

MARYLAND REGISTER

**Proposed Action on Regulations**

<b>Transmittal Sheet</b>  <b>PROPOSED OR REPROPOSED</b>  <b>Actions on Regulations</b>	<b>Date Filed with AELR Committee</b>	<b>TO BE COMPLETED BY DSD</b>
	09/06/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

**1. Desired date of publication in Maryland Register: 10/14/2016**

**2. COMAR Codification**

<b>Title</b>	<b>Subtitle</b>	<b>Chapter</b>	<b>Regulation</b>
10	62	01	01
10	62	08	03 and .05-.07
10	62	09	03
10	62	12	02
10	62	15	04-.07
10	62	19	02 and .04-.06
10	62	20	03
10	62	22	02
10	62	25	03 and .05-.07
10	62	26	03
10	62	28	02

**3. Name of Promulgating Authority**

Department of Health and Mental Hygiene

**4. Name of Regulations Coordinator**

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Secretary

**Telephone No.**

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**Date**

September 6, 2016

**Title 10**

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.01 Definitions**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.08 Medical Cannabis Grower License**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.09 Medical Cannabis Grower Agent**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.12 Inventory Control by Grower**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.15 Medical Cannabis Grower Quality Control**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.19 Medical Cannabis Processor License**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.20 Medical Cannabis Processor**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.22 Medical Cannabis Processor Operations**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.25 Medical Cannabis Dispensary License**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.26 Registered Dispensary Agent**

**Subtitle 62 NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

**10.62.28 Licensed Dispensary Operations**

Authority: See proposal.

**Notice of Proposed Action**

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The Secretary of Health and Mental Hygiene proposes to :

- 1) Amend Regulation .01 under COMAR 10.62.01 Definitions;
- 2) Repeal and adopt new Regulations .03 and .07, and amend Regulations .05 and .06

under COMAR 10.62.08 Medical Cannabis Grower License;

- 3) Amend Regulation .03 under COMAR 10.62.09 Medical Cannabis Grower Agent;
- 4) Amend Regulation .02 under COMAR 10.62.12 Inventory Control by Grower;
- 5) Amend Regulation .04—.07 under COMAR 10.62.15 Medical Cannabis Grower Quality Control;
- 6) Amend Regulations .02, .04 and .05, and repeal and adopt new Regulation .06 under COMAR 10.62.19 Medical Cannabis Processor License;
- 7) Amend Regulation .03 under COMAR 10.62.20 Medical Cannabis Processor;
- 8) Amend Regulation .02 under COMAR 10.62.22 Medical Cannabis Processor Operations;
- 9) Repeal and adopt new Regulations .03 and .07, and amend Regulations .05 and .06 under COMAR 10.62.25 Medical Cannabis Dispensary License;
- 10) Amend Regulation .03 under COMAR 10.62.26 Registered Dispensary Agent; and
- 11) Amend Regulation .02 under COMAR 10.62.28 Licensed Dispensary Operations.

This action was considered at a public meeting on July 12, 2016, notice of which was given by publication on the Commission's website at [http://mmcc.maryland.gov/pages/home/meeting\\_schedule.aspx](http://mmcc.maryland.gov/pages/home/meeting_schedule.aspx), pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

### **Statement of Purpose**

The purpose of this action is to :

- 1) Correct typographical errors and incorrect terminology;
- 2) Clarify the process by which fingerprints are obtained for a criminal history records check;
- 3) Clarify when certain fees need to be paid and when certain fees will be refunded for certain applicants;
- 4) Clarify requirements for financial background information to be sent to the Commission for growers, processors, and dispensaries;
- 5) Clarify the general process for granting a license and the general criteria for obtaining a grower license or a processor license;
- 6) Clarify that when certain inspections and background investigations have been passed, then the Commission may issue a grower license, a processor license, or a dispensary license;
- 7) Require that an inventory control system that is used by a licensed grower, a licensed processor, or a licensed dispensary is to be approved by the Commission;
- 8) Require that an independent testing laboratory used by a licensed grower shall be registered with the Commission;
- 9) Clarify how a certain certificate of analysis should identify and report certain information;
- 10) Require an independent testing laboratory to forward to the Commission a certificate of analysis under certain circumstances; and
- 11) Clarify certain grower quality control procedures.

### **Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

### Estimate of Economic Impact

#### I. Summary of Economic Impact.

These regulations authorize the refunding of certain fees to certain applicants under certain circumstances. The Commission cannot predict if any fees would be refunded under the conditions contemplated in the proposed regulations and if any are refunded, how much would be refunded. As a result, the fiscal impact is indeterminable.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	(E-)	Indeterminable
B. On other State agencies:	NONE	
C. On local governments:	NONE	

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

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

A. The annual license fee for growers is set at \$125,000. The annual license fee for processors is \$40,000. The annual license fee for dispensaries is \$40,000. The Commission cannot predict if any fees would be refunded under the conditions contemplated in the proposed regulations and if any are refunded, how much would be refunded. As a result, the fiscal impact is indeterminable.

D. See A. above.

### Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

### 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, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to [dhmh.regs@maryland.gov](mailto:dhmh.regs@maryland.gov), or fax to 410-767-6483. Comments will be accepted through November 14, 2016. A public hearing has not been scheduled.

### **Economic Impact Statement Part C**

- A. Fiscal Year in which regulations will become effective: FY 2017
- B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
- C. If 'yes', state whether general, special (exact name), or federal funds will be used:
- 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.  
The businesses that would be impacted by these regulations would not fit the definition of small business.
- G. Small Business Worksheet:

Attached Document:

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## **Title 10**

# **DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

### **Subtitle 62 – NATALIE LAPRADE MEDICAL CANNABIS COMMISSION**

#### **10.62.01 Definitions**

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

*10.62.01.01 (downloaded 7/29/2016)*

##### **.01 Definitions.**

- A. (text unchanged)
- B. Terms Defined.

(1)—(24) (text unchanged)

(25) “Processor agent” means an owner, an employee, a volunteer, an officer, or a director of a licensed processor.

[(25)] (26)—[(34)] (35) (text unchanged)

[(35)] (36) “30-day supply” means:

(a) (text unchanged)

(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.

## **10.62.08 Medical Cannabis Grower License**

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

### **.03 Criminal History Record Check.**

A. Each individual listed in the application addenda in Regulation .02C(1) and (2) of this chapter shall:

(1) Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository and the Director of the FBI;

(2) Pay the fee authorized under Criminal Procedure Article, § 10–221(B)(7), Annotated Code of Maryland for access to State criminal history and records; and

(3) Request that the individual’s state and national criminal history record information be forwarded to the Commission.

B. The applicant shall notify the Commission of each individual listed in the application addenda in Regulation .02B(1) and (2) of this chapter who has completed this requirement.

10.62.08.05.

### **.05 Application Review.**

A.—E. (text unchanged)

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

G.—H. (text unchanged)

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)—(5) (text unchanged)

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

(a)—(c) (text unchanged)

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

(i) (text unchanged)

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

J. (text unchanged)

10.62.08.06.

### **.06 Pre-Approval of Application.**

A.—C. (text unchanged)

D. *Pre-Approval for a License.*

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

(2) *The applicant shall submit both the stage 2 application fee and the annual license fee appropriate for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(1), to the Commission by 4p.m. within 14 business days following the issuance of the Commission’s notification.*

E. (text unchanged)

### **.07 Issuance of License.**

A. After the notification by the Commission under Regulation .06 of this chapter, within 90 days:

(1) *If the applicant is an individual, the applicant shall submit to the Commission the three most recent federal tax returns filed by the applicant, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission the applicant’s:*

(a) *Capacity to operate a licensed medical cannabis growing enterprise; and*

(b) *Good moral character;*

(2) *If the applicant is a corporation that has not been operational for at least 1 year before the notification, the owners, officers, and directors of the applicant corporation shall submit to the Commission the three most recent*

*federal tax returns filed by the owners, officers, and directors of the applicant corporation, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission:*

*(a) The capacity of the owners, officers, and directors of the applicant corporation to operate a licensed medical cannabis growing enterprise; and*

*(b) The good moral character of the owners, officers, and directors of the applicant corporation; or*

*(3) If the applicant is a corporation that has been operational for at least 1 year before the notification, the applicant shall submit to the Commission an audited financial statement and the owners, officers, and directors of the applicant corporation shall submit to the Commission the three most recent federal tax returns filed by the owners, officers, and directors of the applicant corporation, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission:*

*(a) The capacity of the owners, officers, and directors of the applicant corporation to operate a licensed medical cannabis growing enterprise; and*

*(b) The good moral character of the owners, officers, and directors of the applicant corporation.*

**B. Pre-Licensing Inspection.**

*(1) The applicant shall notify the Commission that the applicant's premises, procedures, operations, and personnel are ready to be inspected in anticipation of the issuance of a license.*

*(2) The Commission shall notify the applicant when the Commission will carry out the pre-licensing inspection.*

*(3) The Commission shall carry out sufficient inspection and background investigation of finances and related matters to determine that:*

*(a) The criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;*

*(b) The applicant's premises are under the legal control of the applicant;*

*(c) The premises comply with all zoning and planning requirements;*

*(d) The premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter;*

*(e) The staff are trained and prepared to follow the procedures; and*

*(f) The procedures for cultivation and inventory control are as specified in the application.*

*C. The Commission may notify the applicant that the applicant has qualified for a license either to grow medical cannabis or to grow and distribute medical cannabis and may issue such a license on determination that:*

*(1) All inspections demonstrate that the applicant's entity and facility comply with the regulations;*

*(2) The applicant's entity and facility is ready to commence business in compliance with the regulations and application; and*

*(3) Financial and other background investigations have been completed and passed.*

*D. In the event that the Commission does not issue a license, the Commission shall refund the annual license fee promptly.*

## **10.62.09 Medical Cannabis Grower Agent**

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

10.62.09.03.

### **.03 Grower Agent Registration and Criminal History Record.**

A. (text unchanged)

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

(1) (text unchanged)

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

(3) (text unchanged)

C.—D. (text unchanged)

## **10.62.12 Inventory Control by Grower**

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

10.62.12.02.

### **.02 Inventory Control System.**

A. A licensee shall use a perpetual inventory control system *which has been approved by the Commission* 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, *independent testing laboratory*, or a qualifying patient or caregiver.

B.—C. (text unchanged)

## **10.62.15 Medical Cannabis Grower Quality Control**

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

10.62.15.04.

**.04 Independent Testing Laboratory Selection.**

A licensed grower 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] *is registered by the Commission;*

B.—F. (text unchanged)

10.62.15.05.

**.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] *The percentage by weight of each of the following compounds that are present in the batch, and whether the percentage by weight for each of the following compounds conforms to the specifications for the variety:*

(1)—(3) (text unchanged)

(4) Cannabidiolic Acid (CBDA); [and]

(5)—(6) (text unchanged)

(7) Cannabinol (CBN); [and]

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

(1)—(2) (text unchanged)

(3) Any microbiological impurity, including:

(a)—(e) (text unchanged)

(f) Aflatoxin B1, B2, G1, and G2; [and]

(g)—(h) (text unchanged)

(4) Whether the batch is within specification for the characteristics of:

(a)—(c)

(d) Moisture content; *and*

C. *To the Commission each instance in which the batch is out of compliance with the specification for the batch.*

10.62.15.06.

**.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] *indicates the levels of  $\Delta^9$ -Tetrahydrocannabinol (THC), Tetrahydrocannabinolic Acid (THCA), Cannabidiol (CBD), Cannabidiolic Acid (CBDA), and other active ingredients as determined by the Commission conform to the specifications for the variety, the licensed grower may:*

(1)—(3) (text unchanged)

B.—C. (text unchanged)

10.62.15.07.

**.07 Stability Testing and Retention Sampling.**

A. [A licensed grower shall provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to] *The independent testing laboratory shall obtain from each batch from each licensed grower, by means of an appropriate sampling technique, a sufficient number of samples to perform tests for product stability at 6-month intervals to:*

(1)—(2) (text unchanged)

[B. A licensed grower 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.]

B. *The independent testing laboratory shall:*

(1) *Obtain from each batch and lot from each licensed grower and licensed processor, by means of an appropriate sampling technique, a sufficient number of samples to be available for testing of the lot or batch in the event follow-up testing is necessary after an adverse reaction report or other matter; and*

(2) *Retain such samples for 1 year past the date of expiration of the batch or lot.*

**10.62.19 Medical Cannabis Processor License**

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

10.62.19.02.

**.02 Application.**

A.—E. (text unchanged)

[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.]

*F. Criminal History Records Check.*

(1) *Each individual listed in the application addenda in Regulation .02B(1) and (2) shall:*

(a) *Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository and the Director of the FBI;*

(b) *Pay the fee authorized under Criminal Procedure Article, §10-221(b)(7), Annotated Code of Maryland, for access to state criminal history and records; and*

(c) *Request that the individual's state and national criminal history information be forwarded to the Commission.*

(2) *The applicant shall notify the Commission once each individual listed in the application addenda in Regulation .02B(1) and (2) has completed this requirement.*

10.62.19.04.

**.04 Application Review.**

A.—E. (text unchanged)

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

G.—I. (text unchanged)

10.62.19.05.

**.05 Pre-Approval of License Application.**

A.—C. (text unchanged)

D. *Pre-Approval for a License.*

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

(2) *The applicant shall submit both the stage 2 application fee and the annual license fee for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(3), to the Commission by 4p.m. within 14 business days following the issuance of the Commission's notification.*

E. (text unchanged)

10.62.19.06

**.06 Issuance of License.**

A. *After the notification by the Commission and payment of fees under Regulation .05 of this chapter, within 90 days:*

(1) *If the applicant is an individual, the applicant shall submit to the Commission the three most recent federal tax returns filed by the applicant, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission the applicant's:*

(a) *Capacity to operate a licensed medical cannabis processing enterprise; and*

(b) *Good moral character;*

(2) *If the applicant is a corporation that has not been operational for at least 1 year before the notification, the owners, officers, and directors of the applicant corporation shall submit to the Commission the three most recent federal tax returns filed by the owners, officers, and directors of the applicant corporation, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission:*

(a) *The capacity of the owners, officers, and directors of the applicant corporation to operate a licensed medical cannabis processing enterprise; and*

(b) *Good moral character of the owners, officers, and directors of the applicant corporation; or*

(3) *If the applicant is a corporation that has been operational for at least 1 year before the notification, the applicant shall submit to the Commission an audited financial statement and the owners, officers, and directors of the applicant corporation shall submit to the Commission the three most recent federal tax returns filed by the owners, officers, and directors of the applicant corporation, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission:*

(a) *The capacity of the owners, officers, and directors of the applicant corporation to operate a licensed medical cannabis processing enterprise; and*

(b) *The good moral character of the owners, officers, and directors of the applicant corporation.*

*B. Pre-licensing Inspection.*

- (1) *The applicant shall notify the Commission that the applicant's premises, procedures, operations, and personnel are ready to be inspected in anticipation of the issuance of a license.*
- (2) *The Commission shall notify the applicant when the Commission will carry out the pre-licensing inspection.*
- (3) *The Commission shall carry out sufficient inspection and background investigation of finances and related matters to determine that the:*
  - (a) *Criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;*
  - (b) *Applicant's premises are under the legal control of the applicant;*
  - (c) *Premises comply with all zoning and planning requirements;*
  - (d) *Premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .05 of this chapter;*
  - (e) *Staff are trained and prepared to follow the procedures; and*
  - (f) *Procedures for cultivation and inventory control are as specified in the application.*

*C. The Commission may notify the applicant that the applicant has qualified for a license to process medical cannabis and may issue such a license on determination that:*

- (1) *All inspections demonstrate that the applicant's entity and facility comply with the regulations;*
- (2) *The applicant's entity and facility is ready to commence business in compliance with the regulations and application; and*
- (3) *Financial and other background investigations have been completed and passed.*

*D. In the event that the Commission does not issue a license, the Commission shall refund the annual license fee promptly.*

### **10.62.20 Medical Cannabis Processor Agent**

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

*10.62.20.03.*

#### **.03 Processor Agent Registration and Criminal History Record.**

- A. (text unchanged)
- B. A licensee shall apply to register a processor agent by submitting to the Commission:
  - (1) (text unchanged)
  - (2) Documentation of the submission of fingerprints of the processor agent to the Central [Registry] *Repository*;and
  - (3) (text unchanged)
- C.—D. (text unchanged)

### **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

*10.62.22.02.*

#### **.02 Standard Operating Procedures.**

- A. A licensee shall:
  - (1) (text unchanged)
  - (2) [Create and use] *Use a perpetual inventory control system which has been approved by the Commission that identifies and tracks the licensee's stock of medical cannabis from the time [it] medical cannabis is [delivered or produced] received by the licensee, through the stages of processing, to the time it is delivered to another licensee, a licensed grower, a licensed dispensary, independent testing laboratory, or a qualifying patient or caregiver; and*
  - (3) (text unchanged)
- B. (text unchanged)

### **10.62.25 Medical Cannabis Dispensary License**

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

#### **.03 Criminal History Record Request.**

- A. *Each individual listed in the application addenda in Regulation .02B(1) and (2) of this chapter shall:*
  - (1) *Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository and the Director of the FBI;*
  - (2) *Pay the fee authorized under Criminal Procedure Article, §10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records; and*
  - (3) *Request that the individual's state and national criminal history record information be forwarded to the Commission.*

*B. The applicant shall notify the Commission of each individual listed in the application addenda in Regulation .02B(1) and (2) of this chapter who has completed this requirement.*

10.62.25.05.

**.05 Application Review.**

A.—E. (text unchanged)

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

G.—K. (text unchanged)

10.62.25.06.

**.06 Pre-Approval of License Application.**

A.—C. (text unchanged)

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

(1) Within 10 business days of the Commission's decision, the Commission shall notify applicants who have been pre-approved [for] *to pursue* a license.

(2) *The applicant shall submit both the stage 2 application fee and the annual license fee for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(3), to the Commission by 4p.m. within 14 business days following the issuance of the Commission's notification.*

E. (text unchanged)

F. *In the event that the Commission does not issue a license, the Commission shall refund the annual license fee promptly.*

10.62.25.07

**.07 Issuance of License.**

A. *After the notification by the Commission under Regulation .06 of this chapter, within 90 days:*

(1) *If the applicant is an individual, the applicant shall submit to the Commission the three most recent federal tax returns filed by the applicant, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission the applicant's:*

(a) *Capacity to operate a licensed medical cannabis dispensing enterprise; and*

(b) *Good moral character;*

(2) *If the applicant is a corporation that has not been operational for at least 1 year before the notification, the owners, officers, and directors of the applicant corporation shall submit to the Commission the three most recent federal tax returns filed by the owners, officers, and directors of the applicant corporation, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission:*

(a) *The capacity of the owners, officers, and directors of the applicant corporation to operate a licensed medical cannabis dispensing enterprise; and*

(b) *The good moral character of the owners, officers, and directors of the applicant corporation; or*

(3) *If the applicant is a corporation that has been operational for at least 1 year before the notification, the applicant shall submit to the Commission an audited financial statement, and the owners, officers, and directors of the applicant corporation shall submit to the Commission the three most recent federal tax returns filed by the owners, officers, and directors of the applicant corporation, and any other financial, personal, and background information requested by the Commission which will sufficiently establish to the Commission:*

(a) *The capacity of the owners, officers, and directors of the applicant corporation to operate a licensed medical cannabis dispensing enterprise; and*

(b) *The good moral character of the owners, officers, and directors of the applicant corporation.*

B. *Pre-licensing inspection.*

(1) *The applicant shall notify the Commission that the applicant's premises, procedures, operations, and personnel are ready to be inspected in anticipation of the issuance of a license.*

(2) *The Commission shall notify the applicant when the Commission will carry out the pre-licensing inspection.*

(3) *The Commission shall carry out sufficient inspection and background investigation of finances and related matters to determine that:*

(a) *The criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character;*

(b) *The applicant's premises are under the legal control of the applicant;*

(c) *The premises comply with all zoning and planning requirements;*

(d) *The premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter;*

(e) *The staff are trained and prepared to follow the procedures; and*

(f) *The procedures for cultivation and inventory control are as specified in the application.*

C. *The Commission may notify the applicant that the applicant has qualified for a license to dispense medical cannabis and may issue such a license on determination that:*

(1) *All inspections demonstrate that the applicant's entity and facility comply with the regulations;*

(2) *The applicant's entity and facility is ready to commence business in compliance with the regulations and application; and*

(3) *Financial and other background investigations have been completed and passed.*

D. *In the event that the Commission does not issue a license, the Commission shall refund the annual license fee promptly.*

### **10.62.26 Registered Dispensary Agent**

Authority: Health-General Article, §§13-3301, 13-3302, 13-3307, and 13-3308, Annotated Code of Maryland

10.62.26.03.

#### **.03 Dispensary Agent Registration and Criminal History Record.**

A. (text unchanged)

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

(1) (text unchanged)

(2) Documentation of the submission of fingerprints of the dispensary agent to the Central [Registry] *Repository*;

and

(3) (text unchanged)

C.—D. (text unchanged)

### **10.62.28 Licensed Dispensary Operations**

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

10.62.28.02.

#### **.02 Standard Operating Procedure.**

A. A licensee shall:

(1) (text unchanged)

(2) [Create and use] *Use a perpetual inventory control system which has been approved by the Commission that identifies and tracks the licensee's stock of medical cannabis from the time [it] medical cannabis is [delivered or produced] received by the licensee to the time it is delivered to another licensee, a licensed grower, a licensed processor, independent testing laboratory, or a qualifying patient or caregiver;* and

(3) (text unchanged)

B. (text unchanged)

**VAN T. MITCHELL**

**Secretary of Health and Mental Hygiene**