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Natalie M. LaPrade Medical Marijuana Commission

Please send comments to the Commission at dhmh.medicalmarijuanacommission@maryland.gov

DRAFT FOR INFORMAL COMMENT

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 62 NATALIE LAPRADE MEDICAL MARIJUANA 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.XX.

.02 Definitions.

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

B. Terms Defined.

(XX) “Academic medical center” means a hospital that:

(a) Operates a medical residency program for physicians; and

(b) Conducts research that is overseen by the federal Department of Health and Human Services and involves human subjects.

(XX) “All of the processed material” means

(a) The material was produced from a single batch of medical marijuana;

(b) The material has been exposed to the same conditions throughout processing.

(XX) “Association” means employment or volunteer status at a licensed premises.

(XX) Batch.

(a) “Batch” means all of the plants of the same strain of medical marijuana that have been:

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

(ii) Exposed to the same conditions throughout cultivation and processing.

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

(XX) “Bona-fide physician-patient relationship” means a treatment or counseling relationship between a physician and patient in which all of the following are present:

(1) The physician has reviewed the patient’s relevant medical records and completed a full assessment of the patient’s medical history and current medical condition, including a relevant, in-person, medical evaluation of the patient;

(2) The physician has created and maintained records of the patient’s condition in accord with medically accepted standards;

(3) The physician has a reasonable expectation that he or she will provide follow-up care to the patient to monitor the efficacy of the use of medical marijuana as a treatment of the patient’s debilitating medical condition; and

(4) If the patient has given permission, the physician has notified the patient’s primary care physician of the patient’s debilitating medical condition and certification for the use of medical marijuana to treat that condition.

(XX) “Central Repository” means the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services.

(XX) Caregiver.

(a) “Caregiver” means an individual who has agreed to assist with a qualifying patient’s medical use of marijuana.

(b) “Caregiver” includes, for a qualifying patient under the age of 18 years, a parent or legal guardian.

(XX) “*Certifying physician*” means a physician, as defined in Health Occupations Article, §12-101(b), Annotated Code of Maryland, who is approved by the Commission to make marijuana available to patients for medical use in accordance with this subtitle.

(XX) “*Commission*” means the Natalie M. LaPrade Medical Marijuana Commission.

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

(XX) “*Fund*” means the Natalie M. LaPrade Medical Marijuana Commission Fund.

(XX) *Grower*.

(a) “*Grower*” means an entity that produces medical marijuana and is licensed by the Commission to provide medical marijuana to a program or to a licensed dispensary.

(b) “*Grower*” includes the federal government.

(XX) “*Law enforcement agency*” means the Maryland State Police or another law enforcement agency designated by the Maryland State Police to carry out the disposal of waste.

(XX) “*Licensed dispensary*” means a dispensary licensed by the Commission that acquires, possesses, processes, transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, related products including food, tinctures, aerosols, oils, or ointments, or educational materials for use by a qualifying patient or caregiver.

(XX) “*Licensed grower*” means a grower licensed by the Commission.

(XX) “*Licensed premises*” means a location at which a registered grower agent is authorized by the Commission to operate as a licensed grower.

(XX) “*Program*” means a program overseen by an academic medical center through which marijuana is made available to qualifying patients for medical use.

(XX) *“Qualifying patient” means an individual authorized to use medical marijuana while participating in a program operated by an academic medical center.*

(XX) *“Recommendation” means a written communication, signed by certifying physician, of the physician’s medical opinion that a qualifying patient will benefit from the use of medical marijuana.*

(XX) *“Registered dispensary agent” means a dispensary agent registered by the Commission.*

(XX) *“Registered grower agent” means a medical marijuana grower agent who serves as an owner, an employee, a volunteer, an officer, or a director of a licensed grower and who is registered by the Commission.*

(XX) *“Resident” has the same meaning as set forth in COMAR 11.11.06.02.*

(XX) *“Usable marijuana” means the dried leaves and flowers of the marijuana plant and does not include seedlings, seeds, stems, stalks or roots of the plant or the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical administration, food, or drink.*

(XX) *“Written certification” means a certification that:*

(a) Is issued by a certifying physician to a qualifying patient with whom the physician has a bona fide physician-patient relationship; and

(b) Includes a written statement certifying that, in the physician’s professional opinion, after having completed a full assessment of the patient’s medical history and current medical condition, the patient has a condition:

(i) That meets the inclusion criteria and does not meet the exclusion criteria of the certifying physician’s application; and

(ii) For which the potential benefits of the medical use of marijuana would likely outweigh the health risks for the patient.

(XX) “30-day supply” means 120 grams of usable marijuana.

10.62.XX – General Regulations.

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

.01 Scope.

This subtitle governs medical marijuana activities that operate under the Natalie M. LaPrade Medical Marijuana 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 5 year, or*
- (4) is affiliated with an individual or entity described in B(1) through B(3) or this section*

C. An individual or entity that has made a donation to the Fund is prohibited from applying for licensure or approval by the Commission for a period of 5 years.

D. A donation shall be by check made payable to the Commission.

10.62.XX Academic Medical Center Compassionate Use Program

Authority: Health General Article, §§13-3301, 13-3302, and 13-3304—13-3306, Annotated

Code of Maryland

.01 Requests for Applications.

The Commission shall:

A. Issue a request at least annually to academic medical centers for applications regarding programs to be considered; and

B. Post details of the application process on the Commission's website.

.02 Requirements.

A. Medical Conditions. An academic medical center shall include on the application:

(1) A list of the medical conditions to be treated or studied under the program; and

(2) The basis of evidence for the use of medical marijuana to treat a specified medical condition.

B. Patient Inclusion.

(1) An academic medical center shall specify on the application the criteria by which a patient may be included in or excluded from a program.

(2) A program may include a patient if the patient:

(a) Has been diagnosed with a medical condition being treated or studied under the program;

and

(b) Is a resident of Maryland.

(3) A program may include a patient younger than 18 years old if:

(a) The patient's parent or legal guardian has provided written consent; or

(b) The patient is an emancipated minor.

(4) Before including a patient in a program, the program shall obtain written acknowledgement from the patient that:

(a) Medical marijuana is recommended on a trial basis;

(b) Medical marijuana is recommended to treat or study a specified medical condition;

(c) The dosage of medical marijuana may be altered by the program;

- (d) Certain health risks may be associated with the short-term and long-term use of medical marijuana;*
- (e) Scientific research has not established the safety of medical marijuana use by pregnant women;*
- (f) Participation in the program does not protect the patient from liability under federal law;*
- (g) Participation in the program does not authorize use, possession, or transportation of medical marijuana outside of Maryland; and*
- (h) Inclusion in the program may be suspended or revoked at the program's discretion.*
- (5) Before being included in a program, a patient shall agree to:*
 - (a) Obtain medical marijuana only from a grower directed by the program;*
 - (b) Fully inform the program, on a continuing basis, of any medication, drug, supplement, or other substance being used by the patient;*
 - (c) Submit to monitoring for drug use by urinalysis or other means if required by the program;*
 - (d) Take reasonable steps, as established by the program, to prevent the medical marijuana from being lost, stolen, used by any unauthorized individual, or otherwise diverted; and*
 - (e) Surrender any recalled or unused medical marijuana as directed by the program.*
- (6) A patient shall provide a program with:*
 - (a) The name and contact information for any health care provider treating the patient;*
 - (b) A release directing any health care provider to disclose the patient's medical records, substance use disorder treatment records, and mental health records to the program; and*
 - (c) An acknowledgement that a health care provider treating the patient may be contacted by the program to:*
 - (i) Verify medical information;*

(ii) Coordinate patient care; or

(iii) Protect the patient from the risks of substance use disorders or drug interactions.

(7) A program shall remove from the register of the program any patient when the program determines the use of medical marijuana is no longer warranted.

C. Addiction Assessment.

(1) The academic medical center shall specify on the application how patients will be assessed by the program for a substance use disorder before and during participation in the program.

(2) A program shall verify a patient's prescription history before including the patient in the program.

(3) Before including a patient with an active substance use disorder in a program, the program shall weigh the risks and benefits of including the patient in the program.

(4) If a program includes a patient with an active substance use disorder, the program shall monitor and document the course of the patient's substance use disorder while in the program.

(5) A program may choose to exclude a patient because of the patient's history of substance use disorders.

D. Medical Marijuana Grower.

(1) The academic medical center shall specify on the application:

(a) The licensed grower or growers of the medical marijuana to be used by patients participating in the program; and,

(b) Adequate characterization of the medical marijuana sufficient to support the research component of the program.

(2) A recommendation for a patient in a program shall only be presented for medical marijuana at a grower designated by the program.

E. Specification of Treatment and Dosage.

- (1) The academic medical center shall specify on the application the means to determine the length of treatment and dosage permitted under the program.*
- (2) A recommendation provided to a patient participating in a program shall specify:*
 - (a) The type of medical marijuana to be dispensed to the patient;*
 - (b) The quantity of medical marijuana to be dispensed to the patient;*
 - (c) The recommended dosage;*
 - (d) The dosing schedule; and*
 - (e) The method of delivery or means of ingestion.*
- (3) A recommendation shall authorize no more than a 30-day supply of medical marijuana.*
- (4) A recommendation may not be issued without an in-person evaluation by a licensed provider.*
- (5) A program may modify a recommendation at any time as necessary to:*
 - (a) Provide appropriate therapeutic effect to the patient;*
 - (b) Address an adverse drug effect; or*
 - (c) Address a safety issue.*

F. Health Care Providers.

- (1) The academic medical center shall describe on the application how health care providers will be able to participate in a program.*
- (2) An application shall describe how a program will comprehensively train all staff and health care providers associated with the program on:*
 - (a) The evidentiary basis for the use of medical marijuana;*
 - (b) Types of medical marijuana available in the program;*
 - (c) Appropriate dosages of medical marijuana used in the program;*

- (d) Methods of delivery or means of ingestion of medical marijuana;*
- (e) Signs of addiction to marijuana, alcohol, controlled substances, and other drugs of concern;*
- (f) The conditions of the program participation by patients and caregivers;*
- (g) The law regarding illicit marijuana and medical marijuana; and*
- (h) Signs of diversion.*

G. Caregivers.

- (1) The academic medical center shall include on the application a description of whether and how caregivers will be utilized in the program.*
- (2) In consultation with a patient, a program may designate one or two individuals to serve as a caregiver for the patient.*
- (3) Pursuant to the recommendation provided to a patient, a caregiver may:*
 - (a) Obtain medical marijuana for a patient from the grower designated by the program; and*
 - (b) Deliver the medical marijuana directly to the patient.*
- (3) A caregiver may only open a sealed package of medical marijuana in the presence of the patient.*

H. Program Protocol.

- (1) An academic medical center shall include on the application the program protocol submitted by the academic medical center to its institutional review board.*
- (2) An application may not be considered complete until proof of approval by the institutional review board is submitted by the academic medical center.*

I. Program Evaluation and Gathering Data.

- (1) An academic medical center shall include on the application the criteria for evaluating the program and monitoring the treatment of patients in the program.*

(2) A program shall monitor a patient's condition to determine if:

(a) There are any serious adverse effects from the medical marijuana;

(b) The delivery method is appropriate; and

(c) Medical marijuana is effective in treating the condition being studied.

(3) If an adverse effect is life threatening or resulted in death, the program shall report the effect to the Commission within 7 days.

(3) If a serious adverse effect is otherwise suspected,

(a) The program shall within 15 days report the effect to the Commission and the grower; and

(b) The program and grower shall review the production of the batch, the batch testing, and submit a sample for re-testing to determine if:

(i) The production procedure was followed;

(ii) There was any defect in the batch; and

(iii) It is necessary to revise the production procedure.

(4) A program is not required to establish a blind or placebo control group to compare patients participating in the program.

(4) An academic medical center shall include on the application a plan for monitoring aggregate data and outcomes, and publishing results from the program as appropriate.

J. Program Funding.

(1) An academic medical center shall include on the application a description of the sources of funding for the program, including any research grants.

(2) An application shall disclose any potential conflicts of interest related to the funding of the program.

K. Diversion Training and Prevention.

(1) An academic medical center shall describe on the application the program's training of health care providers, patients, and caregivers participating in the program on diversion-related issues.

(2) The training on diversion-related issues required for health care providers participating in a program shall, at a minimum, cover:

(a) The requirement to prevent diversion of medical marijuana;

(b) How to recognize signs of diversion or a tendency to divert; and

(c) Procedures implemented by the program to prevent and discourage diversion.

(3) The program shall train a patient or caregiver on the requirement to prevent diversion.

(4) The training shall include information on the criminal penalties for diversion of medical marijuana provided for in:

(a) Health General Article, §13-3309(B), Annotated Code of Maryland; and

(b) The Controlled Dangerous Substances Act, Criminal Law Article, Title 5, Annotated Code of Maryland.

(5) An application shall describe the steps an academic medical center will take to prevent and monitor for diversion and address violations of the academic medical center's diversion policy.

L. Unused Marijuana.

(1) An academic medical center shall describe on the application how any unused marijuana will be disposed of.

(2) The program shall document the return of or destruction of any unused medical marijuana.

10.62.XX Academic Medical Center Compassionate Use Program Application and Renewal Procedure.

***Authority: Health General Article, §§ 13-3301, 13-3302, and 13-3304—3306, Annotated Code
of Maryland***

.01 Initial Application Review.

A. An application to operate a program may be submitted by an academic medical center at any time.

B. Upon receipt of an application, the Commission shall provide a receipt to the academic medical center that indicates if the application is complete or incomplete.

C. Review Team.

(1) The Commission shall appoint a review team to review an application from an academic medical center.

(2) A member of the review team shall disclose any potential conflicts of interest in relation to a particular application.

(3) After an initial review of an application, the review team may ask the Commission for additional resources or support to provide expertise necessary for the review.

.02 Application Review.

A. A review team shall recommend to the Commission whether to approve or reject an application, or suggest a modification to a program, after reviewing the specifications of the program regarding:

(1) The medical conditions to be treated or studied in the program;

(2) The evidentiary basis for treatment;

(3) The quality of the research protocol;

(4) The integrity of systems to control medical marijuana and prevent diversion;

(5) The sufficiency of policies to prevent and address substance use disorders;

(6) The risks and benefits of participation in the program for a potential patient; and

(7) The program's overall:

(a) Feasibility;

(b) Scientific value;

(c) Rigor;

(d) Coherence; and

(e) Methodology.

B. The Commission may adopt or overrule a recommendation to approve or deny an application.

C. If the Commission votes to approve an application, the program is approved for 1 year following the date the study commences.

D. At least 14 days before a program commences, the program shall notify the Commission of the commencement date.

E. The Commission may approve no more than 5 programs to operate at one time.

.03 Program Amendments

A. Academic medical centers shall submit to the Commission proposed amendments to the program.

B. The Commission shall review and may approve or deny any proposed amendments.

.04 Program Renewal.

A. A program's approval expires 1 year after the date of commencement of the program.

B. A program that intends to renew its license shall submit an application for renewal to the Commission not less than 90 days before the program's approval expires.

C. A program may be renewed for an addition term of 1 year if the program:

(1) Is otherwise entitled to renewal;

(2) Pays to the Commission a renewal fee; and

(3) Submits a renewal application to the Commission on the form the Commission requires.

D. A renewal application that includes modifications of the previous application shall be reviewed pursuant to Regulation .02 of this chapter.

E. A program's approval may not be renewed for a term longer than 1 year.

.05 Approval Rescission.

A. The Commission may rescind approval of a program upon a finding that the program is not in compliance with:

(1) The program's approved application;

(2) The Natalie M. LaPrade Medical Marijuana Commission Act, Health General Article, §13-3301—13-3311, Annotated Code of Maryland, or any other State law; or

(3) This subtitle.

B. The Commission may rescind approval of a program upon a finding that the program employs a person with responsibility for storing or securing medical marijuana, issuing a recommendation, or updating patient and caregiver information to the register, if such person:

(1) Is currently on parole or probation;

(2) In the last 10 years has been convicted of a crime that would be a felony in the State of Maryland; or

(3) In the past 5 years has been convicted of a crime that would be a misdemeanor under the Controlled Dangerous Substances Act of the State of Maryland..

.06 Annual Report.

A. A program shall report to the Commission on the operation of the program at the end of a 1-year approval period.

B. A program's report to the Commission shall include:

- (1) The total number of patients in the program;*
- (2) The number of patients in the program by county of residence;*
- (3) The medical conditions treated in the program;*
- (4) Data regarding the positive and negative outcomes as a result of treatment;*
- (5) A compilation of research studies completed or pending in connection with the program; and*
- (6) the number and nature of adverse events.*

10.62.XX Certifying Physicians.

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

.01 Physician Application for Approval

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

- (1) The physician's:*
 - (a) Full name;*
 - (b) All office addresses and phone numbers;*
 - (c) Current email address;*
 - (d) Maryland Board of Physicians license number;*
 - (e) Representation that the physician's Maryland license to practice medicine is active and in good standing;*
 - (f) Representation that the physician is authorized to prescribe controlled substances by the State of Maryland;*

- (2) *The medical conditions for which the physician will issue written certifications for medical marijuana as set forth in regulation .03 of this chapter;*
 - (3) *The reasons the physician will deny written certification of medical marijuana;*
 - (4) *The physician's plan to screen patients for dependence on substances of abuse before and after a patient is issued a written certification;*
 - (5) *The physician's plan to assess patient outcomes, provide follow-up care, and to collect and analyze data;*
 - (6) *Representation that the physician has completed a Commission-approved online training course;*
 - (7) *Representation that the physician has had the training necessary to treat a patient with medical marijuana for the conditions applied for and to comply with Chapter ____ of the Acts of 2014; and*
 - (8) *Any other criteria deemed necessary by the Commission.*
- B. A Certifying physician may apply to amend the approval at any time.*
- C. The Commission may deny an incomplete or unsatisfactory application.*

.02 Compensation from a Licensed Grower or Licensed Dispensary

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

.03 Terms of Certifying Physician Practice

A. A Certifying Physician may be approved to treat patients who have:

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

(2) A chronic or debilitating disease or medical condition, or who are receiving treatment thereof, that causes:

(a) Cachexia;

(b) Anorexia;

(c) Wasting syndrome;

(d) Severe pain;

(e) Severe nausea;

(f) Seizures or severe or persistent muscle spasms;

(3) The following diseases and conditions:

(a) Glaucoma, if the certifying physician is an ophthalmologist who is a diplomate of the American Board of Ophthalmology; or

(b) Post traumatic stress disorder (PTSD), if the certifying physician is a psychiatrist who is a diplomate of the American Board of Psychiatry and Neurology; or

(4) Any other disease, condition, or treatment thereof which may be approved by the Commission.

B. A certifying physician may provide written certification to a qualifying patient or caregiver, only:

(1) With whom the certifying physician has a bona fide physician-patient relationship;

(2) After a full, in-person assessment of the qualifying patient's medical history and current medical condition;

(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;*
- (5) If the qualifying patient has been screened for dependence on substances of abuse and has been determined by the physician to be of low risk for addiction, dependence, and diversion; and*
- (6) If the certifying physician has determined that the potential benefits of the medical use of marijuana likely outweigh the health risks for the patient.*

D. A certifying physician shall counsel a qualifying patient on the proper use of medical marijuana for the condition.

.04 Written Certification for Qualifying Patients.

- A. The certifying physician shall provide a copy of each written certification to the qualifying patient and to the Commission in the manner it requires.*
- B. A written certification shall include the:*
 - (1) Physician's name, Maryland Board of Physicians license number, and office phone number;*
 - (2) Qualifying patient's name, date of birth, address, county of residence;*
 - (3) Medical condition requiring medical marijuana; and*
 - (4) The date of certification as a qualifying patient.*
- C. A written certification shall expire after 1 year, unless terminated earlier.*
- D. A written certification may be renewed by the certifying physician in the manner required by Regulation .03 of this Chapter if the qualifying patient continues to require medical marijuana for the condition stated in the original certification.*
- E. A certifying physician shall terminate care of a qualifying patient with medical marijuana if:*
 - (1) The qualifying patient meets the physician's exclusion criteria;*
 - (2) Treatment with medical marijuana is no longer necessary for the qualifying patient;*

(3) If adverse effects of medical marijuana outweigh the benefits to the qualifying patient's health; or

(4) If there is evidence that the qualifying patient engaged in diversion of medical marijuana or demonstrates abuse of any substance of abuse.

F. Upon termination of care, a certifying physician shall notify the Commission in a manner the Commission requires within 1 business day of the termination of care.

G. A qualifying patient shall have only 1 certifying physician at any time.

.05 Medical Marijuana Recommendation.

A. A certifying physician shall examine the qualifying patient prior to issuing a recommendation.

B. A recommendation shall include the:

(1) Qualifying Patient's name, date of birth, home address, and phone number; and

(2) Certifying Physician's name, office address, office phone number, and Maryland Board of Physicians license number; and

(3) Condition to be treated with medical marijuana.

.06 Annual Report

A. A certifying physician shall submit an annual report to the Commission in the manner and at the time required by the Commission.

B. The annual report shall include:

(1) The number of qualifying patients issued written certification by the certifying physician categorized by county of residence or Baltimore City;

(2) The medical conditions for which certification was issued;

(3) A summary of the clinical outcomes of the qualifying patients' use of medical marijuana;

(4) A summary of any adverse effects in the use of medical marijuana experienced by any qualifying patient of the certifying physician; and

(5) A summary of steps taken in response to instances of suspected diversion of medical marijuana; and

(6) Any other data required by the Commission.

C. The annual report may not include any personally identifiable information related to any qualifying patient.

.07 Renewal of Approval to Certify

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

B. The Commission shall provide notice of renewal 90 days prior to expiration of the approval.

C. The Commission shall grant approval of the application for renewal if:

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

(2) The certifying physician's registration to prescribe controlled dangerous substances by the State of Maryland is valid;

(3) The certifying physician has completed the continuing education requirements determined by the Commission; and

(4) The certifying physician has submitted annual reports when and in the manner determined by the Commission.

D. If a certifying physician fails to renew an approval to issue written certifications, the certifying physician shall not be permitted to issue written certifications.

.08 Action against a Physician

A. The Commission may report any instance of misconduct by a certifying physician to the Maryland Board of Physicians.

B. The Commission may deny a certifying physician's request for renewal of approval to certify if:

(1) The physician fraudulently applied for approval;

(2) The physician fraudulently issued a written certification;

(3) The physician failed to comply with the requirements set forth in these Regulations; or

(4) Any other ground that serves the purpose of these Regulations.

10.62.XX New Condition Approval Process.

Authority: Health General Article, §§ 13-3307(C) & (D) Annotated Code of Maryland

.01. Petition requirement

Persons seeking to suggest a medical condition, medical treatment or disease for which the Commission will be encouraged to approve physician applications shall submit a written petition to the Commission.

.02 Hearing

At least once per year, the Commission shall conduct a public hearing to evaluate any petition to consider other medical condition, medical treatment or disease that may be included in certifying physician applications.

.03. Petition contents

The Commission shall consider a petition that may include:

A. A medical condition, medical treatment or disease which is generally accepted as valid by the medical community and other experts;

B. The extent to which the condition or the treatments thereof cause chronic pain or severely impair the patient's ability to carry on activities of daily living;

C. 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;

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

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

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

.04 Previously rejected subject.

If a medical condition, medical treatment, or disease in a petition has been previously considered and rejected by the Commission, the Commission may deny the petition without submitting it for public comment unless new scientific research supporting the request is included in the petition.

.05 Additional evidence.

In addition to information provided in a petition, the Commission may examine scientific, medical or other evidence and research pertaining to the petition, and may gather information in person or in writing, from other persons knowledgeable about the medical condition, medical treatment or disease 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 debilitating medical condition considered at the hearing.

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

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

(2) Medical marijuana can reasonably be expected to relieve the pain, suffering and disability of the medical condition or therapy thereof; and

(3) Other medical treatments have been ineffective in doing so.

.07 New Regulation.

If the Commission concludes that physicians will be encouraged to apply to treat the medical condition, medical treatment, or disease that was under consideration, the Commission shall proceed to promulgate regulations to amend 10.62.03 A.(2) accordingly.

10.62.XX Patient Registry and Identification Cards

Authority: Health General Article, §§ 13,3301, 13-3302(D), 13-3303(G), 13-3307(F)(3),

Annotated Code of Maryland

.01 Identification cards for patients and caregivers.

Upon being issued a written certification by a certifying physician, a qualifying patient and caregiver, shall apply to the Commission for an identification card.

A. To apply for an identification card, a qualifying patient shall submit to the Commission:

(1) A copy of the written certification from the qualifying patient's certifying physician;

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

(3) A passport-type photograph taken within 6 months of application;

- (4) *A copy of the qualifying patient's state identification card; and*
- (5) *The required fee.*

B. To apply for an identification card, a caregiver shall submit to the Commission:

- (1) *The name of the qualifying patient for whom the caregiver is providing assistance or is the parent or legal guardian;*
- (2) *Proof that the caregiver is authorized by the qualifying patient to act as caregiver;*
- (3) *A passport type photograph taken within 6 months of application;*
- (4) *The application form as provided by the Commission;*
- (5) *A copy of the caregiver's state identification card; and*
- (6) *The required fee.*

C. The identification card shall contain:

- (1) *The name and date of birth of the card holder;*
- (2) *An expiration date;*
- (3) *A photograph taken within the previous 6 months; and*
- (4) *The qualifying patient identification number assigned by the Commission.*

D. The qualifying patient or caregiver must carry the identification card at all times while in possession of medical marijuana.

E. If the identification card is lost or stolen, the qualifying patient or caregiver shall:

- (1) *Notify local Police within 1 day of discovering the loss;*
- (2) *Notify the Commission in writing and provide a copy of the police report or case number;*
- (3) *Pay the card replacement fee; and*
- (4) *Not use medical marijuana until a new identification card is obtained.*

F. If there is any change in name, address, or caregiver, the qualifying patient shall notify the Commission within 1 business day in the manner required by the Commission and pay the replacement fee to obtain a new identification card.

G. The identification card must be returned to the Commission in a manner to be determined by the Commission within 5 calendar days if:

(1) The certifying physician fails to renew the qualifying patient certification;

(2) A caregiver is no longer assisting the qualifying patient;

(3) The Commission revokes or suspends the certification of a qualifying patient or caregiver.

H. The qualifying patient or caregiver shall begin the renewal process no less than 60 calendar days prior to the expiration date of the current identification card.

.02 Registry

A. Registry of Qualifying Patients and Caregivers.

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

(2) Each entry into the registry shall contain the name of each:

(a) Qualifying patient;

(b) Qualifying patient's certifying physician;

(c) Qualifying patient's caregiver(s), if applicable.

B. A program shall update to the Commission's register within 1 business day of:

(1) The addition of patients and caregivers to the program, and

(2) The removal of patients and caregivers from the program.

C. The Commission shall provide access to the Commission's register to the Maryland State Police on a real-time basis.

D. The Maryland State Police may only access the registry to verify that a patient or caregiver is participating in a program or registered with the Commission.

10.62.XX Application for Medical Marijuana Grower License

Authority: Health General Article, §§ 13-3302, 13-3309 and 13-3312, Annotated Code of Maryland

.01 Definitions.

A. In addition to the definitions set forth in COMAR 10.62.01, 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 Application for a Medical Marijuana Grower License.

A. Application to operate as a licensed grower at a specific location shall be made on a form provided by the Commission.

B. An application shall include:

(1) A business plan including an organizational chart;

(2) Identification of applicant's medical marijuana grower agents and major investors at the time of application;

(3) Details of the applicant's experience, knowledge, and training in the cultivation and processing of medical marijuana;

(4) A security plan;

(5) An integrated plan for quality control;

(6) *A plan for inventorying, safekeeping and tracking medical marijuana from seed to sale as well as for waste plant material;*

(7) *A description of the physical structure;*

(8) *Evidence of legal control of the proposed location;*

(9) *Documentation and source of capitalization;*

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

(11) *A record of tax payments in all jurisdictions in which an applicant has operated as a business for the 5 years prior to the filing of the application; and*

(12) *Any other relevant information to be determined by the Commission.*

C. The application shall be accompanied by the application fee.

D. No party to an application shall have an interest in a license or pending application.

.03 Criminal Background Investigation.

An applicant shall provide to the Director the Central Repository sets of legible fingerprints and the place and date of birth for every medical marijuana grower agent, and a request that the individual's state and national criminal history record be forwarded to the Department of Health and Mental Hygiene for appropriate action.

.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 additional information by the close of business of the seventh business day after the request has been received by the applicant.

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

G. An application is not complete until the Commission receives:

(1) The results of the background check required in Regulation .02 of this Chapter; and

(2) Any required attachment or supplemental information.

H. The Commission shall review completed applications for a license and rank them using an impartial and numerically scored competitive bidding process developed by the Commission based on the following criteria:

(1) Racial, ethnic, and geographic diversity;

(2) Status as a Minority Business Enterprise, as defined in State Finance and Procurement Article, §14-301, Annotated Code of Maryland;

(3) Status as a veteran or military spouse, as defined in Health Occupations Article, §1-701, Annotated Code of Maryland;

(4) Adequacy of safety and security procedures for the growing facility;

(5) The criminal history of all medical marijuana grower agents;

(6) The type of medical marijuana strain designated to be grown and the strain's cannabidiol content;

(7) The capacity of the applicant to prepare medical marijuana in a range of routes of administration;

- (8) Whether the grower will be located in an agricultural zone;*
- (9) The number of dispensaries likely to be served by the applicant in a means as safe, secure, and efficient as possible;*
- (10) Maryland residency and payment of income taxes in Maryland;*
- (11) Experience, knowledge and training in controlled marijuana cultivation and processing;*
- (12) Adequacy of the business plan and financial plan;*
- (13) Whether the proposed facility is appropriately located, including compliance with all zoning and planning requirements; and*
- (14) Any other criteria deemed relevant by the Commission.*

.05 Pre-Approval of Application.

A. The Commission may issue a pre-approval of a license to grow medical marijuana to an applicant following, review, evaluation, and ranking of the application on a determination that the applicant is:

- (1) Of good moral character;*
- (2) Competent to carry out medical marijuana growing operations; and*
- (3) Able to comply with the Commission's regulations.*

B. To determine if the applicant is of good moral character and competent to hold a license, the Commission shall:

- (1) Review and evaluate the contents of an application;*
- (2) Review the results of the criminal background investigations carried out for all medical marijuana grower agents; and*
- (3) Solicit any other information that it deems necessary to make such determination.*

C. Prior to June 1, 2016, in accordance with Health General Article, §13-3309(a)(2), Annotated Code of Maryland, the Commission shall issue no more than 15 licenses.

D. If there are more qualified applications than the number of licenses the Commission will issue and there is a numerical tie for the last license to be issued the license will be determined by public lottery.

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

.06 Issuance of License.

The Commission may issue a license on a determination that:

- A. The application is accurate and complete;*
- B. All inspections are passed; and*
- C. The required license fee has been paid.*

.07 Non-transferability of License.

No license issued pursuant to this chapter shall be assignable or transferable.

.08 Change of Location.

- A. A licensee may apply to change the location of its operation.*
- B. The application shall be made on the form provided by the Commission and accompanied by the specified fee.*
- C. A licensee may not begin cultivation of medical marijuana until all inspections have been passed.*

.09 Renewal of License.

- A. A licensee is eligible to apply to renew a license every two years.*
- B. The Commission shall renew the license that qualifies for renewal.*

C. 90 days prior to the expiration of a license, the Commission shall notify the licensee of the:

- (1) Date on which the license expires;*
- (2) Process and fee required to renew the license; and*
- (3) Consequences of a failure to renew the license.*

D. A licensee who fails to renew a license by the date specified by the Commission shall be required to cease operation of the facility, and shall not provide medical marijuana to any entity until the license is reinstated.

E. A license may be reinstated upon payment of the specified fee and submission of an application approved by the Commission.

F. To renew a license, a licensee shall submit:

- (1) The renewal application as provided by the Commission;*
- (2) A criminal history background check for every medical marijuana grower agent;*
- (3) To full inspection of the operation;*
- (4) Payment of the specified fee; and*
- (5) Any other information required by the Commission.*

10.62.XX Medical Marijuana Grower Agents

Authority: Health General Article, §§ 13-3301, 13-3302, 13-3309, and 13-3312, Annotated

Code of Maryland

.01 Definitions.

A. In addition to the definitions set forth in COMAR 10.62.01, 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 Grower Agent Roster and Criminal History Record Information.

A. A licensee shall:

(1) Apply to the Commission for an identification card for each registered grower agent; and

(2) Create a roster of all registered grower agents;

B. The licensee shall provide access to the roster of registered grower agents to the Commission and to the Maryland State Police.

C. The roster shall include documentation for each registered grower agent of the:

(1) Submission of fingerprints to the Central Registry; and

(2) The request for the criminal history record to be forwarded to the Department of Health and Mental Hygiene.

D. A prospective grower agent shall be disqualified from association with the licensee if the prospective grower agent:

(1) Has ever been convicted of a felony drug offense;

(2) Is currently serving a sentence of parole or probation;

(3) In the last 10 years, has been convicted of a crime that would be a felony in the State; or

(4) In the past 5 years has been convicted of a crime that would be a misdemeanor under the Controlled Dangerous Substances Act.

.03 Termination.

A. Upon termination of a registered grower agent's association:

(1) Take immediate custody of the registered grower agent's identification card from at the time which a registered grower agent ceases to be associated with the grower;

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

*(3) Ensure the terminated registered grower agent can no longer gain access into the facility;
and*

(4) Within 1 business day of the terminated association:

(a) Notify the commission of the termination; and

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

B. The Commission shall notify:

*(1) The Maryland State Police within one day of receiving notification that a registered grower
agent's association with a licensed grower has been terminated.*

.04 Prospective Grower Agent Drug Screen.

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

*B. The drug screen shall be 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 COMAR 17.04.09.06, the screen shall include:

(1) Synthetic cannabinoids; and

(2) 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 shall not
be registered with the Commission as a grower agent.*

. 05 Grower Agent Training.

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

(1) Pertinent laws and regulations;

- (2) Standard operating procedures;*
- (3) Detection and prevention of diversion of medical marijuana;*
- (4) Security procedures;*
- (5) Safety procedures, including responding to a medical emergency, a fire, a chemical spill, and a threatening event such as an armed robbery, invasion, burglary or other criminal incident; and*
- (6) Any other matter determined by the Commission.*

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

.06 Annual Report of Registered Grower Agents.

- A. Every year, on the date determined by the Commission, the licensee shall provide to the Commission the current roster of all registered grower agents.*
- B. The Commission shall suspend the license of any licensee that continues an association with a registered grower agent that:*
 - (1) Has ever been convicted of a felony drug offense;*
 - (2) Is currently serving a sentence of parole or probation;*
 - (3) In the last 10 years, has been convicted of a crime that would be a felony in the State;*
 - (4) In the past 5 years has been convicted of a crime that would be a misdemeanor under the Controlled Dangerous Substances Act.*

.07 Alcohol and Drug Free Workplace Policy.

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

.08 Grower Agent Identification Cards.

- A. *The Commission shall issue identification cards to all registered grower agents.*
- B. *The identification cards issued by the Commission shall include a photograph taken within 6 months of the application.*
- C. *At all times every registered grower agent at a licensed premises shall visibly wear the identification card issued to them by the Commission.*
- D. *The identification card shall display the registered grower agent's name.*
- E. *The identification card shall expire two years after issuance.*
- F. *If a registered grower agent loses the identification card:*
 - (1) *Within 24 hours of becoming aware of the loss, the licensee shall:*
 - (a) *submit a written report on the loss to the local police of jurisdiction and the Commission;*
 - and*
 - (b) *apply for a replacement card and pay replacement card fee.*
 - (2) *A police report and notification to the Commission shall be evidence of registration until a new card is obtained from the Commission.*

10.62.XX – Medical Marijuana Grower Facilities

Authority: Health General Article, §§ 13-3309(a)(3), 13-3309(D), 13-3309(E), Annotated Code of Maryland

.01 Definitions.

A. *In addition to the definitions set forth in COMAR 10.62.01, 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) “Licensed facility” means the physical structure where medical marijuana is cultivated, manufactured, processed, or packaged by a licensee at a licensed premises.

(3) “Licensee” means a licensed grower.

.02 Facilities -- Generally.

A. A licensed facility shall be located within Maryland.

B. A licensed facility cannot be located within 500 feet of a:

(1) School for children in Kindergarten through 12th grade;

(2) Public playground;

(3) Licensed daycare center;

(4) Drug or alcohol treatment facility; or

(5) House of worship.

C. A licensed facility used to distribute medical marijuana shall:

(1) be separate from the area used to cultivate, produce, manufacture or process medical marijuana; and

(2) conform to the building specifications required in _____ of these regulations.

D. A licensed facility shall clearly display in the front of the building, on signage approved by the Commission, the name and street address of the facility, and the direction to entrance, if not obvious, to expedite emergency response.

E. At each licensed premises the license shall be conspicuously displayed.

F. No change or major modification to a licensed facility shall be permitted without approval of the Commission.

.03 Facility Security Hardware.

A. *Each licensed facility that is used to cultivate, manufacture, process, or package medical marijuana shall be constructed to prevent unauthorized entry.*

B. *If the licensed facility is located within a building or structure that also houses a non-licensed facility, any wall between the licensed facility and the non-licensed facility shall be sufficient to prevent unauthorized entry.*

C. *Each exterior door shall have visual or electronic surveillance capable of monitoring the entrance to restrict improper entrance.*

D. *A cipher or chip-activated keyed lock or equivalent shall be used in a door to deny passage by an unauthorized person to the facility and any room in which production, cultivation, storage, or processing medical marijuana takes place, or in which security equipment is located in the licensed facility.*

E. *A greenhouse to be used to cultivate medical marijuana shall meet the following requirements:*

(1) The greenhouse shall be fabricated of polycarbonate or other material that prevents unauthorized entry;

(2) Any ventilation system shall be protected by metal caging material;

(3) The greenhouse shall be surrounded by an eight foot or higher chain link fence topped with multiple strands of barbed wire, located no less than twenty feet from the greenhouse; and

(4) There shall be no vegetation within 15 feet of the greenhouse.

.04 Facility Security Lighting.

A. *Each licensed facility shall be equipped with adequate interior and exterior lighting.*

B. Lighting fixtures of the licensed facility shall be designed and installed sufficient to adequately illuminate both sides of all exterior doors, entrances and windows to ensure proper surveillance.

C. Lighting fixtures of the licensed facility shall be designed and installed sufficient to adequately illuminate all interior doors and passages between rooms of a facility to ensure proper surveillance.

D. Interior lighting of the licensed facility shall be designed and installed sufficient to adequately illuminate work areas for employee safety and comfort.

E. This regulation does not apply to lighting in areas of the facility used to cultivate medical marijuana.

.05 Facility Security Systems.

A. Each licensed facility shall maintain a security system that covers all perimeter entry points and windows.

B. The security system shall be:

(1) Continuously monitored; and

(2) Capable of detecting fire.

C. The security system shall include a panic alarm device mounted at convenient, readily-accessible locations throughout each area of the licensed facility.

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

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

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

(3) Any vault that holds medical marijuana.

E. The security systems shall remain operational until the licensed facility no longer has any medical marijuana, seeds, or cuttings on the premises.

F. All security systems shall be equipped with auxiliary power sufficient to maintain operation for at least 24 hours.

.06 Video Surveillance Requirements.

A. Each facility shall maintain a 24-hour video surveillance recording system.

B. A surveillance camera shall be located and operated to continuously capture each point of ingress and egress.

C. A surveillance camera shall continuously capture activity at each door or entrance to an area where medical marijuana is grown, tested, cured, manufactured, and stored.

D. 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.

E. The storage of all recordings of security video surveillance shall be:

(1) Access-limited;

(2) Secured by a security system that is independent of the main facility security system;

(3) In a format that can be easily accessed for evidentiary purposes; and

(4) For a minimum of 90 days.

F. Any recording of security video surveillance shall be made available to the Commission as requested.

.06 Individuals at a Facility.

A. At least two registered grower agents shall be present at the licensed facility while work or maintenance is being performed.

B. Other than a visitor engaged in regular or routine maintenance of the building or a mechanical, security, electrical, or plumbing system, the public is not allowed to enter or tour any licensee facility without Commission approval.

C. A visitor shall be logged in and out by a supervising employee and a photocopy of a government-issued identification document shall be made and retained for 5 years.

10.62.XX Medical Marijuana Growing Controls

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

.01 Definitions.

A. In addition to the definitions set forth in 10.62.01, 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 grower.

(2) "Licensed facility" means the location where medical marijuana is grown, cultivated, manufactured, processed, or packaged by a licensee.

(3) "Licensee" means a licensed grower.

(4) "Growing media" means commercially produced potting mix.

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

(6) "Green waste" means unused or surplus medical marijuana, recalled medical marijuana, and any plant debris, including dead plants, all unused plant parts, and roots.

.02 Standard Operating Procedure.

A. The licensee shall:

(1) Establish a written standard operating procedure for all aspects of the propagation, cultivation, harvesting, drying, curing, packaging, labeling and handling of medical marijuana products, byproducts, waste products, and the control thereof, to promote good growing and handling practices;

(2) Ensure that each person engaged in the cultivation, manufacturing, processing, packaging, and testing of medical marijuana has the training, education, or experience necessary to perform assigned functions;

(3) Ensure 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;

(4) Escort and maintain visual contact with any visitor while that person is in a licensed facility.

.03 Design and Construction.

A. The licensed facility shall:

(1) Be of suitable size and design to facilitate proper operation;

(2) Be constructed using materials which are durable and can withstand weather extremes;

(3) Be designed to prevent contamination throughout the facility; and

(4) Be designed to be adequately cleaned.

.04 Horticultural Controls.

A. Water.

(1) Water quality shall be tested yearly.

(2) A record of water testing shall be kept onsite and be made available during inspections.

B. Fertilizer.

(1) The licensee shall:

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

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

(c) Maintain records of the type and amounts of fertilizer used.

C. The licensee shall use growing media.

D. The licensee shall install a system to monitor and regulate temperature, humidity, ventilation, and lighting, if used.

E. Facility ventilation shall be sealed or screened with a mesh fine enough to exclude most plant pests.

F. Pest Monitoring.

(1) The licensee shall use Integrated Pest Management practices and techniques to identify and manage plant and pest problems, including:

(a) The implementation of an entry and exit door system sufficient to prevent pest entry;

(b) Regular visual inspection for pests;

(c) The use sticky cards in growing areas; and

(d) Recording any pest detection and relevant circumstances.

G. Pest Control.

(1) The licensee or registered grower agent on site shall maintain a State pesticide applicators license or contract with a licensed State pesticide applicator;

(2) The licensee shall follow State and pesticide label guidelines when applying pesticides, and maintain State required records;

(3) Plants shall be monitored for presence of all fungal diseases; and

(4) Application of fungicides to plants or growing media shall be in a method and at a concentration specified on the product label and as approved by the State for vegetable, fruit or medicinal plant application.

H. Sanitation.

(1) Floors and benches shall be kept free of debris and algae;

(2) Dead plants shall be removed from growing areas;

(3) Floors, benches, pots, and tools and equipment that come into contact with plants shall be cleaned using only sanitizing agents approved for vegetable, fruit, or medicinal plant production;

(4) Rodents and other non-plant related pests shall be controlled using only chemicals approved for use around vegetables, fruit, or medicinal plants;

I. Green Waste.

(1) Green waste shall be disposed of:

(a) In a method approved by the Commission and the State Police; or

(b) Collected and retained until disposed of by a law enforcement agency.

(2) All green waste shall be weighed and documented on a form provided by the Maryland State Police.

.05 Equipment.

A. The licensee shall maintain equipment which comes in contact with medical marijuana to prevent contamination.

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

C. 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.

10.62.XX Quality Control by a Licensed Medical Marijuana Grower.

Authority: Health General Article, §§13-3302, 13-3306, and 13-3308, Annotated Code of Maryland

.01 Production and Process Controls.

A. The licensee shall maintain a secure, tamper-proof log to record each step of the procedure carried out in the course of the propagation, cultivation, harvesting, drying, curing, packaging, labeling and handling of each plant of medical marijuana to ensure consistency and accuracy in the day-to-day production.

C. Each step of the procedure carried out in the course of the propagation, cultivation, harvesting, drying, curing, packaging, labeling and handling of each plant of medical marijuana shall be recorded in the log.

D. The licensee shall record any deviation from the standard operating procedure in any step in the production of any batch in the log.

E. The licensee may not release any batch of medical marijuana if the production of the batch deviated from the standard operating procedure unless:

(1) As a result of independent testing of the batch described in Regulation .11B of this chapter, there is a determination by the licensee that the batch meets the specification for the particular strain, and

(2) The determination is recorded.

.02 Holding and Distribution Procedure.

A. The licensee shall hold packaged medical marijuana in secure storage until released for distribution.

B. Upon receipt of an order, the licensee will repackage the designated quantity of medical marijuana into a container as provided in COMAR 10.62.08.09B and will label the container according to the recommendation and COMAR 10.62.09.03.

.03 Testing.

A. During the process of growth, the licensee shall regularly inspect the plants to ensure proper growth and absence of disease.

B. Before any part of a batch of medical marijuana is packaged, the licensee shall have the batch analyzed to ensure that:

(1) The batch conforms to the chemical profile of the identified strain by assessing the chemical profile markers for Δ^9 -Tetrahydrocannabinol (THC) and Cannabidiol (CBD);

(2) The batch is free of contamination from:

(a) Foreign material such as hair, insects, or any other adulterant;

*(b) Any microbiological impurity, including total aerobic microbial count (TAMC), total yeast microbial count (TYMC), *P. aeruginosa*, and *S. Aureus*;*

(c) Any heavy metal;

(d) Any aflatoxin; and

(e) Any pesticide; and

(3) The batch has the appropriate:

(a) Odor and appearance;

(b) Fineness; and

(c) Moisture content.

C. The licensee shall submit a sample of every batch to an independent laboratory for a certificate of analysis which shall be retained by the grower, and a copy of which shall be provided by the grower to the program.

D. The licensee shall retain and properly store a sample of every batch sufficiently large enough to provide for follow-up testing as required.

E. The licensee shall perform stability testing of retained samples at 6 month periods to:

(1) Ensure product potency and purity; and

(2) Provide support for expiration dating.

10.62.XX Product Tracking by a Licensed Medical Marijuana Grower

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

.01 Definitions.

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

B. Terms Defined.

(1) "Licensee" means a licensed grower.

(2) "Hard goods" means any non-plant material.

(2) "Unique identifier" means any symbol or mark which will enable tracking of medical marijuana from plant to final product.

.02 Inventory Control System.

A. A licensee shall use a perpetual inventory control system that identifies and tracks the licensee's stock of medical marijuana from the time the medical marijuana is propagated from

seed or cutting to the time it is delivered to the academic medical center, licensed dispensary, or qualifying patient or caregiver.

(B) In the event of an adverse reaction, the inventory control system shall enable tracking back to the source of medical marijuana.

(C) The inventory control system shall enable detection of diversion.

.02 Materials Received for Cultivation.

A. Upon receipt of raw material for cultivation, the licensee shall record:

(1) The date delivered;

(2) The number of seeds delivered or the weight of the shipment; and

(3) The species or strain included in the delivery.

B. The licensee shall provide that any incoming component or material used in connection with producing medical marijuana is received and quarantined for inspection by the licensee's staff and kept separate from other inventory prior to release for use in any operation.

C. Hard goods shall be inspected for defects, contamination, and compliance with the licensee's specifications.

.03 Plant Tagging.

A. As soon as practical, each plant shall be tagged with a unique identifier.

B. Tags shall be indelible and tamper-proof.

C. Tags shall be securely attached.

D. Tags shall be made of a material which resists variation in temperature and moisture.

E. Plants shall be entered into the inventory control system.

.04 Control of Harvested Medical Marijuana.

A. Upon the completion of curing or drying of each batch, medical marijuana shall be weighed for inventory control.

B. The licensee shall:

(1) Conduct a physical inventory of the stock at least monthly; and

(2) Compare the physical inventory stock with the perpetual inventory record.

.05 Discrepancy Reporting.

A. If the licensee discerns any discrepancy between the inventory of stock and the inventory record, within 24 hours the licensee shall commence to investigate the discrepancy.

B. If the licensee finds evidence of a loss, within 3 business days the licensee shall report the loss to the Commission and, if appropriate, to the Maryland State Police.

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

(1) Complete an investigation of the circumstances of the discrepancy;

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

(3) Send a final report to the Commission for review.

.06 Product Returned for Destruction.

A licensee shall accept the return of any medical marijuana from a qualifying patient, caregiver, or academic medical center for the purpose of destruction as waste as provided by COMAR 10.62.07.12.

.07 Limitation on Transfer of Medical Marijuana.

A licensee may not sell, transfer, give away, or otherwise dispose of any medical marijuana the licensee, or registered grower agent knows or should have reason to know does not comply with any provision of Chapter _____ of the Acts of 2014, or the regulations thereof.

.08 Duration of Record Keeping.

A. Inventory records shall be maintained for 5 years.

B. For a batch, the period for retaining records shall begin when the licensee's last transaction regarding the batch occurs.

.09 Custody of Recalled Material.

A. The licensee shall develop a procedure to ensure all medical marijuana that is recalled is stored and segregated until its disposal is authorized by the Commission.

B. Within 24 hours of the receipt of notice from the Commission that the disposal of recalled medical marijuana is authorized, the licensee shall take the necessary steps to arrange for the disposal pursuant to 10.62.07.14.

10.62.XX Transportation and Transfer of Medical Marijuana from a Licensed Grower to a Licensed Dispensary.

Authority: Health General Article, §§13-3301, 13-3309(D)-(G), Annotated Code of Maryland

.01 Definitions.

A. In addition to the definitions set forth in COMAR 10.62.01, in this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Grower transportation agent" means a registered grower agent authorized by the licensed grower to transport medical marijuana who meets the criteria specified in .03 of this chapter.

(2) "Medical marijuana transport vehicle" means a vehicle owned or leased by a licensed grower for the purpose of transporting medical marijuana to a licensed dispensary that meets the criteria specified in .06 of this chapter.

(3) “Shipment identification number” means a unique identification number created by the licensed grower for purposes of tracking the transportation of each shipment of medical marijuana.

.02 Electronic Manifest and Chain of Custody Requirements.

A. An electronic manifest and chain of custody shall be created prior to the transport of medical marijuana from a licensed grower to a licensed dispensary.

B. An electronic manifest and chain of custody shall contain the following:

- (1) The name and address of the licensed grower;
- (2) The licensed grower’s shipment identification number;
- (3) The weight and description of each individual package in the shipment;
- (4) The name of the registered grower agent that prepared the shipment;
- (5) The name and address of the receiving licensed dispensary; and
- (6) Any handling instructions.

C. The electronic manifest and chain of custody shall contain the following entries, in the order listed:

- (1) An entry by the registered grower agent who has prepared the shipment, including the date and time of preparation;
- (2) An entry by a grower transportation agent, of the date and time of the placement of the shipment into the medical marijuana transport vehicle;
- (3) An entry by registered dispensary agent receiving the shipment including the date and time of the acceptance;

D. In the event that a registered dispensary agent returns medical marijuana to a licensed grower, a new electronic manifest and a new chain of custody from the licensed dispensary to the licensed grower shall be created in the same manner as detailed in §B of this regulation.

.03 Transportation of Medical Marijuana from a Licensed Grower to a Licensed Dispensary.

- A. Only a licensed grower shall transport medical marijuana to a licensed dispensary.*
- B. Only a grower transportation agent may transport medical marijuana from a licensed grower to a licensed dispensary.*
- C. At least two grower transportation agents shall accompany medical marijuana that is being transported from a licensed grower to a licensed dispensary.*
- D. A grower transportation agent shall maintain a current driver's license at all times.*
- E. A grower transportation agent shall carry appropriate identification, as approved by the Commission, during the transport of medical marijuana.*
- F. Grower transportation agents shall not wear any clothing or symbols that may indicate ownership or possession of marijuana.*

.04 Packaging of Medical Marijuana for Transport by a Licensed Grower.

- A. The weight of individual packages in a shipment shall be entered into the electronic manifest and chain of custody. All medical marijuana for transport from a licensed grower shall be:*
- B. Packaged in tamper-proof opaque material approved by the Commission; and*
- C. Sealed with tamper-proof tape that contains the name, signature, and date of the grower agent responsible for preparing the package.*
- D. Individual packages from a licensed grower that are going to the same licensed dispensary may be sealed within one large opaque tamper-proof container.*

.05 Labeling of Medical Marijuana Packages for Transport by a Licensed Grower

A. Each package of medical marijuana transported from a Licensed Growing Facility to a Licensed Dispensary must be sealed in a tamper-evident package and labeled with the following information:

- (1) The name and address of the licensed grower;*
- (2) The date and time the package was sealed;*
- (3) The licensed grower's shipment identification number;*
- (4) A description of the contents of each package;*
- (5) The total weight of each individual package; and*
- (6) The name and address of the licensed dispensary to receive the medical marijuana.*

B. Labels shall be constructed with weather-resistant and tamper-proof materials.

C. All package labels must be conspicuous.

.06 Medical Marijuana Transport Vehicles.

A. All medical marijuana transport vehicles shall:

- (1) Display current registration from the State of Maryland;*
- (2) Display no markings of ownership or use other than those required by law; and*
- (3) Be insured as required by law.*

B. During transport, medical marijuana shall be:

- (1) In a container within the medical marijuana transport vehicle secured to resist unauthorized entry;*
- (2) Insulated from the grower transportation agents; and*
- (3) Not visible from the outside of the medical marijuana transport vehicle.*

10.62.XX Application for Medical Marijuana Dispensary License

Authority: Health General Article, §§13–3301, 13–3310, Annotated Code of Maryland

.01 Definitions.

A. In addition to the definitions set forth in COMAR 10.62.01, in this and the next chapter, the following terms have the meanings indicated.

B. Terms defined.

(1) "Grower satellite facility" means a dispensary owned by a licensed grower.

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

(3) "Licensed facility" means the premises where medical marijuana is packaged, stored, and dispensed to a qualifying patient or caregiver.

(3) "Licensee" means a licensed dispensary.

.02 Application.

A. An application to operate a licensed dispensary at a specific location shall be submitted on a form provided by the Commission.

B. An application shall include:

(1) A business plan including an organizational chart;

(2) Identification of applicant's medical marijuana dispensary agents and major investors at the time of application;

(3) Details of the applicant's experience, knowledge, and training in the dispensing and processing of medical marijuana;

(4) A plan for counseling qualifying patients and caregivers in the use of medical marijuana by properly trained dispensary agents;

(5) A security plan;

(6) An integrated plan for quality control;

(7) A plan for inventorying, safekeeping and tracking medical marijuana;

- (8) A physical description of the proposed facility;*
- (9) Evidence of legal control of the location of the proposed facility;*
- (10) Documentation and source of capitalization;*
- (11) If the applicant is a corporation, a copy of the articles of incorporation and authorization to do business in Maryland;*
- (12) A record of tax payments in all jurisdictions in which an applicant has operated as a business for the 5 years prior to the filing of the application; and*
- (13) Any other relevant information to be determined by the Commission.*

C. The application shall be accompanied by the required application fee.

D. No party to an application shall have an interest in a license or pending application.

.03 Licensed Grower acting as a Dispensary.

A. At a licensed grower facility or approved grower satellite facility, a licensed grower may dispense medical marijuana in conformity with the regulations in _____ of this subtitle.

B. A separate application shall be submitted and approved by the Commission before a licensed grower may dispense medical marijuana directly to qualified patients and caregivers.

.04 Criminal Background Investigation.

An applicant shall provide to the Director of the Central Repository sets of legible fingerprints and the place and date of birth for every registered dispensary agent, and a request that the individual's state and national criminal history record be forwarded to the Department of Health and Mental Hygiene for appropriate action.

.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 additional information by the close of business of the seventh business day after the request has been received by the applicant.

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

G. An application is not complete until the Commission receives:

- (1) The results of the criminal history record required in Regulation .02 of this Chapter; and*
- (2) Any required attachment or supplemental information.*

H. The Commission shall review completed applications for a license and rank them using an impartial and numerically scored competitive bidding process developed by the Commission based on the following criteria:

- (1) Racial, ethnic, and geographic diversity;*
- (2) Status as a Minority Business Enterprise, as defined in State Finance and Procurement Article, §14-301, Annotated Code of Maryland;*
- (3) Status as a veteran or military spouse, as defined in Health Occupations Article, §1-701, Annotated Code of Maryland;*
- (4) Adequacy of safety and security procedures for the dispensary facility;*
- (5) Plan to enforce the alcohol and drug free workplace policy*
- (6) The criminal history record check of all medical marijuana dispensary agents;*

- (7) The types of medical marijuana strains to be distributed and the strains' cannabidiol content;*
- (8) The capacity of the applicant to prepare or dispense medical marijuana in a range of routes of administration;*
- (9) Maryland residency and payment of income taxes in Maryland;*
- (10) Experience, knowledge and training in controlled marijuana dispensing and processing;*
- (11) Adequacy of the business plan and financial plan;*
- (12) Whether the proposed facility is appropriately located, including compliance with all zoning and planning requirements; and*
- (13) Any other criteria deemed relevant by the Commission.*

.06 Pre-Approval of License Application.

A. The Commission may issue a pre-approval of a license to an applicant following, review, evaluation, and ranking of the application on a determination that the applicant is:

- (1) Of good moral character;*
- (2) Competent to carry out dispensary operations; and*
- (3) Able to comply with the Commission's regulations.*

B. To determine if the applicant is of good moral character and competent to dispense and process medical marijuana, the Commission shall:

- (1) Review and evaluate the contents of an application;*
- (2) Review the results of the criminal history record for all registered dispensary agents; and*
- (3) Solicit any other information that it deems necessary to make such determination.*

C. If there are more qualified applications than the number of licenses the Commission will issue and there is a numerical tie for the last license to be issued the license will be determined by public lottery.

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

.07 Issuance of License.

The Commission may issue a license on a determination that:

- A. The application is accurate and complete;*
- B. All inspections are passed; and*
- C. The required license fee has been paid.*

.08 Non-transferability of License.

No license issued pursuant to this chapter shall be assignable or transferable.

.09 Change of Location.

- A. A licensee may apply to change the location of its operation.*
- B. The application shall be made on the form provided by the Commission and accompanied by the specified fee.*
- C. A licensee may not begin dispensing medical marijuana until all inspections have been passed.*

.10 Renewal of License.

- A. A licensee is eligible to apply to renew a license every two years.*
- B. The Commission shall renew a license that meets the qualifications in §F of this Regulation.*
- C. 90 days prior to the expiration of a medical marijuana dispensary license, the Commission shall notify the dispensary of the:*
 - (1) Date on which the license expires;*
 - (2) Process and fee required to renew the license; and*
 - (3) Consequences of a failure to renew the license.*

D. A licensee who fails to renew a license by the date specified by the Commission shall be required to cease operation of the facility, and shall not provide medical marijuana to any entity until the license is reinstated.

E. A license may be reinstated upon payment of the specified fee and submission of an application approved by the Commission.

F. To renew a license, a licensee shall submit:

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

(2) A criminal history record check for every medical marijuana dispensary agent;

(3) To a full inspection of the operation;

(4) Payment of the specified fee; and

(5) Any other information required by the Commission.

10.62.XX Registered Dispensary Agents.

Authority: Health General Article, §§13–3301, 13–3311, Annotated Code of Maryland

.01 Definitions.

A. In addition to the definitions set forth in COMAR 10.62.01, 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 grower.

.02 Dispensary Agent Roster and Criminal History Record Information.

A. A licensee shall:

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

(2) Create a roster of all registered dispensary agents.

B. A licensee shall:

(1) Take custody of the identification card from a registered dispensary agent on the day on which the registered dispensary agent ceases to be associated with the licensed dispensary; and

(2) Within 1 business day of the terminated association:

(a) Initiate delivery of the identification card to the Commission; and

(b) Notify the Commission of the termination.

C. The Commission shall notify the Maryland State Police within one day of receiving notification that a registered dispensary agent's association with a licensee has been terminated.

D. The licensee shall provide access to the roster of registered dispensary agents to the Maryland State Police.

E. The roster shall include documentation for each registered dispensary agent of the:

(1) Submission of fingerprints to the Central Registry; and

(2) The request for the criminal history record to be forwarded to the Department of Health and Mental Hygiene.

F. A prospective dispensary agent shall be disqualified from association with a licensee if the prospective dispensary agent:

(1) Has ever been convicted of a felony drug offense;

(2) Is currently serving a sentence of parole or probation;

(3) In the last 10 years, has been convicted of a crime that would be a felony in the State; or

(4) In the past 5 years has been convicted of a crime that would be a misdemeanor under the Controlled Dangerous Substances Act.

.03 Prospective Dispensary Agent Drug Screen.

A. *The licensee shall require a prospective dispensary agent to submit to a drug screen prior to commencement of service.*

B. *The drug screen shall be 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 COMAR 17.04.09.06, the screen shall include:*

(1) Synthetic cannabinoids; and

(2) 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 shall not be registered with the Commission as a dispensary agent.*

.04 Dispensary Agent Training.

A. *The licensee shall train all dispensary agents on:*

(1) Pertinent laws and regulations;

(2) Standard operating procedures;

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

(4) Security procedures;

(5) Safety procedures, including responding to a medical emergency, a fire, a chemical spill, and a threatening event such as an armed robbery, invasion, burglary or other criminal incident; and

(6) And any other information determined by the Commission.

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

.05 Annual Report of Registered Dispensary Agents.

A. Every year, on the date determined by the Commission, the licensee shall provide to the Commission the current roster of all registered dispensary agents.

B. The Commission shall suspend the license of any licensee that continues an association with a registered dispensary agent that:

(1) Has ever been convicted of a felony drug offense;

(2) Is currently serving a sentence of parole or probation;

(3) In the last 10 years, has been convicted of a crime that would be a felony in the State;

(4) In the past 5 years has been convicted of a crime that would be a misdemeanor under the Controlled Dangerous Substances Act.

.06 Alcohol and Drug Free Workplace Policy.

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

.07 Dispensary Agent Identification Cards.

A. The Commission shall issue identification cards to all registered dispensary agents to include a photograph taken within 6 months of the application.

B. At all times every registered dispensary agent working or volunteering on the premises of a licensed dispensary shall visibly wear the identification card issued to them by the Commission.

C. The identification card shall display the registered dispensary agent's name.

D. The identification card shall expire two years after issuance.

E. If a registered dispensary agent loses the identification card:

(1) Within 24 hours of becoming aware of the loss, the licensee shall submit a written report on the loss to:

(a) The local police of jurisdiction; and

(b) The Commission.

(2) A police report and notification to the Commission shall be evidence of registration until a replacement identification card is obtained from the Commission.

10.62.XX Medical Marijuana Dispensary Facilities.

Authority: Health General Article, §§13–3301, 13–3310(B)(2)(III), 13-3310(C), Annotated

Code of Maryland

.01 Definitions.

A. In addition to the definitions set forth in COMAR 10.62.01, 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) "Licensed facility" means...

(3) "Licensee" means a licensed dispensary.

.02 Facilities -- Generally.

A. A dispensary license shall be prominently displayed at each location where the licensed dispensary is authorized to operate.

B. A licensed dispensary shall be located within Maryland.

C. A licensed dispensary shall be separated geographically from any facility used to cultivate, harvest, and process, medical marijuana.

D. No registered dispensary agent shall simultaneously be registered as a grower agent, and no registered grower agent shall simultaneously be registered as a dispensary agent.

E. A licensed dispensary shall not be opened within 500 feet of a:

(1) School for children in pre-school through 12th grade;

(2) Public playground;

(3) Licensed daycare center;

(4) Drug or alcohol treatment facility; or

(5) House of worship.

F. A licensed dispensary shall clearly display in the front of the building, on signage approved by the Commission, the name and street address of the facility, and the direction to entrance, if not obvious, to expedite emergency response.

.03 General Facility Security Hardware.

A. The exterior of each licensed dispensary used to dispense medical marijuana shall be constructed of traditional sturdy materials, built to resist unauthorized entry or penetration, trespass, and reasonably anticipated weather conditions.

B. If the licensed dispensary is located within a building or structure that also houses a business or other entity not licensed by the Commission, any interior wall between the licensed dispensary and any other entity may not have any door, window, or portal

C. Each door of a licensed dispensary shall be commercial grade.

D. Each exterior door shall have visual and electronic surveillance capable of monitoring the entrance to restrict entrance by a visitor or unauthorized person.

E. A cipher or chip-activated keyed lock or equivalent shall be used in a door to deny passage by an unauthorized person to the facility and any room in which storage, processing, or security equipment is located in the licensed dispensary.

.04 Vault.

A. Each licensed dispensary shall contain a secure room or vault to store the medical marijuana inventory.

B. A vault shall:

(1) Be constructed of concrete or similar building material that strongly prevents unauthorized entry;

(2) Not be placed adjacent to an exterior wall of the facility; and

(3) Have only one entrance door that:

(a) Meets commercial security standards;

(b) Is equipped with a cipher or chip-activated keyed lock or equivalent;

(c) Is subject to visual and electronic surveillance monitoring; and

(d) Is not visible from public areas of the facility.

C. Other than while the licensed dispensary is open for business and one hour before and one hour after, the inventory of medical marijuana shall be stored in the vault.

.05 Facility Security Lighting.

A. Each licensed dispensary shall be equipped with adequate interior and exterior lighting.

B. Lighting fixtures of the licensed dispensary shall be designed and installed to illuminate:

(1) Both sides of all exterior doors, entrances and portals to ensure proper surveillance at night;

(2) All interior doors and passages between rooms of a facility to ensure proper surveillance;

and

(3) Work areas for employee safety and comfort.

.06 Facility Security Alarm Systems.

A. Each licensed dispensary shall be provided with and fully maintain an operational security alarm system by a licensed alarm service that covers all perimeter entry points and windows.

B. The security alarm system shall be:

- (1) Continuously monitored; and*
- (2) Capable of detecting smoke and fire.*

C. The security alarm system shall include a sufficient number of panic alarm devices mounted at convenient locations throughout each work space of the licensed dispensary to be readily-accessible to all registered dispensary agents present.

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) The vault that holds medical marijuana.*

E. The security system shall remain operational until the licensed dispensary is no longer in business and no longer has on the premises any medical marijuana.

F. All alarm systems shall be equipped with auxiliary power sufficient to maintain operation for at least 24 hours.

.07 Video Surveillance Requirements.

A. Each licensed dispensary shall maintain a 24-hour video camera and surveillance recording system which meets the specifications of the Commission and shall post notices thereof.

B. A surveillance camera shall be located and operated to continuously capture each point of exterior access.

C. A surveillance camera shall continuously capture activity in and at the entrance to the vault.

D. 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.*

E. The storage of all recordings of security video surveillance shall be:

- (1) Access-limited;*
- (2) Secured by a security system that is independent of the main facility security system;*
- (3) In a format that can be easily accessed for evidentiary purposes; and*
- (4) For a minimum of 90 days.*

F. Any recording of security video surveillance shall be made available to the Commission as requested.

.08 Individuals at a Licensed Dispensary.

- A. At least two registered dispensary agents associated with the licensee shall be on duty at the licensed dispensary during hours of operation.*
- B. A person engaged in regular or routine maintenance of the building or a mechanical, security, electrical, or plumbing system, must be accompanied by a registered dispensary agent.*
- C. The public is not allowed to enter or tour any licensed dispensary without Commission approval.*
- D. An employee of the Commission, any appropriate state or local regulatory agency and the Maryland State Police, in the course of their duties may enter a licensed dispensary at any time to carry out a regular or unscheduled inspection.*
- E. A visitor shall be logged in and out by a supervising registered dispensary agent and a photocopy of a government-issued identification document shall be made and retained for 5 years.*

.09 Licensed Dispensary Facility Organization.

- A. Each licensed dispensary shall divide its premises between a public zone and an operations zone.*

B. The public zone shall have:

- (1) A waiting area open to the general public; and*
- (2) A service area in which a qualifying patient or caregiver may consult with a registered dispensary agent and receive medical marijuana.*

C. Within the public zone:

- (1) Qualifying patients and caregivers must be accompanied by a registered dispensary agent.*
- (2) The licensed dispensary shall maintain a tamper-proof log to record the entry and exit of all persons into the service area, other than a registered dispensary agent.*
- (3) The dispensary's hours of business shall be displayed in the public zone.*

D. All operations other than counseling qualifying patients and caregivers and dispensing medical marijuana shall be carried out in the operations zone.

E. The operations zone shall be appropriately divided into separate areas for medical marijuana storage, medical marijuana preparation and packaging, and for use by dispensary agents for breaks, to change clothing, and for dispensary agent lockers.

F. Tamper-proof logbooks or electronic identification logs shall document the movement of registered dispensary agents to and from the operations zone.

G. Appropriate signage shall clearly delineate the separate zones.

H. Doors and other access points between zones shall be secured.

I. Video surveillance and alarms, as described in Regulations .05&.06., shall be used to monitor the separation between zones.

J. All medical marijuana other than that being displayed or processed during business hours shall be kept in secure storage.

K. No person may handle the inventory in a display case or elsewhere in the dispensary other than a registered dispensary agent.

L. Only the following persons may enter an area of a licensed dispensary where medical marijuana is present, and only in accordance with these regulations:

- (1) A registered dispensary agent;*
- (2) A contractor authorized by the dispensary to be on the premises;*
- (3) A qualifying patient or designated primary caregiver; and,*
- (4) A person authorized by the Commission.*

10.62.XX Medical Marijuana Dispensary Procedures.

Authority: Health General Article, §§13–3301, 13–3310(B)(2)(III), 13-3310(C), Annotated Code of Maryland

.01 Definitions.

A. In addition to the definitions set forth in COMAR 10.62.01, in this chapter, the following term has the meaning indicated.

B. Term Defined.

(1) “Grower transportation agent” means a registered grower agent authorized by the licensed grower to transport medical marijuana and who meets the criteria specified in COMAR

10.62.XX.03 of this chapter.

(2) “Dispensary supervisor” means the registered grower agent designated by the licensed dispensary to supervise dispensary operations.

.01 Standard Operating Procedure.

A. A licensed dispensary shall:

(1) Establish a standard operating procedure for all aspects of the receipt, storage, packaging, labeling, handling, tracking and dispensing medical marijuana products and medical marijuana waste; and

(2) Train each registered dispensary agent in the standard operating procedure.

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

.02 Chain of Custody Receipt of Medical Marijuana by a Licensed Dispensary.

A. No licensed dispensary or registered dispensary agent shall:

(1) Acquire medical marijuana from a person or entity other than a licensed grower;

(2) Obtain medical marijuana from outside of the State of Maryland; or

(3) Transport medical marijuana to any place outside the State of Maryland.

B. Upon delivery and before entry into a licensed dispensary's inventory, a registered dispensary agent shall confirm that:

(1) A grower transport agent is carrying appropriate identification;

(2) A grower transport agent provides satisfactory evidence identifying the licensed grower;

(3) The medical marijuana packaging is secure, undamaged, and appropriately labeled;

(4) The medical marijuana is accompanied by a manifest and chain of custody; and

(5) In the presence of the registered grower agent, the weight and identity of the medical marijuana match the accompanying documents and labels.

C. An indication that the shipment is complete in all aspects will be reflected in the electronic signature of both the transporting and receiving agents unless there is a discrepancy.

(1) Any discrepancy in the manifest and chain of custody as identified by a registered grower agent or a registered dispensary agent shall be reported to the agent's supervisor.

(2) If a discrepancy can be immediately rectified, a note shall be made in the electronic manifest and chain of custody that is signed by the accepting dispensary supervisor.

(3) Any discrepancy that cannot be immediately rectified shall be reported to the Commission, and an investigation shall be initiated by the grower and the dispensary.

(4) A preliminary report of any investigation under this Chapter must be reported to the Commission within 7 days, and a written report shall be submitted to the Commission within 30 days.

D. A copy of the electronic manifest and chain of custody for the shipment shall be given to the registered dispensary agent, and the grower transportation agent shall maintain the original copy.

.03 Tracking Medical Marijuana after Receipt by a Licensed Dispensary.

A. Medical marijuana received by a licensed dispensary shall initially be stored in the dispensary's vault along with the appropriate manifest and chain of custody.

B. No medical marijuana shall be removed from the vault until entered in the licensed dispensary's internal inventory system.

C. The inventory control system track the processing of medical marijuana at all stages of packaging or repackaging.

.04 Storage of Medical Marijuana.

A. A licensed dispensary shall maintain the cleanliness of any building or equipment used to store or display medical marijuana.

B. A registered dispensary agent shall:

(1) Comply with the standard operating procedure to maintain the medical marijuana free from contamination; and

(2) Report to a supervisor any personal health condition that might compromise the cleanliness or quality of the medical marijuana the dispensary agent might handle.

C. Medical marijuana that is outdated, damaged, deteriorated, misbranded, adulterated, or whose containers or packages have been improperly or accidentally opened shall be stored separately in the vault until destroyed.

.05 Equipment.

A. The licensee shall maintain equipment which comes in contact with medical marijuana to prevent contamination.

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

C. 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.

.06 Repackaging Medical Marijuana for distribution to a qualifying patient or caregiver.

A. Medical marijuana may only be dispensed to a qualifying patient or a caregiver in a container that:

- (1) Is opaque;
- (2) Is sealed by the dispensary agent;
- (3) Having been opened, cannot appear to be sealed;
- (4) Is significantly difficult for children younger than 5 years old to open, unless a qualifying patient or caregiver requests otherwise;
- (5) Does not imitate the trade dress of any candy, confection, or food; and

(6) Is not attractive to children.

B. Medical marijuana may only be prepared or re-packaged at a licensed dispensary in an area of the operations zone designed, maintained, and used exclusively for such purposes.

.07 Labeling Medical Marijuana for Distribution to a Qualifying Patient or Caregiver.

A. The label of a package of medical marijuana shall be printed in letters no less than one-sixteenth of an inch high.

B. The label for a package of medical marijuana dispensed directly to a qualifying patient or caregiver shall state:

(1) The name of the product;

(2) The batch number of the product;

(3) The cannabinoid profile of the medical marijuana;

(4) Concentrations of any cannabinoid of less than one percent shall be printed with a leading zero before the decimal point;

(5) The quantity of medical marijuana contained within;

(6) Any other ingredients in addition to medical marijuana;

(7) The name of the licensed grower who produced the product;

(8) The name of the licensed dispensary where the product was dispensed;

(9) The date that the medical marijuana was transferred to the qualifying patient or caregiver;

(10) The name of the qualifying patient;

(11) The name of the certifying physician;

(12) The certifying physician's address and telephone number;

(13) Any directions for use;

(14) The cautionary statements required by the program or the Commission, including concise warning that it is a crime to transfer the product to any person, and for any person, other than the patient, to use any of the product;

(15) Any special handling instructions regarding proper storage of the product; and

(16) An expiration date of one year from the date the manufacture of the medical marijuana was completed.

C. Any other information required by the dispensary at its discretion shall be provided in a patient insert.

D. The label shall not contain any false or misleading statement or design.

.08 Dispensing Medical Marijuana.

A. All members of the public visiting a licensed dispensary shall be escorted and maintained in visual contact by a registered dispensary agent.

B. Medical marijuana shall only be dispensed by a registered dispensary agent to a qualifying patient or caregiver.

C. Prior to any distribution of medical marijuana, 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 the recommendation to the qualifying patient;

(3) The recommendation is for the treatment of a medical condition approved by the Commission; and

(4) The quantity to be dispensed does not exceed a 30-day supply.

D. Before medical marijuana is dispensed, a qualifying patient or caregiver shall sign a waiver stating that he or she is not immune from the imposition of any civil, criminal, or other penalties for the following:

- (1) Undertaking any task under the influence of marijuana, when doing so would constitute negligence or professional malpractice;*
- (2) Operating, navigating, or being in actual physical control of any motor vehicle, aircraft, or boat while under the influence of marijuana;*
- (3) Smoking marijuana in any public place;*
- (4) Smoking marijuana in a motor vehicle; or*
- (5) Smoking marijuana on a private property that:*
 - (a) Is rented from a landlord; and*
 - (b) Is subject to a policy that prohibits the smoking of marijuana on the property; or*
- (6) Is subject to a policy that prohibits the smoking of marijuana on the property of an attached dwelling adopted by one of the following entities:*
 - (a) The board of directors of the council of unit owners of a condominium regime; or*
 - (b) The governing body of a homeowners association.*

E. The qualifying patient or caregiver shall sign a receipt for the medical marijuana.

F. The dispensary agent and the qualifying patient or caregiver shall each retain a copy of the receipt.

G. A dispensary agent may provide advice on the different types of medical marijuana available, marijuana strains and products, routes of administration, and how unused marijuana may be returned for disposal.

H. No licensed dispensary shall distribute a sample of medical marijuana.

I. A registered dispensary agent may decline to dispense to a qualifying patient or caregiver if, in the opinion of the dispensary agent, the patient or caregiver:

- (1) Is unable to understand directions for use of the medical marijuana, or*
- (2) Appears to be currently under the influence of drugs or alcohol.*

J. A licensed dispensary shall not permit the consumption of medical marijuana at the licensed premises.

.09 Disposal of Green Waste.

(1) Green waste shall be collected and disposed of:

- (a) in a method approved by the Commission and the State Police; or*
- (b) collected and retained until disposed of by the State Police.*

(2) All green waste shall be weighed and documented on a form provided by the Maryland State Police.

.10 Licensee Records.

A. The licensee shall maintain a searchable, secure, tamper-proof record of distribution that contains:

- (1) The name and address of a patient or consignee;*
- (2) The quantity delivered; and*
- (3) The name, strength, and batch number of the product.*

B. The licensee shall retain the records of production and distribution of each batch and of daily checklists to maintain uniformity from batch to batch.

C. The licensee shall maintain records of test methods and test results for each batch, including graphs, charts, or spectra from laboratory instrumentation.

D. The licensee shall maintain a log of individuals visiting a facility.

E. The licensee shall maintain a duplicate set of all records at a safe, secure, off site location.

.11 Complaints and Adverse Reaction Reports.

A. The licensee shall establish a procedure to document all oral, written, electronic or other product complaints.

B. In the event a complaint is received and associated with a patient adverse reaction, the licensee shall promptly report the complaint to the:

(1) Commission; and

(2) Either:

(a) The academic medical center; or

(b) The Certifying Physician; as applicable.

C. In the event a product recall is ordered or required, the licensee shall establish and follow a procedure to:

(1) Track, identify and remove any recalled product from the channels of distribution and from any patient; and

(2) Reimburse patients or the academic medical center for any recalled product.

10.62.XX Records.

Authority: Health General Article, §§13-3301, 13-3306, 13-3309, 13-3310, Annotated Code of

Maryland

.01 Record Retention.

A. Unless otherwise specified, all licensees shall retain all records for a period of 5 years.

B. Computation of the time period for retention of the records of a batch shall commence 5 years after the last transaction in medical marijuana that was part of the batch.

10.62.XX Inspection.

Authority: Health General Article, §§13-3301, 13-3306, 13-3309, 13-3310, Annotated Code of Maryland

.01 Consent to Inspection.

Submission of an application to be a licensed grower, licensed dispensary, or Academic medical center medical marijuana compassionate use program irrevocably gives the Commission consent to conduct all inspections necessary to ensure compliance with state law and regulations.

.02 Inspection of Applicants.

A. The Commission may inspect all premises of an applicant to be:

- (1) An academic medical center medical marijuana compassionate use program;*
- (2) A licensed grower; or*
- (3) A licensed dispensary.*

B. In the case of a pre-operation facility inspection the inspection will take place at a mutually agreeable time.

.03 Announced and Unannounced Inspections.

A. The Commission may conduct announced and unannounced inspections of the facilities of licensed growers and licensed dispensaries subject to the Commission's regulation, mission, and function, to determine compliance with statute and regulations.

B. Failure by a licensed grower to provide the Commission with immediate access to any 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 marijuana is held, dispensed, sold, produced, delivered, transported, manufactured or otherwise disposed of;

(3) Inspect all equipment, raw and processed material, containers and labeling, and all things therein including records, files, financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls and facilities;

(4) Inventory any marijuana;

(5) Obtain samples for testing of any marijuana, marijuana product, or media used to grow marijuana, any labels or containers for marijuana, paraphernalia, and of any raw or processed material; and

(6) Question personnel present at the location and any agent of the licensee.

D. The Commission, or independent testing laboratory determined by the Commission, may test samples for conformity to product specifications, for pests, mold, mildew, heavy metals, pesticides, or the presence of other substances as determined by the Commission.

E. In the event that an inspector has reasonable suspicion of an operational failure or of conditions that create a likelihood of diversion, contamination, or the risk to the health of any person:

(1) The inspector may:

(a) Suspend the distribution of all medical marijuana from the licensed facility;

(b) Order immediate evacuation of the facility and seal entry door; or

(c) Quarantine all product.

(2) The Commission shall undertake a review of the inspection findings and may:

(a) Issue a product recall;

(b) Request independent testing of affected product;

- (c) May approve a procedure to reprocess the product;*
- (d) Call upon Maryland State Police if diversion is suspected; or*
- (e) Order the destruction of the contaminated product.*

04. Receipts for Materials Removed.

The Commission shall issue an itemized receipt for anything removed in the course of an inspection.

.05 Report of Inspection.

A. At a reasonable time after the conclusion of any inspection, the Commission shall have prepared a report of the observations and findings of the inspection, and suggestions or demands for corrective action, and shall provide to the inspected entity a copy thereof.

B. The inspected entity shall respond in writing to every suggestion or demand for corrective action, and set forth the corrective action to be taken and the timetable for correction, within ten business days from the issuance of the report.

C. If a report finds evidence of operational failures or conditions that create a likelihood of diversion, contamination or the risk to the health of any person, the licensed facility may not distribute, or participate in the distribution of, any medical marijuana until the violation has been corrected and the facility re-inspected.

10.62.XX Discipline and Enforcement.

Authority: Health General Article, §§ 13-3309, Annotated Code of Maryland

.01 Operational Failure Risking Diversion or Endangering Health.

In the event that an inspection reveals operational failures that create a reasonable likelihood of diversion, contamination of medical marijuana, or any risk to the health of a patient or any other person, the Commission may;

- A. *Impose a fine of up to \$10,000;*
- B. *Suspend the license or the approval of the program or licensee; or*
- C. *Revoke the license or the approval of the program or licensee.*

.02 Deviation from Standard Operating Procedure or Program Requirements.

In the event that more than one inspection reveals a pattern of deviations from standard operating procedures or the requirements of the application or the license that does not directly create a risk of endangering the health or safety of a patient, the Commission may:

- A. *Impose a fine of up to \$5,000;*
- B. *Suspend the license or the approval of the program; or*
- C. *Revoke the license or the approval of the program.*

.03 Violation of Administrative Requirements.

If a licensee violates one of the administrative requirements of the subtitle, or the license, the Commission may:

- A. *Impose a fine of up to \$5,000;*
- B. *Suspend the license or the approval of the program; or*
- C. *Revoke the license or the approval of the program.*

10.62.XX Fee Schedule

Authority: Health General Article, §§13-3301, 13-3303, 13-3304, and 13-3309, 13-3310,

Annotated Code of Maryland

.01 Fees.

A. *The following fees are established by the Commission:*

(1) Academic Medical Centers.

(a) Initial Application Fee.....\$100;

(b) *Licensing Fee*.....\$1,000;

(c) *Renewal Fee*.....\$1,000;

(2) *Grower Fees.*

(a) *Initial Application Fee*.....***\$TBD***;

(b) *Biennial Licensing Fee*.....***\$TBD***;

(c) *Renewal Application Fee*.....***\$TBD***.

(3) *Grower Agent Fees.*

(a) *Registration Fee*.....***\$TBD***;

(b) *Replacement Registration Card*.....***\$TBD***;

(4) *Dispensary Fees.*

(a) *Initial Application Fee*.....***\$TBD***;

(b) *Licensing Fee*.....***\$TBD***;

(c) *Renewal Application Fee*.....***\$TBD***;

(5) *Dispensary Agent Fees.*

(a) *Registration Fee*.....***\$TBD***;

(b) *Replacement Registration Card*.....***\$TBD***;

(6) *Qualifying Patient and Caregiver Fees.*

(a) *Identification Card*.....***\$TBD***;

(b) *Replacement Identification Card*.....***\$TBD***;

(7) *Independent Testing Lab Fees.*

(a) *Licensing Fee*.....***\$TBD***;

(b) *Renewal Fee*.....***\$TBD***.

(8) *Miscellaneous Fees.*

(a) Reinstatement of a Lapsed Grower or Dispensary License.....\$TBD;

(b) Returned Check fee.....\$TBD.

B. General Information.

(a) The initial application fee and renewal application fee for growers whose applications are not granted will be assessed a \$_____ fee and be refunded \$_____.

(b) The initial application fee and renewal fee for dispensaries whose applications are not granted will be assessed a \$_____ fee and refunded \$_____.

(c) The Commission may reduce the fee for a qualifying patient and caregiver identification card on a sliding scale dependent upon the qualifying patient's household income.

JOSHUA M. SHARFSTEIN, M.D.

Secretary of Health and Mental Hygiene

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