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 – 10.62.28.

.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) "Association" means employment or volunteer status at a licensed grower or licensed dispensary.

(3) Batch.

(a) "Batch" means all of the plants of the same variety 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) "Bona-fide physician-patient relationship" means a treatment or counseling relationship between a physician and a patient in which the physician has:

(a) Reviewed the patient's relevant medical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant, in-person, medical evaluation of the patient;

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

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

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

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

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

(5) Caregiver.

(a) "Caregiver" means an individual designated by a patient who has agreed to assist with a qualifying patient's medical use of marijuana.

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

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

(7) "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.

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

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

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

(11) “Finished medical marijuana product” means a medical marijuana concentrate or a medical marijuana-infused product packaged and labeled for release to a qualifying patient.

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

(13) “Independent testing laboratory” means a laboratory that is:

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

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

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

(b) Licensed by the Department of Health and Mental Hygiene.

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

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

(16) “Licensed grower” means an entity that:

(a) Cultivates, manufactures, processes, packages or dispenses medical marijuana, processes medical marijuana products; and

(b) Is licensed by the Commission to provide medical marijuana to a program, a qualifying patient, a caregiver or to a licensed dispensary.

(17) “Licensed premises” means the locations at which a licensed grower or licensed dispensary operates.

(18) “Licensed processing dispensary” means a licensed dispensary that has been approved to process medical marijuana concentrate or medical marijuana-infused products.

(19) “Lot” means all of the medical marijuana-infused products or medical marijuana concentrate finished products that are uniform, that are intended to meet specifications, that are manufactured, packaged, or labeled together during a specified time period according to a single lot record.

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

(a) Propylene glycol;

(b) Glycerin;

(c) Water or ice;

(d) Butane;

(e) Propane;

(f) Carbon dioxide or dry ice;

(g) Ethanol;

(i) Isopropanol; or

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

(21) “Medical marijuana grower agent” means an owner, an employee, a volunteer, an officer, or a director of a licensed grower.

(22) “Medical marijuana-infused product” means oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical marijuana concentrate or usable marijuana that has been processed so that the dried leaves and flowers are integrated into other material. Only the weight of the medical marijuana-infused product that is attributable to marijuana shall count toward a 30-day supply.

(23) “Processing” means the manufacture of usable medical marijuana into a medical marijuana concentrate, or manufacture of a medical marijuana-infused product.

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

(25) “Qualifying patient” means:

(a) A resident of Maryland who:

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

(ii) Is enrolled in a research program with a registered academic medical center; and

(b) If under the age of 18 years, has a caregiver.

(26) “Registered dispensary agent” means a dispensary agent who is registered by the Commission.

(27) “Registered grower agent” means a medical marijuana grower agent who is registered by the Commission.

(28) Resident.

(a) “Resident” means an individual who:

(i) Is domiciled in this State and owns, leases, or rents a primary place of residence in this State;

(ii) Is domiciled in another state but lives in a primary place of residence in this State for more than 1 year; or

(iii) Is domiciled in another state and owns, leases, or rents a primary place of residence in Maryland for more than 1 year.

(b) "Resident" does not include an individual who is domiciled in another state and is:

(i) A student enrolled in an accredited school, college, or university of this State, an adjoining state, or the District of Columbia;

(ii) Serving a medical internship in this State;

(iii) A member of the armed forces of the United States or of the United States Public Health Service and serving on active duty in this State, an adjoining state, or the District of Columbia;

(iv) Temporarily employed in Maryland for a period not to exceed 1 year; or

(v) A visitor or vacationer temporarily maintaining or occupying a residence in this State for a period not to exceed 1 year.

(29) "Transportation agent" means either:

(a) A registered grower agent or a registered dispensary agent, authorized by the licensee to transport products containing marijuana, who meets the criteria specified in Regulation .03 of this chapter; or

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

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

(31) Usable marijuana.

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

(b) “Usable marijuana” 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.

(32) “Written certification” means a certification that is issued by a certifying physician for a qualifying patient with whom the physician has a bona fide physician-patient relationship; and

(33) “30-day supply” means 120 grams of usable marijuana.

10.62.02 General Regulations.

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

.01 Scope.

This subtitle governs operations of the Natalie M. LaPrade Medical 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 years, or

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

C. An individual or entity that has made a donation to the Fund may not apply for licensure or approval by the Commission for a period of 5 years from the date of donation.

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

.03 HIPAA Compliance.

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

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

(1) The physician's:

(a) Full name;

(b) Office addresses and phone numbers;

(c) Current email address;

(d) Maryland Board of Physicians license number;

(e) Plan to screen patients for dependence on substances of abuse before and after a patient is issued a written certification; and

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

(2) An attestation that the:

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

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

(c) Physician has completed a Commission-approved training course;

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

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

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

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

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

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

(a) Cachexia;

(b) Anorexia;

(c) Wasting syndrome;

(d) Severe pain;

(e) Severe nausea;

(f) Seizures; or

(g) Severe or persistent muscle spasms;

(4) Have the following diseases and conditions:

(a) Glaucoma, if the certifying physician is a board certified ophthalmologist; or

(b) Post traumatic stress disorder (PTSD), if the certifying physician is a board certified psychiatrist.

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

(1) Severe;

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

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

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

E. The Commission:

(1) Shall approve an application that is complete and satisfactory; and

(2) May deny an incomplete, fraudulent or unsatisfactory application.

F. The Commission shall notify the applicant that the application has been approved.

.02 Written Certification.

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

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

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

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

(4) If the qualifying patient has been screened for dependence on substances of abuse, including chemical testing, if appropriate, and has been determined by the physician to be of low risk for addiction, dependence, or diversion; and

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

B. The certifying physician shall transmit the written certification to the Commission in the manner determined by the Commission and provide a copy of the written certification to the qualifying patient.

C. A written certification shall include the:

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

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

(3) Medical condition requiring medical marijuana; and

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

D. A certifying physician may discuss the use of medical marijuana with a qualifying patient.

E. A certifying physician shall terminate a written certification 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) There is evidence that the qualifying patient engaged in diversion of medical marijuana.

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

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

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

.03 Written Certification Renewal.

A. A qualifying patient may seek renewal of their written certification no less than 30 calendar days after it was issued by notifying their certifying physician.

B. A certifying physician may renew the written certification for a qualifying patient if the certifying physician determines the patient still meets the criteria set forth in regulation .02A of this chapter.

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

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

.04 Compensation from a Licensed Grower or Licensed Dispensary.

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

B. The application shall disclose the specific type of compensation and specific amount or value of compensation, and the services for which the compensation will be paid.

C. The Commission shall deny an application for compensation if the compensation is based on any agreement or arrangement for the certifying physician to refer, direct or recommend qualifying patients to the licensed grower or licensed dispensary to obtain medical marijuana.

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

E. A certifying physician may not serve as the clinical director of a licensed dispensary.

F. The Commission shall publish the approved compensation on the Commission's website.

.05 Annual Report.

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

B. The annual report shall include:

(1) The number of qualifying patients issued written certification by the certifying physician categorized by gender and 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 by age, gender and other relevant criteria as specified by the Commission;

(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.

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

.06 Renewal of Certifying Physician Approval to Certify.

A. An approval is valid for two years.

B. 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.

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

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

(1) The certifying physician attests that:

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

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

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

(3) The certifying physician documents that, within the 2 years before applying to renew an approval to certify, the physician has completed a course approved by the commission of at least 2 hours in the science or use of marijuana in medical practice; and

(4) The certifying physician has otherwise complied with these regulations.

D. If a certifying physician fails to obtain a renewal of an approval to issue written certifications, the certifying physician may not issue written certifications.

.07 Action Against a Physician.

A. The Commission may deny a certifying physician's application for approval to certify if:

(1) The physician fraudulently applied for approval;

(2) The physician fraudulently issued a written certification; or

(3) The physician failed to comply with these regulations.

B. The Commission shall report to the Maryland Board of Physicians any instance of fraud or conduct that threatens public health by a certifying physician.

10.62.04 New Condition Approval Process

Authority: Health General Article, § 13-3307(c) and (d) Annotated Code of Maryland

.01 Requirement of a Petition.

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

.02 Hearing.

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

.03 Petition Contents.

The Commission shall consider a petition that may include:

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

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

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

D. Any information or studies regarding any beneficial or adverse effects from the use of 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 Summary Denial.

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

A. The petition is facially insubstantial; or

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

.05 Additional Evidence.

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

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

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

.06 Commission Determination.

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

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

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

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

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

10.62.05 Patient and Caregiver 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 Registry of Qualifying Patients and Caregivers.

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

B. Each entry into the registry shall include the name of the:

(1) Qualifying patient;

(2) Qualifying patient's certifying physician; and

(3) Qualifying patient's caregiver or caregivers, if applicable.

C. A qualifying patient or qualifying patient's designee shall notify the Commission in writing by electronic means within 72 hours of:

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

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

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

.02 Identification Cards for Patients and Caregivers.

A. Upon being issued a written certification by a certifying physician, a qualifying patient may apply to the Commission for an identification card or to be registered with the Commission by submitting to the Commission:

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

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

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

(4) The required fee as specified in COMAR 10.62.28.

B. Upon being designated a caregiver by a qualifying patient, a caregiver shall apply to the Commission for an identification card, and shall submit to the Commission:

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

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

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

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

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

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

(7) The required fee as specified in COMAR 10.62.28; and

(8) A signed acknowledgement that the caregiver understands the restrictions on the use or redistribution of medical marijuana set forth in COMAR 10.62.22.04.

C. An identification card shall contain:

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

(2) An expiration date one year from the date of issue;

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

(4) The qualifying patient identification number or the caregiver identification number assigned by the Commission.

D. If the identification card is lost, destroyed or stolen, within 72 hours of becoming aware of the loss, destruction or theft, the qualifying patient or caregiver shall:

(1) Report the loss, destruction or theft to the local law enforcement agency and the Commission; and

(2) Apply for a replacement card and pay the replacement card fee specified in COMAR 10.62.28.

E. A police report or law enforcement case number regarding the loss, destruction or theft of an identification card and a copy of the notification to the Commission shall be evidence that a person is a qualifying patient or a caregiver until a new card is obtained from the Commission.

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

(1) Notify the Commission within 72 hours in the manner required by the Commission; and

(2) If seeking a replacement identification card, pay the replacement fee to obtain a new identification card.

G. A qualifying patient shall return an identification card to the Commission in a manner to be determined by the Commission within 5 business days if a certifying physician fails to renew a qualifying patient certification.

H. A qualifying patient or his or her designee shall notify the Commission of a change in caregiver within 72 hours.

I. A caregiver shall return his or her identification card with respect to a qualifying patient to the Commission in a manner to be determined by the Commission within 5 business days if:

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

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

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

.03 Renewal of Identification Card.

A. A qualifying patient shall renew their identification card before it expires in a manner to be determined by the Commission.

B. A caregiver shall renew their identification card before it expires in a manner to be determined by the Commission.

.04 Misuse of Identification Card.

A. If a person attempts to use a qualifying patient identification card that is not issued to him or her, any dispensary agent to whom it is offered shall confiscate it and initiate the return of the card to the Commission within 5 business days.

B. If a person presents to a law enforcement officer an identification card of a qualifying patient that was not issued to him or her, the law enforcement officer shall confiscate the identification card and initiate the return of the card to the Commission as soon as possible.

C. The Commission may notify the certifying physician and revoke the identification card of a qualifying patient who allows his or her identification card to be used by another person.

10.62.06 Medical Marijuana Grower License

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

.01 Definitions.

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

B. Terms Defined.

(1) "Audited financial statement" means an audited financial statement that is performed by a certified public accountant licensed or with practice privileges in Maryland pursuant to Title 2 of the Business Occupations and Professions Code that is prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants and in the case of a publicly owned corporation in conformity with the standards of the Public Company Oversight Board.

(2) "Footnoted financial statement" means the presentation of information that includes

(a) In the case of an individual, a personal balance sheet as of the end of the year prior to the submission of an application for a license under this title by certified public accountant licensed or with practice privileges in Maryland pursuant to Title 2 of the Business Occupations and Professions Code which contains a footnote that none of the assets included therein result from illegal activities; and

(b) In the case of a company or partnership, an audited financial statement which contains a footnote that none of the assets included therein result from illegal activities.

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

(4) “Licensee” means a licensed grower.

.02 Application for a Medical Marijuana Grower License.

A. An applicant shall submit an application for a license in a manner determined by the Commission.

B. An application shall include:

(1) Identification of applicant’s potential medical marijuana grower agents and each individual investor with 5 percent or more of investment known at the time of application;

(2) A business plan including an organizational chart;

(3) Documentation and source of adequate capitalization;

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

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

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

(7) A security plan;

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

(9) The medical marijuana varieties proposed to be grown with proposed cannabinoid profiles and evidence of success in alleviating symptoms of specific diseases or conditions;

(10) A plan for quality control;

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

(a) Medical marijuana from “seed to sale,” and

(b) Waste plant material prior to destruction; and

(12) A disposal plan for medical marijuana waste.

C. A grower planning to operate as a dispensary of medical marijuana shall submit a dispensary application.

D. The application shall be accompanied by the application fee specified in COMAR 10.62.28.

E. Any party applying for a license shall have an interest in only one license application.

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

.03 Criminal History Record Check.

An applicant shall provide for every individual identified in the application specified in Regulation .02B(1) of this chapter to the Director of the Central Repository:

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

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

.04 Consent for Investigation.

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

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

(2) Conduct a background investigation of the individual.

B. An applicant shall authorize the Commission to have access to any and all information the applicant has provided to any other jurisdiction while seeking a similar license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the applicant.

.05 Application Review.

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

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

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

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

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

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

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

(1) The criminal history record required in Regulation .03 of this chapter; and

(2) Any required or requested attachment or supplemental information.

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

(1) The proposed location in an agricultural zone;

(2) Racial, ethnic, and geographic diversity;

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

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

(5) Quality of proposed safety and security procedures;

(6) The medical marijuana varieties proposed to be grown with proposed cannabinoid profiles, including varieties with high cannabidiol content, and evidence of success in alleviating symptoms of specific diseases or conditions;

(7) Quality of the plan to grow, cure, process and package medical marijuana;

(8) Quality of experience, knowledge, and training in commercial horticultural or agricultural production;

(9) Quality of quality control plan;

(10) Quality of inventory control plan;

(11) Quality of medical marijuana waste disposal plan;

(12) Quality of plan to enforce the alcohol and drug free workplace policy;

(13) Quality of the business plan;

(14) Demonstration of adequate capitalization;

(15) Maryland residency; and

(16) History of payment of income taxes in Maryland and other jurisdictions, if applicable.

.06 Pre-Approval of Application.

A. Limitation on number of licenses:

(1) Until May 31, 2016, in accordance with Health General Article, §13-3309(a)(2), Annotated Code of Maryland, in consideration of the ranking of the applications in accordance with regulation .04, the Commission may issue pre-approvals of a license up to a total of 15 licenses.

(2) Beginning June 1, 2016, the Commission may issue the number of pre-approvals of a license necessary to meet the demand for medical marijuana by qualifying patients in an affordable, accessible, secure and efficient manner.

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

C. The Commission may deny issuing a pre-approval of a license if the criminal history record demonstrates an absence of good moral character, or if the payment of taxes due in any jurisdiction is in arrears, for any individual identified in the application specified in Regulation .02B(1) of this chapter.

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

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

.07 Issuance of License.

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

(1) A footnoted financial statement for each individual, partnership, corporation or other entity review that has invested, or is proposed to invest, 5 percent or more of the capital of the applicant; and

(2) Evidence of adequate surety bond and insurance.

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

(1) The footnoted financial statement submitted regarding the applicant individuals and entities specified in Regulation .02C(1) of this chapter reveal no evidence that demonstrates the absence of good moral character;

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

(3) The proposed premises:

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

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

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

(4) The required license fee specified in COMAR 10.62.28 has been paid.

.08 Change of Ownership of License.

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

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

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

(3) The Commission does not object to the transfer or assignment within 180 business days of its receipt of notice; and

(4) The transferee has paid the required fee specified in COMAR 10.62.28.

B. The Commission may deny transfer of an interest in a license if the criminal history record or the background investigation demonstrates an absence of good moral character, or the payment of taxes due in any jurisdiction is in arrears, for any proposed transferee.

.09 Change of Location.

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

B. The application shall be made in a manner determined by the Commission and accompanied by the fee specified in COMAR 10.62.28.

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

.10 Renewal of License.

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

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

(1) Date on which the license expires;

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

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

C. A licensee who fails to apply for renewal of a license by the date specified by the Commission:

(1) Shall cease operation of the premises;

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

D. A license may be reinstated upon:

(1) Payment of the fee specified in COMAR 10.62.28; and

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

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

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

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

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

(4) Payment of the fee specified in COMAR 10.62.28.

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

G. If the Commission does not renew a license due to a failed inspection or an inadequate application for renewal:

(a) The licensee may apply for reinstatement by:

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

(2) Amending the application for renewal; and

(b) The Commission may reinstate a license.

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

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

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

(3) The licensee has repeatedly failed inspections.

10.62.07 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 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 Generally.

A grower agent shall be at least 21 years of age.

.03 Grower Agent Registration and Criminal History Record.

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

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

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

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

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

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

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

.04 Registered Grower Agent Identification Cards.

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

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

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

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

(1) Report the loss, destruction or theft to a local law enforcement agency and the Commission;

(2) Apply for a replacement card; and

(3) Pay a replacement card fee specified in COMAR 10.62.28.

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

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

.05 Termination.

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

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

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

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

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

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

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

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

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

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

D. If a registered grower agent did not return the agent's registration card within 30 days of the termination, the Commission will place a notice in the register of that fact.

.06 Prospective Grower Agent Drug Screen.

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

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

C. In addition to the drugs to be screened in accordance with COMAR 17.04.09.06, the screen shall include:

(1) Illegal synthetic cannabinoids and compounds as required by the Commission; 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 may not be registered by the Commission.

.07 Grower Agent Training.

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

(1) Federal and State medical marijuana laws and regulations, and laws and regulations pertinent to pesticide application, groundwater, and other laws related to the agent's responsibilities;

(2) Standard operating procedures;

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

(4) Security procedures; and

(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.

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

.08 Alcohol and Drug Free Workplace Policy.

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

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

.09 Annual Verification of Registered Grower Agents.

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

10.62.08 Medical Marijuana Grower Premises

Authority: Health General Article, §§ 13-3309(a)(3), (d), and (e), Annotated Code of Maryland

.01 Definitions.

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

B. Terms Defined.

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

(2) "Licensee" means a licensed grower.

.02 Premises Generally.

A. A licensed premises shall be located within Maryland.

B. A licensed premises used to distribute medical marijuana shall:

(1) Be separate from the premises used to cultivate, produce, manufacture or process medical marijuana;

(2) Conform to COMAR 10.62.19.04 relating to dispensary premises specifications regarding a Vault and COMAR 10.62.19.09 relating to licensed dispensary premises organization; and

(3) Conform to local zoning and planning requirements.

C. The license shall be conspicuously displayed at each licensed premises.

D. Modification of Premises.

(1) A licensee shall apply to the Commission for approval to make major renovations or modifications to a licensed premises.

(2) No major renovation or modification shall be undertaken without approval of the Commission.

.03 Field Cultivation Premises.

A. Licensed premises for field cultivation of medical marijuana shall be situated to maintain the greatest achievable level of privacy and security.

B. Physical Security.

(1) An area of cultivation shall be securely surrounded by fencing and gates constructed to prevent unauthorized entry.

(2) Security fencing shall be of chain link fencing at least 8 feet high topped with multiple strands of barbed wire.

C. Fencing and gates shall be equipped with a security alarm system that:

(1) Covers the entire perimeter;

(2) Is continuously monitored; and

(3) Is capable of detecting power loss.

D. The premises shall be protected by a video surveillance recording system to ensure:

(1) Surveillance of the entire perimeter of the area of cultivation;

(2) Surveillance over all portions of the security fence and all gates; and

(3) Adherence to the video surveillance requirements of this chapter.

E. A video surveillance system shall be supported by adequate security lighting which may include motion control sensors if necessary to protect light-dark cycles for proper cultivation.

.04 Security Hardware.

A. A licensed premises shall be constructed to prevent unauthorized entry.

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

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

D. In addition, a groundlevel greenhouse to be used to cultivate medical marijuana shall be surrounded by:

(1) An 8 foot or higher chain link fence topped with multiple strands of barbed wire, located no less than 20 feet from a greenhouse; and

(2) A 15 foot area free of vegetation.

.05 Security Lighting.

A. Lighting fixtures of the licensed grower shall be designed and installed to:

(1) Ensure proper surveillance of:

(a) Both sides of all exterior doors, entrances and portals; and

(b) All interior doors and passages between rooms; and

(2) Illuminate work areas for employee safety.

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

.06 Security Alarm Systems.

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

B. A security system shall be:

(1) Continuously monitored;

(2) Capable of detecting smoke and fire; and

(3) Capable of detecting power loss.

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

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

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

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

(3) A vault that holds medical marijuana.

E. A security alarm system shall remain operational until a licensed premises no longer has any medical marijuana, seeds, or cuttings on the premises.

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

.07 Video Surveillance Requirements.

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

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

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

(3) That provides a continuous date and time stamp for every recorded frame.

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

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

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

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

(1) At the licensed premises; and

(2) At an off-site location.

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

(1) Access-limited;

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

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

(4) For a minimum of 90 business days.

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

.08 Individuals at Premises.

A. A visitor to a non-public area of the licensed premises shall:

(1) Be logged in and out by a registered grower agent;

(2) Offer proof of identity by means of a government-issued identification document that shall be photocopied;

(3) Be under continuous visual supervision by a registered grower agent while on the premises; and

(4) Not touch any plants or medical marijuana.

B. A log of visitors shall be retained for 5 years.

10.62.09 Medical Marijuana Growing Controls

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

.01 Definitions.

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

B. Terms Defined.

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

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

(3) “Hard goods” means any non-plant material used in the cultivation or processing of medical marijuana.

(4) “License” means a license issued by the Commission to operate as a grower.

(5) “Licensee” means a licensed grower.

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

.02 Standard Operating Procedure.

A licensee shall establish a written standard operating procedure for:

A. All aspects of the irrigation, propagation, cultivation, fertilization, 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;

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

C. Ensuring 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.

.03 Design and Construction.

A licensed premises shall be:

A. Of suitable size and design to facilitate proper operation;

B. Constructed using materials which are durable and can withstand weather extremes; and

C. Designed to:

(1) Prevent contamination throughout the premises; and

(2) Allow adequate cleaning.

.04 Horticultural Controls.

A. Standard operating procedure for receipt of material and hard goods.

(1) A licensee shall quarantine material and hard goods that are received to be used to produce medical marijuana.

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

(3) Material and hard goods shall not be released from quarantine by a licensee until they:

(a) Pass inspection; and

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

B. Water.

(1) If water is obtained from a municipal water supply, a licensee shall have the quality of the water tested by an independent testing laboratory annually.

(2) If the water is obtained from a source other than a municipal water supply, a licensee shall have the quality of the water tested by an independent testing laboratory every 6 months.

(3) Medical marijuana may be irrigated only by water that meets or exceeds the standards for contamination set forth in the standard operating procedure.

(4) The licensee shall keep a record of water quality testing on site and make it available for inspection.

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

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

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

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

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

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

(1) Temperature;

(2) Humidity;

(3) Ventilation; and

(4) Lighting, if used.

F. A licensee shall seal or screen the premises ventilation system with a mesh or filtering system fine enough to exclude most plant pests.

G. Pest Monitoring.

(1) A licensee shall use, as part of the standard operating procedure, integrated pest management practices and techniques to identify and manage plant and pest problems, including:

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

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

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

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

H. Pest Control as part of the standard operating procedure.

(1) If using a restricted use pesticide, a licensee or registered grower agent on site shall:

(a) Maintain a valid State pesticide applicators license; or

(b) Contract with a commercial State licensed pesticide applicator.

(2) When applying a pesticide or fungicide, a licensee shall:

(a) Follow State and pesticide label guidelines; and

(b) Maintain State-required records.

I. Sanitation. A licensee shall, as part of the standard operating procedure:

(1) Keep floors and benches free of debris, non-cannabis plants and algae;

(2) Remove dead and substandard plants from growing areas;

(3) Clean floors, benches, pots, tools, and equipment that come into contact with plants using only sanitizing agents are labeled as approved for vegetable, fruit, or medicinal plant production; and

(4) Control rodents and other non-plant related pests:

(a) By using chemicals are labeled as approved for use around vegetables, fruit, or medicinal plants; or

(b) By other commercially acceptable practices.

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

.05 Equipment.

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

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

C. A licensee shall have any scale, balance, or other measurement device, and any automatic, mechanical, or electronic equipment routinely calibrated by a calibration laboratory accredited to International Organization for Standardization (ISO) standard ISO/IEC 17025 by an

accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

10.62.10 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. A licensee shall cultivate each plant and produce each batch of medical marijuana in conformity with the standard operating procedure.

B. A licensee shall record each step of the propagation, cultivation, fertilization, harvesting, drying, curing, packaging, labeling and handling of a batch of medical marijuana in a secure, tamper-evident log, to ensure:

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

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

C. A licensee shall record any deviation from the standard operating procedure in the log.

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

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

(2) The determination is recorded.

.02 In-Process Inspection by Grower.

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

.03 Holding Procedure.

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

.04 Independent Testing Laboratory Selection and Responsibility.

The licensee shall use an independent testing laboratory:

A. That has adopted a standard operating procedure to test medical marijuana that is approved either by:

(2) An accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement; or

(2) The Department of Health and Mental Hygiene.

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

C. To analyze the samples according to

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

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

D. To issue a certificate of analysis; and

E. To destroy the remains of the sample of medical marijuana after analysis is completed.

.05 Contents of Certificate of Analysis.

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

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

(1) Δ9-Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabivarinic Acid (THCA);

(3) Cannabidiol (CBD);

(4) Cannabidiolic Acid (CBDA); and

(5) The terpenoids described in the most current version of the Cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP);

(6) Cannabigerol (CBG); and

(7) Cannabinol (CBN);

B. That the presence of the following contaminants does not exceed the levels determined by the Commission:

(1) Mercury, lead, cadmium, or arsenic;

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

(3) Any microbiological impurity, including:

(a) Total aerobic microbial count (TAMC);

(b) Total yeast mold count (TYMC);

(c) P. aeruginosa;

(d) Aspergillus spp.;

(e) S. Aureus;

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

(g) Ochratoxin A.; and

(h) Pesticide residue; and

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

(a) Odor

(b) Appearance;

(c) Fineness; and

(d) Moisture content.

.06 Grower Determination That a Batch May be Released.

A. If a licensed grower, upon review of the certificate of analysis, determines that a batch meets the specification for the variety, the grower may:

(1) Assign an expiration date to the batch;

(2) Release the batch for distribution; and

(3) Revise the status of the batch in the inventory control.

B. A licensee shall retain every certificate of analysis.

.07 Stability Testing and Retention Sampling.

A. A licensee shall provide a sample from each released batch to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to:

(1) Ensure product potency and purity; and

(2) Provide support for expiration dating.

B. A licensee shall retain a sample from each released batch:

(1) Sufficient to provide for follow-up testing if necessary; and

(2) Properly store the sample for one year past the date of expiration of the batch.

.08 Report of Products Offered for Distribution.

A licensee shall submit to the Commission on the first day of every month a list of the products and their specifications that the licensee offered for distribution in the previous month.

10.62.11 Complaints, Adverse Events, and Recall

Authority: Health General Article, §§13-3302, 13-3304, 13-3307 13-3309, 13-3310, Annotated Code of Maryland

.01 Definition.

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

B. Terms Defined.

(1) "Serious adverse event" means an undesirable experience associated with the use of medical marijuana where the outcome was death, life-threatening, hospitalization, disability or permanent damage, congenital anomaly/birth defect, required intervention to prevent permanent impairment or damage, or an other important medical event including, but not limited to allergic bronchospasm, seizures/convulsions, or the development of drug dependence or abuse.

(2) "Medical marijuana" means any product containing medical marijuana including medical marijuana concentrate and medical marijuana-infused product.

.02 Receipt and Documentation of Complaints and Adverse Events.

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

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

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

(1) The Commission;

(2) Either the licensed grower from which the medical marijuana originated or the licensed processing dispensary from which the medical marijuana concentrate originated; and

(3) Either the program in which the patient is participating or the certifying physician caring for the qualifying patient.

.04 Complaint Investigation by Grower or Dispensary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

E. The Commission may review the investigation of any licensee under this chapter, and if it determines that it is in the interest of public health, the Commission may:

(1) Order a recall of all products derived from or included in the batch or lot of medical marijuana that is associated with a substantive complaint or serious adverse event; and

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

.05 Custody of Returned Recalled Material.

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

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

10.62.12 Inventory Control by Grower

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

.01 Definitions.

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

B. Terms Defined.

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

(2) “Licensee” means a licensed grower.

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

.02 Inventory Control System.

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

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

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

.03 Materials Received for Cultivation.

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

(1) The date delivered; and

(2) The number of clones or seeds delivered or the weight of the seeds for each variety in the shipment.

.04 Plant Tagging and Entry into Inventory Control.

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

(1) Create a unique identifier for each plant;

(2) Assign a batch number to each plant in a batch;

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

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

(5) Securely attach the tag to a container in which a plant is grown until a plant is large enough to securely hold a tag.

B. Tags shall be indelible and tamper-evident.

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

.05 Control of Harvested Medical Marijuana.

A licensee shall:

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

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

.06 Discrepancy Reporting.

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

B. If the licensee finds evidence of a theft or diversion within 1 business day the licensee shall report the theft or diversion to the Commission and to the Maryland State Police.

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

(1) Complete the audit;

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

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

.07 Product Returned for Destruction.

A licensee shall accept the return of any medical marijuana from a qualifying patient, a caregiver, or an academic medical center to destroy.

.08 Bar on Distribution of Non-complying Medical Marijuana.

A.A licensee or registered grower agent may not distribute any medical marijuana to any person if the licensee or registered grower agent knows, or should have reason to know, that the distribution does not comply with any provision of Chapter 256 of the Acts of 2014, or this subtitle.

B. A licensee or registered grower agent may not distribute any medical marijuana to any person if the licensee or registered grower agent knows, or should have reason to know, that the medical marijuana does not comply with any provision of Chapter 256 of the Acts of 2014, or this subtitle.

10.62.13 Dispensing of Medical Marijuana by a Licensed Grower

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

.01 Definitions.

A. The following terms have the meanings indicated.

B. Terms Defined.

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

(2) "Licensee" means a licensed grower.

(3) "Satellite premises" means a dispensary owned and operated by a licensed grower at a location removed from the premises at which a licensee grows medical marijuana.

.02 Location of Dispensary at Premises Where Medical Marijuana is Grown.

A licensee may distribute medical marijuana to qualifying patients and caregivers at the premises at which the licensee grows medical marijuana in conformity with COMAR chapters 10.62.15 through 10.62.22:

A. Only by use of a separate entrance from the primary entrance to the premises at which the licensee grows medical marijuana; or

B. At premises that are located in close proximity to the premises at which the licensee grows medical marijuana.

.03 Licensed Grower Satellite Dispensary Premises.

A. A licensee may distribute medical marijuana to qualifying patients and caregivers in conformity with COMAR chapters 10.62.15 through 10.62.22 at the premises of a single satellite facility which does not need to be close to the premises at which the licensee grows medical marijuana.

B. A licensee shall construct and operate a satellite premises in conformity to COMAR 10.62.19, relating to medical marijuana dispensary premises.

C. A licensee may hire employees or use volunteers at a satellite premises in conformity to COMAR 10.62.18, relating to registered dispensary agents.

10.62.14 Shipment of Products Containing Marijuana Between Licensees

Authority: Health General Article, §§13–3301 and 13-3309(d)-(g), Annotated Code of Maryland

.01 Definitions.

A. The following terms have the meanings indicated.

B. Terms Defined.

(1) “Medical marijuana transport vehicle” means a vehicle owned, or leased by a licensee, for the purpose of transporting products containing marijuana that meets the criteria specified in Regulation .08 of this chapter.

(2) “Secure transportation company” means a business that is licensed, whose employees are bonded, and that provides highly secure vehicles for the transportation of valuables.

(3) “Shipment identification number” means a unique identification number created by the shipping licensee to track a shipment of products containing marijuana.

(4) “Shipping licensee” means the licensee that initiates the shipment.

.02 Electronic Manifest System.

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

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

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

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

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

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

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

(6) Any handling or storage instructions.

.03 Creation of Manifest.

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

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

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

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

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

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

.04 Transportation Agents.

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

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

.05 Transportation of Products Containing Marijuana.

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

B. A shipping licensee shall use at least two transportation agents, who shall carry identification approved by the Commission, to accompany shipment of products containing marijuana.

C. When a transportation agent takes custody of a shipment of products containing marijuana, a transportation agent shall:

(1) Log into the electronic manifest

(2) Confirm that each package in the shipment is labeled as described in the electronic manifest and record that confirmation in the electronic manifest;

(3) Obtain in the electronic manifest the signature of the registered grower agent or registered dispensary agent who delivers the shipment to the transportation agent; and

(4) Record in the electronic manifest the date and time the shipment is secured in the medical marijuana transport vehicle.

D. During shipment, packages containing marijuana shall be:

(1) Securely stored within a medical marijuana transport vehicle to resist unauthorized access;

(2) Isolated from access by a transportation agent; and

(3) Not visible from the outside of the medical marijuana transport vehicle.

.06 Packaging Products Containing Marijuana for Shipment.

A. A licensee, prior to shipping an order of products containing marijuana, shall repackage, if necessary, the shipment into a container:

(1) Constructed of tamper-evident opaque material approved by the Commission; and

(2) Sealed with tamper-evident tape.

B. The shipping licensee shall create an electronic manifest for each package in a shipment.

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

.07 Labeling of Packages for Shipment.

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

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

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

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

(4) The shipment identification number;

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

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

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

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

.08 Medical Marijuana Transport Vehicle.

A medical marijuana transport vehicle shall:

A. Have and display current registration from the State;

B. Be insured as required by law; and

C. Not display any sign or illustration related to marijuana or a licensee.

10.62.15 Licensed Dispensary and Licensed Processing Dispensary.

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

.01 Definitions.

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

B. Terms defined.

(1) "Audited financial statement" means an audited financial statement that is performed by a certified public accountant licensed or with practice privileges in Maryland pursuant to Title 2 of the Business Occupations and Professions Code that is prepared in accordance with the Professional Standards of the American Institute of Certified Public Accountants and in the case of a publicly owned corporation in conformity with the standards of the Public Company Oversight Board.

(2) "Footnoted financial statement" means the presentation of information that includes

(a) In the case of an individual, a personal balance sheet as of the end of the year prior to the submission of an application for a license under this title by certified public accountant licensed or with practice privileges in Maryland pursuant to Title 2 of the Business Occupations and Professions Code which contains a footnote that none of the assets included therein result from illegal activities; and

(b) In the case of a company or partnership, an audited financial statement which contains a footnote that none of the assets included therein result from illegal activities.

(3) "License" means a license issued by the Commission to operate as a licensed dispensary or a licensed processing dispensary.

(4) "Licensee" means a licensed dispensary or licensed processing dispensary.

.02 Application.

A. An applicant shall submit an application for a license in a manner determined by the Commission.

B. The application shall specify the applicant's intent:

(1) To operate to as a licensed dispensary to distribute medical marijuana to qualifying patients and caregivers;

(2) To operate as a licensed processing dispensary; or

(3) To operate as both a licensed processing dispensary and a licensed dispensary.

C. All applications to be a licensed dispensary or licensed processing dispensary shall include:

(1) Identification of applicant's potential dispensary agents and each individual investor with 5 percent or more of investment known at the time of application;

(2) A business plan including an organizational chart;

(3) Documentation and source of adequate capitalization;

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

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

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

(7) A security plan;

(8) A plan for quality control;

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

(10) A plan for the disposal of medical marijuana waste; and

(11) A plan for training employees and volunteers.

D. An application to operate as a licensed dispensary to distribute medical marijuana to qualifying patients and caregivers shall include:

(1) A plan for counseling qualifying patients and caregivers in the use of medical marijuana; and

(2) The medical marijuana varieties proposed to be dispensed with proposed cannabinoid profiles and evidence of success in alleviating symptoms of specific diseases or conditions.

E. An application to operate as a licensed processing dispensary shall include:

(1) Details of the applicant's experience, knowledge, and training in the operation of a laboratory; and

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

F. The application shall be accompanied by the application fee specified in COMAR 10.62.28.

G. Any party applying for a license shall have an interest in only one license application.

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

.03 Licensed Grower Acting as a Dispensary.

At a licensed grower premises or approved grower satellite premises, a licensed grower may dispense medical marijuana in conformity with this subtitle.

.04 Criminal History Record Request.

An applicant shall provide for every individual identified in the application specified in Regulation .02C(1) of this chapter to the Director of the Central Repository:

A. Two sets of legible fingerprints taken in a format approved by the Director of CJIS and FBI and the fee authorized under section 10-221(B)(7) of the Criminal Procedure article for access to State criminal history and records for each dispensary agent and investor identified in the application; and

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

.05 Consent for Investigation.

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

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

(2) Conduct a background investigation of the individual.

B. An applicant shall authorize the Commission to have access to any and all information the applicant has provided to any other jurisdiction while seeking a similar license in that other jurisdiction, as well as the information obtained by that other jurisdiction during the course of any investigation it may have conducted regarding the applicant.

.06 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 requested information by the close of business of the 14th business day after the request has been received by the applicant.

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

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

(1) The criminal history record required in Regulation .04 of this chapter; and

(2) Any required or requested attachment or supplemental information.

H. The Commission, or a Commission approved third party, shall review completed applications for a license to be a licensed dispensary and rank the applications using an impartial and numerically scored competitive bidding process developed by the Commission based on the following criteria:

(1) Racial, ethnic, and geographic diversity of the applicants;

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

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

(4) Quality of proposed safety and security procedures;

(5) The medical marijuana varieties proposed to be dispensed with proposed cannabinoid profiles, including varieties with high cannabidiol content;

(6) Quality of the quality control plan;

(7) Quality of the inventory control plan;

(8) Quality of the plan to dispose of medical marijuana waste;

(9) Quality of the plan to dispense medical marijuana;

(10) Quality of the plan to counsel qualifying patients and caregivers in the use of medical marijuana;

(11) Quality of the plan to utilize the clinical director and to train dispensary agents;

(12) Quality of the plan to enforce the alcohol and drug free workplace policy;

(13) Quality of the business plan;

(14) Demonstration of adequate capitalization;

(15) Maryland residency of the applicant; and

(16) History of payment of income taxes in Maryland and other jurisdictions, if applicable.

I. The Commission, or a Commission approved third party, shall review completed applications for a license to be a licensed processing dispensary and rank the applications using an impartial and numerically scored competitive bidding process developed by the Commission based on the following criteria:

(1) Racial, ethnic, and geographic diversity of the applicants;

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

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

(4) Quality of proposed safety and security procedures;

(5) The medical marijuana concentrates and medical marijuana-infused products proposed to be manufactured with proposed cannabinoid profiles;

(6) Quality of the quality control plan;

(7) Quality of the inventory control plan;

(8) Quality of the plan to dispose of medical marijuana waste;

(9) Quality of the plan to process and package medical marijuana;

(10) Nature of applicant's experience operating a laboratory;

(11) Quality of the plan to enforce the alcohol and drug free workplace policy;

(12) Quality of the business plan;

(13) Demonstration of adequate capitalization;

(14) Maryland residency of the applicant; and

(15) History of payment of income taxes in Maryland and other jurisdictions, if applicable.

.07 Pre-Approval of License Application.

A. Number of Pre-approvals.

(1) In consideration of the ranking of the applications in accordance with regulation .06, the Commission may issue pre-approvals of up to two licensed dispensaries (other than as a licensed processing dispensary that does not dispense medical marijuana to qualifying patients) per

Senatorial district after taking into consideration the number of grower premises or grower satellite premises licensed to dispense medical marijuana located in the Senatorial district.

(2) The Commission shall pre-approve a number of licenses for licensed processing dispensaries sufficient to supply the demand for medical marijuana concentrates and medical marijuana-infused products in a range of routes of administration desired by qualifying patients.

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

C. The Commission may deny issuing a pre-approval of a license if the criminal history record demonstrates an absence of good moral character, or if the payment of taxes due in any jurisdiction is in arrears, for any individual identified in the application specified in Regulation .02C(1) of this chapter.

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

.08 Issuance of License.

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

(1) A footnoted financial statement for each individual, partnership, corporation or other entity review that has invested, or is proposed to invest, 5 percent or more of the capital of the applicant; and

(2) Evidence of adequate surety bond and insurance.

B. The Commission may issue a license either to be a licensed dispensary distributing directly to patients or to be a licensed processing dispensary on a determination that:

(1) The footnoted financial statement submitted regarding the applicant individuals and entities specified in Regulation .02C(1) of this chapter reveal no evidence that demonstrates the absence of good moral character;

(2) All inspections are passed and all of the applicant's operations conform to the specifications of the application as pre-approved pursuant to Regulation .07 of this chapter;

(3) The proposed premises:

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

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

(c) Conform to the specifications of the application as pre-approved pursuant to Regulation .07 of this chapter; and

(4) The required license fee specified in COMAR 10.62.28 has been paid.

.09 Change of Ownership of License.

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

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

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

(3) The Commission does not object to the transfer or assignment within 180 business days of its receipt of notice; and

(4) The transferee has paid the required fee specified in COMAR 10.62.28.

B. The Commission may deny transfer of an interest in a license if the criminal history record or the background investigation demonstrates an absence of good moral character, or the payment of taxes due in any jurisdiction is in arrears, for any proposed transferee.

.10 Change of Location.

A. A licensee may apply to change the location of its operation.

B. The application shall be made in a manner determined by the Commission and accompanied by the fee as specified in COMAR 10.62.28.

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

.11 Renewal of License.

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

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

(1) Date on which the license expires;

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

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

C. A licensee who fails to apply for renewal of a license by the date specified by the Commission:

(1) Shall cease operations at all premises;

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

D. A license may be reinstated upon:

(1) Payment of the fee specified in COMAR 10.62.28; and

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

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

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

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

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

(4) Payment of the fee specified in COMAR 10.62.28.

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

G. If the Commission does not renew a license due to a failed inspection or an inadequate application for renewal:

(a) The licensee may apply for reinstatement by:

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

(2) Amending the application for renewal; and

(b) The Commission may reinstate a license.

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

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

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

(3) The licensee has repeatedly failed inspections.

10.62.16 Medical Marijuana Concentrates and Medical Marijuana-Infused Products

Authority: Health General Article §§ 13-3301, 13-3310, 13-3313, 13-3316, Annotated Code of Maryland

.01 Definitions.

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

B. Terms defined.

(1) “License” means a license issued by the Commission to operate as a dispensary.

(2) “Licensee” means a licensed processing dispensary.

(3) “Tincture” means a marijuana-infused solution typically comprised of alcohol, glycerin, or vegetable oils derived either directly from the marijuana plant or from a processed marijuana extract.

.02 Controls for Processing Medical Marijuana Concentrates and Medical Marijuana-Infused Products.

A. A licensed processing dispensary that processes medical marijuana concentrates and medical marijuana-infused products shall:

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

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

(a) Fully trained to safely operate and maintain the system used for processing;

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

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

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

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

B. A licensed processing dispensary shall use the methods, equipment, solvents, and gases set forth in this chapter when processing medical marijuana concentrates.

C. If a licensed processing dispensary uses a solvent-based extraction method the following solvents must be at least 99% pure:

(1) Butane;

(2) Isobutane;

(3) Propane;

(4) Heptane; or

(5) Other solvents or gases exhibiting low to minimal potential human health-related toxicity approved by the Secretary of the Department of Health and Mental Hygiene.

D. When using the solvents required in §C of this regulation, a licensed processing dispensary shall:

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

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

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

E. If a licensed processing dispensary uses carbon dioxide gas extraction:

(1) It shall use a professional grade, closed-loop system;

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

(2) The licensee shall follow all applicable OSHA regulations, and local fire, safety and building codes in the processing and the storage of the solvents; and

(3) It shall use carbon dioxide that is at least 99 percent pure.

F. A licensed processing dispensary may use heat, screens, presses, steam distillation, ice water, and other methods to produce medical marijuana concentrates.

.03 Independent Testing Laboratory Selection and Responsibility.

Upon successful completion of a validation process, the licensee shall use an independent testing laboratory:

A. That has adopted a standard operating procedure to test medical marijuana and medical marijuana concentrate that is approved either by:

(1) An accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement; or

(2) The Department of Health and Mental Hygiene.

B. To have an agent of the independent testing laboratory obtain samples according to a statistically valid sampling method for each lot;

C. To analyze the samples according to

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

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

D. To issue a certificate of analysis; and

E. To destroy the remains of the sample of medical marijuana after analysis is completed.

.04 Contents of Certificate of Analysis.

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

A. Whether the chemical profile of the lot conforms to the specifications for the lot for the following compounds:

(1) Δ9-Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabivarinic Acid (THCA);

(3) Cannabidiol (CBD);

(4) Cannabidiolic Acid (CBDA);

(5) The terpenoids described in the most current version of the Cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP);

(6) Cannabigerol (CBG); and

(7) Cannabinol (CBN);

B. That the presence of the following contaminants does not exceed the levels determined by the Commission:

(1) Any solvent or processing chemicals;

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

(3) Any microbiological impurity, including:

(a) Total aerobic microbial count (TAMC);

(b) Total yeast mold count (TYMC);

(c) P. aeruginosa;

(d) Aspergillus spp.;

(e) S. Aureus;

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

(g) Ochratoxin A.; and

(4) Whether the batch is within specification for:

(a) Odor; and

(b) Appearance.

.05 Licensed Processing Dispensary Determination That a Batch May be Released.

A. If a licensed processing dispensary, upon review of the certificate of analysis, determines that a lot meets the specification for the product, the licensed processing dispensary may:

(1) Assign an expiration date to the lot;

(2) Release the lot for distribution; and

(3) Revise the status of the lot in the inventory control.

B. A licensee shall retain every certificate of analysis.

.06 Stability Testing and Retention Sampling.

A. A licensee shall provide a sample from each released lot to an independent testing laboratory sufficient to perform stability testing at 6-month intervals to:

(1) Ensure product potency and purity; and

(2) Provide support for expiration dating.

B. A licensee shall retain a sample from each released lot:

(1) Sufficient to provide for follow-up testing if necessary; and

(2) Properly store the sample for one year past the date of expiration of the lot.

.07 Packaging of Finished Medical Marijuana Product.

A. All items shall be individually packaged at the original point of processing.

B. A package of finished medical marijuana product shall:

(1) Be plain;

(2) Be opaque;

(3) Be child-resistant, if applicable or appropriate;

(4) Not bear any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;

(5) Not bear any statement, artwork or design that could reasonably mislead any person to believe that the package contains anything other a finished medical marijuana product;

(6) Not bear any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed, manufactured, or used by any State, county or municipality or any agency thereof;

(7) Not bear any cartoon, color scheme, image or graphic;

(8) Not bear any feature that might make the package attractive to children;

(9) Bear a finished-product lot number and an expiration date;

(10) Bear a clear warning that:

(a) The contents may be lawfully consumed only by a qualifying patient named on an attached label;

(b) It is a illegal for any person to possess or consume the package or contents other than the qualifying patient; and

(c) It is a illegal to transfer the package or contents to any person other than the transfer by a caregiver to a qualifying patient;

(11) Bear a clear warning to keep the package and its contents away from children;

(12) Bear the Maryland Poison Control Center emergency telephone number;

(13) Bear the telephone number of the licensee for reporting an adverse patient event;

(14) Bear any allergen warning required by law;

(15) Bear a listing of the non-medical marijuana ingredients;

(16) Bear an itemization, including weight, of all cannabinoid and terpenoid ingredients specified for the product; and

(17) Leave space for a licensed dispensary to attach a personalized label for the qualifying patient.

.08 Report of Products Offered for Distribution.

A licensee shall submit to the Commission on the first day of every month a list of the products and their specifications that the licensee offered for distribution in the previous month.

10.62.17 Licensed Dispensary Clinical Director

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

.01 Clinical Director Responsibilities.

A. A licensed dispensary shall appoint an individual who is a Maryland-licnesed physician, nurse practitioner or pharmacist to function as clinical director.

B. A clinical director shall:

(1) Develop and provide initial training to each registered dispensary agent who will work with qualifying patients at a licensed dispensary, and at least once every 6 months commencing on the date the license is issued, on the provision of information to qualifying patients related to:

(a) Therapeutic use of medical marijuana;

(b) Risks, benefits, and side effects associated with medical marijuana;

(c) Self-assessment of the qualifying patient's symptoms, including rating scales for pain, cachexia or wasting syndrome, nausea, seizures, muscle spasms, and agitation; and

(d) Recognizing symptoms of substance use disorders;

(2) Develop and provide initial training to each registered dispensary agent who will work with qualifying patients at a licensed dispensary, and at least once every 6 months commencing on the date the license is issued, on recognition of an individual who appears to be impaired or abusing substances of abuse; and

(3) Lead the program of review and improvement of the standard operating procedure of the licensed dispensary in the provision of patient education and support.

C. A clinical director shall lead the development and dissemination of:

(1) Educational materials for qualifying patients and caregivers regarding:

(a) Possible side effects from and contraindications for use of medical marijuana, including potential impairment:

(i) In the use or operation of a motor vehicle, other vehicle, vessel, aircraft, or heavy equipment;

(ii) In professional or employment responsibilities; or

(iii) When caring for children;

(b) Different varieties and strengths of medical marijuana and their medical uses;

(c) Potential drug-to-drug interactions (including prescription drugs, controlled dangerous substances, non-prescription drugs, and supplements), and interactions with alcohol;

(d) Techniques to use medical marijuana, medical marijuana products, and marijuana paraphernalia;

(e) Signs and symptoms of substance abuse, including tolerance, dependence and withdrawal;

(f) Treatment of substance use disorders and available programs to treat substance use disorders;

(g) Documenting the qualifying patient's symptoms or course of the condition;

(h) Using a rating scale for symptoms of various kinds; and

(i) Sharing their self-assessment with a qualifying physician or primary care physician;

(2) Materials to train registered dispensary agents in communication with qualifying patients' certifying physicians regarding side effects, contraindications and qualifying patient dosages; and

(3) A policy to refuse to provide medical marijuana to an individual who appears to be impaired or to be abusing medical marijuana.

D. During a licensed dispensary's hours of operation, a clinical director, or an individual who is a Maryland-licensed physician, nurse practitioner or pharmacist, and is designated by the clinical director to serve as clinical director in the clinical director's absence, shall be on the premises of the licensed dispensary or readily available by telephone or equivalent means to respond to a qualifying patient, a caregiver or a registered dispensary agent who has a question regarding the medical use of marijuana outside the training materials and educational materials provided at the licensed dispensary.

E. A clinical director shall not be a certifying physician.

F. A clinical director may serve as clinical director for more than one licensed dispensary.

10.62.18 Registered Dispensary Agents

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

.01 Definitions.

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

B. Terms Defined.

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

(2) "Licensee" means a licensed dispensary or licensed processing dispensary.

.02 Dispensary Agent Registration and Criminal History Record.

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

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

(1) The name, address and date of birth of a dispensary agent;

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

(3) The request for the criminal history record of the dispensary agent to be forwarded to the Natalie M. LaPrade Commission.

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

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

.03 Registered Dispensary Agent Identification Cards.

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

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

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

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

(1) Report the loss, destruction or theft to a local law enforcement agency and the Commission;

(2) Apply for a replacement card; and

(3) Pay a replacement card fee specified in COMAR 10.62.28.

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

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

.04 Termination.

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

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

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

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

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

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

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

(b) Whether the terminated registered dispensary agent has returned the agent's registration card; and

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

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

D. If a registered dispensary agent did not return the agent's registration card within 30 days, the Commission will place a notice in the register of that fact.

.05 Prospective Dispensary Agent Drug Screen.

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

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

C. In addition to the drugs to be screened in accordance with COMAR 17.04.09.06, the screen shall include:

(1) Illegal synthetic cannabinoids and compounds as required by the Commission; 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, may not be registered by the Commission.

.06 Dispensary Agent Training.

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

(1) Federal and State medical marijuana laws and regulations, and other laws and regulations pertinent to the dispensary agent's responsibilities;

(2) Standard operating procedures;

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

(4) Security procedures; and

(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.

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

.07 Alcohol and Drug Free Workplace Policy.

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

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

.08 Annual Verification of Registered Dispensary Agents.

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

10.62.19 Licensed Dispensary and Licensed Processing Dispensary Premises

Authority: Health General Article, §§13–3301 and 13–3310(b)(2)(iii) and (c), Annotated Code of Maryland

.01 Definitions.

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

B. Terms Defined.

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

(2) "Licensee" means a licensed dispensary or licensed processing dispensary.

.02 Premises Generally.

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

B. The premises of a licensee shall be separate from any premises used to cultivate, harvest or cure medical marijuana.

C. The premises of a licensed dispensary that distributes medical marijuana to a qualifying patient shall be separate from the premises of a licensed processing dispensary.

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

E. A dispensary license or processing dispensary license shall be conspicuously displayed at each location where the licensee is authorized to operate.

F. Renovations.

(1) A licensee shall apply to the Commission for approval to make major renovations or modifications to the premises of a licensee.

(2) No major renovation or modification shall be undertaken without approval of the Commission.

.03 Security Hardware.

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

B. If the premises of a licensee are located within a building or structure that also houses a non-licensed entity, any wall between the premises of the licensee and the premises of a non-licensed entity shall be sufficient to prevent unauthorized entry.

C. A cipher or chip-activated keyed lock or equivalent shall be used in a door to deny passage by an unauthorized individual to the premises and any room in which storage, packaging, processing or dispensing medical marijuana takes place, or in which security equipment is located in the premises of a licensee.

.04 Vault or Secure Room.

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

B. The vault or secure room:

(1) Shall be constructed of concrete or similar building material that prevents unauthorized entry;

(2) May not be placed adjacent to an exterior wall of the premises; and

(3) Shall have only one entrance door that:

(a) Meets commercial security standards;

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

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

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

C. Other than while the licensed dispensary is open for business and 1 hour before and 1 hour after, the inventory of medical marijuana shall be stored in the vault or secure room.

.05 Security Lighting.

Lighting fixtures of the licensee shall be designed and installed to:

A. Ensure proper surveillance of:

(1) Both sides of all exterior doors, entrances and portals; and

(2) All interior doors and passages between rooms; and

B. Illuminate work areas for employee safety.

.06 Security Alarm Systems.

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

B. The security alarm system shall be:

(1) Continuously monitored;

(2) Capable of detecting smoke and fire;

(3) Capable of detecting power loss.

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

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

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

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

(3) Any vault that holds medical marijuana.

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

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

.07 Video Surveillance Requirements.

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

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

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

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

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

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

D. A surveillance camera shall continuously capture activity at each entrance to an area where medical marijuana is packaged, tested, processed, stored or dispensed.

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

(1) At the licensed premises; and

(2) At an off-site location.

F. Recordings of security video surveillance shall be:

(1) Access-limited;

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

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

(4) For a minimum of 90 business days.

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

.08 Individuals at a Licensee.

A. A visitor to a non-public area of the premises of a licensee shall:

(1) Be logged in and out by a registered dispensary agent;

(2) Offer proof of identity by means of a government-issued identification document that shall be photocopied;

(3) Be under continuous visual supervision by a registered dispensary agent while on the premises; and

(4) Not touch any medical marijuana.

B. A log of visitors shall be retained for 5 years.

.09 Licensed Dispensary Premises Organization.

A. A licensed dispensary distributing medical marijuana to qualifying patients and caregivers shall divide the licensed dispensary's premises between a public zone and an operations zone.

B. Public Zone.

(1) The public zone shall have:

(a) A waiting area open to the general public; and

(b) A service area in which a qualifying patient or caregiver may consult with a registered dispensary agent and receive medical marijuana.

(2) The licensed dispensary shall maintain a tamper-evident log to record the entry and exit of all individuals other than a registered dispensary agent into the service area.

(3) The dispensary's hours of business shall be displayed in or at the entrance to the public zone.

C. Operations Zone.

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

(2) The operations zone shall be appropriately divided into separate areas for:

(a) Medical marijuana storage;

(b) Medical marijuana preparation and packaging;

(c) Use by dispensary agents for breaks; and

(d) Changing clothing and dispensary agent lockers.

(3) Tamper-evident logbooks or electronic identification logs shall document the movement of persons to and from the operations zone.

G. Appropriate signage shall clearly delineate the separate zones.

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

I. Security alarms systems and video surveillance, as described in Regulations .06 and .07 of this chapter, shall be used to monitor the separation between zones.

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

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

10.62.20 Licensed Dispensary and Licensed Processing Dispensary Operations

Authority: Health General Article, §§13–3301 and 13–3310(b)(2)(iii) and (c), Annotated Code of Maryland

.01 Definitions.

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

B. Term Defined.

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

(2) “Licensee” means a licensed dispensary or a licensed processing dispensary.

.02 Standard Operating Procedure.

A. A licensee shall:

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

(2) Create and use a perpetual inventory control system that identifies and tracks the licensee's stock of medical marijuana from the time it is delivered or produced to the time it is delivered to an academic medical center, another licensee, a licensed grower, or a qualifying patient or caregiver;

and

(3) 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.

.03 Receipt of Products Containing Marijuana.

A. No licensee or licensed grower that dispenses medical marijuana to patients shall:

(1) Acquire medical marijuana from an individual or entity in Maryland other than a licensee; (2) Acquire medical marijuana from outside of Maryland unless authorized by the Commission; or

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

B. A receiving licensee or licensed grower shall detail in the standard operating procedure the steps set forth in sections C, D and H of this regulation, or their equivalent, and a shipping licensee or licensed grower shall detail in its standard operating procedure the steps set forth in sections C through H of this regulation, or their equivalent, to assure:

(1) The integrity of the shipment of products containing marijuana;

(2) The integrity of the electronic manifest and inventory control system; and

(3) The quality of the products in the shipment.

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

D. An agent of the receiving licensee shall:

(1) Log into the electronic manifest;

(2) Take custody of a shipment of products containing marijuana;

(3) Confirm that:

(a) The transportation agent is carrying appropriate identification;

(b) The packaging is secure, undamaged, and appropriately labeled;

(c) Each package in the shipment is labeled as described in the electronic manifest; and

(d) The contents of the shipment are as described in the electronic manifest;

(4) Record the confirmations in the electronic manifest;

(5) Obtain in the electronic manifest the signature of the transportation agent who delivers the shipment;

(6) Record in the electronic manifest the date and time the receiving agent takes custody of the shipment;

(7) Enter the products containing marijuana into the inventory control system;

(8) Segregate the items in the shipment from the stock;

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

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

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

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

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

H. Discrepancy in the shipment.

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

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

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

(4) The shipping licensee shall submit to the Commission, within 7 business days of the observation of the discrepancy, a preliminary report of an investigation of a discrepancy, and within 30 business days a final report of the investigation.

.04 Sanitary Storage of Medical Marijuana.

A. A licensee 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. A licensee shall separately store in the vault until disposed of any medical marijuana that is outdated, damaged, deteriorated, misbranded, adulterated, or whose containers or packages have been improperly or accidentally opened.

.05 Equipment Sanitation, Accuracy and Maintenance Logs.

A. The licensee shall maintain the sanitation of equipment that comes in contact with medical marijuana to prevent contamination in accordance with the approved standard operating procedure.

B. The licensee shall ensure that:

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

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

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

(1) Cleaning of equipment;

(2) The maintenance of equipment; and

(3) The calibration of equipment.

10.62.21 Licensed Dispensary Packaging and Labeling for Distribution

Authority: Health General Article, §§13–3301 and 13–3310(b)(2)(iii) and (c), Annotated Code of Maryland

.01 Packaging Medical Marijuana for Distribution to a Qualifying Patient or Caregiver.

A. A licensed dispensary may only distribute medical marijuana in a package that shall:

(1) Be plain;

(2) Be opaque;

(3) Be child-resistant, if applicable, appropriate or requested by a qualifying patient or caregiver;

(4) Not bear any resemblance to the trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;

(5) Not bear any statement, artwork or design that could reasonably mislead any person to believe that the package contains anything other an a finished medical marijuana product;

(6) Not bear any seal, flag, crest, coat of arms, or other insignia that could reasonably mislead any person to believe that the product has been endorsed, manufactured, or used by any State, county or municipality or any agency thereof;

(7) Not bear any cartoon, color scheme, image or graphic;

(8) Not bear any feature that might make the package attractive to children;

(9) Identify the licensee that produced the finished medical marijuana product or that grew the medical marijuana in the package;

(10) Bear a finished-product lot number and an expiration date;

(11) Bear a clear warning that:

(a) The contents may be lawfully consumed only by the qualifying patient named on the attached label;

(b) It is illegal for any person to possess or consume the package or contents other than the qualifying patient; and

(c) It is illegal to transfer the package or contents to any person;

(12) Bear a clear warning to keep the package and its contents away from children;

(13) Bear the Maryland Poison Control Center emergency telephone number;

(14) Bear the telephone number of the licensee to call to report an adverse patient event;

(15) Bear any allergen warning or nutrition labeling required by law, if applicable;

(16) Bear a listing of the non-medical marijuana ingredients, if applicable;

(17) Bear a conspicuous itemization, including weight, of all cannabinoid and terpenoid ingredients specified for the product; and

(18) Bear a personalized label for the qualifying patient.

B. Information printed on the package must be in English, in letters at least one-sixteenth of an inch high.

C. If a statement of the presence of any cannabinoid is expressed as a percentage of the total weight of the package and the concentration of the cannabinoid is less than 1 percent, the percentage shall be written with a leading zero before the decimal point.

D. 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.

.02 Label for Distribution to a Qualifying Patient.

A. A licensee shall print a label for a package of medical marijuana for a qualifying patient in English in letters no less than one-sixteenth of an inch high, and may also print a label in another language if requested by a qualifying patient or caregiver.

B. A licensee shall not distribute a package of medical marijuana without a label securely attached.

C. A licensee shall state on a label of a package of medical marijuana:

(1) The name of the qualifying patient;

(2) The name of the certifying physician;

(3) The name of the licensee where the product was dispensed;

(4) The date that the medical marijuana was dispensed;

(5) The name of the product;

(6) The strength of applicable cannabinoid and terpenoid compounds displayed in units appropriate to the dosage form;

(7) The quantity of medical marijuana dispensed, displayed in units appropriate to the dosage form;

(8) Any directions for use of the product; and

(9) The instructions for proper storage or handling of the product.

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

D. The label may not:

(1) Contain any false or misleading statement or design; or

(2) Include any statement, image or design that may not be included on the package.

10.62.22 Dispensing Medical Marijuana.

Authority: Health General Article, §§13–3301 and 13–3310(b)(2)(iii) and (c), Annotated Code of Maryland

.01 Use of Written Certification.

A. A written certification is only valid at a single dispensary for the duration of the certification.

B. A dispensary shall notify the Commission that a qualifying patient or caregiver has presented a written certification at that dispensary.

.02 Visitors and Activities at a Licensed Dispensary.

A. Other than in the waiting area of the public zone of a licensed dispensary, a registered dispensary agent shall:

(1) Escort a member of the public visiting a licensed dispensary; and

(2) Maintain visual contact at all times.

B. A licensed dispensary may not permit the consumption of medical marijuana at the licensed premises.

.03 Procedure for Dispensing Medical Marijuana.

A. A registered dispensary agent shall dispense medical marijuana only to a qualifying patient or caregiver.

B. Before 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; and

(2) A certifying physician issued a valid written certification to the qualifying patient.

C. A dispensary agent may provide advice on:

(1) The available types of medical marijuana, marijuana varieties, and finished medical marijuana products;

(2) Methods by which medical marijuana can be taken; and

(3) How unused marijuana may be returned for disposal.

D. A qualifying patient or caregiver may obtain a portion of a 30-day supply at any time once the written certification is presented to a licensed dispensary, provided the portion being sought when added to portions previously obtained does not exceed a 30-day supply.

E. A registered dispensary agent may decline to dispense medical marijuana to a qualifying patient or caregiver if, in the professional opinion of the registered dispensary agent, the patient or caregiver appears to be currently under the influence of drugs or alcohol.

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

G. A written certification, if not used to purchase medical marijuana within 120 days of issuance, becomes null and void.

.04 Acknowledgement by qualifying patient or caregiver

A. Before medical marijuana is dispensed, a qualifying patient or caregiver shall sign an acknowledgement stating that the qualifying patient understands that the qualifying patient is not immune from the imposition of any civil, criminal, or other penalties for the following:

(1) Operating, navigating, or being in actual physical control of any motor vehicle, aircraft, or boat while under the influence of marijuana;

(2) Smoking marijuana in any public place;

(3) Smoking marijuana in a motor vehicle; or

(4) Undertaking any task under the influence of marijuana, when doing so would constitute negligence or professional malpractice;

(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) Smoking marijuana on a private property that is subject to a policy that prohibits the smoking of marijuana on the property of an attached dwelling adopted by:

(a) The board of directors of the council of unit owners of a condominium regime; or

(b) The governing body of a homeowners association.

B. Before medical marijuana is dispensed, a qualifying patient or caregiver shall sign an acknowledgement stating that the qualifying patient understands that:

(1) The qualifying patient has a duty to keep all medical marijuana away from children and must take steps to prevent children from obtaining or using medical marijuana;

(2) It is illegal to transfer medical marijuana to any person, other than the transfer by a caregiver to a qualifying patient;

(3) Obtaining medical marijuana does not exempt a qualifying patient or caregiver from prosecution under Federal law and the penalties provided by Federal law;

(4) Scientific research has not established the safety of the use of medical marijuana by pregnant women; and

(5) The use of marijuana to treat a medical condition is not approved by the U.S. Food and Drug Administration.

.05 Dispensing Controls.

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

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

C. A registered dispensary agent shall record in the inventory control each item or the weight of medical marijuana that was dispensed.

.06 Limit on Transfer of Medical Marijuana.

A. A licensee, or registered dispensary agent, may not transfer any medical marijuana to any person if the licensee or registered dispensary agent knows, or should have reason to know, that the transfer does not comply with any provision of Chapter 256 of the Acts of 2014, or this subtitle.

B. A licensee, or registered dispensary agent, may not transfer any medical marijuana to any person if the licensee or registered dispensary agent knows, or should have reason to know, that the medical marijuana does not comply with any provision of Chapter 256 of the Acts of 2014, or this subtitle.

.07 Report of Products Offered for Distribution.

A licensee shall submit to the Commission on the first day of every month a list of the products and their specifications that the licensee offered for distribution in the previous month.

.08 Disposal of Green Waste.

A licensee may either ship any medical marijuana that is surplus or out of date or that is waste from processing or repackaging to a licensed grower for disposal or dispose of such material in accordance with its approved waste disposal plan.

10.62.23 Records

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

.01 Definition

In this chapter, "Licensee" means a licensed grower, a licensed processing dispensary, and a licensed dispensary.

.02 Licensee Records.

A. A licensee shall maintain, independent of the inventory control, a searchable, secure, tamper-evident record of each distribution that contains:

(1) The name and address of the recipient;

(2) The quantity delivered; and

(3) The name, strength, batch number and lot number of the product.

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

C. A licensee shall maintain a record of test methods and test results for each batch and lot, including graphs, charts, or spectra from laboratory instrumentation.

D. A licensee shall maintain a log of individuals visiting each premises.

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

.03 Record Retention.

Unless otherwise specified, a licensee, a certifying physician and an academic medical center shall retain a record for a period of 5 years.

10.62.24 Inspection.

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

.01 Definition.

A. In this chapter, the following term has the meaning indicated.

B. Term Defined. "Inspector" means any member of the Commission or any State employee or contractor designated by the Commission to carry out an inspection under this chapter.

.02 Consent to Inspection.

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

.03 Inspection of Applicants.

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

(1) An academic medical center compassionate use program;

(2) A licensed grower;

(3) A licensed processing dispensary; or

(4) A licensed dispensary.

B. The Commission shall inspect all aspects of an applicant's operation to make a determination that the operation conforms to the terms of the application.

C. In the case of an inspection before the issuance of a license, the Commission shall arrange the inspection to take place at a mutually agreeable time.

.04 Announced and Unannounced Inspections.

A. The Commission may conduct announced and unannounced inspections of the facilities of licensed growers, licensed processing dispensaries 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 or licensed dispensary to provide the Commission with immediate access to any part of a premises, requested material, information, or agent as part of an inspection may result in the imposition of a civil fine, suspension of license, or revocation of license.

C. During an inspection, the Commission may:

(1) Review and make copies of all records;

(2) Enter any place, including a vehicle, in which 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) Inspect any equipment, instruments, tools or machinery used to process medical marijuana, medical marijuana concentrate or medical marijuana-infused product; and

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

.05 Laboratory Testing as Part of Inspection.

A. During an inspection, the Commission may obtain samples for testing of any marijuana, medical marijuana concentrate, medical marijuana-infused product, media used to grow marijuana, chemicals or solvents used to process medical marijuana concentrate, any labels or containers for marijuana, paraphernalia, any waste material, and of any raw or processed material.

B. If the inspector has grounds to question the quality of any medical marijuana, the inspector may contract with an independent testing laboratory to analyze the samples for any deviation from specification questioned by the inspector.

C. Analysis of marijuana shall conform to the most current version of the Cannabis Inflorescence monograph published by the American Herbal Pharmacopeia (AHP) or a scientifically valid methodology that is equal or superior to that of the AHP monograph.

D. Analysis of other materials shall conform to a scientifically valid methodology for the analysis of such material.

E. A written report of the testing under this regulation shall be provided to the inspector.

.06 Action Upon Findings in Inspection.

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

A. An inspector may:

(1) Suspend the distribution of some or all medical marijuana from the licensed premises;

(2) Order immediate evacuation of the premises and seal the entry door; or

(3) Quarantine some or all medical marijuana.

B. The Commission shall undertake a review of the inspection findings and may:

(1) Request a recall of the medical marijuana;

(2) Request independent testing of affected medical marijuana;

(3) Approve a procedure to reprocess the medical marijuana;

(4) Notify the Maryland State Police if diversion is suspected; or

(5) Order the destruction of contaminated or substandard medical marijuana.

C. The inspector or Commission may notify the local fire department or police department, or appropriate regulatory agency, regarding a risk to public health and safety.

.07 Receipt and Chain of Custody for Materials Removed.

The Commission shall leave a receipt and create a documented chain of custody for anything removed in the course of an inspection.

.08 Report of Inspection.

A. An inspector shall:

(1) Prepare a report of:

(a) The observations and findings of the inspection; and

(b) Any suggestions or demands for corrective action;

(2) Deliver a copy of the report to the inspected entity and obtain a receipt for the delivery; and

(3) Discuss the inspection and inspection report with the licensee, if possible.

B. If an inspection report contains a suggestion or demand for corrective action, within 10 business days from the delivery of the report, the inspected entity shall:

(1) Respond in writing to every suggestion or demand for corrective action; and

(2) Set forth the plan for corrective action to be taken and the timetable for correction.

C. If an inspector finds evidence of operational failures or conditions that create a likelihood of diversion, contamination, or the risk to public health, an inspector may direct that the licensed premises not distribute or participate in the distribution of any medical marijuana until the violation has been corrected and the premises pass re-inspection.

10.62.25 Discipline and Enforcement

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

.01 Operational Failure Risking Diversion or Endangering Health.

In the event the Commission finds there is a reasonable likelihood of diversion, contamination of medical marijuana, or any risk to the health of a patient or any other individual, after a hearing in accordance with the State Government Article section 10-201 et seq., the Commission may;

A. Impose a fine of up to $10,000 per violation on a licensed grower;

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 Pattern of Deviation from Standard Operating Procedure or Program Requirements.

In the event the Commission finds there is a pattern of deviations from standard operating procedures or the terms set forth in the application or the license that does not directly create a risk of endangering the health or safety of a patient, after a hearing in accordance with the State Government Article section 10-201 et seq., the Commission may:

A. Impose a fine of up to $5,000 per violation on a licensed grower;

B. Suspend the license or the approval of the program; or

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

.03 Violation of Requirements.

In the event the Commission finds that a licensee violated a requirement of this subtitle, after a hearing in accordance with the State Government Article section 10-201 et seq., the Commission may:

A. Impose a fine of up to $5,000 per violation on a licensed grower;

B. Suspend the license or the approval of the program; or

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

10.62.26 Academic Medical Center Program Application Contents.

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 Medical Conditions.

An academic medical center shall include on the application:

A. A list of the medical conditions to be treated or studied under the program; and

B. The basis of evidence for the use of medical marijuana to treat a specified medical condition.

.03. Patient Inclusion.

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

B. A program may include a patient if the patient:

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

(2) Is a resident of the State.

C. A program may include a patient younger than 18 years old if:

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

(2) The patient is an emancipated minor.

D. Before including a patient in a program, the program shall obtain written acknowledgement from the patient that:

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

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

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

(4) Certain health risks may be associated with the short-term and long-term use of medical marijuana;

(5) Scientific research has not established the safety of medical marijuana use by pregnant women;

(6) Participation in the program does not protect the patient from liability under federal law;

(7) Participation in the program does not authorize use, possession, or transportation of medical marijuana outside of Maryland; and

(8) Inclusion in the program may be suspended or revoked at the program's discretion.

E. Before being included in a program, a patient shall agree to:

(1) Obtain medical marijuana only from a grower directed by the program;

(2) Fully inform the program, on a continuing basis, of any medication, drug, supplement, or other substance being used by the patient;

(3) Submit to monitoring for drug use by urinalysis or other means if required by the program;

(4) 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

(5) Surrender any recalled or unused medical marijuana as directed by the program.

F. 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.

G. 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.

.04. Addiction Assessment.

A. 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.

B. A program shall verify a patient's prescription history before including the patient in the program.

C. 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.

D. 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.

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

.05 Medical Marijuana Grower or Dispensary.

A. The academic medical center shall specify on the application:

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

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

B. A recommendation for a patient in a program shall only be presented for medical marijuana at the licensed grower or licensed dispensary designated by the program.

.06 Specification of Treatment and Dosage.

A. The academic medical center shall specify on the application the means to determine the length of treatment and dosage permitted under the program.

B. A recommendation provided to a patient participating in a program shall specify:

(1) The type of medical marijuana to be dispensed to the patient;

(2) The quantity of medical marijuana to be dispensed to the patient;

(3) The recommended dosage;

(4) The dosing schedule; and

(5) The method of delivery or means of ingestion.

C. A recommendation shall authorize no more than a 30-day supply of medical marijuana.

D. A recommendation may not be issued without an in-person evaluation by a licensed provider.

E. A program may modify a recommendation at any time as necessary to:

(1) Provide appropriate therapeutic effect to the patient;

(2) Address an adverse drug effect; or

(3) Address a safety issue.

.07 Health Care Providers.

A. The academic medical center shall describe on the application how health care providers will be able to participate in a program.

B. An application shall describe how a program will comprehensively train all staff and health care providers associated with the program on:

(1) The evidentiary basis for the use of medical marijuana;

(2) Types of medical marijuana available in the program;

(3) Appropriate dosages of medical marijuana used in the program;

(4) Methods of delivery or means of ingestion of medical marijuana;

(5) Signs of addiction to marijuana, alcohol, controlled substances, and other drugs of concern;

(6) The conditions of the program participation by patients and caregivers;

(7) The law regarding illicit marijuana and medical marijuana; and

(8) Signs of diversion.

.08 Caregivers.

A. The academic medical center shall include on the application a description of whether and how caregivers will be utilized in the program.

B. In consultation with a patient, a program may designate one or two individuals to serve as a caregiver for the patient.

C. Pursuant to the recommendation provided to a patient, a caregiver may:

(1) Obtain medical marijuana for a patient from the licensed grower or licensed dispensary designated by the program; and

(2) Deliver the medical marijuana directly to the patient.

D. A caregiver may only open a sealed package of medical marijuana in the presence of the patient.

.09 Program Protocol.

A. An academic medical center shall include on the application the program protocol submitted by the academic medical center to its institutional review board.

B. An application may not be considered complete until proof of approval by the institutional review board is submitted by the academic medical center.

.10 Program Evaluation and Gathering Data.

A. An academic medical center shall include on the application the criteria for evaluating the program and monitoring the treatment of patients in the program.

B. A program shall monitor a patient's condition to determine if:

(1) There are any serious adverse events from the medical marijuana;

(2) The delivery method is appropriate; and

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

C. If the outcome of the adverse event is death, life threatening, hospitalization, disability or permanent damage, congenital anomaly/birth defect, required intervention to prevent permanent impairment or damage, or another important medical event, the program shall report the effect to the Commission within 7 business days.

D. If a serious adverse event is otherwise suspected,

(1) The program shall within 15 business days report the event to the Commission and the licensed grower or licensed dispensary; and

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

(a) The production procedure was followed;

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

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

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

F. 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.

.11 Program Funding.

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

B. An application shall disclose any potential conflicts of interest related to the funding of the program.

.12 Diversion Training and Prevention.

A. 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.

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

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

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

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

C. The program shall train a patient or caregiver on the requirement to prevent diversion.

D. The training shall include information on the criminal penalties for diversion of medical marijuana provided for in:

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

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

E. 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.

.13 Unused Marijuana.

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

B. The program shall document the return of or destruction of any unused medical marijuana.

10.62.27 Academic Medical Center Program Application 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 shall be approved for 1 year following the date the study commences.

D. At least 14 business 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 shall expire 1 year after the date of commencement of the program.

B. A program that intends to renew the program's license shall submit an application for renewal to the Commission not less than 90 business 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 the renewal fee specified in COMAR 10.62.28; 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) 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 an individual with responsibility for storing or securing medical marijuana, issuing a recommendation, or updating patient and caregiver information to the register, if that individual has ever been convicted of a felony drug offense.

.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.

10.62.28 Fee Schedule

Authority: Health General Article, §§13-3301, 13-3303, 13-3304, 13-3309, and 13-3310, Annotated Code of Maryland

.01 Fees.

A. The following fees are established by the Commission:

(1) Grower fees:

(a) License as Grower-only:

(i) Application fee.....$6,000 (Stage 1: $2,000; Stage 2: $4,000);

(ii) Biennial license fee.....$250,000 (to be paid in a $125,000 installment each year);

(b) License as Grower and Dispensary:

(i) Application fee.....$11,000 (Stage 1: $3,000; Stage 2: $8,000);

(ii) Biennial licensing fee.....$330,000 (to be paid in a $165,000 installment each year);

(2) Grower agent fees:

(a) Registration fee.....$200;

(b) Replacement registration card fee.....$100;

(3) Licensed Dispensary fees:

(a) Application fee..... $5,000 (Stage 1: $1,000; Stage 2: $4,000);

(b) Biennial license fee.....$80,000 (to be paid in a $40,000 installment each year);

(4) Licensed Processing Dispensary fees:

(a) Application fee..... $5,000 (Stage 1: $1,000; Stage 2: $4,000);

(b) Biennial license fee.....$80,000 (to be paid in a $40,000 installment each year);

(5) Dispensary agent fees:

(a) Registration fee.....$200;

(b) Replacement registration card fee.....$100;

(6) Qualifying patient and caregiver fees:

(a) Identification card base fee.....$100 or a lesser fee based on need as determined by the Commission;

(b) Replacement identification card.....$50 or a lesser fee based on need as determined by the Commission;

(7) Academic medical center fees:

(a) Initial application fee.....$100;

(b) License fee.....$1,000;

(c) Renewal fee.....$1,000;

(8) Miscellaneous fees:

(a) Transfer of ownership of grower license, processing dispensary license or dispensary license.....$7,000; and

(b) Change in the location of grower, processing dispensary or dispensary premises.....$7,000.

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