Natalie M. LaPrade Medical Marijuana Commission

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

DRAFT FOR INFORMAL PUBLIC COMMENT

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 62 ACADEMIC MEDICAL CENTER COMPASSIONATE USE PROGRAMS

10.62.01 General Regulations

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

.01 Scope.

This subtitle governs academic medical center compassionate use programs that operate under the Natalie M. LaPrade Medical Marijuana Commission.

.02 Definitions.

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

B. Terms Defined.

(1) "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.

(2) "All of the processed material" means

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

(b) The material has been produced at the same time; and

(c) All of the material has been exposed to the same conditions throughout processing.

(3) 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.

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

(5) "Caregiver" means an individual designated by a program to assist a patient in a program obtain medical marijuana.

(6) "Commission" means the Natalie M. LaPrade Medical Marijuana Commission.

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

(8) "Fund" means the Natalie M. LaPrade Medical Marijuana Commission Fund.

(9) Grower.

(a) "Grower" means an entity that produces medical marijuana and is licensed by the Commission to provide medical marijuana to a program.

(b) "Grower" includes the federal government.

(10) "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.

(11) "Licensee" means a grower licensed by the Commission to cultivate, manufacture, process, package, distribute, or test medical marijuana for use in a program.

(12) Patient.

(a) "Patient" means an individual authorized to use medical marijuana while participating in a program operated by an academic medical center.

(b) "Patient" includes the parent or legal guardian of an individual participating in a program who is younger than 18 years old.

(13) "Program" means an investigational use-type program overseen by an academic medical center through which marijuana is made available to patients for medical use.

(14) "Recommendation" means an authorization for a patient to obtain medical marijuana signed by an authorized prescriber as defined in Health Occupations Article, §12-101(b), Annotated Code of Maryland.

(15) "Unused or surplus medical marijuana" means any harvested or unharvested marijuana, both processed and unprocessed, which is possessed by a licensee that:

(a) Is spoiled or is unusable for medical purposes; and

(b) Has been or appears to have been tampered with.

.03 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; or

(3) Has sought licensure or approval within the past 5 years.

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.

.04 Expenditures.

10.62.02 Academic Medical Center Compassionate Use Program—Application and Program Requirements

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) A justification 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 shall 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 if:

(i) The program does not adequately benefit the patient or poses a danger to the patient; or

(ii) There is evidence of diversion or misuse of medical marijuana by the patient.

(5) Before being included in a program, a patient shall agree to:

(a) Obtain medical marijuana only from the 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 specified 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 grower of the medical marijuana to be used by patients participating in the program; and,

(b) Scientific details of the types of medical marijuana used in 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 adverse drug 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 drug effect is suspected,

(a) The program shall promptly 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.

10.62.03 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 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.

.04 Approval Recission.

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 has been convicted for any felony offense involving dishonesty or that endangered public safety, or for any criminal violation of the Maryland Controlled Dangerous Substances Act.

.05 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; and

(5) A compilation of research studies completed or pending in connection with the program.

.06 Program Inspection.

A. A program shall be subject to random and unannounced inspection by the Commission.

B. An inspection by the Commission may include all components of a program, including the records kept by the program.

10.62.04 Patient Registry and Identification Cards

Authority: Health General Article, §§ 13-3301, 13-3302, 13-3304—13-3306, and 13-3308—13-3310, Annotated Code of Maryland

.01 Patient and Caregiver Register.

A. Register of Patients and Caregivers.

(1) The Commission shall establish a register of patients and caregivers participating in the program.

(2) A program shall update to the Commission's register within 1 business day of:

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

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

(3) The Commission shall provide access to the Commission's register to the Maryland State Police as follows:

(a) Access to the register shall be available on a real-time basis; and

(b) The register shall only be accessed to verify that a patient or caregiver is participating in a program.

(4) A program shall inform a patient or caregiver on State and federal laws regarding medical marijuana.

.02 Issuance of Identification Cards.

A. The Commission may issue a photographic identification card to patients and caregivers participating in the program.

B. Identification cards shall include information required by the Commission.

C. A patient or caregiver shall return the Commission his or her identification card when the patient or caregiver leaves or is removed from a program.

D. A program or grower, to establish positive identification of a patient or caregiver, may require a patient or caregiver to present a government-issued photographic identification card along with the Commission-issued identification card.

E. The Commission may charge a fee for the issuance of an identification or a replacement identification card.

.03 Temporary Identification Cards.

A. At the time a patient enters the program and is provided with a recommendation to use and obtain medical marijuana, the program shall issue a temporary identification card to the patient.

B. The validity of a temporary identification expires 30 days after it is issued by the program.

10.62.05 Application for Medical Marijuana Grower License

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

.01 Application for License.

A. Application for a license to operate as a grower and for a license to operate at a location shall be made on the form prescribed by the Commission.

B. An application to license a facility shall describe the express purpose of the facility and include a description of the physical structure.

C. Information that is a trade secret, confidential business and financial information, about security of information systems, an alarm or security system, or that is a personnel record that is part of an application, is exempt from the Maryland Public Information Act, State Government Article sections 10-601 – 10-628, and may not be disclosed to the public.

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

E. The Commission may deny an application that contains an intentional misstatement, omission, misrepresentation or untruth.

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

G. If the applicant is a corporation, the applicant shall provide the Commission with a copy of the articles of incorporation and authorization to do business in Maryland.

H. If the applicant is a partnership, the applicant shall provide the Commission with a copy of the partnership agreement and authorization to do business in Maryland.

I. An applicant shall provide a record of Maryland tax payments for the 5 years before the application, if any.

J. An application is not complete until the Commission receives from the Central Repository the criminal history record of every person pertinent to the application.

K. An application shall include any required attachment or supplemental information.

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

M. The applicant shall provide requested additional information by the close of business of the seventh business day after the request has been received by the applicant.

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

.02 Criminal Background Investigation.

A. An individual filing an application shall provide the Central Repository with a set of electronic fingerprints, the place and date of birth, and a request that the individual's criminal history record be forwarded to the Commission.

B. An application on behalf of an entity shall provide the Central Repository with a set of electronic fingerprints, the place and date of birth, and a request that the individual's criminal history record be forwarded to the Commission of any individual:

(1) Owning an interest of 2 percent or more in the entity filing the application;

(2) Lending $20,000 or more to the entity filing the application; or

(3) Who is an officer, director, or has any position of responsibility or decision making authority in the entity filing the application.

C. An application on behalf of a partnership shall provide the Central Repository with a set of electronic fingerprints, the place and date of birth of each partner, and a request that each partner's criminal history record be forwarded to the Commission of all partners.

.03 Licensed Premises.

A. An applicant shall submit an application for each premise at which the applicant will carry out any business under the license..

B. An application shall provide evidence that the applicant has legal control of each premise to be covered by license by deed, lease, contract, or other document.

.04 Process for Issuing License.

A. On a determination that the applicant is of good moral character and competent to participate in the program and comply with program regulations, the Commission may issue a license pursuant to Health General Article, §13-3308, Annotated Code of Maryland, to provide marijuana to a program.

B. To determine if the applicant is of good moral character and competent the Commission shall:

(1) Review and evaluate the contents an application; and

(2) Review the criminal background investigations carried out for all individuals, corporations and other entities associated with an application.

.05 Certificate of Operation.

A. The Commission may issue a certificate of operation to a licensee at a facility to provide medical marijuana to a program on a determination that the application is:

(1) Accompanied by the specified fee; and

(2) Accurate and complete.

B. A licensee may not begin cultivation of medical marijuana until all inspections are completed and a certificate of operation has been issued by the Commission.

.06 Transfer of License.

A. A prospective transferee of a license shall apply in the manner provided by Regulation .01 of this chapter.

B. The commission shall review the application of a prospective transferee of a license as provided by Regulations .02 to .05 of this chapter.

.07 Change of Location of Licensed Premises.

A. A licensee may apply for permission to change the location of its licensed premises.

B. The application shall be made on the form prescribed by the Commission and accompanied by the fee.

C. A licensee may not begin cultivation of medical marijuana until a certificate of operation has been issued by the Commission.

10.62.06 Medical Marijuana Grower Employees and Facilities

Authority: Health General Article, §§13-3302, and 13-3308—13-3310, Annotated Code of Maryland

.01 Incorporation by Reference.

In this chapter, the following documents are incorporated by reference COMAR 17.04.09.04—.08 with the following changes:

A. "Applicant for sensitive classification" means "prospective or current employee";

B. "Appointing authority" means "licensee" ;

C. "State employment" and "state service" mean "employment in the program or by a license";

D. "State Medical Director" means "licensee"; and

E. "Secretary" means the "Commission".

. 02 Employee Protection.

A. The licensee shall implement pre-employment and safety procedures, approved by the Commission, for all licensee employees.

B. An employee shall be trained to respond to a medical emergency, a fire, a chemical spill, a criminal incident and a threatening event such as an armed robbery, invasion, or burglary.

.03 Employee Roster and Criminal History Record Information.

A. The licensee shall create a roster of all employees.

B. The licensee shall report to the Commission within 48 hours all hires and discharges of employees or any changes in any employee status.

C. The licensee shall provide access to the roster of employees to the Maryland State Police.

D. The roster shall include documentation of each employee's submission of electronic fingerprints and a request for criminal history record information to be forwarded to the Commission.

E. A prospective employee who has a conviction for any felony offense involving dishonesty, that endangered public safety, or for any criminal violation of the Maryland Controlled Dangerous Substances Act shall be disqualified from employment.

.04 Prospective Employee Drug Screen.

A. The licensee shall require a prospective employee to submit to a pre-employment drug screen.

B. The drug screen shall be accomplished pursuant to 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 employee who has a positive response to any tested substance on a drug screen that meets the requirements of COMAR 17.04.09.07 shall be disqualified from employment.

.05 Annual Criminal History Check.

A. Every year, on the anniversary of the issuance of the license, each owner of more than 2 percent of the licensed entity, each lender of $20,000 or more to the licensee, each partner, officer, director, employee and person in any position of responsibility or decision making

authority of the licensee shall submit their electronic fingerprints to the Central Repository and request the criminal history record information be forwarded to the licensee and the Commission.

B. The Commission shall suspend the license of any licensee that continues to employ a person who or contract with an entity that has been convicted for any felony offense involving dishonesty or that endangered public safety, or for any criminal violation of the Maryland Controlled Dangerous Substances Act.

.06 Annual Licensee and Employee Drug Screen.

A. Every year, on the anniversary of the issuance of the license, each owner of more than 2 percent of the licensed entity, each lender of $20,000 or more to the licensee, each partner, officer, director, employee and person in any position of responsibility or decision making authority of the licensee shall submit to a drug screen for evidence of drug use.

B. At any time, upon the occurrence of a circumstance that suggests that it would be appropriate, an employee may be subjected to a drug screen.

C. The drug screen referenced in §B of this regulation shall be accomplished pursuant to procedures set forth in COMAR 17.04.09.04—.08.

D. 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.

E. The license of any licensee who employs an individual who has a positive response to any tested substance without medical justification on a drug screen that meets the requirements of COMAR 17.04.09.07 shall be suspended unless waived by the Commission.

.07 Other Conditions of Employment.

A. An employee shall declare that the employee will adhere to the written alcohol and drug free workplace policy adopted by the licensee and approved by the Commission.

B. Each employee shall be trained to recognize diversion or the misappropriation of any chemical, chemical substance, plant material, or equipment specific to the cultivation, manufacturing, processing, or packaging of medical marijuana for use in this program.

.08 Employee Identification.

A. The Commission shall issue identification cards to all licensees and employees.

B. The Commission may charge a fee for the issuance of an identification card and replacement identification card.

C. At all times all licensed individuals on the premises of a licensed facility shall visibly wear an identification card issued by the Commission.

D. The identification card shall display a photograph of the employee taken within 6 months before the identification card is issued.

E. The card shall display the employee's name.

F. If an employee loses the identification card, the employee cannot work until the identification card is replaced.

.09 Facilities -- Generally.

A. At each licensed location the license shall be conspicuously displayed.

B. A licensed facility shall be located within Maryland.

C. A licensed facility used in this program to distribute medical marijuana for program patients shall be separated geographically from a facility used to cultivate, produce, manufacture, process, or package medical marijuana.

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

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

(1) School;

(2) House of worship;

(3) Daycare center; or

(4) Drug or alcohol treatment facility.

F. A licensed facility shall clearly display in the front of the building the street address of the facility, and the direction to entrance, if not obvious, to expedite emergency response.

G. No signage on a licensed facility may mention medical marijuana or display images of marijuana leaves or paraphernalia.

.10 Facility Security Hardware.

A. Each licensed facility that is used to cultivate, manufacture, process, or package medical marijuana in this program shall have a hardened exterior structure, constructed of concrete or similar building materials to resist entry or penetration.

B. If the licensed facility is located within a building or structure that also houses a non-program facility such as a business or other entity, any interior wall between the licensed facility and the non-program facility shall be hardened with concrete or similar building materials to resist entry or penetration.

C. If the licensed facility is located within a building or structure that also houses a non-program facility such as a business or other entity, any interior wall between the licensed facility and the non-program facility may not have any door, window, or portal of any kind.

D. Each door of a licensed facility shall be commercial grade.

E. Each exterior door shall have visual or electronic surveillance capable of monitoring the entrance to restrict improper entrance by a visitor or unwanted person.

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

.11 Facility SecurityLighting.

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 portals 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 used to cultivate or grow medical marijuana.

.12 Facility Security Alarm Systems.

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

B. The security alarm system shall be:

(1) Continuously monitored; and

(2) Capable of detecting fire.

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

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

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

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

(3) Any vault or room that holds medical marijuana.

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

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

.13 Video Surveillance Requirements.

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

B. A surveillance camera shall be located and operated to continuously capture each point of exterior 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 surveillance camera shall be focused to fully capture activity at each point-of-sale area.

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

(1) On the facility premises; and

(2) At an off-site location.

F. Storage on-site of a recording of security video surveillance shall be kept at the facility in a manner that is:

(1) Access-limited; and

(2) Independently secured and protected by an alarm system that is independent of the main facility alarm system.

G. Storage off-site of a recording of security video surveillance shall be kept at a location and in a manner that is:

(1) Access-limited; and

(2) Independently secured and protected by an alarm system that is independent of the main facility alarm system.

H. A recording of security video surveillance shall be stored for a minimum period of 90 days.

I. A recording of security video surveillance shall be stored in a format that can be easily accessed for viewing.

J. Access to any video feed and recording of security video surveillance shall be made available to the Commission as requested.

.14 Individuals at a Facility.

A. For the purpose of this regulation, "employee" includes the license holder.

B. At least two employees of the licensee shall be on location at a licensed facility at any time.

C. Other than at a point-of-sale designated location and except for a person 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.

D. An employee of the Commission, any appropriate state or local regulatory agency and the Maryland State Police may enter the facility at any time for a regular or unscheduled inspection of any facility in the course of their duty.

E. 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 as provided by Regulation .13 of Chapter 10.62.07.

10.62.07 Medical Marijuana Manufacturing Controls

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

.01 Standard Operating Procedure.

The licensee shall:

A. Establish written standard operating procedures for all aspects of the propagation, cultivation, harvesting, drying, curing, packaging, labeling and handling of all medical marijuana products, byproducts, waste products, and the control thereof to promote good manufacturing practice;

B. Ensure that each person engaged in the growing, processing, packaging, and testing of medical marijuana has the training, education, or experience necessary to perform assigned functions; and

C. Ensure that all personnel practice good hygiene and wear protective clothing as necessary to protect the product from contamination.

.02 Design and Construction.

The licensed facility shall be:

A. Of suitable size, construction, and design to facilitate proper operation, cleaning, and maintenance; and

B. Designed so that the flow of components, products, packaging and labeling through the building prevents contamination.

.03 Lighting.

The licensee shall ensure that lighting is sufficient:

A. For proper operation and inspection of all areas of growing, curing, drying, packaging, and testing; and

B. To inspect all areas to provide proper sanitation.

.04 Ventilation, Heating, Cooling, and Humidity Control.

The licensee shall ensure that:

A. Air filtration is adequate to provide for odor containment and contamination control; and

B. The ventilation system minimizes contamination.

.05 Water, Sanitation, Contamination and Waste Water.

A. The licensee shall:

(1) Provide an adequate standardized water supply to the plants;

(2) Treat water leaving the facility to the standard provided by local environmental requirements; and

(3) Provide an adequate pest control system for a clean environment.

B. The licensee shall only use sanitizing agents that meet the requirements for use around medicinal plants.

C.. In the course of producing and growing medical marijuana, the licensee may not use any of the following substances, techniques or materials:

(1) Any pesticide, fungicide, fertilizer, rodenticide, drug, or substance banned by the:

(a) U.S. or Maryland Departments of Agriculture;

(b) U.S. Environmental Protection Agency; or

(c) Food and Drug Administration;

(2) Any substance or technique deemed unlawful by the:

(a) Department of Health and Mental Hygiene;

(b) Department of the Environment; or

(c) Commission; or

(3) Any equipment, packaging material, storage container, or bin that contains a banned substance.

.06 Equipment.

A. Cleaning and Maintenance.

(1) The licensee shall provide that equipment which comes in contact with medical marijuana is clean and maintained at appropriate intervals to prevent malfunction and product contamination.

(2) The licensee shall provide that cleaning and maintenance equipment logs are maintained to ensure the safety and quality of the product.

B. Calibration.

(1) The licensee shall provide that automatic, mechanical, or electronic equipment is routinely calibrated and periodically checked to ensure proper performance.

(2) The licensee shall provide that any scale, balance, or other measurement device is routinely calibrated and periodically checked to ensure accuracy.

.07 Control of Components.

A. The licensee shall provide that any incoming component or material,or any raw material used in connection with producing medical marijuana, including plant material, 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.

B. The licensee shall ensure that:

(1) All packaging material is inspected for any defect before release for use; and

(2) Any rejected item is separated from inventory for return or disposal as appropriate to prevent use.

C. The licensee shall maintain an inventory control system of all raw materials used in connection with producing medical marijuana, other than seeds, cuttings, clones, and plants, that come into contact with medical marijuana while it is being cultivated and produced.

.08 Production and Process Controls.

A. The licensee shall establish and follow a written standard operating procedure for all aspects of the propagation, cultivation, harvesting, drying, curing, packaging, labeling and handling of all medical marijuana products, byproducts, waste products, and the control thereof, which shall be made available for inspection by the commission.

B. 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.

.09 Plant Tagging.

The licensee shall tag each plant with a unique plant and batch number, either at the time the clone is cut or the seed is germinated.

.10 Holding and Distribution Procedure.

A. Packaged Product Storage. The licensee shall hold the packaged product in secure storage until released for distribution.

B. Repackaging for Distribution. 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.

.11 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.

.12 Waste.

A. A licensee shall dispose of unused or surplus medical marijuana and its by-products by giving it to the law enforcement agency for destruction.

B. All unused or surplus medical marijuana and its by-products shall be weighed and documented on a form provided by and submitted to the Maryland State Police before being delivered to the law enforcement agency by the licensee for destruction.

.13 Records and Reports.

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 license shall:

(1) Retain the records of production and distribution for 5 years after distribution; and

(2) Have the records readily available for inspection by the Commission.

C. The licensee shall maintain, make available for inspection by the Commission, and retain for 5 years a secure, tamper-resistant log regarding equipment cleaning, maintenance and calibration for each piece of major equipment.

D. The licensee shall maintain, make available for inspection by the Commission, and retain for 5 years after distribution of a batch, batch records and daily checklists to maintain uniformity from batch to batch.

E. The licensee shall maintain, make available for inspection by the Commission, and retain for 5 years after a test is conducted, batch records of test methods and test results, including graphs, charts, or spectra from laboratory instrumentation.

F. The licensee shall maintain, make available for inspection by the Commission, and retain for 5 years after a visit the log of individuals visiting a facility.

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

.14 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) Academic medical center.

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.

10.62.08 Product Tracking

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

.01 Inventory System and Discrepancy Reporting.

A. A licensee shall install 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 or qualified patient.

B. Upon the completion of curing/drying, the medical marijuana shall be weighed to establish a baseline weight for inventory control.

C. The licensee shall ensure that the inventory control system that the licensee uses has the capacity to reconcile the licensee's records and the associated transaction history and sale or transfer receipts.

D. 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.

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

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

G. 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.

.02 Receiving Raw Materials for Cultivation.

The licensee shall record:

A. The name and principal address of the original source of :

(1) The seeds;

(2) The cuttings;

(3) The clones, and

(4) Any other raw material;

B. The identity and quantity of the raw material received;

C. The date the raw material was received;

D. The signature and legibly printed name of the individual:

(1) Delivering the raw material; and

(2) Receiving the raw material.

.03 Processed Medical Marijuana Inventory Control.

Medical marijuana processed from plant material into any edible product, extract, or other form shall require an additional inventory entry listing which includes the:

A. Name of the product;

B. Batch number;

C. Quantity of plant material used;

D. Expiration date of the product;

E. Date of processing;

F. Name and signature of individual performing the processing; and

G. Name and signature of the manager verifying the processing if that individual is different from the individual performing the processing.

.04 Point of Sale or Transfer.

A. To initiate the distribution of medical marijuana at licensed premises, a patient or caregiver shall present:

(1) Identification from the Commission; and

(2) Another government-issued photo identification.

B. If satisfied that the individual has established his or her identity, the licensee shall check the program database to establish that the individual is currently a patient or caregiver in the program.

C. Before the medical marijuana is distributed, the patient shall enter in an appropriate register his or her signature and name legibly printed.

.05 Product Returned for Destruction.

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

B. The licensee shall notify the academic medical center of quantity of medical marijuana returned by a patient

.06 Limitation on Transfer of Medical Marijuana.

A licensee may not sell, transfer, give away, or otherwise dispose of any medical marijuana the licensee, or any employee of the licensee, knows or should have reason to know does not comply with any provision of Chapter 403 of the Acts of 2013, or the regulations thereof.

.07 Duration of Record Keeping.

The licensee shall retain any record of inventory and supporting documentation for a batch or package for 5 years after the last transaction regarding a package or part of a batch.

.08 Custody of Recalled Material.

A. The licensee shall develop a procedure to ensure all medical marijuana, other than retention samples, that is recalled is securely 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.

.09 Packaging.

A. The licensee may not sell or transfer any medical marijuana unless it is packaged in a container and in a manner approved by the Commission.

B. The licensee shall distribute medical marijuana to a patient in a container that:

(1) Has been designed or constructed to be significantly difficult for children younger than 5 years old to open unless requested otherwise by the patient; and

(2) Does not permit the product to be seen without opening the container.

C. The licensee shall ensure that on each container of medical marijuana there is a securely affixed tamper-evident seal.

10.62.09 Medical Marijuana Labeling.

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

.01 Labeling—General.

A. The licensee shall ensure that the text of the label does not make any false or misleading statements regarding health or physical benefits to the patient.

B. Label Text.

(1) The text of the label on a container shall be unobstructed and conspicuous.

(2) A licensee may affix multiple labels to a container, provided that none of the information required by this regulation is obstructed so that it cannot be read.

C. Once a label with an expiration date has been affixed to a container, a licensee may not alter that date or affix a new label.

D. A person may not alter, deface, or remove any label or the text of any label from a container as long as any of the original contents remain in the container.

.02 Labeling Medical Marijuana for an Academic Medical Center.

A. A licensee may not distribute any medical marijuana unless the label lists each material used in the cultivation and production of the product, including any chemical additive, pesticide, herbicide, or fertilizer.

B. A licensee may not distribute any medical marijuana unless the label states:

(1) Name and license number of the licensee;

(2) Name of the strain;

(3) Batch number assigned to the product;

(4) Concentration (in percentage) of:

(a) Δ^9-Tetrahydrocannabinol (THC);

(b) Cannabidiol (CBD); and

(c) Other cannabinoids in the product for which the academic medical center requires measurement;

(5) Concentrations of a cannabinoid of less than 1 percent shall be printed with a leading zero before the decimal point;

(6) Any other information required by the academic medical center at its discretion; and

(7) the product expiration date of one year from the date the manufacture of the medical marijuana was completed.

.03 Medical Marijuana Transferred Directly to the Patient.

A. Except for medical marijuana dispensed to an inpatient in a hospital or related institution, the licensee shall label each container dispensed in accordance with this regulation.

B. The licensee shall print all information on the label of a container in a font that is easily read and no less than one-sixteenth of an inch high.

C. The licensee shall dispense medical marijuana directly to a patient in accordance with the program's protocol.

D. The label for medical marijuana transferred directly to the patient shall contain or list:

(1) Name of the product;

(2) Batch number of the product;

(3) Concentration (in percentage) of the active cannabinoids:

(a) Δ^9-Tetrahydrocannabinol (THC);

(b) Cannabidiol (CBD);

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

(5) Any other information required by the academic medical center at its discretion;

(6) The quantity of product;

(7) The name of the licensee distributing the medical marijuana;

(8) The date that the order was filled;

(9) The name of the program;

(10) The name of the patient;

(11) Any directions for use;

(12) The cautionary statements required by the program or the Commission, including a 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;

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

(14) The product expiration date of one year from the date the manufacture of the medical marijuana was completed.

10.62.10 Inspection.

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

.01 Pre-operation Inspection.

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

A. An academic medical center medical marijuana compassionate use program; or

B. A licensed grower.

.02 Regular Inspection.

The Commission shall routinely inspect the operations of a licensee or an applicant and question personnel to ensure that the facility is managed properly and procedures are being followed regarding but not limited to the following areas of operation:

A. Sanitation;

B. Prevention of contamination;

C. Receipt of raw materials;

D. Storage;

E. Labeling;

F. Monitoring of patients;

G. Counseling of patients; and

H. Record keeping.

.03 Random and unannounced inspection.

The Commission shall carry out unannounced inspections for all academic medical centers and licensees to ensure that programs, facilities and operations are being managed as required.

10.62.11 Discipline and Enforcement.

Authority: Health General Article, §§13-3302, 13-3304, 13-3306 and 13-3308—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

C. Revoke the license or the approval of the program.

.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.

10.62.12 Fee Schedule

Authority: Health General Article, §§13-3302, 13-3304, and 13-3308, Annotated Code of Maryland

.01 Fees.

The following fees are established by the Commission:

A. Program Fees.

(1) Application Fee.....$___;

(2) Renewal Fee.....$___:

B. Grower Fees.

(1) Application Fee.....$___;

(2) Licensing Fee.....$___;

(3) Renewal Fee.....$__.

C. Miscellaneous Fees.

(1) Patient and Caregiver Identification Card.....$___;

(2) Patient and Caregiver Replacement Identification Card.....$___;

(3) Licensee and Employee Identification Card.....$___;

(4) Licensee and Employee Replacement Identification Card.....$___.

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