batch of cannabidiol oil or THC-A product.
290	Establishes the requirements for labeling of batches of oil, including results of batch testing by a laboratory.	§§ 54.1-3307 and 54.1-3442.6	The labeling and name of batched products is important for the purpose of sample testing of active ingredients. If the sample batch is small, the label for dispensing the oil product may be affixed to the named batch.
295	Sets out the requirements for labeling of the dispensed cannabidiol or THC-A oil	§§ 54.1-3307 and 54.1-3442.6	The provisions of section 295 are almost identical to provision in subsections E and F in section 290, which now only addresses labeling of batches of oil. The additional labeling are requirements (name of patient, physician, directions for use, name and address of processor) are identical to requirements for medications dispensed by a pharmacy.
300	Sets out requirement for laboratories that are testing the batches of cannabis for	§§ 54.1-3307 and 54.1-3442.6	The standards for testing of cannabis batches were taken from regulations in other states (primarily CT). Since the production of oils is similar to a manufacturing process, it is necessary to set standards for content of substances that may be potentially harmful

	microbiological contaminants, mycotoxins, heavy metals, and pesticide chemical residue for an analysis of the active ingredients.		to very vulnerable patients. If a sample of a batch does not pass the tests, the entire batch of cannabis must be disposed. If it does pass the required tests, the entire batch can be released for immediate manufacturing, packaging and labeling for sale. Rules are also adopted to ensure independence of the laboratory and the qualification of the person or persons conducting the tests.
310	Sets out the requirements for dispensing of oils, including presentation of the registration of the patient, the written certification, and photo ID. The dispensing is limited to a 90-day supply.	§§ 54.1-3307, 54.1-3408.3, 54.1-3442.6 and 54.1-3442.7	The Code was amended in 2018 to allow for delivery of the oil after the initial dispensing. Provisions were amended to specify the identification required at the time of initial dispensing at the processor, for retention of certification documentation, and for identification required prior to any subsequent dispensing.
320	Requires reporting of dispensing errors and establishment of a quality assurance program	§§ 54.1-3307 and 54.1-3442.6 18VAC110-20-418. Continuous Quality Improvement Programs.	All pharmacies are required to maintain a continuous quality improvement program in which there are written policies and procedures for detecting and preventing dispensing errors. Since pharmaceutical processors will be dispensaries of oils, similar rules are adopted for them.
330	Sets out the requirements for disposal of cannabidiol oil or THC-A oil	§ 54.1-3442.6 (C)	The rules for disposal are intended to mitigate the risk of diversion of the plants, seeds, extracts, or oils by requiring disposal in a manner to render them non-recoverable and in the presence of an authorized representative of the board. The record of disposal includes information about the method and witnesses and must be retained for 3 years for date of disposal.

Changes from the Emergency Regulation

10	Definitions	The definition of "dispensing error" was amended to include more specificity about what the Board would consider to be a dispensing error that must be reported. It would include variation from the intended oil to be dispensed, failure to exercise professional judgment, and delivery of the oil to the incorrect patient. *The definition is virtually identical for this chapter as in Chapter 20 for the practice of pharmacy. Since the dispensing of oils is a pharmacist function, just as the dispensing of a prescribed drug, the definition of a dispensing error should be the same.* The definition of "temperature and humidity" was amended to broaden the range for the three phases of growth.

		The change was in response to comment from experts in the field stating that the low range needed to be 71 degrees rather than 77 to account for night time temperatures.
20	Fees	The fees for a parent or guardian of a qualifying patient were reduced. In the current emergency regulation, the fee for registration of a parent or guardian is $50, and the annual renewal fee is $50. In the proposed regulation, the registration and fees are reduced to $25. The Board also eliminated the requirement that a replacement registration (with a charge of $25) be required for a patient, parent or guardian whose information has changed. A replacement registration and charge are required still required if the registration certificate has been lost, stolen, or destroyed. *The reductions were made in response to comments from parents for whom the additional charges were burdensome.*
40	Prohibited practices for practitioners	The prohibition on practitioners who issue certificates receiving, accepting, or soliciting anything of value from a person associated with a pharmaceutical processor was amended to allow them to receive "information on products or educational materials on the benefits and risks of THC-A and cannabidiol oil." *The amendment was in response to comment from parties who advocated for being able to provide educational materials to practitioners. They also requested that processors be allowed to pay for practitioners to attend meetings and educational events, but the Board did not agree with such an allowance.*
70	Reporting requirements for patients, parents, etc.	In subsection, the requirement for submission of a <u>fee</u> for a replacement registration for any change that results in information on the patient, parent, or legal guardian's registration being inaccurate was eliminated in response to the request to make it less costly for patients and parents.
130	Process for granting a pharmaceutical processor permit	Subsection A was amended to clarify use of the word "agents' in the requirement for criminal background checks. The word "delivery" was inserted before "agents."
170	Pharmaceutical processor employee licenses and registrations	Subsection C was reworded to clarify that the pharmacy technician performing the delegated tasks listed in regulation must have had two years of experience working as a pharmacy technician, not just two years of registration as a technician. Subsection D was amended to include a registered pharmacy intern who has completed his first professional year among the practitioners who may perform duties in the processor. *The amendment was in response to comment that pharmacy interns are allowed to dispense in a pharmacy under supervision and should be allowed similar tasks in a pharmaceutical processor.* Subsection J was amended to clarify that a person who has had his pharmacist license or pharmacy technician registration reinstated after suspension or revocation and who is current and unrestricted is allowed to be an employee or agent of a processor.
180	Employee training	Subsection C was amended to specify how often in-service training of employees should be offered; it was determined that at least once a year was adequate.

200	Responsibilities of the PIC	Subsection A was amended to clarify that the rule prohibiting a pharmacist-in-charge from being the PIC for more than one processor at any time also applies to being PIC for a processor and a pharmacy at any time.
210	General provisions for processors	Subsection H was amended to include in the counseling that must be provided to patients information on the disposal of the oils in a manner that renders them non-recoverable. *There is concern about the proper disposal of all types of drugs, so this provision is in keeping with those concerns.*
220	Prohibitions for processors	Subsection D was amended to allow the posting of product information and pricing on a website to be included among the exceptions to the prohibition on advertising. *The amendment is consistent with rules in other states and was requested by commenters.*
230	Inventory requirements	Subsection B was divided and a new subsection C set out to include the content of records that must be maintained. In addition to information already required by emergency regulation, the following were included: 1) date of disposition in case the oil was disposed of rather than sold; 2) the address of the patient, parent or guardian; and 3) the method of disposal, if disposed rather than sold.
240	Security requirements	Subsection D was amended to change "no less than two times per year" to "at least every six months." *The change is a clarification of the Board's intent.*
270	Reportable events; security	Subsection D was added to require a pharmacist or a processor to immediately notify the Board if an employee is convicted of a felony or a violation referenced in the Code. *While an initial criminal background check may prevent such a person from working a processor, a subsequent conviction would not be known to the Board since ongoing background checks are not required.*
290	Labeling of batch of cannabidiol oil or THC-A oil products	The requirements for the contents of a label was amended to delete the word "final" in (d) before testing and packaging and to add the word "pesticide" before chemical residue analysis in (h). *Both changes are clarifications of the Board's intent.*
300	Laboratory requirements; testing	Subsection A 2 is amended to include experience or a degree in chemical sciences as well as biological sciences as qualifying a person to oversee the testing. *The change was requested by a commenter.* Subsection D was amended to require the laboratory to give a "certificate of analysis" rather than "results in writing." *The change is intended to clarify that processors must have an analysis of their product before it is sold to patients.* Subsection E was amended to specify that processor must require a laboratory to return or properly dispose of any Cannabis products or materials. *The emergency regulations just said "Cannabis" which was not specific enough.* In subsection F, there were technical edits made to the charts.
330	Disposal of cannabidiol oil or THC-A oil	Subsection A was amended to remove the authority for an agent of the Board to dispose of excess materials, but to add that the disposal be done in accordance with a plan

		approved by the Board rather than in the presence of an agent of the Board. Subsection B was amended to require the destruction to be witnessed by the PIC and an agent of the Board or another pharmacist not employed by the processor. *The changes were made to facilitate destruction in a more timely manner rather than having Cannabis stored until an agent of the Board was available to witness.*