MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee 05/20/2015	TO BE COMPLETED BY DSD Date Filed with Division of State Documents Document Number Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 6/26/2015

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	62	01	01 and .02
10	62	02	01-.04
10	62	03	01-.03
10	62	04	01-.06
10	62	05	01 and .02
10	62	06	01-.07
10	62	07	01-.06
10	62	08	01-.11
10	62	09	01-.09
10	62	10	01-.08
10	62	11	01-.04
10	62	12	01-.08
10	62	13	01 and .02
10	62	14	01 and .02
10	62	15	01-.08
10	62	16	01-.05
10	62	17	01-.04
10	62	18	01-.06

10	62	19	01-.09
10	62	20	01-.09
10	62	21	01-.07
10	62	22	01-.06
10	62	23	01-.07
10	62	24	01
10	62	25	01-.10
10	62	26	01-.09
10	62	27	01-.09
10	62	28	01-.05
10	62	29	01 and .02
10	62	30	01-.09
10	62	31	01
10	62	32	01-.03
10	62	33	01-.08
10	62	34	01-.04
10	62	35	01

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator **Telephone Number**
Michele Phinney 410-767-5623

Mailing Address

201 W. Preston Street

City	State	Zip Code
Baltimore	MD	21201

Email
michele.phinney@maryland.gov

5. Name of Person to Call About this Document **Telephone No.**
Kristen Neville 410-764-5978

Email Address
kristen.neville@maryland.gov

6. Check applicable items:
X- New Regulations
_ Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: .

_ Repeal of Existing Regulations

_ Recodification

_ Incorporation by Reference of Documents Requiring DSD Approval

_ Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

_ Yes **X-** No

8. Incorporation by Reference

_ Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

X- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

_ OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Erin B. Purdy, Assistant Attorney General, (telephone #410-767-1877) on May 19, 2015. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title	**Telephone No.**
Secretary	410-767-6500

Date

May 20, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.01 Definitions

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.02 General Regulations

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.03 Certifying Physicians

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.04 Patient and Caregiver Registry

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

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Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

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10.62.07 New Condition Approval Process

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.08 Medical Cannabis Grower License

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10.62.09 Medical Cannabis Grower Agent

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Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.12 Inventory Control by Grower

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.13 Medical Cannabis Shipment Packaging

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.14 Licensed Grower Dispensary Facility

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.15 Medical Cannabis Grower Quality Control

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.16 Licensed Independent Testing Laboratory Registration

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.17 Complaints, Adverse Events, and Recall

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.18 Shipment of Products Between Licensees

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.19 Medical Cannabis Processor License

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.20 Medical Cannabis Processor Agent

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10.62.21 Medical Cannabis Processor Premises

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.22 Medical Cannabis Processor Operations

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10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

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10.62.25 Medical Cannabis Dispensary License

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10.62.26 Dispensary Agent

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10.62.27 Licensed Dispensary Premises

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10.62.28 Licensed Dispensary Operations

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10.62.29 Licensed Dispensary Packaging and Labeling for Distribution

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.30 Dispensing Medical Cannabis

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.31 Licensed Dispensary Clinical Director

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.32 Records

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.33 Inspection

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.34 Discipline and Enforcement

Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.35 Fee Schedule

Authority: See attached.

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to :
1) Adopt new Regulations .01 and .02 under a new chapter COMAR 10.62.01 Definitions;
2) Adopt new Regulations .01—.04 under a new chapter COMAR 10.62.02 General Regulations;
3) Adopt new Regulations .01—.03 under a new chapter COMAR 10.62.03 Certifying Physicians;
4) Adopt new Regulations .01—.06 under a new chapter COMAR 10.62.04 Patient and Caregiver Registry;
5) Adopt new Regulations .01 and .02 under a new chapter COMAR 10.62.05 Written Certifications;
6) Adopt new Regulations .01—.07 under a new chapter COMAR 10.62.06 Patient and Caregiver Identification Cards;
7) Adopt new Regulations .01—.06 under a new chapter COMAR 10.62.07 New Condition Approval Process;
8) Adopt new Regulations .01—.11 under a new chapter COMAR 10.62.08 Medical Cannabis Grower License;
9) Adopt new Regulations .01—.09 under a new chapter COMAR 10.62.09 Medical Cannabis Grower Agent;
10) Adopt new Regulations .01—.08 under a new chapter COMAR 10.62.10 Medical Cannabis Grower Premises;
11) Adopt new Regulations .01—.04 under a new chapter COMAR 10.62.11 Medical Cannabis Growing Controls;
12) Adopt new Regulations .01—.08 under a new chapter COMAR 10.62.12 Inventory Control by Grower;
13) Adopt new Regulations .01 and .02 under a new chapter COMAR 10.62.13 Medical

Cannabis Shipment Packaging;
14) Adopt new Regulations .01 and .02 under a new chapter COMAR 10.62.14 Licensed Grower Dispensary Facility;
15) Adopt new Regulations .01—.08 under a new chapter COMAR 10.62.15 Medical Cannabis Grower Quality Control;
16) Adopt new Regulations .01—.05 under a new chapter COMAR 10.62.16 Licensed Independent Testing Laboratory Registration;
17) Adopt new Regulations .01—.04 under a new chapter COMAR 10.62.17 Complaints, Adverse Events, and Recall;
18) Adopt new Regulations .01—.06 under a new chapter COMAR 10.62.18 Shipment of Products Between Licensees;
19) Adopt new Regulations .01—.09 under a new chapter COMAR 10.62.19 Medical Cannabis Processor License;
20) Adopt new Regulations .01—.09 under a new chapter COMAR 10.62.20 Medical Cannabis Processor Agent;
21) Adopt new Regulations .01—.07 under a new chapter COMAR 10.62.21 Medical Cannabis Processor Premises;
22) Adopt new Regulations .01—.06 under a new chapter COMAR 10.62.22 Medical Cannabis Processor Operations;
23) Adopt new Regulations .01—.07 under a new chapter COMAR 10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products;
24) Adopt new Regulation .01 under a new chapter COMAR 10.62.24 Medical Cannabis Finished Products Packaging;
25) Adopt new Regulations .01—.10 under a new chapter COMAR 10.62.25 Medical Cannabis Dispensary License;
26) Adopt new Regulations .01—.09 under a new chapter COMAR 10.62.26 Dispensary Agent;
27) Adopt new Regulations .01—.09 under a new chapter COMAR 10.62.27 Licensed Dispensary Premises;
28) Adopt new Regulations .01—.05 under a new chapter COMAR 10.62.28 Licensed Dispensary Operations;
29) Adopt new Regulations .01 and .02 under a new chapter COMAR 10.62.29 Licensed Dispensary Packaging and Labeling for Distribution;
30) Adopt new Regulations .01—.09 under a new chapter COMAR 10.62.30 Dispensing Medical Cannabis;
31) Adopt new Regulation .01 under a new chapter COMAR 10.62.31 Licensed Dispensary Clinical Director;
32) Adopt new Regulations .01—.03 under a new chapter COMAR 10.62.32 Records;
33) Adopt new Regulations .01—.08 under a new chapter COMAR 10.62.33 Inspection;
34) Adopt new Regulations .01—.04 under a new chapter COMAR 10.62.34 Discipline and Enforcement; and
35) Adopt new Regulation .01 under a new chapter COMAR 10.62.35 Fee Schedule.
At this time, the Secretary of Health and Mental Hygiene is also withdrawing:
(1) New Regulations .01 and .02 under a new chapter, COMAR 10.62.01 Definitions;
(2) New Regulations .01 — .03 under a new chapter, COMAR 10.62.02 General

Regulations;
(3) New Regulations .01 — .07 under a new chapter, COMAR 10.62.03 Certifying Physicians;
(4) New Regulations .01 — .06 under a new chapter, COMAR 10.62.04 New Condition Approval Process;
(5) New Regulations .01 — .04 under a new chapter, COMAR 10.62.05 Patient and Caregiver Registry and Identification Cards;
(6) New Regulations .01 —.10 under a new chapter, COMAR 10.62.06 Medical Marijuana Grower License;
(7) New Regulations .01 —.09 under a new chapter, COMAR 10.62.07 Medical Marijuana Grower Agents;
(8) New Regulations .01 —.08 under a new chapter, COMAR 10.62.08 Medical Marijuana Grower Premises;
(9) New Regulations .01 —.05 under a new chapter, COMAR 10.62.09 Medical Marijuana Growing Controls;
(10) New Regulations .01 —.08 under a new chapter, COMAR 10.62.10 Quality Control by a Licensed Medical Marijuana Grower;
(11) New Regulations .01 —.05 under a new chapter, COMAR 10.62.11 Complaints, Adverse Events, and Recall;
(12) New Regulations .01 —.08 under a new chapter, COMAR 10.62.12 Inventory Control by Grower;
(13) New Regulations .01 —.03 under a new chapter, COMAR 10.62.13 Dispensing of Medical Marijuana by a Licensed Grower;
(14) New Regulations .01 —.08 under a new chapter, COMAR 10.62.14 Shipment of Products Containing Marijuana Between Licensees;
(15) New Regulations .01 —.11 under a new chapter, COMAR 10.62.15 Licensed Dispensary and Licensed Processing Dispensary;
(16) New Regulations .01 —.08 under a new chapter, COMAR 10.62.16 Medical Marijuana Concentrates and Medical Marijuana-Infused Products;
(17) New Regulation .01 under a new chapter, COMAR 10.62.17 Licensed Dispensary Clinical Director;
(18) New Regulations .01 —.08 under a new chapter, COMAR 10.62.18 Registered Dispensary Agents;
(19) New Regulations .01 —.09 under a new chapter, COMAR 10.62.19 Licensed Dispensary and Licensed Processing Dispensary Premises;
(20) New Regulations .01 —.05 under a new chapter, COMAR 10.62.20 Licensed Dispensary and Licensed Processing Dispensary Operations;
(21) New Regulations .01 and .02 under a new chapter, COMAR 10.62.21 Licensed Dispensary Packaging and Labeling for Distribution;
(22) New Regulations .01 —.08 under a new chapter, COMAR 10.62.22 Dispensing Medical Marijuana;
(23) New Regulations .01 —.03 under a new chapter, COMAR 10.62.23 Records;
(24) New Regulations .01 —.08 under a new chapter, COMAR 10.62.24 Inspection;
(25) New Regulations .01 —.03 under a new chapter, COMAR 10.62.25 Discipline and Enforcement;
(26) New Regulations .01 —.13 under a new chapter, COMAR 10.62.26 Academic

Medical Center Program Application Contents;
(27) New Regulations .01 —.06 under a new chapter, COMAR 10.62.27 Academic Medical Center Program Application Procedure; and
(28) New Regulation .01 under a new chapter, COMAR 10.62.28 Fee Schedule, as proposed in the 42:2 Md.R.214—244 (January 23, 2015).

This action was considered at a public meeting on April 22, 2015, notice of which was given by publication on the Commission's website at http://mmc.maryland.gov/ pursuant to State Government Article § 10-506(c)(1), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to :
1) Define certain terms;
2) Establish standards for individuals to register as a qualifying patient to obtain medical cannabis;
3) Establish requirements for licensed physicians in the State to be registered to recommend medical cannabis;
4) Establish requirements for grower operations, dispensaries, and processors to be licensed by the Commission;
5) Establish requirements for grower agents, dispensary agents, and processor agents to be registered with the Commission;
6) Establish requirements for individuals to become caregivers to qualifying patients;
7) Establish application processes for applicants to be certifying physicians, qualifying patients or caregivers, licensed growers, licensed dispensaries, licensed processors, registered grower agents, registered, processor agents, or registered dispensary agents;
8) Establish structural, security, procedural, and staffing requirements for the premises of licensed dispensaries, licensed growers, and licensed processors;
9) Establish growing controls and quality controls for licensed growers;
10) Provide that a licensed grower dispensary, where medical cannabis shall be dispensed, shall be constructed and operated in accordance with regulations that apply to licensed dispensary premises;
11) Establish a process for approving qualifying patients who suffer from new conditions not specified in the statute;
12) Establish a procedure for transporting medical marijuana products between licensees;
13) Establish inventory control standards for licensed growers;
14) Authorize the Commission to inspect licensed growers, licensed dispensaries, licensed processors, and registered independent testing laboratories;
15) Establish controls for processing and labeling medical cannabis concentrates and medical cannabis-infused products;
16) Require that an independent testing laboratory shall register with the Commission and meet certain standards of care;
17) Set standards for licensed dispensary packaging and labeling;
18) Authorize the Commission to take certain disciplinary actions against certain licensees for certain offenses;
19) Establish a procedure to receive, organize, store, and respond to all complaints

regarding medical cannabis and adverse events;
20) Authorize a licensed dispensary to have a clinical director on staff who is a licensed physician, nurse practitioner, or pharmacist;
21) Establish certain renewal procedures for certifying physicians, qualifying patients, licensed growers, licensed dispensaries, licensed processors, independent testing laboratories; and
22) Establish certain fees to fund the operations of the Commission.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

Because these regulations are implementing a new program and bringing a new industry to the State, the Commission cannot estimate the economic impact to the State, except to say that demand for certain services will increase, such as construction, security, architectural, legal, laboratory testing, and secure transport. The new industry will also increase jobs in the areas in which medical marijuana facilities choose to locate.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(E-)	$2,500,000-$3,000,000
B. On other State agencies:	(E-)	Indeterminate
C. On local governments:	NONE	

	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(+)	Indeterminate
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminate

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. The Commission estimates that $2.5 – 3 million is needed to fund the operations of the Commission. The Commission based these figures on a number of items including indirect costs, salaries, IT costs, rent for office space, office supplies, shared services

employees, telephone, postage, mileage reimbursement for Commissioners, investigators, and inspectors, the cost of inspections and investigations, laboratory costs for testing, consultants for vetting applications, costs for an Assistant Attorney General, Office of Administrative Hearings, travel and hotel stays for investigators and inspectors, printing costs, office equipment and maintenance, software maintenance, and training programs.

B. The Commission cannot estimate the costs to any other agencies at this time.

D. The Commission cannot estimate the cost to regulated industries because this a new program and industry in the State.

F. The Commission cannot estimate the impact to the public because it cannot predict the number of qualifying patients or caregivers who will apply for medical marijuana or the impact of the program generally on the public.

Economic Impact on Small Businesses

The proposed action has a meaningful economic impact on small business. An analysis of this economic impact follows.
As this will be a new and growing industry in the State, it is expected that there to be a positive impact for small businesses through the creation of jobs in the industry. As the program starts, there will be a cost to small businesses for licensing, security, construction, and other startup costs. The Commission cannot estimate the exact impact at this time.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, Maryland 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through July 27, 2015. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2016

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

General funds will continue to be needed until the program is operational.

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 62 – NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION

10.62.01 Definitions

Authority: Health General Article, §§13-3301—13-3303, Annotated Code of Maryland

.01 Scope.

This chapter defines terms used in COMAR 10.62.02 – 10.62.35.

.02 Definitions.

A. In this subtitle, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Association" means employment or volunteer status at a licensed grower, licensed processor, or licensed dispensary.

(2) Batch.

(a) "Batch" means all of the plants of the same variety of medical cannabis that have been:

(i) Grown, harvested, and processed together; and

(ii) Exposed to substantially similar conditions throughout cultivation and processing.

(b) "Batch" includes all of the processed materials produced from those plants.

(3) "Bona fide physician-patient relationship" means a treatment or counseling relationship between a physician and a patient in which the physician has:

(a) Reviewed the patient's relevant medical records and completed an in person assessment of the patient's medical history and current medical condition;

(b) Created and maintained records of the patient's condition in accord with medically accepted standards; and

(c) A reasonable expectation that the physician will monitor the progress of the patient while using medical cannabis and take any medically indicated action:

(i) To provide follow-up care to the patient;

(ii) Regarding the efficacy of the use of medical cannabis as a treatment of the patient's severe or debilitating medical condition; and

(iii) Regarding any adverse event associated with the use of medical cannabis.

(4) Caregiver.

(a) "Caregiver" means an individual 21 years old or older designated by a patient who has agreed to assist with a qualifying patient's medical use of medical cannabis.

(b) "Caregiver" means, for a qualifying patient younger than 18 years old, a parent, or legal guardian.

(5) "Central Repository" means the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services.

(6) "Certifying physician" means a physician, as defined in Health Occupations Article, §14-101(i), Annotated Code of Maryland, who is registered by the Commission.

(7) "Commission" means the Natalie M. LaPrade Medical Cannabis Commission.

(8) "Criminal history record information" has the meaning provided by Criminal Procedure Article, §10-201(d)(3), Annotated Code of Maryland.

(9) "Dispensary agent" means an owner, a member, an employee, a volunteer, an officer or a director of a licensed dispensary.

(10) "Fund" means the Natalie M. LaPrade Medical Cannabis Commission Fund.

(11) "Independent testing laboratory" means a facility, entity, or site that offers or performs tests of medical cannabis and products containing medical cannabis:

(a) Accredited as operating to ISO standard 17025 by an accreditation body:

(i) Operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011; and

(ii) That is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA); and

(iii) That is independent from all other persons involved in the Maryland cannabis industry; and

(b) Registered with the Commission.

(12) "Law enforcement agency" means a governmental police force, sheriff's office, security force, or law enforcement organization of the State, a county, or a municipal corporation that by statute, ordinance, or common law is authorized to enforce the general criminal laws of the State.

(13) "Licensed dispensary" means an entity licensed by the Commission that acquires, possesses, repackages, processes, transfers, transports, sells, distributes, or dispenses, products containing medical cannabis, related supplies, related products including tinctures, aerosols, oils, or ointments, or educational materials for use by a qualifying patient or caregiver.

(14) "Licensed grower" means an entity that cultivates, manufactures, packages or distributes medical cannabis to licensed processors, licensed dispensaries or registered independent testing laboratories.

(15) "Licensed premises" means the locations at which a licensed grower, licensed processor, or licensed dispensary operates.

(16) "Licensed processor" means an entity licensed by the Commision that:

(a) Transforms the medical cannabis into another product or extract; and

(b) Packages and labels medical cannabis.

(17) "Lot" means all of a medical cannabis finished product that is uniform, that is intended to meet specifications, and that is manufactured, packaged, or labeled together during a specified time period according to a single lot record.

(18) "Medical cannabis" means any product containing usable cannabis or medical cannabis finished product.

(19) "Medical cannabis concentrate" means a product derived from medical cannabis that is kief, hashish, bubble hash, oil, wax, or other product, produced by extracting cannabinoids from the plant through the use of:

(a) Solvents;

(b) Carbon dioxide; or

(c) Heat, screens, presses or steam distillation.

(20) "Medical cannabis finished product" means any product containing a medical cannabis concentrate or a medical cannabis-infused product packaged and labeled for release to a qualifing patient.

(21) Medical Cannabis-Infused Product.

(a) "Medical cannabis-infused product" means oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical cannabis concentrate or usable cannabis that has been processed so that the dried leaves and flowers are integrated into other material.

(b) "Medical cannabis-infused product" does not include a food as that term is defined in Health-General Article, §21-101, Annotated Code of Maryland.

(22) "Medical cannabis grower agent" means an owner, an employee, a volunteer, an officer, or a director of a licensed grower.

(23) "Medical cannabis transport vehicle" means a vehicle owned, or leased by a licensee, for the purpose of transporting products containing cannabis that meets the criteria specified in Regulation .06 of this chapter.

(24) "Processing" means the manufacture of usable medical cannabis into a medical cannabis concentrate, or manufacture of a medical cannabis-infused product.

(25) "Qualifying patient" means an individual who:

(a) Lives in the State or, during that time an individual is present in the State, is physically present in the State for the purpose of receiving medical care from a medical facility in the State;

(b) Has been provided with a written certification by a certifying physician in accordance with a bona fide physician-patient relationship; and

(c) If younger than 18 years old, has a caregiver.

(26) "Registered dispensary agent" means a dispensary agent who is registered by the Commission in accordance with COMAR 10.62.26.

(27) "Registered grower agent" means a medical cannabis grower agent who is registered by the Commission in accordance with COMAR 10.62.09.

(28) "Registered processor agent"means a medical cannabis processor agent who is registered by the Commission in accordance with COMAR 10.62.20.

(29) "Serious adverse event" means an undesirable experience associated with the use of medical cannabis where the outcome was death, life-threatening, hospitalization, disability or permanent damage, congenital anomaly/birth defect; required intervention to prevent permanent impairment or damage, or any other important medical event.

(30) "Shipment identification number" means a unique identification number created by the shipping licensee to track a shipment of products containing cannabis.

(31) "Transportation agent" means:

(a) A registered grower agent, registered processor agent or a registered dispensary agent, authorized by the licensee to transport products containing medical cannabis, who meets the criteria specified in COMAR 10.62.18; or

(b) A licensed and bonded courier of a secure transportation company.

(32) "Variety" means the name of a cultivar or varietal of medical cannabis used by a licensed grower to consistently identify and control medical cannabis from batch to batch.

(33) Usable Cannabis.

(a) "Usable cannabis" means the dried leaves and flowers of the cannabis plant.

(b) "Usable cannabis" does not include seedlings, seeds, stems, stalks or roots of the plant or the weight of any non-cannabis ingredients combined with cannabis, such as ingredients added to prepare a topical administration.

(34) "Written certification" means a certification that is issued by a certifying physician for a qualifying patient with whom the physician has a bona fide physician-patient relationship.

(35) "30-day supply" means:

(a) 120 grams of usable cannabis unless the physician determines this amount would be inadequate to meet the medical needs of the qualifying patient; or

(b) In the case of a medical cannabis-infused product, 36 grams of Δ9-Tetrahydrocannabinol (THC) unless the physician determines this amount would be inadequate to meet the medical needs of the qualifying patient.

10.62.02 General Regulations

Authority: Health General Article, §§13-3301—13-3316, Annotated Code of Maryland

.01 Scope.

This subtitle governs operations of the Natalie M. LaPrade Medical Cannabis Commission.

.02 Donations.

A. The Commission may accept private donations to the Fund subject to the conditions established by the Commission.

B. Donations to the Fund may not be accepted from an individual or entity that:

(1) Is licensed or approved by the Commission;

(2) Is seeking licensure or approval by the Commission;

(3) Has sought licensure or approval within the past 2 years, or

(4) Is affiliated with an individual or entity described in §B(1)—(3) of this regulation.

C. An individual or entity that has made a donation to the Fund may not apply for licensure or approval by the Commission for a period of 2 years from the date of donation.

.03 HIPAA Compliance.

All Commission activities shall be conducted in compliance with HIPAA regulations.

.04 Encouragement of Applications.

A. The Commission shall broadly publicize that the Commission will be seeking:

(1) The submission of applications for licenses to grow, process, and dispense medical cannabis; and

(2) The submission of applications to register patients, physicians, and independent testing laboratories from all interested persons throughout the State.

B. The Commission shall encourage applications from applicants who qualify as minority business enterprises, as defined in State Finance and Procurement Article, §14-301, Annotated Code of Maryland.

C. The Commission shall work ith a wide variety of public and private agencies, organizations and groups to publicize the application and registration processes and encourage all interested persons to contact the Commission for additional information or assistance.

10.62.03 Certifying Physicians

Authority: Health General Article, §§ 13-3301, 13-3302, and 13-3307, Annotated Code of Maryland

.01 Physician Application for Registration.

A. A physician seeking registration as a certifying physician shall submit an application provided by the Commission that includes:

(1) The physician's:

(a) Full name;

(b) Social Security Number;

(c) Office addresses and phone numbers;

(d) Current email address;

(e) Maryland Board of Physicians license number; and

(f) Plan to assess patient outcomes, provide follow-up care, and to collect and analyze data;

(2) An attestation that the:

(a) Physician's Maryland license to practice medicine is active, unrestricted, and in good standing;

(b) Physician is registered to prescribe controlled substances by the State; and

(c) A standard patient evaluation will be completed and include:

(i) A history;

(ii) A physical examination;

(iii) A review of symptoms; and

(iv) Any other pertinent medical information;

(3) The medical conditions for which the physician may issue written certifications for medical cannabis;

(4) The physician's other inclusion criteria; and

(5) The reasons the physician may deny issuing a written certification of medical cannabis.

B. The Commission encourages physicians to apply to register as a certifying physician to treat patients who:

(1) Have a chronic or debilitating disease or medical condition that results in the patient being admitted into hospice or receiving palliative care;

(2) Have a chronic or debilitating disease or medical condition or are receiving treatment for a chronic or debilitating disease or medical condition that causes:

(a) Cachexia;

(b) Anorexia;

(c) Wasting syndrome;

(d) Severe or chronic pain;

(e) Severe nausea;

(f) Seizures; or

(g) Severe or persistent muscle spasms;

(3) Have the following diseases and conditions:

(a) Glaucoma; or

(b) Post traumatic stress disorder (PTSD).

C. A physician may be registered as a certifying physician to treat a patient who has a condition that is:

(1) Severe;

(2) For which other medical treatments have been ineffective; and

(3) If the symptoms reasonably can be expected to be relieved by the medical use of cannabis.

D. A certifying physician may apply to amend the approval at any time.

E. The application shall be deemed approved unless the Commission notifies the applicant that the application has been denied.

.02 Compensation from a Licensed Grower, Licensed Processor or Licensed Dispensary.

A. A certifying physician may not receive compensation, including promotion, recommendation, advertising, subsidized rent, or anything of value, from a licensed grower, licensed processor, or a licensed dispensary unless the certifying physician submits an application to the Commission for approval for the compensation.

B. The application shall disclose:

(1) The specific type of compensation and specific amount or value of compensation and the services for which the compensation will be paid; and

(2) An attestation that the compensation does not violate the:

(a) Maryland Medical Practice Act, codified at Health Occupations Article, §14-101 et. seq., Annotated Code of Maryland; or

(b) Patient referral laws codified at Health Occupations Article, §1-301 et. seq., Annotated Code of Maryland.

C. The Commission shall deny an application for compensation if:

(1) The compensation is based on any agreement or arrangement for the certifying physician to refer, direct, or recommend qualifying patients to the licensed grower, licensed processor, or licensed dispensary to obtain medical cannabis;

(2) The physician refuses to attest that the compensation would not violate the Maryland Medical Practice Act, codified at Health Occupations Article, §14-101 et. seq., Annotated Code of Maryland or the patient referral laws codified at Health Occupations Article, §1-301 et. seq., Annotated Code of Maryland; or

(3) The compensation would violate the:

(a) Maryland Medical Practice Act, codified at Health Occupations Article, §14-101 et. seq., Annotated Code of Maryland; or

(b) Patient referral laws codified at Health Occupations Article, §1-301 et. seq., Annotated Code of Maryland.

D. The Commission may deny an application for compensation if the compensation agreement may create an appearance that the compensation compromises the independent judgment of the certifying physician in the treatment of a patient.

E. If the Commission denies an application for compensation, the Commission shall provide the physician with written notice pursuant to State Government Article, §§10-201-10-226, Annotated Code of Maryland. The physician shall be entitled to a hearing to review the denial pursuant to State Government Article, §§10-201-10-226, Annotated Code of Maryland.

.03 Renewal of Certifying Physician Registration to Certify.

A. An approval is valid for 2 years.

B. A certifying physician shall apply to renew a registration to certify at the time of renewal of the physician's license to practice medicine by the Maryland Board of Physicians.

C. The Commission shall provide a certifying physician with notice of renewal 90 business days before expiration of the registration.

D. The Commission shall grant the application for renewal of registration if:

(1) The certifying physician attests that:

(a) The certifying physician's license to practice medicine in Maryland is active, unrestricted and in good standing; and

(b) The certifying physician's registration by the State to prescribe controlled dangerous substances is valid; and

(2) The certifying physician has otherwise complied with this chapter.

E. If a certifying physician fails to obtain a renewal of a registration to issue written certifications, the certifying physician may not issue written certifications.

10.62.04 Patient and Caregiver Registry

Authority: Health General Article. §§13-3301, 13-3302(d), 13-3303(g) and 13-3307(f)(3), Annotated Code of Maryland

.01 Registry.

The Commission shall establish a registry of qualifying patients and caregivers.

.02 Registration of Patients.

An individual seeking to become a qualifying patient shall register with the Commission by:

A. Logging onto the Commission website;

B. Providing name, address, date of birth, address; and

C. Uploading an image of a government identification document to establish identity.

.03 Patient Unique Identifier.

The Commission shall issue a unique patient identifier to each person who registers with the Commission.

.04 Registration of a Caregiver.

A. A qualifying patient may designate an individual 21 years old or older to serve as a caregiver by logging onto the Commission website.

B. Upon being designated a caregiver by a qualifying patient, a caregiver shall register with the Commission by logging onto the Commission website for caregiver registration and submitting:

(1) The name and other details of the qualifying patient for whom the caregiver is:

(a) Providing assistance; or

(b) A parent or legal guardian;

(2) Proof that the caregiver is authorized to act as a caregiver by the qualifying patient;

(3) Details to identify the caregiver;

(4) A current, clear photograph of the caregiver's face taken within 6 months of application;

(5) An attestation that the caregiver is not the caregiver for more than five qualifying patients;

(6) A copy of the caregiver's government identification card or other proof of identity;

(7) The required fee as specified in COMAR 10.62.35; and

(8) An attestation that the caregiver understands the restrictions on the use or redistribution of medical cannabis set forth in COMAR 10.62.30.05.

C. If designated to serve as a caregiver by another qualifying patient, a registered caregiver may update his or her registration by logging onto the Commission website and submitting the name and other details of the additional qualifying patient for whom the caregiver is providing assistance or for whom the caregiver is a parent or legal guardian.

.05 Addition or Termination of a Caregiver.

A. A qualifying patient may terminate a caregiver by logging onto the Commission website and making the change.

B. Provided the qualifying patient does not have more than two caregivers, a qualifying patient may add a caregiver by logging onto the Commission website and making the change.

.06 Law Enforcement Access to Registry.

The Commission shall provide access to the Commission's register to a Maryland law enforcement agency on a real-time basis only for just cause to verify that a patient or caregiver is registered with the Commission.

10.62.05 Written Certifications

Authority: Health General Article, §§ 13-3301, 13-3302, and 13-3307, Annotated Code of Maryland

.01 Issuing a Written Certification.

A. A certifying physician may determine that a patient qualifies for a written certification only:

(1) If the qualifying patient has registered with the Commission;

(2) For whom the certifying physician has a bona fide physician-patient relationship;

(3) If the qualifying patient meets the certifying physician's inclusion criteria;

(4) If the qualifying patient does not meet the certifying physician's exclusion criteria;and

(5) If the certifying physician has determined that the potential benefits of the medical use of cannabis likely outweigh the health risks for the patient.

B. The certifying physician shall:

(1) Log onto the website of the Commission to transmit the written certification to the Commission; and

(2) If requested, provide a copy of the written certification to the qualifying patient.

C. A written certification shall include the:

(1) Physician's name, Maryland Board of Physicians license number, and office telephone number;

(2) Qualifying patient's name, date of birth, address, and county of residence;

(3) Medical condition requiring medical cannabis; and

(4) The date of qualification as a qualifying patient.

D. A written certification may contain, if applicable, a written statement certifying that, in the physician's professional opinion, a 30-day supply of medical cannabis would be inadequate to meet the medical needs of the qualifying patient.

E. A certifying physician may discuss the use of medical cannabis with a qualifying patient.

F. A certifying physician shall terminate a written certification if:

(1) The qualifying patient meets the physician's exclusion criteria;

(2) Treatment with medical cannabis is no longer necessary for the qualifying patient;

(3) Adverse effects of medical cannabis outweigh the benefits to the qualifying patient's health; or

(4) There is evidence that the qualifying patient engaged in diversion of medical cannabis.

G. A certifying physician may terminate a written certification if the qualifying patient demonstrates abuse of any substance of abuse.

H. A certifying physician shall notify the Commission within 1 business day of the termination of a written certification.

I. A qualifying patient shall have only one certifying physician at any time.

.02 Written Certification Renewal.

A. A qualifying patient may seek renewal of a written certification not less than 30 calendar days after it was issued by notifying the patient's certifying physician.

B. A certifying physician may renew the written certification for a qualifying patient if the certifying physician determines the patient still meets the criteria set forth in Regulation .01A of this chapter.

C. Upon renewing a written certification for a qualifying patient, a certifying physician shall notify the Commission.

D. A certifying physician may not renew a written certification unless the physician has made a full, in-person assessment of the qualifying patient within the 365 days before the reissuance.

10.62.06 Patient and Caregiver Identification Cards

Authority: Health General Article, §§13-3301, 13-3302(d), 13-3303(g) and 13-3307(f)(3), Annotated Code of Maryland

.01 Patient Identification Cards.

A. A qualifying patient may apply to the Commission for an identification card as part of the qualifying process by logging onto the Commission website and submitting:

(1) The completed application form as provided by the Commission;

(2) A current, clear photograph of the applicant's face taken within 6 months of application;

(3) A copy of the qualifying patient's government identification card or other proof of identity; and

(4) The required fee as specified in COMAR 10.62.35.

B. An identification card shall contain:

(1) The name and date of birth of the cardholder;

(2) An expiration date 2 years from the date of issue;

(3) A current, clear photograph of the applicant's face taken within the previous 6 months; and

(4) The qualifying patient registry number assigned by the Commission.

C. A qualifying patient in hospice care is exempt from obtaining an identification card.

.02 Caregiver Identification Cards.

A. Upon being designated a caregiver by a qualifying patient, a caregiver shall:

(1) Apply to the Commission for an identification card; and

(2) Submit to the Commission:

(a) The name of the qualifying patient for whom the caregiver is providing assistance or for whom the caregiver is a parent or legal guardian;

(b) Proof that the caregiver is authorized to act as a caregiver by the qualifying patient;

(c) A current, clear photograph of the applicant's face taken within 6 months of application;

(d) The completed application in a format determined by the Commission;

(e) An attestation that the caregiver is not the caregiver for more than five qualifying patients;

(f) A copy of the caregiver's government identification card or other proof of identity;

(g) The required fee as specified in COMAR 10.62.35; and

(h) An attestation that the caregiver understands the restrictions:

(i) That it is illegal to transfer medical cannabis to any person, other than the transfer by a caregiver to a qualifying patient; and

(ii) On the use or redistribution of medical cannabis set forth in COMAR 10.62.30.05.

B. An identification card shall contain:

(1) The name and date of birth of the cardholder;

(2) An expiration date 2 years from the date of issue;

(3) A current, clear photograph of the applicant's face taken within the previous 6 months; and

(4) The caregiver registration number assigned by the Commission.

.03 Loss, Destruction or Theft of Identification Card.

If an identification card is lost, destroyed or stolen, within 72 hours of becoming aware of the loss, destruction or theft, the cardholder shall:

A. Report the loss, destruction, or theft to the Commission; and

B. Apply for a replacement card; and

C. Pay the replacement card fee specified in COMAR 10.62.35.

.04 Change of Name or Address.

If there is any change in the qualifying patient or the caregiver name or address, the qualifying patient or caregiver shall:

A. Notify the Commission within 30 days; and

B. If seeking a replacement identification card, pay the identification card replacement fee to obtain a new identification card.

.05 Circumstances Requiring Return of Identification Card to Commission.

A. If a certifying physician fails to renew a qualifying patient certification, a qualifying patient shall return an identification card to the Commission within 5 business days.

B. A caregiver shall return his or her identification card with respect to a qualifying patient to the Commission within 5 business days if:

(1) A certifying physician terminates or fails to renew a written certification of a qualifying patient; or

(2) A caregiver is no longer assisting a qualifying patient.

.06 Renewal of Identification Card.

A. A qualifying patient shall renew their identification card before it expires.

B. A caregiver shall renew their identification card before it expires.

.07 Misuse of Identification Card.

A. If an individual attempts to use a qualifying patient or caregiver identification card to whom it has not been issued, any registered dispensary agent to whom it is offered shall confiscate it and initiate the return of the card to the Commission within 5 business days.

B. If a person presents to a law enforcement officer an identification card of a qualifying patient or caregiver to whom it has not been issued, the law enforcement officer shall confiscate the identification card and initiate the return of the card to the Commission as soon as possible.

C. The Commission may notify the certifying physician and revoke the identification card of a qualifying patient or caregiver who allows another person to use an identification card which has been issued to the qualifying patient or caregiver.

10.62.07 New Condition Approval Process

Authority: Health General Article, §13-3304(d) and (e), Annotated Code of Maryland

.01 Requirement of a Petition.

A person who wishes to suggest a medical condition, medical treatment, or disease for Commission consideration shall submit a petition to the Commission in a format determined by the Commission.

.02 Hearing.

At least once per year if needed, the Commission shall conduct a public hearing to evaluate any petition to consider other medical conditions, medical treatments, or diseases that may be treated by using medical cannabis and included in certifying physician applications.

.03 Petition Contents.

The Commission shall consider a petition that may include:

A. The severity of a condition or the treatments thereof;

B. The degree to which other medical treatments have been ineffective to alleviate pain, suffering, disability or the symptoms of the condition or the treatment thereof;

C. Evidence that supports a finding that the use of medical cannabis alleviates pain, suffering, disability or symptoms of the condition or the treatment thereof;

D. Any information or studies regarding any beneficial or adverse effects from the use of medical cannabis in patients with the medical condition, medical treatment, or disease that is the subject of the petition; and

E. Letters of support from physicians or other licensed health care professionals knowledgeable about the condition, treatment, or disease.

.04 Summary Denial.

The Commission may deny a petition, without submitting it for public comment if the petition:

A. Is facially insubstantial; or

B. Pertains to a medical condition, medical treatment, or disease that has been previously considered and rejected by the Commission, unless scientific research not previously considered in a prior Commission review is included in the petition.

.05 Additional Evidence.

In addition to information provided in a petition, the Commission may:

A. Examine scientific, medical, or other evidence and research pertaining to the petition; and

B. Gather information in-person or in writing, from other persons knowledgeable about the medical conditions, medical treatments, or diseases being considered.

.06 Commission Determination.

A. Following the public hearing, the Commission shall consider the public comments and any additional information or expertise available to the Commission for each proposed severe medical condition, medical treatment or disease considered at the hearing.

B. The Commission may conclude that physicians will be encouraged to apply to register with the Commission to treat the medical condition, medical treatment, or disease upon a determination that:

(1) The medical condition, medical treatment, or disease is debilitating;

(2) The pain, suffering and disability of the medical condition, disease or medical treatment thereof can reasonably be expected to be relieved by medical cannabis; and

(3) Other medical treatments have been ineffective in providing relief.

10.62.08 Medical Cannabis Grower License

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, and 13-3312, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meaning indicated.

B. Terms Defined.

(1) "Audited financial statement" means an audited financial statement that is:

(a) Performed by a certified public accountant licensed or with practice privileges in Maryland pursuant to Business Occupations and Professions Article, Title 2, Annotated Code of Maryland;

(b) Prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants; and

(c) In the case of a publicly owned corporation, in conformity with the standards of the Public Company Oversight Board.

(2) "License" means a license issued by the Commission to operate as a grower.

(3) "Licensee" means a licensed grower.

.02 Application for a Medical Cannabis Grower License.

A. An applicant shall submit an application for a license.

B. An application shall be:

(1) Completed on a form developed by the Commission; and

(2) Submitted to the Commission for consideration.

C. In addition to the application form, the applicant shall submit the following documents to be included as addenda to the application form:

(1) A list identifying the applicant's potential medical cannabis grower agents;

(2) A list identifying each individual investor with 5 percent or more of investment known at the time of application;

(3) A detailed business plan including an organizational chart;

(4) Documentation and source of adequate capitalization;

(5) If the applicant is a corporation or business entity, a copy of the articles of incorporation and authorization to do business in Maryland;

(6) A record of tax payments in all jurisdictions in which an applicant has operated as a business for the 5 years before the filing of the application;

(7) A description of the proposed premises, including a preliminary site plan;

(8) A security plan;

(9) Details of the applicant's experience, knowledge, and training in commercial horticultural or agronomic production;

(10) The medical cannabis varieties proposed to be grown with proposed cannabinoid profiles;

(11) A plan for quality control;

(12) A plan for inventorying, safekeeping and tracking:

(a) Medical cannabis from "seed to sale," and

(b) Waste plant material prior to destruction; and

(13) A disposal plan for medical cannabis waste.

D. A grower planning to operate as a dispensary of medical cannabis shall submit a dispensary application.

E. The application shall be accompanied by the stage 1 application fee specified in COMAR 10.62.35.

F. A party applying for a license shall have an interest in only one grower license application.

G. An applicant shall amend an application within 3 business days to include the name and documentation of a request to forward the criminal history record information to the Commission of:

(1) A new individual investor of an interest of 5 percent or more; or

(2) Another manager or director of the entity, even after a license is issued.

.03 Criminal History Record Check.

For each individual identified in the application specified in Regulation .02B(1) of this chapter, an applicant shall provide to the Director of the Central Repository:

A. Two sets of legible fingerprints taken in a format approved by the Director of CJIS and the Director of the FBI and the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland for access to State criminal history and records for each medical cannabis grower agent and investor identified in the application; and

B. A request that the individual's state and national criminal history record information be forwarded to the Commission.

.04 Consent for Investigation.

A. An individual who is required to provide personal and background information under this chapter shall provide a statement that irrevocably gives consent to the Commission and persons authorized by the Commission to:

(1) Verify all information provided in the application documents; and

(2) Conduct a background investigation of the individual.

B. An applicant shall waive any contractual, statutory, or common law obligation of confidentiality and authorize any government agency in any jurisiction to release to and provide access to the Commission of any and all information the applicant has provided to any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the applicant.

C. An applicant shall release all financial institutions, fiduciaries, and other parties from any contractual, statutory or common law obligation of confidentiality to provide financial, personal and background information to the Commission relevant to the applicant's capacity to manage a licensed growing facility and the applicant's good moral character.

.05 Application Review.

A. The burden of proving an applicant's qualifications rests on the applicant.

B. The Commission may deny an application that contains a misstatement, omission, misrepresentation, or untruth.

C. An application shall be complete in every material detail.

D. The Commission may request any additional information the Commission determines is necessary to process and fully investigate an application.

E. The applicant shall provide requested additional information by the close of business of the 14th business day after the request has been received by the applicant.

F. If the applicant does not provide the requested information within 14 business days, the Commission may consider the application to be suspended.

G. The Commission intends to award the licenses to the best applications that most efficiently and effectively ensure public safety and safe access to medical cannabis.

H. The Commission shall provide guidelines and detailed instructions for submitting the application form for the Commission's consideration.

I. The Commission, or a Commission independent contractor, shall review for a pre-approval for a license the submitted applications as described in Regulations .02B and .05E of this chapter. The applications shall be ranked based on the following weighted criteria:

(1) Operational factors will be afforded 20 percent weight, including:

(a) A detailed operational plan for the cultivation of medical cannabis; and

(b) Summaries of policies and procedures for:

(i) Cultivation;

(ii) Growth;

(iii) Processing; and

(iv) Packaging;

(2) Safety and Security factors will be afforded 20 percent weight, including:

(a) Detailed plan or information describing the security features and procedures;

(b) Detailed plan describing how the grower will prevent diversion; and

(c) Detailed plan describing safety procedures;

(3) Commercial horticultural or agricultural factors will be afforded 15 percent weight, including, experience, knowledge and training in:

(a) Horticultural production; or

(b) Agricultural production;

(4) Production control factors will be afforded 15 percent weight, including:

(a) A detailed quality control plan;

(b) A detailed inventory control plan; and

(c) A detailed medical cannabis waste disposal plan;

(5) Business and economic factors will be afforded 15 percent weight, including:

(a) A business plan demonstrating a likelihood of success, a sufficient business ability and experience on the part of the applicant, and providing for appropiate employee working conditions, benefits and training;

(b) Demonstration of adequate capitalization;

(c) A detailed plan evidencing how the grower will enforce the alcohol and drug free workplace policy

(6) Additional factors that will be afforded 15 percent weight, including:

(a) Demonstrated Maryland residency among the owners and investors;

(b) Evidence that applicant is not in arrears regarding any tax obligation in Maryland and other jurisdictions;

(c) A detailed plan evidencing how the grower will distribute to dispensaries and processors; and,

(d) A list of proposed medical cannabis varieties proposed to be grown with proposed cannabinoid profiles, including:

(i) Varieties with high cannabidiol content; and

(ii) Whether the strain has any demonstrated success in alleviating symptoms of specific diseases or conditions.

J. For scoring purposes, the Commission may take into account the geographic location of the growing operation to ensure there is geographic diversity in the award of licenses.

.06 Pre-Approval of Application.

A. Limitation on Number of Licenses.

(1) The Commission may issue pre-approval of up to 15 licenses:

(a) Until May 31, 2018, in accordance with Health General Article, §13-3306(a)(2), Annotated Code of Maryland; and

(b) In consideration of the ranking of the applications in accordance with Regulation .05 of this chapter.

(2) Beginning June 1, 2018, the Commission may issue the number of pre-approvals of a license necessary to meet the demand for medical cannabis by qualifying patients in an affordable, accessible, secure and efficient manner.

B. If there are more qualified applications than the number of licenses available and there is a numerical tie for the last license to be issued, the license shall be determined by public lottery.

C. The Commission may deny issuing a pre-approval of a license if, for any individual identified in the application specified in Regulation .02B(1) of this chapter:

(1) The criminal history record information or any other evidence that demonstrates an absence of good moral character; or

(2) The payment of taxes due in any jurisdiction is in arrears.

D. Within 10 business days of the Commission's decision, the Commission shall notify an applicant who has been pre-approved for a license.

E. The Commission may rescind pre-approval of a grower license if the grower is not operational within 1 year of pre-approval.

.07 Issuance of License.

A. After an applicant has been issued a pre-approval for a license under this chapter the applicant shall submit to the Commission, as part of its application:

(1) An audited financial statement for the applicant and any proposed grower agents; and

(2) Payment of the stage 2 application fee specified in COMAR 10.62.35

B. The Commission may issue a license either to grow medical cannabis or to grow medical cannabis and distribute it to qualifying patients and caregivers on a determination that:

(1) All inspections are passed and all of the applicant's operations conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter;

(2) The proposed premises:

(a) Are under the legal control of the applicant;

(b) Comply with all zoning and planning requirements; and

(c) Conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter; and

(3) The first year's license fee specified in COMAR 10.62.35 has been paid.

.08 Change of Ownership of License.

A. No interest of 5 percent or more of a license issued pursuant to this chapter shall be assignable or transferable unless:

(1) The Commission has received notice of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;

(2) The transferee has had forwarded the criminal history record information and audited financial statement to the Commission of the transferee;

(3) The Commission does not object to the transfer or assignment within 45 days of its receipt of notice; and

(4) The transferee has paid the required fee specified in COMAR 10.62.35.

B. The Commission may deny transfer of an interest in a license for any proposed transferee if the:

(1) Criminal history record information or the background investigation demonstrate an absence of good moral character; or

(2) Payment of taxes due in any jurisdiction is in arrears..

.09 Change of Location.

A. A licensee may apply to change the location of the licensee's operation.

B. The licensee shall submit an application to the Commission along with the fee specified in COMAR 10.62.35.

C. A licensee may not begin cultivation or dispensing of medical cannabis at a new location until all inspections have been passed.

.10 Renewal of License.

A. A licensee is eligible to apply to renew a license every 2 years.

B. Ninety days before the expiration of a license, the Commission shall notify the licensee of the:

(1) Date on which the license expires;

(2) Process and the fee required to renew the license; and

(3) Consequences of a failure to renew the license.

C. At least 30 business days before a license expires a licensee shall submit:

(1) The renewal application as provided by the Commission;

(2) Proof that fingerprints have been submitted to CJIS and the FBI for every grower agent and investor of an interest of 5 percent or more;

(3) To full inspection of the operation, unless a full inspection was satisfactorily completed within 3 months before the date of the license expiration; and

(4) Payment of the fee specified in COMAR 10.62.35.

D. The Commission shall renew a license that meets the requirements for renewal as stated in §C of this regulation.

E. If the Commission does not renew a license due to a failed inspection or an inadequate application for renewal, the licensee may apply for reinstatement by:

(1) Submitting a plan to correct the deficiencies noted during an inspection; and

(2) Amending the application for renewal.

F. The Commission may decline to renew a license if:

(1) The plan to correct deficiencies identified in an inspection is deficient;

(2) The amended application for renewal is deficient; or

(3) The licensee has repeatedly failed inspections.

G. A licensee who fails to apply for renewal of a license by the date specified by the Commission, or whose license was not renewed by the Commission:

(1) Shall cease operations at all premises; and

(2) May not provide medical cannabis to any entity or person.

H. A license may be reinstated upon:

(1) Payment of the reinstatement fee specified in COMAR 10.62.35; and

(2) Submission of a reinstatement application approved by the Commission.

.11 Annual Report on Minority Owners and Employees.

On June 1 of each year, each licensee shall submit a report in a manner determined by the Commission regarding the licensee's minority owners and employees.

10.62.09 Medical Cannabis Grower Agent

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, and 13-3312, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meaning indicated.

B. Terms Defined.

(1) "License" means a license issued by the Commission to operate as a licensed grower.

(2) "Licensee" means a licensed grower.

.02 Grower Agent Generally.

A grower agent shall be 21 years old or older.

.03 Grower Agent Registration and Criminal History Record.

A. Each medical cannabis grower agent shall be registered with the Commission before the agent may volunteer or work for a licensed grower.

B. A licensed grower shall apply to register a grower agent by submitting to the Commission:

(1) The name, address, date of birth, and Social Security Number of a grower agent;

(2) Documentation of the submission of fingerprints of the grower agent to the Central Registry; and

(3) The request for the criminal history record information of the grower agent to be forwarded to the Commission.

C. A prospective grower agent may not be registered if the prospective grower agent has ever been convicted of a felony drug offense.

D. The Commission, after review of the criminal history record information, may disqualify any prospective grower agent from registration for an absence of good moral character.

.04 Registered Grower Agent Identification Cards.

A. The Commission shall issue to each registered grower agent a identification card which includes a photograph of the face of the registered grower agent taken no more than 6 months before the date of the application.

B. At all times every registered grower agent at a licensed premises shall visibly wear the identification card issued to the registered grower agent by the Commission.

C. The identification card shall be renewed every 2 years.

D. If a registered grower agent's identification card is lost, destroyed or stolen, within 24 hours of becoming aware of the loss, destruction or theft, the licensee shall:

(1) Report the loss, destruction or theft to the Commission;

(2) Apply for a replacement card; and

(3) Pay a replacement card fee specified in COMAR 10.62.35.

E. An identification card remains the property of the Commission and the Commission may order the return or seizure of an identification card if the registration is revoked or expires.

F. If a registered grower agent's identification card is lost, destroyed or stolen, a copy of notification to the Commission shall be evidence of registration until a new card is obtained from the Commission.

.05 Termination.

A. As soon as possible upon termination of a registered grower agent's association with a licensed grower, the licensed grower shall:

(1) Take custody of a terminated registered grower agent's identification card;

(2) Obtain any keys or other entry devices from a terminated registered grower agent; and

(3) Ensure a terminated registered grower agent can no longer gain access to the licensed premises.

B. Within 1 business day of a termination of a registered grower agent's association with a licensed grower, a licensed grower shall:

(1) Notify the Commission:

(a) Of a termination and the circumstances of a termination; and

(b) Whether a terminated registered grower agent has returned the agent's identification card; and

(2) Initiate delivery of a terminated registered grower agent's identification card to the Commission.

C. The Commission shall revoke a registration of a grower agent upon receiving notification that a grower agent is no longer associated with a licensed grower.

D. If a registered grower agent did not return the agent's identification card within 30 days of the termination, the Commission shall notify the Maryland State Police and place a notice in the register of that fact.

.06 Prospective Grower Agent Drug Screen.

A. The licensee shall require a prospective grower agent to submit to a drug screen before commencement of association.

B. The drug screen shall be carried out following the procedures set forth in COMAR 17.04.09.04—.08.

C. In addition to the drugs to be screened in accordance with COMAR 17.04.09.06, the screen shall include any other drugs as required by the Commission.

D. Unless medically justified, a prospective grower agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered by the Commission.

.07 Grower Agent Training.

A. The licensee shall train all registered grower agents on:

(1) Federal and State medical cannabis laws and regulations and other laws and regulations pertinent to the grower agent's responsibilities;

(2) Standard operating procedures;

(3) Detection and prevention of diversion of medical cannabis;

(4) Security procedures; and

(5) Safety procedures, including responding to;

(a) A medical emergency;

(b) A fire;

(c) A chemical spill; and

(d) A threatening event such as:

(i) An armed robbery;

(ii) An invasion;

(iii) A burglary; or

(iv) Any other criminal incident.

B. The licensee shall retain training materials and attendance records and make the training materials available for inspection by the Commission.

.08 Alcohol and Drug Free Workplace Policy.

A. Each registered grower agent shall declare in writing that the registered grower agent will adhere to the State alcohol and drug free workplace policy, as identified in COMAR 21.11.08.03.

B. The licensee shall retain the declaration in a registered grower agent's personnel record.

.09 Annual Verification of Registered Grower Agents.

Every year, on a date determined by the Commission, the licensee shall notify the Commission that the licensee has verified that no registered grower agent has been convicted of a felony drug offense.

10.62.10 Medical Cannabis Grower Premises

Authority: Health General Article, §§13-3306(a)(3), (d), and (e), Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meaning indicated.

B. Terms Defined.

(1) "License" means a license issued by the Commission to operate as a grower.

(2) "Licensee" means a licensed grower.

.02 Premises Generally.

A. A licensed premises shall be located within Maryland,

B. The premises and operations of a licensee shall conform to local zoning and planning requirements.
C. The grower license shall be conspicuously displayed at each licensed premises.
D. Modification of Premises.
(1) A licensee shall notify the Commission of proposed major renovations or modifications to a licensed premises.
(2) No major renovation or modification shall be undertaken without notification to the Commission.

.03 Additional Provisions for Field or Greenhouse Cultivation Premises.
A. Licensed premises for field cultivation of medical cannabis shall be situated to maintain the greatest achievable level of privacy and security.
B. Physical Security. An area of cultivation shall be securely surrounded by fencing and gates constructed to prevent unauthorized entry.
C. Fencing and gates shall be equipped with a security alarm system that:
(1) Covers the entire perimeter;
(2) Is continuously monitored; and
(3) Is capable of detecting power loss.
D. The premises shall be protected by a video surveillance recording system to ensure:
(1) Surveillance of the entire perimeter of the area of cultivation;
(2) Surveillance over all portions of the security fence and all gates; and
(3) Adherence to the video surveillance requirements of this chapter.
E. A video surveillance system shall be supported by adequate security lighting which may be modified as necessary to include motion control sensors to protect light-dark cycles for proper cultivation.

.04 Security of Premises.
A licensed premises shall be constructed to prevent unauthorized entry.

.05 Security Lighting.
A. Lighting fixtures of the licensed grower shall be designed and installed to ensure proper surveillance.
B. This regulation does not apply to lighting in areas of the premises used to cultivate medical cannabis.

.06 Security Alarm Systems.
A. A licensee shall maintain a security alarm system that covers all perimeter entry points and portals at all premises.
B. A security system shall be:
(1) Continuously monitored;
(2) Capable of detecting smoke and fire; and
(3) Capable of detecting power loss.
C. A security alarm system shall include panic alarm devices mounted at convenient, readily-accessible locations throughout the licensed premises.
D. A second, independent security alarm system shall be used to protect:
(1) A location where records are stored on-site;
(2) A location where records are stored off-site; and
(3) A cabinet or room that holds medical cannabis.
E. A security alarm system shall remain operational until a licensed premises no longer has any medical cannabis, seeds, or cuttings on the premises.
F. A security alarm system shall be equipped with auxiliary power sufficient to maintain operation for at least 48 hours.

.07 Video Surveillance Requirements.
A. A licensee shall maintain a motion-activated video surveillance recording system at all premises that:
(1) Records all activity in images of high quality and high resolution capable of clearly revealing facial detail;
(2) Operates 24-hours a day, 365 days a year without interruption; and
(3) Provides a date and time stamp for every recorded frame.
B. A licensee shall post appropriate notices advising visitors of the video surveillance.
C. A surveillance camera shall be located and operated to capture each exit from the premises.
D. A surveillance camera shall capture activity at each entrance to an area where medical cannabis is grown, tested, cured, manufactured, processed or stored.
E. A recording of all images captured by each surveillance camera shall be kept:
(1) At the licensed premises; and
(2) At an off-site location.
F. The storage of all recordings of security video surveillance shall be:
(1) Access-limited;
(2) Secured by a security alarm system that is independent of the main premises security alarm system;
(3) In a format that can be easily accessed for investigational purposes; and

(4) Retained for a minimum of 30 calendar days.

G. Any recording of security video surveillance shall be made available to the Commission or law enforcement agency for just cause as requested.

.08 Visitor to a Non-Public Area of the Premises.

A. When a visitor is admitted to a non-public area of the premises of a licensee, a registered grower agent shall:

(1) Log the visitor in and out;

(2) Retain with the log a photocopy of the visitor's government-issued identification;

(3) Continuously visually supervise the visitor while on the premises; and

(4) Ensure that the visitor does not touch any plant or medical cannabis.

B. The licensee shall maintain a log of all visitors to non-public areas for 2 years.

10.62.11 Medical Cannabis Growing Controls

Authority: Health General Article, §§13-3301, 13-3302, and 13-3306, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Green waste" means unused, surplus, returned, or out of date medical cannabis, recalled medical cannabis, and any plant debris, including dead plants, all unused plant parts, and roots.

(2) "Growing media" means commercially produced potting mix or hydroponic solution or any other substrate used for growing.

(3) "License" means a license issued by the Commission to operate as a grower.

(4) "Licensee" means a licensed grower.

(5) "Unique identifier" means any symbol or mark that enables tracking of final product to the grower, seed, or plant from which the medical cannabis originated.

.02 Standard Operating Procedures.

A licensee shall establish written standard operating procedures to promote good growing and handling practices including:

A. All aspects of the:

(1) Irrigation, propagation, cultivation, fertilization;

(2) Harvesting, drying, curing;

(3) Rework or reprocessing;

(4) Packaging, labeling and handling of medical cannabis products, byproduct; and

(5) Waste products, and the control thereof, to promote good growing and handling practices;

B. Requiring that each individual engaged in the cultivation, manufacturing, handling, packaging, and testing of medical cannabis has the training, education, or experience necessary to perform assigned functions; and

C. Requiring that all registered grower agents practice good hygiene and wear protective clothing as necessary to protect the product as well as themselves from exposure to potential contaminants.

D. Requirements for Receipt of Material.

(1) A licensee shall quarantine material that is received to be used to produce medical cannabis.

(2) A licensee shall inspect material for defects, contamination, and compliance with a licensee's specifications.

(3) Material may not be released from quarantine by a licensee until the material:

(a) Passes inspection; and

(b) Is determined to be acceptable for use as intended.

.03 Horticultural Controls.

A. Water. The licensee shall keep a record of water quality testing on site and make it available for inspection.

B. Fertilizer. As part of the standard operating procedure, a licensee shall:

(1) Adopt a nutrient management plan prepared by a certified nutrient management consultant;

(2) Use fertilizer or hydroponic solution of a type, formulation, and at a rate, to support healthy growth of medical cannabis; and

(3) Maintain records of the type and amounts of fertilizer and any growth additives used.

C. A licensee shall specify in the standard operating procedure the use of growing media or hydroponic solution.

D. Unless the medical cannabis is field grown, a licensee shall install, as part of the standard operating procedure, a system to monitor, record, and regulate:

(1) Temperature;

(2) Humidity;

(3) Ventilation; and

(4) Lighting, if used.

E. Unless the medical cannabis is field grown, a licensee shall seal or screen the premises ventilation system with a mesh or filtering system fine enough to exclude most plant pests.

F. Pest Monitoring. A licensee shall use, as part of the standard operating procedure, integrated pest management practices and techniques to identify and manage plant pathogen and pest problems, including:

(1) A door control system sufficient to prevent pest entry;

(2) Regular visual inspection of plants and growing areas for the presence of pests;

(3) The use of sticky cards in growing areas; and

(4) Identification and recording of all pests or pathogens detected and the measures taken for control.

G. Pest Control. Pesticide applicators and applications shall follow State and federal pesticide requirements for any pesticide applied.

H. Sanitation. Sanitation shall be in compliance with the licensee's standard operating procedures.

I. Green Waste. A licensee shall weigh, document, and destroy all green waste in accordance with the standard operating procedures.

.04 Equipment.

A. A licensee shall maintain equipment that comes in contact with medical cannabis to prevent contamination.

B. A licensee shall maintain cleaning and equipment maintenance logs.

C. A licensee shall have any scale, balance, or other measurement device, and any automatic, mechanical, or electronic equipment routinely calibrated by a calibration laboratory accredited to International Organization for Standardization (ISO) standard ISO/IEC 17025 by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

10.62.12 Inventory Control by Grower

Authority: Health General Article, §§13-3301, 13-3302, and 13-3306(e), Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Inventory control" means the record of the inventory in the perpetual inventory control system used by the licensee in accordance with this chapter;

(2) "Licensee" means a licensed grower.

(3) "Unique identifier" means any symbol or mark which will enable tracking of medical cannabis from plant to final product by means of the inventory control.

.02 Inventory Control System.

A. A licensee shall use a perpetual inventory control system that identifies and tracks the licensee's stock of medical cannabis from the time the medical cannabis is propagated from seed or cutting to the time it is delivered to a licensed dispensary, licensed processor or a qualifying patient or caregiver.

B. In the event of a serious adverse event, an inventory control system shall be capable of tracking medical cannabis from a qualifying patient back to the source of medical cannabis.

C. The inventory control system shall be designed to promptly identify a discrepancy in the stocks.

.03 Materials Received for Cultivation.

Upon receipt of raw material for cultivation, a licensee shall record in the inventory control:

A. The date delivered; and

B. The number of cuttings or seeds delivered or the weight of the seeds for each variety in the shipment.

.04 Plant Tagging and Entry into Inventory Control.

A. For each plant, as soon as practical, a licensee shall:

(1) Create a unique identifier for each plant;

(2) Assign each plant to a batch;

(3) Enter information regarding the plant into the inventory control system;

(4) Create a tag with the unique identifier and batch number; and

(5) Securely attach the tag to a plant container or plant.

B. Tags shall be indelible and tamper-evident.

C. Tags shall be made of a material that resists variation in temperature and moisture.

.05 Control of Harvested Medical Cannabis.

A licensee shall:

A. Upon completion of curing or drying of each batch, weigh medical cannabis to update inventory control for the batch; and

B. At least monthly, conduct a physical inventory of the stock and compare the physical inventory of stock with inventory control.

.06 Discrepancy Reporting.

A. If a licensee discerns a discrepancy between the inventory of stock and inventory control outside of normal weight loss due to moisture loss and handling, the licensee shall commence an investigation of the discrepancy within 1 business day.

B. If the licensee finds evidence of a theft or diversion within 1 business day, the licensee shall report the theft or diversion to the:

(1) Commission; and

(2) Maryland State Police.

C. Within 30 business days of discovering a discrepancy, the licensee shall:

(1) Complete the investigation;

(2) Amend the licensee's standard operating procedures, if necessary; and

(3) Send a report of the audit to the Commission.

.07 Product Returned for Destruction.

A licensee shall accept the return of any medical cannabis from a qualifying patient or a caregiver to destroy.

.08 Bar on Distribution of Non-Complying Medical Cannabis.

A. A licensee or registered grower agent may not distribute any medical cannabis to any person if the licensee or registered grower agent knows, or may have reason to know, that the distribution does not comply with any provision of the Health -General Article, Title 13, Subtitle 33, Annotated Code of Maryland or this subtitle.

B. A licensee or registered grower agent may not distribute any medical cannabis to any person if the licensee or registered grower agent knows, or may have reason to know, that the medical cannabis does not comply with any provision of the Health – General Article, Title 13, Subtitle 33, Annotated Code of Maryland or this subtitle.

10.62.13 Medical Cannabis Shipment Packaging

Authority: Health General Article, §§13-3301, 13-3302, 13-3306(b) and (e), 13-3307(f), 13-3309(f) and 13-3311(c), Annotated Code of Maryland

.01 Packaging Products Containing Medical Cannabis for Shipment.

A. Before shipping an order of products containing medical cannabis, a licensee, shall if necessary, repackage the shipment into a container:

(1) Constructed of tamper-evident opaque material; and

(2) Sealed with tamper-evident tape.

B. Multiple packages that are being shipped to the same recipient may be sealed within one large opaque tamper-evident container.

.02 Labeling of Packages for Shipment.

A. Each package in a shipment of products containing cannabis shall be labeled with:

(1) The date and time of the sealing of the package for shipment;

(2) The name and signature of the registered grower agent, registered processor agent, or registered dispensary agent who prepared the package and sealed the package;

(3) The name and address of the shipping licensee;

(4) The shipment identification number;

(5) A description, including the weight, of each item, contained in the package; and

(6) The name and address of the licensee, or other party if applicable, to receive the shipment.

B. A label shall be made of weather-resistant and tamper-evident materials.

C. A label shall be conspicuously placed on a package.

10.62.14 Licensed Grower Dispensary Facility

Authority: Health General Article, §§13–3301, 13-3302 13-3306(c), and 13–3307, Annotated Code of Maryland

.01 Definitions.

A. The following terms have the meanings indicated.

B. Terms Defined.

(1) "Dispensary license" means a license issued by the Commission to operate as a dispensary.

(2) "Licensed grower dispensary facilty" means a facility where a licensed grower may dispense medical cannabis.

(3) "Licensee" means a licensed grower.

.02 Licensed Grower Dispensary Facility.

A. A licensee may dispense medical cannabis to qualifying patients and caregivers in conformity with COMAR 10.62.25 — 10.62.31 at a facility for which the licensee has obtained a license to dispense medical cannabis.

B. A licensed grower dispensary facility shall be constructed and operated in conformity to COMAR 10.62.27, relating to medical cannabis dispensary premises.

C. A licensee may hire employees or use volunteers at a licensed grower dispensary facility in conformity to COMAR 10.62.26.

10.62.15 Medical Cannabis Grower Quality Control

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, and 13-3311, Annotated Code of Maryland

.01 Production and Process Controls.

A. A licensee shall cultivate each plant and produce each batch of medical cannabis in conformity with the standard operating procedures.

B. A licensee shall record the cultivation process in accordance to standard operating procedures to ensure:

(1) Consistency of the batch with the variety; and

(2) Accuracy of the day-to-day production.

C. A licensee shall record any deviation defined as a material change from the standard operating procedure which would impact the quality of the batch in the log.

D. A licensee may not release any batch of medical cannabis if there was any deviation in production of the batch from the standard operating procedure unless:

(1) After independent testing of the batch in accordance with the criteria set forth in Regulation .04 of this chapter the batch is tested by an independent testing laboratory and the licensee determines, as a result of such testing, that the batch meets the specification for the variety; and

(2) The determination is recorded.

.02 In-Process Inspection by Grower.

During the process of cultivation, a licensee shall regularly inspect each plant to ensure proper growth and absence of pests and disease.

.03 Holding Procedure.

A licensee shall hold medical cannabis in secure, segregated storage until released for distribution.

.04 Independent Testing Laboratory Selection.

The licensee shall use an independent testing laboratory:

A. That has adopted a standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;

B. To obtain samples of each batch according to a statistically valid sampling method by an agent of an independent testing laboratory;

C. To analyze the samples according to:

(1) The most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP); or

(2) A scientifically valid methodology that is equal or superior to that of the AHP monograph;

D. In the event of a test result which falls out of specification, the laboratory shall follow their standard operating procedure to confirm or refute the original result;

E. To issue a certificate of analysis; and

F. To destroy the remains of the sample of medical cannabis after analysis is completed.

.05 Contents of Certificate of Analysis.

An independent testing laboratory shall issue a certificate of analysis for each batch, with supporting data, to report:

A. Whether the chemical profile of the batch conforms to the variety for the following compounds:

(1) Δ9-Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinolic Acid (THCA);

(3) Cannabidiol (CBD);

(4) Cannabidiolic Acid (CBDA); and

(5) The terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopeia (AHP);

(6) Cannabigerol (CBG); and

(7) Cannabinol (CBN); and

B. That the presence of the following contaminants does not exceed the levels as required by the AHP monograph:

(1) Heavy metals, mercury, lead, cadmium, or arsenic;

(2) Foreign material such as hair, insects, or any similar or related adulterant;

(3) Any microbiological impurity, including:

(a) Total aerobic microbial count (TAMC);

(b) Total yeast mold count (TYMC);

(c) P. aeruginosa;

(d) Aspergillus spp.;
(e) S. aureus;
(f) Aflatoxin B1, B2, G1, and G2; and
(g) Ochratoxin A.; and
(h) Pesticide residue; and
(4) Whether the batch is within specification for the characteristics of:
(a) Odor;
(b) Appearance;
(c) Fineness; and
(d) Moisture content.

.06 Grower Determination That a Batch May be Released.

A. If a licensed grower, upon review of the certificate of analysis, determines that a batch meets the specification for the variety, the grower may:
(1) Assign an expiration date to the batch;
(2) Release the batch for distribution; and
(3) Revise the status of the batch in the inventory control.
B. If a licensed grower receives test results that do not meet specifications, the licensed grower may rework or reprocess the batch according to their standard operating procedure. The reworked or reprocessed batch shall be resampled and retested by the independent testing laboratory to ensure that all required specifications are met.
C. A licensee shall retain every certificate of analysis.

.07 Stability Testing and Retention Sampling.

A. A licensee shall provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to:
(1) Ensure product potency and purity; and
(2) Provide support for expiration dating.
B. A licensee shall retain a sample from each released batch:
(1) Sufficient to provide for follow-up testing if necessary; and
(2) Properly store the sample for one year past the date of expiration of the batch.

.08 Report of Products Offered for Distribution.

A licensee shall submit to the Commission quarterly a list of the products and their specifications that the licensee offered for distribution in the previous quarter.

10.62.16 Independent Testing Laboratory Registration

Authority: Health General Article, §§13-3301, 13-3302, and 13-3311, Annotated Code of Maryland

.01 Definition.

A. In this chapter, the following term have the meaning indicated.
B. Terms Defined.
(1) "Accreditation body" means a nonprofit, impartial organization that requires conformance to ISO/IEC 17025 requirements and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement for Testing.
(2) "Certification of accreditation" means a certificate issued by an accrediting body for the independent testing laboratory facility, entity or site to be registered in Maryland.
(3) "Independent testing laboratory" means any facility, entity, or site in Maryland that offers or performs tests of medical Cannabiscannabis or products containing medical cannabis and is independent of any entity that grows, processes or dispenses cannabis.
(4) "Scope of accreditation" means a document issued by the accreditation body which describes the methodologies, range, and parameters for testing medical cannabis or products containing medical cannabis for which the accreditation has been granted.

.02 Registration.

A. An independent testing laboratory shall register with the Commission.
B. To register, an independent laboratory shall:
(1) Submit a completed independent laboratory registration form;
(2) Pay the registration fee specified in COMAR 10.62.35.01.
(3) Submit a copy of the certification of accreditation accompanied by the scope of accreditation; and
(4) Submit the name, address, date of birth and Social Security Number of each independent testing laboratory employee and a copy of the application form completed by each independent testing laboratory employee.
C. The Commission may issue a provisional registration to an independent testing laboratory that has not yet been issued a certification of accreditation in Maryland if the independent testing laboratory:
(1) Submits a completed independent laboratory registration form;

(2) Pays the registration fee specified in COMAR 10.62.35.01;

(3) Submits a copy of the contract with the accreditation body applying to become accredited accompanied by a copy of the proposed scope of the accreditation;

(4) Submits evidence the independent testing laboratory has been accredited by the accreditation body in another jurisdiction; and

(5) Submits the name, address, and date of birth and Social Security Number of each independent testing laboratory employee and a copy of the application form completed by each independent testing laboratory employee.

D. Once it has obtained a certification of accreditation, a provisionally registered independent testing laboratory shall apply to be registered, but:

(1) The term of the registration may not exceed the term of the provisional registration; and

(2) No additional registration fee need be paid for that term.

.03 Standards of Care.

A. The independent testing laboratory shall follow the methodologies, ranges, and parameters which are contained in the scope of the accreditation for testing medical cannabis or products containing medical cannabis.

B. The independent testing laboratory shall require each independent testing laboratory employee to complete and execute an application for employment on a form provided by the Commission.

C. The independent testing laboratory shall establish and follow written procedures for verifying the experience and education of laboratory employees.

D. The independent testing laboratory shall submit the registration information for each independent testing laboratory employee within 15 days after the date the independent testing laboratory employee was hired.

E. Upon termination of the association of the registered independent testing laboratory employee with the independent testing laboratory, the independent testing laboratory shall:

(1) Obtain any keys or other entry devices from the terminated independent testing laboratory employee;

(2) Ensure the terminated independent laboratory employee can no longer gain access to the laboratory premises; and

(3) Within 1 business day of the termination of independent laboratory employee, the independent testing laboratory shall notify the Commission of the termination.

F. The independent testing laboratory shall notify the Commission within 1 business day after the independent testing laboratory obtains notice of any kind that its accreditation has been denied, suspended or revoked.

.04 Term and Renewal.

A. The registration is valid for 2 years.

B. The registration may be renewed by submitting to the Commission:

(1) A copy of the independent testing laboratory registration form;

(2) Payment of the registration fee specified in COMAR 10.62.35; and

(3) Submission of copies of the most recent:

(a) Assessment from the accreditation body; and

(b) Periodic review of the proficiency testing of the results obtained by the independent testing laboratory.

.05 Independent Testing Laboratory Responsibilities.

No independent testing laboratory may handle, test, or analyze cannabis or cannabis products unless the independent testing laboratory:

A. Has been registered by the Commission;

B. Is independent from all other persons and entities involved in the medical cannabis industry;

C. Is accredited by an accreditation body or has a provisional registration from the Commission; and

D. Has established standard operating procedures that provide for adequate chain of custody controls for samples transferred to the independent testing laboratory for testing.

10.62.17 Complaints, Adverse Events, and Recall

Authority: Health General Article, §§13-3301, 13-3302, 13-3304, 13-3305, 13-3306, 13-3307 13-3309, 13-3311, Annotated Code of Maryland

.01 Receipt and Documentation of Complaints and Adverse Events.

A licensed grower, licensed processor, licensed dispensary, certifying physician, and the Commission shall establish a procedure to receive, organize, store and respond to all oral, written, electronic or other complaints regarding medical cannabis and adverse events.

.02 Report of Serious Adverse Event to Commission and Interested Parties.

In the event a complaint associated with a serious adverse event is received, a licensee, or certifying physician, shall promptly report the complaint to:

A. The Commission;

B. Either the licensed grower from which the medical cannabis originated, or the licensed processor from which the medical cannabis concentrate originated; and

C. The certifying physician caring for the qualifying patient.

.03 Complaint Investigation by Grower or Dispensary.

A. Whenever a complaint regarding the quality or safety of medical cannabis is received by a licensed grower, licensed processor or licensed dispensary, a licensee shall, within 24 hours, review the complaint to determine if it is substantive or reports a serious adverse event.

B. If a licensee determines that the complaint is substantive or reports a serious adverse event, a licensee shall:

(1) Promptly determine the batch number or lot number of the medical cannabis, the medical cannabis finished product, and medical cannabis concentrate that is the subject of the complaint; and

(2) Investigate the record and circumstances of the production of the batch and lot to determine:

(a) If there was a deviation from the standard operating procedure in the production of the medical cannabis by reviewing production logs; and

(b) If the sample meets specification by submitting parts of the retention samples of the batch and lot to an independent testing laboratory.

C. If sample analysis of the batch or lot reveals that the batch or lot fails to meet specification, the licensee shall:

(1) Order a recall of all products derived from or included in the batch or lot;

(2) Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis products from such a batch or lot of the recall; and

(3) Offer and pay reimbursement for any returned medical cannabis.

D. In a case of a report of a serious adverse event or a substantive complaint, if the investigation reveals a deviation from the standard operating procedure in the production of the batch or lot, the licensee may:

(1) Order a recall of all products derived from or included in the batch or lot;

(2) Notify all patients, caregivers, and dispensaries who may have obtained medical cannabis products from such a batch or lot of the recall; and

(3) Offer and pay reimbursement for any returned medical cannabis.

.04 Custody of Returned Recalled Material.

A. The licensee shall develop a procedure to ensure medical cannabis that is recalled is stored and segregated until disposal of recalled material is authorized by the Commission.

B. Within 24 hours of the receipt of notice from the Commission that the disposal of recalled medical cannabis is authorized, the licensee shall dispose of the recalled medical cannabis according to the standard operating procedure.

10.62.18 Shipment of Products Between Licensees

Authority: Health General Article, §§13-3301, 13-3302, 13-3306(b) and (e), 13-3307(f), 13-3309(f) and 13-3311(c), Annotated Code of Maryland

.01 Definitions.

A. The following terms have the meanings indicated.

B. Terms Defined.

(1) "Receiving licensee" means the licensee that receives the shipment.

(2) "Secure transportation company" means a business that is licensed, whose employees are bonded, and that provides highly secure vehicles for the transportation of valuables, and can assure that medical cannabis is secured at all times during transport.

(3) "Shipping licensee" means the licensee that initiates the shipment.

.02 Electronic Manifest System.

A. A licensee shall install an electronic manifest system to record the chain of custody for the shipment of products containing medical cannabis.

B. An electronic manifest system shall include a chain of custody that records:

(1) The name and address of the shipping licensee;

(2) The shipping licensee's shipment identification number;

(3) The weight and description of each individual package that is part of the shipment, and the total number of individual packages;

(4) The name of the registered grower agent or registered dispensary agent that prepared the shipment;

(5) The name and address of the receiving licensee or other receiving party if applicable; and

(6) Any handling or storage instructions.

.03 Creation of Manifest.

A. An electronic manifest shall be created by the shipping licensee for each shipment of products containing cannabis.

B. The electronic manifest shall contain, at a minimum, the following entries as a chain of custody, in the order listed:

(1) An entry by the registered grower agent or registered dispensary agent who has prepared the shipment, including the date and time of preparation;

(2) An entry by a shipping licensee's transportation agent, of the date and time of the placement of the shipment into the medical cannabis transport vehicle;

(3) An entry by licensee's agent receiving the shipment including the date and time of the acceptance; and

(4) If any other person had custody or control of the shipment, that person's identity, the circumstances, duration, and disposition.

.04 Transportation Agents.

A. A transportation agent driving a medical cannabis transport vehicle shall have a current driver's license.

B. While on duty, a transportation agent may not wear any clothing or symbols that may indicate ownership or possession of cannabis.

.05 Transportation of Products Containing Medical Cannabis.

A. Either a secure transportation company or a shipping licensee shall transport products containing medical cannabis.

B. A shipping licensee shall use one transportation agent, who shall carry identification approved by the Commission, to:

(1) Accompany shipment of products containing medical cannabis; and

(2) Ensure that the product is secured at all times during transport.

.06 Medical Cannabis Transport Vehicle.

A medical cannabis transport vehicle:

A. Shall have and display current registration from the State;

B. Shall be insured as required by law; and

C. May not display any sign or illustration related to medical cannabis or a licensee.

10.62.19 Medical Cannabis Processor License

Authority: Health General Article, §§13–3301, 13-3302, 13-3309 and 13–3310, Annotated Code of Maryland

.01 Definitions.

A. In this chapter the following terms have the meanings indicated.

B. Terms Defined.

(1) "Audited financial statement" means an audited financial statement that is performed by a certified public accountant licensed or with practice privileges in Maryland, pursuant to Business Occupations and Professions Article, Title 2, Annotated Code of Maryland, that:

(a) Is prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants; and

(b) In the case of a publicly owned corporation in conformity with the standards of the Public Company Oversight Board;

(2) "License" means a license issued by the Commission to operate as a licensed processor; and

(3) "Licensee" means a licensed processor.

.02 Application.

A. An applicant shall submit to the Commission an application for a license.

B. An application on a form developed by the Commission shall be completed and submitted to the Commission for consideration. In addition to the application form, the applicant shall submit the following documents to be included as addenda to the application form:

(1) A list identifying the applicant's potential processor agents;

(2) A list identifying each individual investor with 5 percent or more of investment known at the time of application;

(3) A detailed business plan including an organizational chart;

(4) Documentation and source of adequate capitalization;

(5) If the applicant is a corporation, a copy of the articles of incorporation and authorization to do business in Maryland;

(6) Evidence that no tax obligation is in arrears in any jurisdiction on the part of the applicant and any investor with 5 percent or more of investment known at the time of application;

(7) A description of the proposed premises, including a preliminary site plan;

(8) A security plan;

(9) A plan for quality control;

(10) A plan for inventorying, safekeeping and tracking medical cannabis from entry into inventory to sale or disposal of medical cannabis waste;

(11) A plan for the disposal of medical cannabis waste;

(12) A plan for training employees and volunteers;

(13) Details of the applicant's experience, knowledge, and training in:

(a) the operation of a laboratory;

(b) the operation or management of a pharmaceutical manufacturing business; or

(c) the operation or management of a consumer products business; and

(14) A plan of the medical cannabis concentrates and medical cannabis-infused products proposed to be manufactured and the processes to be used.

C. The application shall be accompanied by the stage 1 application fee specified in COMAR 10.62.35.

D. Any party applying for a license shall have an interest in only one processor license.

E. An applicant shall amend an application within 3 business days to include the name and documentation of a request to forward the criminal history record information and audited financial statement to the Commission of a new individual investor of an interest of 5 percent or more, or another manager or director of the entity, even after a license is issued.

F. For each individual identified in the application specified in COMAR 10.62.19.02B(1) and (2) of this chapter, an applicant shall provide to the Director of the Central Repository:

(1) Two sets of legible fingerprints taken in a format approved by the Director of CJIS and the Director of the FBI and the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records for each processor agent and investor identified in the application; and

(2) A request that the individual's state and national criminal history record information be forwarded to the Commission.

.03 Consent for Investigation.

A. An individual who is required to provide personal and background information under this chapter shall provide a statement that irrevocably gives consent to the Commission and persons authorized by the Commission to:

(1) Verify all information provided in the application documents; and

(2) Conduct a background investigation of the individual.

B. An applicant shall waive any contractual, statutory, or common law obligation of confidentiality and authorize any government agency in any jurisiction to release to and provide access to the Commission of any and all information the applicant has provided to any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the applicant.

C. An applicant shall release all financial institutions, fiduciaries and other parties from any contractual, statutory or common law obligation of confidentiality to provide financial, personal and background information to the Commission relevant to the applicant's capacity to manage a licensed processor and the applicant's good moral character.

.04 Application Review.

A. The burden of proving an applicant's qualifications rests on the applicant.

B. The Commission may deny an application that contains a misstatement, omission, misrepresentation, or untruth.

C. An application shall be complete in every material detail.

D. The Commission may request any additional information the Commission determines is necessary to process and fully investigate an application.

E. The applicant shall provide requested additional information by the close of business of the 14th business day after the request has been received by the applicant.

F. If the applicant does not provide the requested information within 14 business days, the Commission may consider the application to be suspended.

G. The Commission intends to award the licenses to the best applications that most efficiently and effectively ensure public safety and safe access to medical cannabis and medical cannabis-infused products.

H. The Commission shall provide guidelines and detailed instructions for submitting the application form for the Commission's consideration.

I. The Commission, or a Commission independent contractor, shall review for a pre-approval for a license the submitted applications as described in Regulations .02B and .04E of this chapter. The applications shall be ranked based on the following weighted criteria:

(1) Operational Factors will be afforded 20 percent weight, including:

(a) A detailed operational plan for the production of medical cannabis extracts and medical cannabis-infused products; and

(b) Summaries of policies and procedures for:

(i) Laboratory operations;

(ii) Processing; and

(iii) Packaging;

(2) Safety and Security factors will be afforded 20 percent weight, including:

(a) Detailed plan or information describing the security features and procedures;

(b) Detailed plan describing how the processor will prevent diversion; and

(c) Detailed plan describing safety procedures;

(3) Commercial laboratory, pharmaceutical manufacturing and consumer products production factors will be afforded 15 percent weight, including, experience, knowledge and training in:

(a) Chemical plant management;
(b) Pharmaceutical manufacturing; and
(c) Consumer product production;
(4) Production control factors will be afforded 15 percent weight, including:
(a) A detailed quality control plan;
(b) A detailed inventory control plan; and
(c) A detailed medical cannabis waste disposal plan;
(5) Business and economic factors will be afforded 15 percent weight, including:
(a) A business plan:
(i) Demonstrating a likelihood of success;
(ii) Demonstrating a sufficient business ability and experience on the part of the applicant; and
(iii) Providing for appropiate employee working conditions, benefits, and training;
(b) Demonstration of adequate capitalization;
(c) A detailed plan evidencing how the processor will enforce the alcohol and drug free workplace policy;
(6) Additional factors that will be afforded 15 percent weight, including:
(a) Demonstrated Maryland residency among the owners and investors;
(b) Evidence that applicant is not in arrears regarding any tax obligation in Maryland and other jurisdictions;
(c) A detailed plan evidencing how the processor will distribute to dispensaries; and,
(d) A list of proposed medical cannabis extracts and medical cannabis-infused products proposed to be produced with proposed cannabinoid profiles, including:
(i) Varieties with high cannabidiol content; and
(ii) Whether the product has any demonstrated success in alleviating symptoms of specific diseases or conditions.

.05 Pre-Approval of License Application.

A. The Commission shall pre-approve a number of licenses for licensed processors sufficient to supply the demand for medical cannabis concentrates and medical cannabis-infused products in a range of routes of administration desired by qualifying patients.

B. If there are more qualified applications than the number of licenses available and there is a numerical tie for the last license to be issued, the last pre-approved license shall be determined by public lottery.

C. The Commission may deny issuing a pre-approval of a license if, for any individual identified in the application specified in COMAR 10.62.19.02B(1) and (2) of this chapter:
(1) The criminal history record information or background information demonstrates an absence of good moral character; or
(2) The payment of taxes due in any jurisdiction is in arrears.

D. Within 10 business days of the Commission's decision, the Commission shall notify applicants who have been pre-approved for a license.

E. The Commission may rescind pre-approval of a processor license if the processor is not operational within 1 year of pre-approval.

.06 Issuance of License.

A. After an applicant has been issued a pre-approval for a license under this chapter, the applicant shall submit to the Commission, as part of its application:
(1) An audited financial statement for the applicant and for each individual, partnership, corporation, or other entity review that has invested, or is proposed to invest, 5 percent or more of the capital of the applicant; and
(2) Payment of the stage 2 application fee specified in COMAR 10.62.35.

B. The Commission may issue a license to be a licensed processor on a determination that:
(1) The criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;
(2) All inspections are passed and all of the applicant's operations conform to the specifications of the application as pre-approved pursuant to Regulation .05 of this chapter;
(3) The proposed premises:
(a) Are under the legal control of the applicant;
(b) Comply with all zoning and planning requirements; and
(c) Conform to the specifications of the application as pre-approved pursuant to Regulation .07 of this chapter; and
(4) The first year's license fee specified in COMAR 10.62.35 has been paid.

.07 Change of Ownership of License.

A. No interest of 5 percent or more of a license issued pursuant to this chapter shall be assignable or transferable unless:
(1) The Commission has received notice in a manner determined by the Commission of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;

(2) The transferee has had forwarded the criminal history record information and audited financial statement to the Commission of the transferee;

(3) The Commission does not object to the transfer or assignment within 45 days of its receipt of notice; and

(4) The transferee has paid the required fee specified in COMAR 10.62.35.

B. The Commission may deny transfer of an interest in a license if, for any proposed transferee:

(1) The criminal history record information or the background investigation demonstrate an absence of good moral character; or

(2) The payment of taxes due in any jurisdiction is in arrears.

.08 Change of Location.

A. A licensee may apply to change the location of the licensee's operation.

B. The licensee shall submit an application to the Commission along with the fee specified in COMAR 10.62.35.

C. A licensee may not begin dispensing or processing medical cannabis at a new location until all inspections have been passed.

.09 Renewal of License.

A. A licensee is eligible to apply to renew a license every 2 years.

B. Ninety days before the expiration of a license, the Commission shall notify the licensee of the:

(1) Date on which the license expires;

(2) Process and the fee required to renew the license; and

(3) Consequences of a failure to renew the license.

C. At least 30 business days before a license expires a licensee shall submit:

(1) The renewal application as provided by the Commission;

(2) Proof that fingerprints have been submitted to CJIS and the FBI for every processor agent and investor of an interest of 5 percent or more;

(3) To full inspection of the operation, unless a full inspection was satisfactorily completed within 3 months before the date of the license expiration; and

(4) Payment of the fee specified in COMAR 10.62.35.

D. The Commission shall renew a license that meets the requirements for renewal as stated in §C of this regulation.

E. If the Commission does not renew a license due to a failed inspection or an inadequate application for renewal, the licensee may apply for reinstatement by:

(1) Submitting a plan to correct the deficiencies noted during an inspection; and

(2) Amending the application for renewal.

F. The Commission may decline to renew a license if:

(1) The plan to correct deficiencies identified in an inspection is deficient;

(2) The amended application for renewal is deficient; or

(3) The licensee has repeatedly failed inspections.

G. A licensee who fails to apply for renewal of a license by the date specified by the Commission, or whose license was not renewed by the Commission:

(1) Shall cease operations at all premises; and

(2) May not provide medical cannabis to any entity or person.

H. A license may be reinstated upon:

(1) Payment of the reinstatement fee specified in COMAR 10.62.35; and

(2) Submission of a reinstatement application approved by the Commission.

10.62.20 Medical Cannabis Processor Agent

Authority: Health General Article, §§13–3301, 13-3302, 13-3309 and 13–3310, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meaning indicated.

B. Terms Defined.

(1) "License" means a license issued by the Commission to operate as a licensed processor.

(2) "Licensee" means a licensed processor.

.02 Processor Agent Generally.

A processor agent shall be 21 years old or older.

.03 Processor Agent Registration and Criminal History Record.

A. A processor agent shall be registered with the Commission before the agent may volunteer or work for a licensee.

B. A licensee shall apply to register a processor agent by submitting to the Commission:

(1) The name, address, date of birth and Social Security Number of a processor agent;

(2) Documentation of the submission of fingerprints of the processor agent to the Central Registry; and

(3) The request for the criminal history record information of the processor agent to be forwarded to the Commission.

C. A prospective registered processor agent may not be registered by the Commission if the prospective registered processor agent has ever been convicted of a felony drug offense.

D. The Commission, after review of the criminal history record information, may disqualify any prospective registered processor agent from registration for an absence of good moral character.

.04 Registered Processor Agent Identification Cards.

A. The Commission shall issue to each registered processor agent a identification card that shall include a photograph of the face of the registered processor agent taken no more than 6 months before the date of the application.

B. At all times at the premises of a licensee every registered processor agent shall visibly wear the identification card issued to the registered processor agent by the Commission.

C. The identification card shall be renewed every 2 years.

D. If a registered processor agent's identification card is lost, destroyed or stolen, within 24 hours of becoming aware of the loss, destruction or theft, the licensee shall:

(1) Report the loss, destruction or theft to the Commission;

(2) Apply for a replacement card; and

(3) Pay a replacement card fee specified in COMAR 10.62.35.

E. An identification card remains the property of the Commission and the Commission may order the return or seizure of an identification card if the registration is revoked or expires.

F. If a registered processor agent's identification card is lost, destroyed, or stolen, a copy of notification to the Commission shall be evidence of registration until a new card is obtained from the Commission.

.05 Termination.

A. As soon as possible upon termination of a registered processor agent's association with a licensee, the licensee shall:

(1) Take custody of the terminated registered processor agent's identification card;

(2) Obtain any keys or other entry devices from the terminated registered processor agent; and

(3) Ensure the terminated registered processor agent can no longer gain access to the premises of the licensee.

B. Within 1 business day of the termination of a registered processor agent's association with a licensee, the licensee shall:

(1) Notify the commission in a manner to be determined by the Commission:

(a) Of the termination and the circumstances of a termination; and

(b) Whether the terminated registered processor agent has returned the agent's identification card; and

(2) Initiate delivery of the terminated registered processor agent's identification card to the Commission.

C. The Commission shall revoke a registration of a processor agent upon receiving notification that a processor agent is no longer associated with a licensee.

D. If a registered processor agent did not return the agent's identification card within 30 days, the Commission shall notify the Maryland State Police and place a notice in the register of that fact.

.06 Prospective Processor Agent Drug Screen.

A. The licensee shall require a prospective processor agent to submit to a drug screen before commencement of association.

B. The drug screen shall be carried out following the procedures set forth in COMAR 17.04.09.04—.08.

C. In addition to the drugs to be screened in accordance with COMAR 17.04.09.06, the screen shall include any other drugs as required by the Commission.

D. Unless medically justified, a prospective processor agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered by the Commission.

.07 Processor Agent Training.

A. The licensee shall train all registered processor agents on:

(1) Federal and State medical cannabis laws and regulations and other laws and regulations pertinent to the processor agent's responsibilities;

(2) Standard operating procedures;

(3) Detection and prevention of diversion of medical cannabis;

(4) Security procedures; and

(5) Safety procedures, including responding to;

(a) A medical emergency;

(b) A fire;

(c) A chemical spill; and

(d) A threatening event such as:

(i) An armed robbery;

(ii) An invasion;

(iii) A burglary; or

(iv) Any other criminal incident.

B. The licensee shall retain training materials and attendance records and make the training materials available for inspection by the Commission.

.08 Alcohol and Drug Free Workplace Policy.

A. A registered processor agent shall declare in writing that the registered processor agent shall adhere to the State alcohol and drug free workplace policy as identified in COMAR 21.11.08.03.

B. The licensee shall retain the declaration in the registered processor agent's personnel record.

.09 Annual Verification of Registered Processor Agents.

Every year, on a date determined by the Commission, the licensee shall notify the Commission that the licensee has verified that no registered processor agent has been convicted of a felony drug offense.

10.62.21 Medical Cannabis Processor Premises

Authority: Health General Article, §§13–3301, 13-3302 and 13–3309, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meaning indicated.

B. Terms Defined.

(1) "License" means a license issued by the Commission to operate as a processor.

(2) "Licensee" means a licensed processor.

.02 Premises Generally.

A. The premises of a licensee shall be located within Maryland.

B. The premises and operations of a licensee shall conform to all local zoning and planning requirements.

C. A processor license shall be displayed at each location where the licensee is authorized to operate.

D. No major renovation or modification shall be undertaken without notification to the Commission.

.03 Security of Premises.

The premises of a licensee shall be constructed to prevent unauthorized entry.

.04 Security Lighting.

Lighting fixtures of the licensee shall be designed and installed to ensure proper surveillance.

.05 Security Alarm Systems.

A. A licensee shall maintain a security alarm system that covers all perimeter entry points and windows at all premises.

B. The security alarm system shall be:

(1) Continuously monitored;

(2) Capable of detecting smoke and fire;

(3) Capable of detecting power loss.

C. The security alarm system shall include panic alarm devices mounted at convenient, readily-accessible locations throughout the licensed premises.

D. A second, independent alarm system shall be used to protect:

(1) The location where records are stored on-site;

(2) The location where records are stored off-site; and

(3) Any room that holds medical cannabis.

E. The security alarm system shall remain operational until the premises of the licensee no longer have any medical cannabis on the premises.

F. All security alarm systems shall be equipped with auxiliary power sufficient to maintain operation for at least 48 hours.

.06 Video Surveillance Requirements.

A. A licensee shall maintain a motion activated video surveillance recording system at all premises that:

(1) Records all activity in images of high quality and high resolution capable of clearly revealing facial detail;

(2) Operates 24-hours a day, 365 days a year without interruption; and

(3) Provides a date and time stamp for every recorded frame.

B. A licensee shall post appropriate notices advising visitors of the video surveillance.

C. A surveillance camera shall be located and operated to capture activity at each exit from the premises.

D. A surveillance camera shall capture activity at each entrance to an area where medical cannabis is processed, tested, packaged, and stored.

E. A recording of all images captured by each surveillance camera shall be kept at:

(1) The licensed premises; and

(2) An off-site location.

F. Recordings of security video surveillance shall be:

(1) Access-limited;
(2) Secured by a security alarm system that is independent of the main premises security alarm system;
(3) In a format that can be easily accessed for investigational purposes; and
(4) Retained for a minimum of 30 calendar days.

G. Any recording of security video surveillance shall be made available to the Commission or law enforcement agency for just cause as requested.

.07 Visitor to the Premises.

A. When a visitor is admitted to a non-public area of the premises of a licensee, a registered processor agent shall:
(1) Log the visitor in and out;
(2) Retain with the log a photocopy of the visitor's government-issued identification;
(3) Continuously visually supervise the visitor while on the premises; and
(4) Ensure that the visitor does not touch any plant or medical cannabis.

B. The licensee shall maintain a log of all visitors to non-public areas for 2 years.

10.62.22 Medical Cannabis Processor Operations

Authority: Health General Article, §§13–3301, 13-3302, 13-3306(b) and (e), 13-3307(f), 13-3309 and 13-3311(c), Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meaning indicated.

B. Term Defined.
(1) "Licensee" means a licensed processor.
(2) "Processor supervisor" means the registered processor agent designated by the licensed processor to supervise processor operations.
(3) "Receiving licensee" means the licensee that receives the shipment.
(4) "Shipping licensee" means the licensee that initiates the shipment.

.02 Standard Operating Procedures.

A. A licensee shall:
(1) Establish standard operating procedures for all aspects of the receipt, processing, storage, packaging, labeling, handling, tracking and shipping of products containing cannabis and medical cannabis waste;
(2) Create and use a perpetual inventory control system that identifies and tracks the licensee's stock of medical cannabis from the time it is delivered or produced to the time it is delivered to another licensee, a licensed grower, or a qualifying patient or caregiver; and
(3) Train each registered processor agent in the standard operating procedureand retain attendance records.

B. A copy of the standard operating procedure shall be readily available on site for inspection by the Commission.

.03 Receipt of Products Containing Cannabis.

A. A licensee may not:
(1) Acquire medical cannabis from an individual or entity in Maryland other than a licensee;
(2) Acquire medical cannabis from outside of Maryland unless authorized by the Commission; or
(3) Transport medical cannabis to any place outside of Maryland.

B. A receiving licensee shall detail in the standard operating procedure the steps set forth in §C, D and H of this regulation, or their equivalent, and a shipping licensee shall detail in its standard operating procedure the steps set forth in §C—H of this regulation, or their equivalent, to assure:
(1) The integrity of the shipment of products containing cannabis;
(2) The integrity of the electronic manifest and inventory control system; and
(3) The quality of the products in the shipment.

C. Upon arrival of a medical cannabis transport vehicle, the transportation agent shall notify an appropriate registered processor agent to continue the chain of custody of the shipment of products containing cannabis.

D. An agent of the receiving licensee shall:
(1) Log into the electronic manifest;
(2) Take custody of a shipment of products containing cannabis;
(3) Confirm that:
(a) The transportation agent is carrying appropriate identification;
(b) The packaging is secure, undamaged, and appropriately labeled;
(c) Each package in the shipment is labeled as described in the electronic manifest; and
(d) The contents of the shipment are as described in the electronic manifest;
(4) Record the confirmations in the electronic manifest;
(5) Obtain in the electronic manifest the signature or identification number of the transportation agent who delivers the shipment;
(6) Record in the electronic manifest the date and time the receiving agent takes custody of the shipment;
(7) Enter the products containing cannabis into the inventory control system;

(8) Segregate the items in the shipment from the inventory until the item can be inspected;

(9) Inspect each item to ensure that the packaging of each item is undamaged, accurate and complete; and

(10) Upon determining the item passes inspection, release the item into the stock.

E. The transportation agent shall provide a copy of the electronic manifest for the shipment to the receiving licensee.

F. The transportation agent shall provide the completed electronic manifest to the shipping licensee.

G. The shipping licensee shall retain the electronic manifest for the shipment for 5 years.

H. Discrepancy in the Shipment.

(1) A discrepancy between the electronic manifest and the shipment, identified by either a transportation agent or a receiving agent, shall be reported by each agent to each agent's supervisor.

(2) If a discrepancy can be immediately rectified, the accepting processor supervisor shall record the rectification in the electronic manifest.

(3) A discrepancy that cannot be immediately rectified shall be reported to the Commission by the receiving licensee within 24 hours of the observation of the discrepancy and an investigation of the discrepancy shall be initiated by the shipping licensee.

(4) The shipping licensee shall submit to the Commission:

(a) Within 7 business days of the observation of the discrepancy, a preliminary report of an investigation of a discrepancy; and

(b) Within 30 business days a final report of the investigation.

.04 Sanitary Storage of Medical Cannabis.

A. A licensee's standard operating procedure shall provide for maintaining the cleanliness of any building or equipment used to store or display medical cannabis.

B. A licensee shall have a standard operating procedure to:

(1) Maintain the medical cannabis free from contamination; and

(2) Require a processor agent to report any personal health condition that might compromise the cleanliness or quality of the medical cannabis the processor agent might handle.

C. A licensee's standard operating procedure shall provide for disposal and segregated storage of any medical cannabis:

(1) That is outdated, damaged, deteriorated, misbranded, or adulterated; or

(2) Whose containers or packages have been improperly or accidentally opened.

.05 Equipment Sanitation, Accuracy and Maintenance Logs.

A. A licensee's standard operating procedure shall provide for maintaining the sanitation of equipment that comes in contact with medical cannabis.

B. The licensee shall ensure that:

(1) Automatic, mechanical, or electronic equipment is routinely calibrated and periodically checked to ensure proper performance; and

(2) Any scale, balance, or other measurement device is routinely calibrated and periodically checked to ensure accuracy.

C. The licensee shall maintain an accurate log recording the:

(1) Cleaning of equipment;

(2) The maintenance of equipment; and

(3) The calibration of equipment.

.06 Report of Products Offered for Distribution.

A licensee shall submit to the Commission at the end of the month following each calendar quarter a list of the products and the products' specifications that the licensee offered for distribution in the previous calendar quarter.

10.62.23 Medical Cannabis Concentrates and Medical Cannabis-Infused Products

Authority: Health General Article, §§13-3301, 13-3302, 13-3309, and 13-3311, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "License" means a license issued by the Commission to operate as a processor.

(2) "Licensee" means a licensed processor.

(3) "Tincture" means a cannabis-infused solution derived either directly from the cannabis plant or from a processed cannabis extract and typicallly combined with alcohol, glycerin, or vegetable oils.

.02 Controls for Processing of Medical cannabis Concentrates and Medical cannabis-Infused Products.

A. A licensed processor of medical cannabis concentrates and medical cannabis-infused products shall:

(1) Develop standard operating procedures, good manufacturing practices, and a training plan before producing medical cannabis concentrates and medical cannabis-infused products;

(2) Require that any person involved in processing medical cannabis concentrates and medical cannabis-infused products is:

(a) Appropriately trained in accordance to their job description to safely operate and maintain the system used for processing and attendance records are retained;

(b) Has direct access to applicable material safety sheets and labels; and

(c) Follows OSHA protocols for handling and storage of all chemicals;

(3) Assign a unique lot number to each lot of medical cannabis concentrate or medical cannabis-infused product; and

(4) Carry out a validation process on the first 10 lots of any new medical cannabis concentrate, medical cannabis-infused product, or process, to establish the validity of the production process.

B. A processor shall establish a standard operating procedure for the methods, equipment, solvents, and gases when processing medical cannabis concentrates and medical cannabis-infused products.

C. If a licensee uses a solvent-based extraction method the solvents shall be at least 99 percent pure.

D. A standard operating procedure of a licensed processor shall require:

(1) Use of solvents in a professional grade, closed-loop extraction system designed to recover the solvents;

(2) Work in a spark-free environment with proper ventilation; and

(3) Following all applicable OSHA regulations, and local fire, safety and building codes in the processing and storage of the solvents.

E. If a licensee uses carbon dioxide gas extraction the standard operating procedure shall require:

(1) Every vessel be rated to a minimum of 900 pounds per square inch;

(2) Use a professional grade, closed-loop system;

(3) Follow all applicable OSHA regulations, and local fire, safety and building codes in the processing and the storage of the solvents; and

(4) Use carbon dioxide that is at least 99 percent pure.

F. A licensed processor may use heat, screens, presses, steam distillation, ice water, and other methods to produce medical cannabis concentrates.

.03 Independent Testing Laboratory Selection and Responsibility.

Upon successful completion of a validation process, the licensee shall use an independent testing laboratory:

A. That has adopted a standard operating procedure to test medical cannabis and medical cannabis concentrate that is approved by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;

B. To have an agent of the independent testing laboratory obtain samples according to a statistically valid sampling method for each lot;

C. To analyze the samples according to

(1) The most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP); or

(2) A scientifically valid methodology that is equal or superior to that of the AHP monograph;

D. In the event of a test result which falls out of specification, the laboratory shall follow their standard operating procedure to confirm or refute the original result;

E. To destroy the remains of the sample of medical cannabis after analysis is completed; and

F. To destroy the remains of the sample of medical cannabis after analysis is completed.

.04 Contents of Certificate of Analysis.

A. An independent testing laboratory shall issue a certificate of analysis for each lot, with supporting data, to report:

(1). Whether the chemical profile of the lot conforms to the specifications for the lot for the following compounds:

(a) Δ9-Tetrahydrocannabinol (THC);

(b) Tetrahydrocannabinolic Acid (THCA);

(c) Cannabidiol (CBD);

(d) Cannabidiolic Acid (CBDA);

(e) The terpenes described in the most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP);

(f) Cannabigerol (CBG); and

(g) Cannabinol (CBN); and

(2) That the presence of the following contaminants do not exceed the levels as required by the AHP monograph:

(a) Any residual solvent or processing chemicals;

(b) Foreign material such as hair, insects, or any similar or related adulterant;

(c) Any microbiological impurity, including:

(i) Total aerobic microbial count (TAMC);

(ii) Total yeast mold count (TYMC);

(iii) P. aeruginosa;

(iv) Aspergillus spp.;

(v) S. aureus;
(vi) Aflatoxin B1, B2, G1, and G2; and
(vii) Ochratoxin A.; and
(d) Whether the batch is within specification for:
(i) Odor; and
(ii) Appearance.
B. Residual levels of volatile organic compounds (VOCs) shall be below the specifications as set by the United States Pharmacoepia (USP Chapter 467).

.05 Licensed Processor Determination That a Lot May be Released.
A. If a licensed processor, upon review of the certificate of analysis, determines that a lot meets the specification for the product, the licensed processor may:
(1) Assign an expiration date to the lot;
(2) Release the lot for distribution; and
(3) Revise the status of the lot in the inventory control.
B. If a licensed processor receives test results that the lot does not meet specifications, the licensed processor may rework or reprocess the lot according to their standard operating procedure.
C. The reworked or reprocessed lot shall be resampled and retested by the independent testing laboratory to meet all required specifications.
D. A licensee shall retain every certificate of analysis.

.06 Stability Testing and Retention Sampling.
A. A licensee shall provide a sample from each released lot to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to:
(1) Ensure product potency and purity; and
(2) Provide support for expiration dating.
B. A licensee shall retain a sample from each released lot:
(1) Sufficient to provide for follow-up testing if necessary; and
(2) Properly store the sample for 1 year past the date of expiration of the lot.

.07 Report of Products Offered for Distribution.
A licensee shall submit to the Commission within 30 days following the end of a quarter a list of the products and the products' specifications that the licensee offered for distribution in the quarter.

10.62.24 Medical Cannabis Finished Products Packaging

Authority: Health General Article, §§13-3301, 13-3302, 13-3307, and 13-3309, Annotated Code of Maryland

.01 Packaging of Medical Cannabis Finished Product.
A. All items shall be individually packaged at the original point of processing.
B. Packaging Requirements. A package of medical cannabis finished product shall:
(1) Be plain;
(2) Be opaque;
(3) Be tamper-evident, and if applicable or appropriate, child-resistant;
(4) Bear a finished-product lot number and an expiration date;
(5) Bear a clear warning that:
(a) The contents may be lawfully consumed only by a qualifying patient named on an attached label;
(b) It is a illegal for any person to possess or consume the contents of the package other than the qualifying patient; and
(c) It is a illegal to transfer the package or contents to any person other than a transfer by a caregiver to a qualifying patient;
(6) Bear a clear warning to keep the package and its contents away from children other than a qualifying patient;
(7) Bear the Maryland Poison Control Center emergency telephone number;
(8) Bear the name of the licensee that packaged the medical cannabis finished product and the telephone number of the licensee for reporting an adverse patient event;
(9) Bear any allergen warning required by law;
(10) Bear a listing of the non-medical cannabis ingredients;
(11) Bear an itemization, including weight, of all cannabinoid and terpene ingredients specified for the product, and concentrates of any cannabinoid of less than one percent shall be printed with a leading zero before the decimal point; and
(12) Leave space for a licensed dispensary to attach a personalized label for the qualifying patient.
C. Packaging Prohibitions. A package of medical cannabis finished product may not bear any:
(1) Resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;

(2) Statement, artwork or design that could reasonably mislead any person to believe that the package contains anything other a medical cannabis finished product;

(3) Seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed, manufactured, or used by any State, county or municipality or any agency thereof; and

(4) Cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

10.62.25 Medical Cannabis Dispensary License

Authority: Health General Article, §§13–3301, 13-3302 and 13–3307, Annotated Code of Maryland

.01 Definitions.

A. In this chapter the following terms have the meanings indicated.

B. Terms Defined.

(1) "Audited financial statement" means an audited financial statement that is performed by a certified public accountant licensed or with practice privileges in Business Occupations and Professions Article, Title 2, Annotated Code of Maryland, that is prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants and in the case of a publicly owned corporation in conformity with the standards of the Public Company Oversight Board.

(2) "License" means a license issued by the Commission to operate as a licensed dispensary.

(3) "Licensee" means a licensed dispensary.

.02 Application.

A. An applicant shall submit to the Commission a application for a license for each Senatorial district in which it is competing for a license.

B. An application on a form developed by the Commission shall be completed and submitted to the Commission for consideration. In addition to the application form, the applicant shall submit the following documents to be included as addenda to the application form:

(1) A list identifying the applicant's potential dispensary agents;

(2) A list identifying each individual investor with 5 percent or more of investment known at the time of application;

(3) A detailed business plan including an organizational chart;

(4) Documentation and source of adequate capitalization;

(5) If the applicant is a corporation, a copy of the articles of incorporation and authorization to do business in Maryland;

(6) Evidence that no tax obligation is in arrears in any jurisdiction on the part of the applicant and any investor with 5 percent or more of investment known at the time of application;

(7) A description of the proposed premises, including a preliminary site plan;

(8) A security plan;

(9) A plan for quality control;

(10) A plan for inventorying, safekeeping and tracking medical cannabis from entry into inventory to sale or disposal of medical cannabis waste;

(11) A plan for the disposal of medical cannabis waste;

(12) A plan for training employees and volunteers;

(13) A plain for counseling qualifying patients and caregivers in the use of medical cannabis; and

(14) A plan of the medical cannabis and medical cannabis-infused products proposed to be dispensed with the proposed cannabinoid profiles.

C. The application shall be accompanied by the stage 1 application fee specified in COMAR 10.62.35.

D. An applicant shall amend an application within 3 business days to include the name and documentation of a request to forward the criminal history record information and audited financial statement to the Commission of a new individual investor of an interest of 5 percent or more, or another manager or director of the entity, even after a license is issued.

E. Any party applying for a license shall have an interest in only one license.

.03 Criminal History Record Request.

For each individual identified in the application specified in Regulation .02B(1) and (2) of this chapter, an applicant shall provide to the Director of the Central Repository:

A. Two sets of legible fingerprints taken in a format approved by the Director of CJIS and the Director of the FBI and the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records for each dispensary agent and investor identified in the application; and

B. A request that the individual's state and national criminal history record information be forwarded to the Commission.

.04 Consent for Investigation.

A. An individual who is required to provide personal and background information under this chapter shall provide a statement that irrevocably gives consent to the Commission and persons authorized by the Commission to:

(1) Verify all information provided in the application documents; and

(2) Conduct a background investigation of the individual.

B. An applicant shall waive any contractual, statutory, or common law obligation of confidentiality and authorize any government agency in any jurisiction to release to and provide access to the Commission of any and all information the applicant has provided to any other jurisdiction while seeking a cannabis-related license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the applicant.

C. An applicant shall release all financial institutions, fiduciaries, and other parties from any contractual, statutory or common law obligation of confidentiality to provide financial, personal and background information to the Commission relevant to the applicant's capacity to manage a licensed dispensary and the applicant's good moral character.

.05 Application Review.

A. The burden of proving an applicant's qualifications rests on the applicant.

B. The Commission may deny an application that contains a misstatement, omission, misrepresentation, or untruth.

C. An application shall be complete in every material detail.

D. The Commission may request any additional information the Commission determines is necessary to process and fully investigate an application.

E. The applicant shall provide requested additional information by the close of business of the 14th business day after the request has been received by the applicant.

F. If the applicant does not provide the requested information within 14 business days, the Commission may consider the application to be suspended.

G. The Commission intends to award the licenses to the best applications that most efficiently and effectively ensure public safety and safe access to medical cannabis and medical cannabis-infused products.

H. The Commission shall provide guidelines and detailed instructions for submitting the application form for the Commission's consideration.

I. The Commission, or a Commission independent contractor, shall review for a pre-approval for a license the submitted applications, as described in Regulations .02B and .05E of this chapter, for each Senatorial district. The applications shall be ranked based on the following weighted criteria:

(1) Operational factors will be afforded 20 percent weight, including:

(a) A detailed operational plan for the dispensing of medical cannabis extracts and medical cannabis-infused products; and

(b) Summaries of policies and procedures for:

(i) Counseling and educating patients and caregivers;

(ii) Packaging; and

(iii) Labeling;

(2) Safety and security factors will be afforded 20 percent weight, including:

(a) Detailed plan or information describing the security features and procedures;

(b) Detailed plan describing how the dispensary will prevent diversion; and

(c) Detailed plan describing safety procedures;

(3) Medical cannabis professionalism factors will be afforded 15 percent weight, including:

(a) Experience, knowledge and training in training dispensary agents in the science and use of medical cannabis; and

(b) Use of a clinical director;

(4) Retail management factors will be afforded 15 percent weight, including:

(a) A detailed plan to preserve the quality of the medical cannabis;

(b) A plan to minimize any negative impact on the surrounding community and businesses;

(c) A detailed inventory control plan; and

(d) A detailed medical cannabis waste disposal plan;

(5) Business and economic factors will be afforded 15 percent weight, including:

(a) A business plan:

(i) Demonstrating a likelihood of success;

(ii) Demonstrating a sufficient business ability and experience on the part of the applicant; and

(iii) Providing for appropiate employee working conditions, benefits and training;

(b) Demonstration of adequate capitalization; and

(c) A detailed plan evidencing how the dispensary will enforce the alcohol and drug free workplace policy;

(6) Additional factors that will be afforded 15 percent weight, including:

(a) Demonstrated Maryland residency among the owners and investors;

(b) Evidence that applicant is not in arrears regarding any tax obligation in Maryland and other jurisdictions; and

(c) The medical cannabis extracts and medical cannabis-infused products proposed to be dispensed with proposed cannabinoid profiles, including varieties with high cannabidiol content, and the varieties of routes of administration.

J. An applicant that is ranked first or second in more than one senatorial district may elect to move to stage 2 of the application process in only one district.

K. In a Senatorial district in which the top ranking applicants chose not to move to phase 2, lesser ranked applicants will move up in rank.

.06 Pre-Approval of License Application.

A. Number of Pre-approvals. In consideration of the ranking of the applications in accordance with Regulation .05, the Commission may issue pre-approvals of up to two licensed dispensaries per Senatorial district, other than the number of licenced grower dispensary facilities located in the Senatorial district.

B. If there are more qualified applications than the number of licenses available and there is a numerical tie for the last license to be issued, the last pre-approved license shall be determined by public lottery.

C. The Commission may deny issuing a pre-approval of a license if, for any individual identified in the application specified in Regulation .02B(1) and (2) of this chapter:

(1) The criminal history record information or background information demonstrate an absence of good moral character; or

(2) The payment of taxes due in any jurisdiction is in arrears.

D. Within 10 business days of the Commission's decision, the Commission shall notify applicants who have been pre-approved for a license.

E. The Commission may rescind pre-approval of a dispensary license if the dispensary is not operational within 1 year of pre-approval.

.07 Issuance of License.

A. After an applicant has been issued a pre-approval for a license under this chapter the applicant shall submit to the Commission, as part of its application:

(1) An audited financial statement for the applicant and for each individual, partnership, corporation, or other entity review that has invested, or is proposed to invest, 5 percent or more of the capital of the applicant;

(2) Payment of the stage 2 application fee specified in COMAR 10.62.35.

B. The Commission may issue a dispensary license on a determination that:

(1) The criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;

(2) All inspections are passed and all of the applicant's operations conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter;

(3) The proposed premises:

(a) Are under the legal control of the applicant;

(b) Comply with all zoning and planning requirements; and

(c) Conform to the specifications of the application as pre-approved pursuant to Regulation .07 of this chapter; and

(4) The first year's license fee specified in COMAR 10.62.35 has been paid.

.08 Change of Ownership of License.

A. No interest of 5 percent or more of a license issued pursuant to this chapter shall be assignable or transferable unless:

(1) The Commission has received notice of the intent of the owner of the interest, or of the estate of the owner of the interest, to transfer or assign an interest in a license to another party;

(2) The transferee has had forwarded the criminal history record information and audited financial statement to the Commission of the transferee;

(3) The Commission does not object to the transfer or assignment within 45 days of its receipt of notice; and

(4) The transferee has paid the required fee specified in COMAR 10.62.35.

B. The Commission may deny transfer of an interest in a license if, for any proposed transferee:

(1) The criminal history record information or the background investigation demonstrate an absence of good moral character; or

(2) The payment of taxes due in any jurisdiction is in arrears.

.09 Change of Location.

A. A licensee may apply to change the location of the licensee's operation.

B. The licensee shall submit an application to the Commission along with the fee specified in COMAR 10.62.35.

C. A licensee may not begin dispensing medical cannabis at a new location until all inspections have been passed.

.10 Renewal of License.

A. A licensee is eligible to apply to renew a license every 2 years.

B. Ninety days before the expiration of a license, the Commission shall notify the licensee of the:

(1) Date on which the license expires;
(2) Process and the fee required to renew the license; and
(3) Consequences of a failure to renew the license.
C. At least 30 business days before a license expires a licensee shall submit:
(1) The renewal application as provided by the Commission;
(2) Proof that fingerprints have been submitted to CJIS and the FBI for every processor agent and investor of an interest of 5 percent or more;
(3) To full inspection of the operation, unless a full inspection was satisfactorily completed within 3 months before the date of the license expiration; and
(4) Payment of the fee specified in COMAR 10.62.35.
D. The Commission shall renew a license that meets the requirements for renewal as stated in §C of this regulation.
E. If the Commission does not renew a license due to a failed inspection or an inadequate application for renewal, the licensee may apply for reinstatement by:
(1) Submitting a plan to correct the deficiencies noted during an inspection; and
(2) Amending the application for renewal.
F. The Commission may decline to renew a license if:
(1) The plan to correct deficiencies identified in an inspection is deficient;
(2) The amended application for renewal is deficient; or
(3) The licensee has repeatedly failed inspections.
G. A licensee who fails to apply for renewal of a license by the date specified by the Commission, or whose license was not renewed by the Commission:
(1) Shall cease operations at all premises; and
(2) May not provide medical cannabis to any entity or person.
H. A license may be reinstated upon:
(1) Payment of the reinstatement fee specified in COMAR 10.62.35; and
(2) Submission of a reinstatement application approved by the Commission.

10.62.26 Registered Dispensary Agent

Authority: Health General Article, §§13–3301, 13-3302, 13-3307 and 13–3308, Annotated Code of Maryland

.01 Definitions.
A. In this chapter, the following terms have the meaning indicated.
B. Terms Defined.
(1) "License" means a license issued by the Commission to operate as a licensed dispensary.
(2) "Licensee" means a licensed dispensary.

.02 Dispensary Agent Generally.
A dispensary agent shall be 21 years old or older.

.03 Dispensary Agent Registration and Criminal History Record.
A. A dispensary agent shall be registered with the Commission before the agent may volunteer or work for a licensee.
B. A licensee shall apply to register a dispensary agent by submitting to the Commission:
(1) The name, address, date of birth and Social Security Number of a dispensary agent;
(2) Documentation of the submission of fingerprints of the dispensary agent to the Central Registry; and
(3) The request for the criminal history record information of the dispensary agent to be forwarded to the Commission.
C. A prospective registered dispensary agent may not be registered by the Commission if the prospective registered dispensary agent has ever been convicted of a felony drug offense.
D. The Commission, after review of the criminal history record information, may disqualify any prospective registered dispensary agent from registration for an absence of good moral character.

.04 Registered Dispensary Agent Identification Cards.
A. The Commission shall issue to each registered dispensary agent a identification card that shall include a photograph of the face of the registered dispensary agent taken no more than 6 months before the date of the application.
B. At all times at the premises of a licensee every registered dispensary agent shall visibly wear the identification card issued to the registered dispensary agent by the Commission.
C. The identification card shall be renewed every 2 years.
D. If a registered dispensary agent's identification card is lost, destroyed or stolen, within 24 hours of becoming aware of the loss, destruction or theft, the licensee shall:
(1) Report the loss, destruction or theft to a the Commission;
(2) Apply for a replacement card; and
(3) Pay a replacement card fee specified in COMAR 10.62.35.

E. An identification card remains the property of the Commission and the Commission may order the return or seizure of an identification card if the registration is revoked or expires.

F. If a registered dispensary agent's identification card is lost, destroyed, or stolen, a copy of notification to the Commission shall be evidence of registration until a new card is obtained from the Commission.

.05 Termination.

A. As soon as possible upon termination of a registered dispensary agent's association with a licensee, the licensee shall:

(1) Take custody of the terminated registered dispensary agent's identification card;

(2) Obtain any keys or other entry devices from the terminated registered dispensary agent; and

(3) Ensure the terminated registered dispensary agent can no longer gain access to the premises of the licensee.

B. Within 1 business day of the termination of a registered dispensary agent's association with a licensee, the licensee shall:

(1) Notify the Commission:

(a) Of the termination and the circumstances of a termination; and

(b) Whether the terminated registered dispensary agent has returned the agent's identification card; and

(2) Initiate delivery of the terminated registered dispensary agent's identification card to the Commission.

C. The Commission shall revoke a identification card of a dispensary agent upon receiving notification that a dispensary agent is no longer associated with a licensee.

D. If a registered dispensary agent did not return the agent's identification card within 30 days, the Commission shall notify the Maryland State Police and place a notice in the register of that fact.

.06 Prospective Dispensary Agent Drug Screen.

A. The licensee shall require a prospective dispensary agent to submit to a drug screen before commencement of association.

B. The drug screen shall be carried out following the procedures set forth in COMAR 17.04.09.04—.08.

C. In addition to the drugs to be be screened in accordance with the procedures set forth in COMAR 17.09.04-.08, the screen shall include any other drugs as required by the Commission.

D. Unless medically justified, a prospective dispensary agent who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 may not be registered by the Commission.

.07 Registered Dispensary Agent Training.

A. The licensee shall train all registered dispensary agents on:

(1) Federal and State medical cannabis laws and regulations and other laws and regulations pertinent to the dispensary agent's responsibilities;

(2) Standard operating procedures;

(3) Detection and prevention of diversion of medical cannabis;

(4) Security procedures; and

(5) Safety procedures, including responding to;

(a) A medical emergency;

(b) A fire;

(c) A chemical spill; and

(d) A threatening event such as:

(i) An armed robbery;

(ii) An invasion;

(iii) A burglary; or

(iv) Any other criminal incident.

B. Every 12 months registered dispensary agents shall be educated on the most recent data regarding:

(1) The pharmacology of cannabis and its active components;

(2) The potential therapeutic and adverse effects of medical cannabis;

(3) Dosage forms of medical cannabis and their pharmacodynamic impact;

(4) Potential drug interactions and consumer safety issues with marijuana use; and

(5) Recognition of symptoms of substance use disorders and acute intoxication.

C. The licensee shall retain training materials and attendance records and make the training materials available for inspection by the Commission.

.08 Alcohol and Drug Free Workplace Policy.

A. A registered dispensary agent shall declare in writing that the registered dispensary agent shall adhere to the State alcohol and drug free workplace policy, as identified in COMAR 21.11.08.03.

B. The licensee shall retain the declaration in the registered dispensary agent's personnel record.

.09 Annual Verification of Registered Dispensary Agents.

Every year, on a date determined by the Commission, the licensee shall notify the Commission that the licensee has verified that no registered dispensary agent has been convicted of a felony drug offense.

10.62.27 Licensed Dispensary Premises

Authority: Health General Article, §§13–3301, 13-3302 and 13–3307, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meaning indicated.

B. Terms Defined.

(1) "License" means a license issued by the Commission to operate as a dispensary.

(2) "Licensee" means a licensed dispensary.

.02 Premises Generally.

A. The premises of a licensee shall be located within Maryland.

B. The premises of a licensed dispensary shall be separate from the premises of a licensed processor.

C. The dispensary license shall be displayed at the location where the licensee is authorized to operate.

D. The premises and operations of a licensee shall conform to all local zoning and planning requirements.

E. No major renovation or modification shall be undertaken without notification to the Commission.

.03 Security of Premises.

The premises of a licensee shall be constructed to prevent unauthorized entry.

.04 Secure Room.

A. A licensed dispensary shall contain a secure room to store the medical cannabis inventory.

B. The secure room:

(1) Shall be constructed of concrete or similar building material that prevents unauthorized entry;

(2) May not be placed adjacent to an exterior wall of the premises; and

(3) Shall have only one entrance door that:

(a) Meets commercial security standards;

(b) Is equipped with a cipher or chip-activated keyed lock or equivalent; and

(c) Is not visible from public areas of the premises.

C. Other than while the licensed dispensary is open for business and 1 hour before and 1 hour after, the inventory of medical cannabis shall be stored in the secure room.

.05 Security Lighting.

Lighting fixtures of the licensee shall be designed and installed to ensure proper surveillance.

.06 Security Alarm Systems.

A. A licensee shall maintain a security alarm system that covers all perimeter entry points, windows and portals at the premises.

B. The security alarm system shall be:

(1) Continuously monitored;

(2) Capable of detecting smoke and fire;

(3) Capable of detecting power loss.

C. The security alarm system shall include panic alarm devices mounted at convenient, readily-accessible locations throughout the licensed premises.

D. A second, independent alarm system shall be used to protect:

(1) The location where records are stored on-site;

(2) The location where records are stored off-site; and

(3) Any secure room that holds medical cannabis.

E. The security alarm system shall remain operational until the premises of the licensee no longer have any medical cannabis on the premises.

F. All security alarm systems shall be equipped with auxiliary power sufficient to maintain operation for at least 48 hours.

.07 Video Surveillance Requirements.

A. A licensee shall maintain a motion-activated video surveillance recording system at the premises that:

(1) Records all activity in images of high quality and high resolution capable of clearly revealing facial detail;

(2) Operates 24-hours a day, 365 days a year without interruption; and

(3) Provides a date and time stamp for every recorded frame.

B. A licensee shall post appropriate notices advising visitors of the video surveillance.

C. A surveillance camera shall be located and operated to capture activity at each exit from the premises.

D. A surveillance camera shall capture activity at each entrance to an area where medical cannabis is packaged, tested, processed, stored or dispensed.

E. A recording of all images captured by each surveillance camera shall be kept at:

(1) The licensed premises; and

(2) An off-site location.

F. Recordings of security video surveillance shall be:

(1) Access-limited;

(2) Secured by a security alarm system that is independent of the main premises security alarm system;

(3) In a format that can be easily accessed for investigational purposes; and

(4) Retained for a minimum of 30 calendar days.

G. Any recording of security video surveillance shall be made available to the Commission or law enforcement agency for just cause as requested.

.08 Licensed Dispensary Premises Organization.

A. A licensee shall divide the licensed dispensary premises between a public zone and an operations zone.

B. Public Zone.

(1) The public zone shall have:

(a) A waiting area open to the general public; and

(b) A service area in which a qualifying patient or caregiver may consult with a registered dispensary agent and receive medical cannabis.

(2) The licensed dispensary shall restrict entry into the service area to qualifying patients and caregivers.

(3) The licensed dispensary's hours of business shall be displayed at the entrance to the public zone.

C. Operations Zone.

(1) All operations other than consulting with qualifying patients and caregivers and dispensing medical cannabis shall be carried out in the operations zone.

(2) The operations zone shall be appropriately divided into separate areas for:

(a) Medical cannabis storage;

(b) Medical cannabis preparation and packaging;

(c) Use by dispensary agents for breaks; and

(d) Changing clothing and dispensary agent lockers.

(3) Tamper-evident logbooks or electronic identification logs shall document the movement of persons to and from the operations zone.

D. Appropriate signage shall clearly delineate the separate zones.

E. Doors and other access points between zones shall be secured.

F. Security alarms systems and video surveillance, as described in Regulations .06 and .07 of this chapter, shall be used to monitor the separation between zones.

G. All medical cannabis, other than that being displayed, being processed, or being dispensed during business hours, shall be kept in a secure room.

H. No individual other than a registered dispensary agent may handle the inventory in a display case or elsewhere in the dispensary until dispensed.

.09 Visitor to a Non-Public Area of the Premises.

A. When a visitor is admitted to a non-public area of the premises of a licensee, a registered dispensary agent shall:

(1) Log the visitor in and out;

(2) Retain with the log a photocopy of the visitor's government-issued identification;

(3) Continuously visually supervise the visitor while on the premises; and

(4) Ensure that the visitor does not touch any medical cannabis.

B. The licensee shall maintain a log of all visitors to non-public areas for 2 years.

10.62.28 Licensed Dispensary Operations

Authority: Health General Article, §§13–3301, 13-3302 and 13–3307, Annotated Code of Maryland

.01 Definitions.

A. In this chapter, the following terms have the meaning indicated.

B. Terms Defined.

(1) "Dispensary supervisor" means the registered dispensary agent designated by the licensed dispensary to supervise dispensary operations.

(2) "Licensee" means a licensed dispensary.

(3) "Receiving licensee" means the licensee that receives the shipment.

(4) "Shipping licensee" means the licensee that receives the shipment.

.02 Standard Operating Procedure.

A. A licensee shall:

(1) Establish a standard operating procedure for all aspects of the receipt, storage, packaging, labeling, handling, tracking and dispensing of products containing medical cannabis and medical cannabis waste;

(2) Create and use a perpetual inventory control system that identifies and tracks the licensee's stock of medical cannabis from the time it is delivered or produced to the time it is delivered to another licensee, a licensed grower, or a qualifying patient or caregiver; and

(3) Train each registered dispensary agent in the standard operating procedure and retain attendance records.

B. A copy of the standard operating procedure shall be readily available on site for inspection by the Commission.

.03 Receipt of Products Containing Cannabis.

A. A licensee or licensed grower that dispenses medical cannabis to patients may not:

(1) Acquire medical cannabis from an individual or entity in Maryland other than a licensee;

(2) Acquire medical cannabis from outside of Maryland unless authorized by the Commission; or

(3) Transport medical cannabis to any place outside of Maryland.

B. A receiving licensee shall detail in the standard operating procedure the steps set forth in §§C, D, and H of this regulation, or their equivalent, and a shipping licensee shall detail in its standard operating procedure the steps set forth in §C—H of this regulation, or their equivalent, to assure:

(1) The integrity of the shipment of products containing cannabis;

(2) The integrity of the electronic manifest and inventory control system; and

(3) The quality of the products in the shipment.

C. Upon arrival of a medical cannabis transport vehicle, the transportation agent shall notify an appropriate registered dispensary agent or registered grower agent to continue the chain of custody of the shipment of products containing cannabis.

D. An agent of the receiving licensee shall:

(1) Log into the electronic manifest;

(2) Take custody of a shipment of products containing cannabis;

(3) Confirm that:

(a) The transportation agent is carrying appropriate identification;

(b) The packaging is secure, undamaged, and appropriately labeled;

(c) Each package in the shipment is labeled as described in the electronic manifest; and

(d) The contents of the shipment are as described in the electronic manifest;

(4) Record the confirmations in the electronic manifest;

(5) Obtain in the electronic manifest the signature or the identification number of the transportation agent who delivers the shipment;

(6) Record in the electronic manifest the date and time the receiving agent takes custody of the shipment;

(7) Enter the products containing cannabis into the inventory control system;

(8) Segregate the items in the shipment from the inventory until the item can be inspected;

(9) Inspect each item to ensure that the packaging of each item is undamaged, accurate and complete; and

(10) Upon determining the item passes inspection, release the item into the inventory.

E. The transportation agent shall provide a copy of the electronic manifest for the shipment to the receiving licensee.

F. The transportation agent shall provide the completed electronic manifest to the shipping licensee.

G. The shipping licensee shall retain the electronic manifest for the shipment for 5 years.

H. Discrepancy in the Shipment.

(1) If the licensee finds evidence of a theft or diversion within 1 business day the licensee shall report the theft or diversion to the Commission and to the Maryland State Police.

(2) Within 30 business days of discovering the discrepancy, the licensee shall:

(a) Complete an investigation;

(b) Amend the licensee's standard operating procedures, if necessary; and

(c) Send a report of the investigation to the Commission.

(3) The shipping licensee shall submit to the Commission:

(a) Within 7 business days of the observation of the discrepancy, a preliminary report of an investigation of a discrepancy; and

(b) Within 30 business days a final report of the investigation.

.04 Sanitary Storage of Medical Cannabis.

A. A licensee shall maintain the cleanliness of any building or equipment used to store or display medical cannabis.

B. A registered dispensary agent shall:

(1) Comply with the standard operating procedure to maintain the medical cannabis free from contamination; and

(2) Report to a supervisor any personal health condition that might compromise the cleanliness or quality of the medical cannabis the dispensary agent might handle.

C. A licensee shall separately store in the secure room until disposed of any medical cannabis:

(1) That is outdated, damaged, deteriorated, misbranded, or adulterated; or

(2) Whose containers or packages have been improperly or accidentally opened.

.05 Equipment Sanitation, Accuracy and Maintenance Logs.

A. The licensee shall maintain the sanitation of equipment that comes in contact with medical cannabis to prevent contamination in accordance with the approved standard operating procedure.

B. Pursuant to the approved standard operating procedure, the licensee shall require that:

(1) Automatic, mechanical, or electronic equipment is routinely calibrated and periodically checked to ensure proper performance; and

(2) Any scale, balance, or other measurement device is routinely calibrated and periodically checked to ensure accuracy.

C. Pursuant to the approved standard operating procedure, the licensee shall maintain an accurate log recording the:

(1) Cleaning of equipment;

(2) The maintenance of equipment; and

(3) The calibration of equipment.

10.62.29 Licensed Dispensary Packaging and Labeling for Distribution

Authority: Health General Article, §§13–3301, 13-3302 and 13–3307, Annotated Code of Maryland

.01 Packaging Medical Cannabis for Distribution to a Qualifying Patient or Caregiver.

A. A licensed dispensary may only distribute medical cannabis in a package that complies with the requirements and restrictions of §B—F of this regulation.

B. Packaging Requirements. A package of medical cannabis for distribution to a qualifying patient or caregiver shall:

(1) Be plain;

(2) Be opaque;

(3) If appropriate or requested by a qualifying patient or caregiver, be child-resistant;

(4) Identify the licensee that produced the medical cannabis finished product or that grew the medical cannabis in the package;

(5) Bear a finished-product lot number and an expiration date;

(6) Bear a clear warning that:

(a) The contents may be lawfully consumed only by the qualifying patient named on the attached label;

(b) It is illegal for any person to possess or consume the contents of the package other than the qualifying patient; and

(c) It is illegal to transfer the package or contents to any person other than for a caregiver to transfer it to a qualifying patient;

(7) Bear a clear warning to keep the package and its contents away from children;

(8) Bear the Maryland Poison Control Center emergency telephone number;

(9) Bear the telephone number of the licensee to call to report an adverse patient event;

(10) If applicable, bear any allergen warning or nutrition labeling required by law;

(11) If applicable, bear a listing of the non-medical cannabis ingredients;

(12) Bear a conspicuous itemization, including weight, of all cannabinoid and terpene ingredients specified for the product; and

(13) Bear a personalized label for the qualifying patient.

C. Packaging Prohibitions. A package of medical cannabis for distribution to a qualifying patient or caregiver may not:

(1) Bear any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;

(2) Bear any statement, artwork or design that could reasonably mislead any person to believe that the package contains anything other an a medical cannabis finished product;

(3) Bear any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed, manufactured, or used by any State, county or municipality or any agency thereof; or

(4) Bear any cartoon, color scheme, image, graphic or feature that might make the package attractive to children.

D. Information printed on the package shall be in English, in letters at least one-sixteenth of an inch high.

E. If a statement of the presence of any cannabinoid is expressed as a percentage of the total weight of the contents and the concentration of the cannabinoid is less than 1 percent, the percentage shall be written with a leading zero before the decimal point.

F. At a licensed dispensary medical cannabis may only be prepared or re-packaged in an area of the operations zone designed, maintained, and used exclusively for such purposes.

.02 Label for Distribution to a Qualifying Patient.

A. A licensee shall print a label for a package of medical cannabis for a qualifying patient in English in letters no less than one-sixteenth of an inch high. If requested by a qualifying patient or caregiver, the licensee may also print a label in another language.

B. A licensee may not distribute a package of medical cannabis without a label securely attached.

C. A licensee shall state on a label of a package of medical cannabis:

(1) The name of the qualifying patient;

(2) The name of the certifying physician;
(3) The name of the licensee where the product was dispensed;
(4) The date that the medical cannabis was dispensed;
(5) The name of the product;
(6) The strength of applicable cannabinoid and terpene compounds:
(a) Displayed in units appropriate to the dosage form; and
(b) Concentrations of any cannabinoid of less than one percent shall be printed with a leading zero before the decimal point;
(7) The quantity of medical cannabis dispensed, displayed in units appropriate to the dosage form;
(8) Any directions for use of the product; and
(9) The instructions for proper storage or handling of the product.
D. Any other information required by the dispensary at its discretion may be provided in a patient insert.
E. The label may not:
(1) Contain any false or misleading statement or design; or
(2) Include any statement, image or design that may not be included on the package.

10.62.30 Dispensing Medical Cannabis

Authority: Health General Article, §§13–3301, 13-3302, 13-3307, 13-3313 and 13–3314, Annotated Code of Maryland

.01 Use of Written Certification.
A dispensary shall notify the Commission that a qualifying patient or caregiver has presented a written certification at that dispensary or has requested a delivery based upon a written certification.

.02 Visitor and Activity at a Licensed Dispensary.
A. In the service area of a licensed dispensary, a registered dispensary agent shall:
(1) Escort a member of the public; and
(2) Maintain visual contact at all times.
B. A licensed dispensary may not permit the consumption of medical cannabis at the licensed premises.

.03 Procedure for Dispensing Medical Cannabis.
A. A registered dispensary agent shall dispense medical cannabis only to a qualifying patient or caregiver who has presented a government-issued identification card.
B. Before any distribution of medical cannabis, a dispensary agent shall query the Commission data network and verify that:
(1) The qualifying patient or caregiver is currently registered;
(2) A certifying physician issued a valid written certification to the qualifying patient, and
(3) The amount of medical cannabis that has already been dispensed pursuant to the written certification.
C. A dispensary agent may provide information on:
(1) The available types of medical cannabis, cannabis varieties, and medical cannabis finished products;
(2) Methods by which medical cannabis can be taken; and
(3) How unused cannabis may be returned for disposal.
D. 30-day Supply.
(1) A qualifying patient or caregiver may obtain a portion of a 30-day supply at any time once the written certification is presented to a licensed dispensary, provided the portion being sought when added to portions previously obtained does not exceed a 30-day supply.
(2) The dispensary agent shall enter the weight of usable cannabis or the weight of Δ9-Tetrahydrocannabinol (THC) dispensed in the Commission data network.
E. A registered dispensary agent may decline to dispense medical cannabis to a qualifying patient or caregiver if, in the professional opinion of the registered dispensary agent, the patient or caregiver appears to be currently under the influence of drugs or alcohol.
F. A licensed dispensary may not distribute a sample of medical cannabis.
G. If not used to purchase medical cannabis within 120 days of issuance, a written certification becomes null and void.

.04 Delivery of Medical Cannabis to a Qualifying Patient or Caregiver.
A. A qualifying patient or caregiver shall first telephone a registered dispensary to request the delivery of medical cannabis:
(1) The qualifying patient or caregiver shall provide identification that a dispensary agent can verify by means established by the Commission; and
(2) The qualifying patient or caregiver shall also provide a complete and verifiable delivery address.
B. During the telephone conversation with the qualifying patient or caregiver, a registered dispensary agent may provide information on:
(1) The available types of medical cannabis, cannabis varieties, and medical cannabis finished products:
(2) Methods by which medical cannabis can be used; and

(3) How unused cannabis may be returned for disposal.

C. Before any delivery of medical cannabis, a dispensary agent shall query the Commission data network and verify that:

(1) The qualifying patient or caregiver is currently registered;

(2) A certifying physician issued a valid written certification to the qualified patient; and

(3) The amount of medical cannabis requested does not exceed the 30-day supply;

D. 30-Day Supply.

(1) A qualifying patient or caregiver may obtain by delivery a portion of a 30-day supply at any time once the written certification is presented to a licensed dispensary, provided the portion being sought for delivery when added to portions previously obtained does not exceed a 30-day supply.

(2) The dispensary agent shall enter the weight dispensed in the Commission data network prior to delivery.

E. Only a qualified patient or caregiver may accept delivery of medical cannabis.

F. Only a registered dispensary agent may deliver medical cannabis.

.05 Attestation by Qualifying Patient or Caregiver.

A. Before medical cannabis is dispensed, either in person or by delivery, a qualifying patient or caregiver shall attest that the qualifying patient or caregiver understand that the qualifying patient and caregiver are not immune from the imposition of any civil, criminal, or other penalties for the following:

(1) Operating, navigating, or being in actual physical control of any motor vehicle, aircraft, or boat while under the influence of medical cannabis;

(2) Smoking medical cannabis in any public place;

(3) Smoking medical cannabis in a motor vehicle; or

(4) Undertaking any task under the influence of medical cannabis, when doing so would constitute negligence or professional malpractice;

(5) Smoking medical cannabis on a private property that:

(a) Is rented from a landlord; and

(b) Is subject to a policy that prohibits the smoking of medical cannabis or marijuana on the property; or

(6) Smoking medical cannabis on a private property that is subject to a policy that prohibits the smoking of medical cannabis on the property of an attached dwelling adopted by:

(a) The board of directors of the council of unit owners of a condominium regime; or

(b) The governing body of a homeowners association.

B. As used in §A(5) and (6) of this regulation, vaporization of medical cannabis is not smoking.

C. Before medical cannabis is dispensed, a qualifying patient or caregiver shall attest that the qualifying patient or caregiver understands that:

(1) The qualifying patient or caregiver shall:

(a) Keep all medical cannabis away from children other than the qualifying patient; and

(b) Take steps to prevent children from obtaining or using medical cannabis;

(2) It is illegal to transfer medical cannabis to any person, other than the transfer by a caregiver to a qualifying patient;

(3) Obtaining medical cannabis does not exempt a qualifying patient or caregiver from prosecution under Federal law and the penalties provided by Federal law;

(4) Scientific research has not established the safety of the use of medical cannabis by pregnant women; and

(5) The use of medical cannabis to treat a medical condition is not approved by the U.S. Food and Drug Administration.

.06 Dispensing Controls.

A. In cases of delivery, at the point of delivery a qualified patient or caregiver shall display identification to the delivering dispensary agent.

B. The qualifying patient or caregiver shall sign a receipt for the medical cannabis.

C. The dispensary agent and the qualifying patient or caregiver shall each retain a copy of the receipt.

D. A registered dispensary agent shall record in the inventory control and in the Commission data network each item dispensed including lot and batch number and the weight of medical cannabis that was dispensed.

.07 Limit on Transfer of Medical Cannabis.

A licensee or registered dispensary agent may not transfer any medical cannabis to any person if the licensee or registered dispensary agent knows, or may have reason to know, that the transfer or the medical cannabis does not comply with any provision of the Health – General Article, Title 13, Subtitle 33, Annotated Code of Maryland or this subtitle.

.08 Report of Products Offered for Distribution.

A licensee shall submit to the Commission on the last day of the month following each quarter a list of the products and the products' specifications that the licensee offered for distribution in the quarter.

.09 Disposal of Green Waste.

A licensee may either ship any medical cannabis that is surplus or out of date or that is waste from processing or repackaging:

A. To a licensed grower for disposal; or

B. Dispose of such material in accordance with the licensee's approved waste disposal plan.

10.62.31 Licensed Dispensary Clinical Director

Authority: Health General Article, §§13–3301, 13-3302, 13-3307 and 13–3314, Annotated Code of Maryland

.01 Clinical Director Responsibilities.

A licensed dispensary may appoint an individual who is a Maryland-licensed physician, nurse practitioner or pharmacist to function as clinical director.

10.62.32 Records

Authority: Health General Article, §§13-3301, 13-3302, 13-3306, 13-3309 and 13-3311, Annotated Code of Maryland

.01 Definition.

In this chapter, "Licensee" means a licensed grower, a licensed processor, and a licensed dispensary.

.02 Licensee Records.

A. A licensee shall maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution that contains:

(1) The name and address of the recipient;

(2) The quantity delivered; and

(3) The name, strength, batch number and lot number of the product.

B. Upon request, a licensee shall provide in a reasonable time and manner to a certifying physician a copy of the record of each distribution by the licensee to a qualifying patient of the certifying physician of the quantity delivered, name, strength, batch number and lot number of medical cannabis.

C. A licensee shall retain the records of production and distribution of each batch and lot and of daily checklists to maintain uniformity from batch to batch, and lot to lot.

D. A licensee shall maintain a record of test methods and test results for each batch and lot, including graphs, charts, or spectra from laboratory instrumentation.

E. A licensee shall maintain a log of individuals visiting each premises.

F. A licensee shall maintain a duplicate set of all records at a secure, off site location.

.03 Record Retention.

Unless otherwise specified, a licensee, or a certifying physician shall retain a record for a period of 5 years.

10.62.33 Inspection

Authority: Health General Article, §§13-3301, 13-3302 13-3306, 13-3307, 13-3309, and 13-3311, Annotated Code of Maryland

.01 Definition.

In this chapter, "Inspector" means any member of the Commission or any State employee or contractor designated by the Commission to carry out an inspection under this chapter.

.02 Consent to Inspection.

Submission of an application to be a licensed grower, licensed processor, or licensed dispensary, independent testing laboratory irrevocably gives the Commission consent to conduct all inspections necessary to ensure compliance with State law and regulations.

.03 Inspection of Applicants.

A. The Commission may inspect all premises of an applicant to be:

(1) A licensed grower;

(2) A licensed processor;

(3) A licensed dispensary; or

(4) A independent testing laboratory.

B. The Commission shall inspect all aspects of an applicant's operation to make a determination that the operation conforms to the terms of the application.

C. In the case of an inspection before the issuance of a license, the Commission shall arrange the inspection to take place at a mutually agreeable time.

.04 Announced and Unannounced Inspections.

A. The Commission may conduct announced and unannounced inspections of the facilities of licensed growers, licensed processors, licensed dispensaries, and independent testing laboratories subject to the Commission's regulation, mission, and function, to determine compliance with statute and regulations.

B. Failure by a licensed grower, licensed processor, licensed dispensary or registered independent testing laboratory to provide the Commission with immediate access to any part of a premises, requested material, information, or agent as part of an inspection may result in the imposition of a civil fine, suspension of license, or revocation of license.

C. During an inspection, the Commission may:

(1) Review and make copies of all records;

(2) Enter any place, including a vehicle, in which medical cannabis is held, dispensed, sold, produced, tested, delivered, transported, manufactured or otherwise disposed of;

(3) Inspect all equipment, raw and processed material, containers and labeling, and all things therein including:

(a) Records;

(b) Files;

(c) Financial data;

(d) Sales data;

(e) Shipping data;

(f) Pricing data;

(g) Employee data;

(h) Research;

(i) Papers;

(j) Processes;

(k) Controls; and

(l) Facilities;

(4) Inventory any medical cannabis;

(5) Inspect any equipment, instruments, tools or machinery used to process:

(a) Medical cannabis;

(b) Medical cannabis concentrate; or

(c) Medical cannabis-infused product; and

(6) Question personnel present at the location and any agent of the licensee.

.05 Sample Collection and Testing as Part of Inspection.

A. During an inspection, the Commission may obtain samples for testing of any:

(1) Cannabis;

(2) Medical cannabis concentrate;

(3) Medical cannabis-infused product;

(4) Media used to grow cannabis;

(5) Chemicals or solvents used to process medical cannabis concentrate;

(6) Labels or containers for cannabis;

(7) Paraphernalia;

(8) Any waste material; and

(9) Raw or processed material.

B. If the inspector has grounds to question the quality of any medical cannabis, the inspector may contract with an independent testing laboratory to analyze the samples for any deviation from specification questioned by the inspector.

C. Analysis of cannabis shall conform to the most current version of the cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP) or a scientifically valid methodology that is equal or superior to that of the AHP monograph.

D. Analysis of other materials shall conform to a scientifically valid methodology for the analysis of such material.

E. A written report of the testing under this regulation shall be provided to the inspector.

.06 Action Upon Findings in Inspection.

In the event that an inspector has reasonable suspicion of an operational failure or of conditions that create a likelihood of diversion, contamination, or a risk to the public health:

A. An inspector may:

(1) Suspend the distribution of some or all medical cannabis from the licensed or registered premises;

(2) Order immediate evacuation of the premises and seal the entry door; or

(3) Quarantine some or all medical cannabis;

B. The Commission shall undertake a review of the inspection findings and may:

(1) Request a recall of the medical cannabis;

(2) Request independent testing of affected medical cannabis;

(3) Approve a procedure to reprocess the medical cannabis;

(4) Notify the Maryland State Police if diversion is suspected; or

(5) Order the destruction of contaminated or substandard medical cannabis; and

C. The inspector or Commission may notify the local fire department or police department, or appropriate regulatory agency, regarding a risk to public health and safety.

.07 Receipt and Chain of Custody for Materials Removed.

The Commission shall leave a receipt and create a documented chain of custody for anything removed in the course of an inspection.

.08 Report of Inspection.

A. An inspector shall:

(1) Prepare a report of:

(a) The observations and findings of the inspection; and

(b) Any suggestions or demands for corrective action;

(2) Deliver a copy of the report to the inspected entity and obtain a receipt for the delivery; and

(3) If possible, discuss the inspection and inspection report with the licensee.

B. If an inspection report contains a suggestion or demand for corrective action, within 10 business days from the delivery of the report, the inspected entity shall:

(1) Respond in writing to every suggestion or demand for corrective action; and

(2) Set forth the plan for corrective action to be taken and the timetable for correction.

C. If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, or the risk to public health, an inspector may direct that the licensed premises may not distribute or participate in the distribution of any medical cannabis until the violation has been corrected and the premises pass re-inspection.

10.62.34 Discipline and Enforcement

Authority: Health General Article, § 13-3301, 13-3302, 13-3304, 13-3306, 13-3307, 13-3309, 13-3311 Annotated Code of Maryland

.01 Operational Failure Risking Diversion or Endangering Health.

In the event the Commission finds there is a reasonable likelihood of diversion, contamination of medical cannabis, or any risk to the health of a patient or any other individual, after written notice and a hearing in accordance with the State Government Article, §§10-201—10-226, Annotated Code of Maryland, the Commission may:

A. Impose a fine of up to $10,000 per violation on a licensed grower, licensed processor, licensed dispensary or registered independent testing laboratory;

B. Deny the license or registration;

C. Suspend the license, licensee, agent, employee, registration or registrant; or

D. Revoke the licenses, licensee, agent, employee, registration or registrant.

.02 Pattern of Deviation from Standard Operating Procedure.

In the event the Commission finds there is a pattern of deviations from standard operating procedures or the terms set forth in the application or the license but the pattern does not directly create a risk of endangering the health or safety of a patient, after written notice and a hearing in accordance with the State Government Article, §§10-201—10-226, Annotated Code of Maryland, the Commission may:

A. Impose a fine of up to $5,000 per violation on a licensed grower, licensed processor, licensed dispensary, or independent testing laboratory;

B. Deny the license or registration;

C. Suspend the license, registration, licensee, registrant, or agent; or

D. Revoke the license or registration.

.03 Violation of Requirements.

In the event the Commission finds that a licensee, registrant, agent or employee violated a requirement of this subtitle, after written notice and a hearing in accordance with the State Government Article, §§10-201—10-226, Annotated Code of Maryland, the Commission may:

A. Impose a fine of up to $5,000 per violation on a licensed grower, licensed processor, licensed dispensary or independent testing laboratory;

B. Suspend the license, registrant, licensee, registrant, employee or agent; or

C. Revoke the license or registration.

.04 Action Against a Physician.

A. After written notice and a hearing in accordance with the State Government Article, §§10-201—10-226, Annotated Code of Maryland, the Commission may deny a certifying physician's application for registration, or revoke registration to certify if the physician:

(1) Fraudulently applied for approval;

(2) Fraudulently issued a written certification; or

(3) Failed to comply with this chapter.

B. The Commission shall report to the Maryland Board of Physicians any instance of fraud or conduct that threatens public health by a certifying physician.

10.62.35 Fee Schedule

Authority: Health General Article, §§13-3301, 13-3302, 13-3303, 13-3304, 13-3306, 13-3307, 13-3309, and 13-3311, Annotated Code of Maryland

.01 Fees.

A. The following fees are established by the Commission:

(1) Grower fees:

(a) License as Grower-only:

(i) Application fee.....$6,000 (Stage 1: $2,000; Stage 2: $4,000);

(ii) Annual license fee.....$125,000;

(b) License as Grower and Dispensary:

(i) Application fee.....$11,000 (Stage 1: $3,000; Stage 2: $8,000);

(ii) Annual licensing fee.....$165,000;

(2) Grower agent fees:

(a) Registration fee.....$200;

(b) Replacement identification card fee.....$100;

(3) Licensed Processor fees:

(a) Application fee..... $6,000 (Stage 1: $2,000; Stage 2: $4,000);

(b) Annual license fee.....$40,000;

(4) Processor Agent fees:

(a) Registration fee..... $200;

(b) Replacement identification card fee…….$100;

(5) Licensed Dispensary fees;

(a) Application fee…. $5,000 (Stage 1: $1,000; Stage 2: $4,000);

(b) Annual license fee…..$40,000;

(6) Dispensary agent fees:

(a) Registration fee.....$200;

(b) Replacement identification card fee.....$100;

(7) Qualifying patient and caregiver fees:

(a) Identification card base fee.....$50;

(b) Replacement identification card fee.....$100;

(8) Independent Testing Laboratory fees:

(a) Registration fee……$100;

(b) Renewal fee……..$100;

(9) Independent Testing Laboratory Employee fees:

(a) Registration fee…$200;

(b) Replacement identification card fee…..$100;

(10) Miscellaneous fees:

(a) Transfer of ownership of grower license, processor or dispensary license.....$7,000;

(b) Change in the location of grower, processor or dispensary premises.....$7,000; and

(c) License reinstatement fee……$2,000.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene

FEE JUSTIFICATION FOR
PROPOSED COMAR 10.62.01-10.62.35

(1) Explain/justify why an increase or decrease is necessary:

The fees being proposed are projected to support the cost of running the medical cannabis program in the State.

(2) How much money is needed to operate effectively or to eliminate an operating fund deficit?

Approximately $2.5 – 3 million is needed to run the program and develop and maintain IT structure and databases.

(3) In what year was the most recent fee increase?

N/A. This is a new program.

(4) Is the fee revenue retained by the Proposing Unit or passed through to a national organization that administers a uniform licensing exam?

Retained by the Proposing Unit

(5) Describe any measures taken to mitigate the need for increased revenue:

N/A

(6) Describe any special circumstances that have had an adverse impact on the Proposing Unit's operating expenses.

N/A

(7) Describe any consideration given by the Proposing Unit as to the hardship a fee increase may have on the regulated profession.

N/A. These fees are needed to start and run the program.

(8) Describe any efforts to solicit the opinions of licensees regarding the Proposing Unit's effectiveness and performance.

The Commission is not fully operational at this point.