**PROPOSAL**

**Maryland Register**

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**Title 10
MARYLAND DEPARTMENT OF HEALTH**

**Subtitle 62 NATALIE M. LAPRADE MEDICAL CANNABIS COMMISSION**

**Notice of Proposed Action**

[19-187-P]

The Secretary of Health proposes to:

(1) Amend Regulations **.06** and **.10** under **COMAR 10.62.08 Medical Cannabis Grower License**;

(2) Amend Regulations **.05**and **.09**under **COMAR 10.62.19 Medical Cannabis Processor License**;

(3) Amend Regulation **.10** under **COMAR 10.62.25 Medical Cannabis Dispensary License**;

(4) Adopt new Regulation **.08** **under COMAR 10.62.34 Discipline and Enforcement**;

(5) Amend Regulation **.01** under **COMAR****10.62.35 Fee Schedule**; and

(6) Adopt new Regulations **.01—.06** under a new chapter, **COMAR 10.62.36****Academic Research**.

**Statement of Purpose**

The purpose of this action is to:

(1) Authorize the Maryland Medical Cannabis Commission (MMCC) to award up to 22 medical cannabis grower licenses;

(2) Authorize the MMCC to award up to 28 medical cannabis processor licenses;

(3) Establish an initial licensing period of up to 6 years for medical cannabis growers, processors, and dispensaries;

(4) Require the MMCC to establish enforcement procedures for newly codified advertising restrictions; and

(5) Establish a registration process for academic research institutions to obtain medical cannabis for bona fide research projects.

**Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

**Estimate of Economic Impact**

The proposed action has no economic impact.

**Economic Impact on Small Businesses**

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

**Impact on Individuals with Disabilities**

The proposed action has no impact on individuals with disabilities.

**Opportunity for Public Comment**

Comments may be sent to Jake Whitaker, Acting Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through October 28, 2019. A public hearing has not been scheduled.

**10.62.08 Medical Cannabis Grower License**

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

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

A. **[**Limitation on Number of Licenses.

(1)**]** The Commission may issue pre-approval of up to **[**15**]** *22* licenses**[**:

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

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

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

B.—E. (text unchanged)

**.10 Renewal of License.**

A. A **[**licensee is eligible to apply to renew a**]** *medical cannabis grower* license **[**every 2 years.**]***is valid for:*

*(1) 6 years on initial licensure; and*

*(2) 4 years on renewal.*

B.—H. (text unchanged)

**10.62.19 Medical Cannabis Processor License**

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

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

A. The Commission **[**shall pre-approve a number of licenses for licensed processors sufficient to supply the demand for medical cannabis concentrates and medical cannabis-infused products in a range of routes of administration desired by qualifying patients**]***may issue pre-approval of up to 28 licenses*.

B.—E. (text unchanged)

**.09 Renewal of License.**

A. A **[**licensee is eligible to apply to renew a**]** *medical cannabis processor* license **[**every 2 years.**]***is valid for:*

*(1) 6 years on initial licensure; and*

*(2) 4 years on renewal.*

B.—H. (text unchanged)

**10.62.25 Medical Cannabis Dispensary License**

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

**.10 Renewal of License.**

A. A **[**licensee is eligible to apply to renew a**]** *medical cannabis dispensary* license **[**every 2 years.**]***is valid for:*

*(1) 6 years on initial licensure; and*

*(2) 4 years on renewal.*

B.—H. (text unchanged)

**10.62.34 Discipline and Enforcement**

Authority: Health-General Article, §*13-3313.1*, Annotated Code of Maryland

***.08 Advertising Restrictions.***

*A. All advertisements for medical cannabis, medical cannabis products, edible cannabis products, and medical cannabis-related services shall comply with the requirements of Health-General Article, §13-3313.1, Annotated Code of Maryland.*

*B. A licensee, registrant, agent, or employee who violates §A of this regulation:*

*(1) Is subject to a fine not exceeding:*

*(a) $500 for a first violation;*

*(b) $1,000 for a second violation occurring within 24 months after the first violation; and*

*(c) $5,000 for each subsequent violation occurring within 24 months after the preceding violation; and*

*(2) May elect to:*

*(a) Pay the imposed fine; or*

*(b) Request a hearing not later than 30 days after receipt of notice of the fine.*

*C. In accordance with the hearing provisions of Regulation .05 of this chapter, the Commission may deny, suspend, or revoke the license or registration of a licensee, registrant, agent, or employee who violates §A of this regulation.*

*D. A person may voluntarily submit an advertisement to the Commission for an advisory opinion on whether the advertisement complies with the requirements of Health-General Article, §13-3313.1, Annotated Code of Maryland.*

*E. The Commission shall:*

*(1) Review a copy of any advertisement submitted in the form prescribed by the Commission; and*

*(2) Provide an advisory opinion on whether the advertisement complies with Health-General Article, §13-3313.1, Annotated Code of Maryland, within 30 days of receipt of the request.*

**10.62.35 Fee Schedule**

Authority: Health-General Article, §13-3303(i), Annotated Code of Maryland

**.01 Fees.**

The following fees are established by the Commission:

A.—H. (text unchanged)

I. Independent Testing Laboratory Employee fees:

(1) (text unchanged)

(2) Replacement identification card fee — $100; **[**and**]**

*J. Academic Research Institution fees:*

*(1) Academic research institution:*

*(a) Registration fee — $1,000; and*

*(b) Renewal fee for each subsequent or modified research project — $500;*

*(2) Academic research representative registration fee — $100; and*

*(3) Academic research representative card replacement fee — $100; and*

**[**J.**]***K.*(text unchanged)

***10.62.36 Academic Research***

*Authority: Health-General Article, §13-3304.1, Annotated Code of Maryland*

***.01 Definitions.***

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

*B. Terms Defined.*

*(1) “Academic research institution” means an institution of higher education, a related medical facility, or an affiliated biomedical research firm that filed a registration with the Commission under Health-General Article, §13-3304.1, Annotated Code of Maryland, to purchase medical cannabis for the purpose of conducting a bona fide research project.*

*(2) “Academic research representative” has the meaning stated in Health-General Article, §13-3301, Annotated Code of Maryland.*

*(3) Institution of Higher Education.*

*(a) “Institution of higher education” means an institution of postsecondary education lawfully operating in the State that generally limits enrollment to graduates of secondary schools, and awards degrees at the associate, baccalaureate, or graduate level.*

*(b) “Institution of higher education” includes public, independent, and private nonprofit and for-profit institutions of higher education.*

*(4) “Research protocol” means a written plan for conducting a bona fide research project relating to the health effects, medical uses, properties, or composition of medical cannabis that includes the following information:*

*(a) Name, address, date of birth, Social Security number, institutional affiliation, and qualifications, including a curriculum vitae and list of publications, for the primary researcher;*

*(b) Title, expected duration, primary objectives, statement of purpose, and description of the bona fide research project;*

*(c) Type and amount of medical cannabis or medical cannabis products, and the dosage, route, and method of administration necessary to conduct the bona fide research project; and*

*(d) Standard operating procedures for the safe and secure receipt, storage, packaging, labeling, handling, tracking, and dispensing of products containing medical cannabis and medical cannabis waste.*

***.02 Academic Research Institution Registration.***

*A. An academic research institution shall register with the Commission in order to purchase, through an academic research representative, medical cannabis from a licensed grower, processor, or dispensary in Maryland.*

*B. To register, an academic research institution shall submit:*

*(1) The academic research institution registration fee specified in COMAR 10.62.35; and*

*(2) A completed academic research institution registration form provided by the Commission, including a research protocol.*

*C. This chapter may not limit an academic research institution from partnering with a licensed grower, processor, or dispensary to conduct a bona fide research project.*

***.03 Academic Research Representative Registration and Criminal History Record.***

*A. An academic research representative shall be registered with the Commission before the representative may purchase medical cannabis for a registered academic research institution.*

*B. A registered academic research institution shall apply to register an academic research representative by submitting to the Commission:*

*(1) The academic research institution representative fee specified in COMAR 10.62.35 for each*

*academic research representative; and*

*(2) A completed academic research representative registration form provided by the Commission.*

*C. Criminal History Record.*

*(1) An academic research institution shall submit to the Commission:*

*(a) The name, address, date of birth, and Social Security number of an academic research representative;*

*(b) Documentation of the submission of fingerprints of the prospective academic research representative to the Central Registry; and*

*(c) The request for the criminal history record information of the prospective academic research representative to be forwarded to the Commission.*

*(2) A prospective academic research representative may not be registered if the prospective academic research representative has ever been convicted of a felony drug offense, except as provided in Health-General Article, §13-3310(d), Annotated Code of Maryland.*

*(3) The Commission, after review of the criminal history record information, may disqualify from registration any prospective academic research representative who has been convicted of or has pleaded nolo contendere to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside.*

*D. Identification Cards.*

*(1) The Commission shall issue each registered academic research representative:*

*(a) A unique identifier; and*

*(b) An identification card.*

*(2) The identification card shall be valid for the expected duration of the research project stated in the research protocol or 3 years from the date the card is issued, whichever is earlier.*

*(3) If a registered academic research representative’s identification card is lost, destroyed, or stolen, the academic research institution, within 72 hours of being notified, shall:*

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

*(b) Apply for a replacement card; and*

*(c) Pay the replacement card fee specified in COMAR 10.62.35.*

*(4) 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.*

*(5) If a registered academic research representative’s card is lost, destroyed, or stolen, a copy of the notification to the Commission shall be evidence of registration until a new card is obtained from the Commission.*

*E. Termination.*

*(1) As soon as possible upon termination of a registered academic research representative’s association with a registered academic research institution, the registered academic research institution shall:*

*(a) Take custody of the terminated registered academic research representative’s identification card;*

*(b) Obtain any keys or other entry devices from the terminated registered academic research representative; and*

*(c) Ensure the terminated registered academic research representative can no longer gain access to the premises of the registered academic research institution where the medical cannabis is stored.*

*(2) Within 5 business days of the termination of a registered academic research representative’s association with a registered academic research institution, the institution shall:*

*(a) Notify the Commission of the termination and the circumstances of a termination; and*

*(b) Initiate delivery of the terminated registered academic research representative’s identification card to the Commission.*

***.04 Purchase of Medical Cannabis.***

*A. The Commission-issued identification card allows a registered academic research representative to purchase the type and amount of medical cannabis specified in the research protocol from a licensed grower, processor, or dispensary.*

*B. Prior to obtaining the medical cannabis, the registered academic research representative shall submit to the Commission for approval a copy of a written authorization from the academic research institution to purchase medical cannabis for the purpose of conducting a bona fide research project.*

*C. The written authorization shall include:*

*(1) The period that the authorization to possess the medical cannabis remains in effect;*

*(2)  The quantity of the medical cannabis requested; and*

*(3)  Any other special requirements.*

*D. Upon Commission approval, a licensed dispensary may dispense medical cannabis to a registered academic research representative in accordance with COMAR 10.62.30.06.*

*E. An academic research representative may only purchase medical cannabis that:*

*(1) Is from a licensed grower, processor, or dispensary; and*

*(2) Has met the testing requirements established in COMAR 10.62.15 or COMAR 10.62.23.*

***.05 Inspection and Reporting Requirements.***

*A. Submission of a registration form under Regulation .02 of this chapter gives the Commission consent to conduct at least two inspections per year, one announced and one unannounced, to ensure compliance with State law and regulations.*

*B. The Commission may inspect all premises of a registered academic research institution used to conduct research relating to medical cannabis to determine that:*

*(1) The research using medical cannabis is ongoing and consistent with the associated research protocol;*

*(2) The academic research institution provides for the safe, secure storage of the medical cannabis; and*

*(3) There is written documentation of the chain of custody of the medical cannabis.*

*C. Failure by a registered academic research institution to provide the Commission with prompt access to any part of a premises or to any requested material, information, or employee as part of an inspection may result in the imposition of a civil fine, suspension of registration, or revocation of registration.*

*D. Reporting Requirements.*

*(1) The registrant shall submit to the Commission:*

*(a) An annual report on the progress and status of any research project; and*

*(b) A final report of the findings of the research project to the Commission within 365 days of the completion of the research project.*

*(2) The final report shall provide a brief summary of the research findings.*

*(3)  A published article or document on the research project may serve as the final report.*

***.06 Term and Renewal.***

*A. The registration is valid for the term indicated on the registration form approved by the Commission.*

*B. The registrant may apply for an extension of the registration beginning 90 days before the expiration of the registration.*

*C. The registration shall remain valid unless:*

*(1) There is a change in the research project; or*

*(2) The academic research institution withdraws the registration.*

*D. A change in the research project occurs if the registered academic research institution:*

*(1) Substantially deviates or demonstrates a pattern of deviation from the research protocol or the terms set forth in the registration;*

*(2) Diverts or contaminates medical cannabis, or otherwise risks the health of a patient or any other individual; or*

*(3) Fails to comply with this chapter.*

ROBERT R. NEALL
Secretary of Health