

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulations  
Department of Health and Mental Hygiene  
(DLS Control No. 16-205)**

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**Overview and Legal and Fiscal Impact**

The regulations make several revisions to the current regulations governing the Natalie M. LaPrade Medical Cannabis Commission including clarifying (1) the criminal history records check process; (2) the payment and refunding of fees; (3) requirements for financial background information from growers, processors, and dispensaries; (4) the general process for granting certain licenses and the criteria for obtaining certain licenses; and (5) certain grower quality control procedures. The regulations also require certain inventory control systems to be approved by the commission and an independent testing laboratory used by a licensed grower to be registered with the commission.

The regulations present no legal issues of concern.

The regulations have no material fiscal impact on State or local agencies.

**Regulations of COMAR Affected**

**Department of Health and Mental Hygiene:**

Natalie LaPrade Medical Cannabis Commission: Definitions: COMAR 10.62.01.01  
Medical Cannabis Grower License: COMAR 10.62.08.03 and .05 through .07  
Medical Cannabis Grower Agent: COMAR 10.62.09.03  
Inventory Control by Grower: COMAR 10.62.12.02  
Medical Cannabis Grower Quality Control: COMAR 10.62.15.04 through .07  
Medical Cannabis Processor License: COMAR 10.62.19.02 and .04 through .06  
Medical Cannabis Processor: COMAR 10.62.20.03  
Medical Cannabis Processor Operations: COMAR 10.62.22.02  
Medical Cannabis Dispensary License: COMAR 10.62.25.03 and .05 through .07  
Registered Dispensary Agent: COMAR 10.62.26.03  
Licensed Dispensary Operations: COMAR 10.62.28.02

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**Legal Analysis**

**Background**

According to the Natalie M. LaPrade Medical Cannabis Commission, many of the regulations are in response to feedback on current regulations. Specifically, the commission received feedback that the current requirement for applicants to provide “audited financial

statements” before the applicants were operational did not make sense and was expensive and burdensome. The regulations also authorize the commission to refund annual license fees paid to the commission under certain circumstances. The commission determined that applicants would have to spend a significant amount of money in getting to the second stage of license approval and that it was fair to refund some of the fees paid if the commission did not ultimately issue a license.

## **Summary of Regulations**

The regulations add a definition of “processor agent” which is identical to the definition in §13-3301(1) of the Health-General Article. The regulations clarify the process by which fingerprint specimens are to be obtained for a criminal history record check when applying for a medical cannabis grower, processor, or dispensary license. The regulations also authorize the commission to withdraw, rather than suspend, an application for a grower, processor, or dispensary license and clarify when the stage two application fee and the annual license fee is to be provided to the commission when a grower, processor, or dispensary license is pre-approved.

The regulations repeal and replace the process for issuing grower, processor, and dispensary licenses. The regulations require an applicant who has been pre-approved for a grower, processor, or dispensary license to submit certain tax returns or financial statements and certain other personal and background information to the commission within 90 days after notification of the pre-approval. In addition, the requirements for the pre-licensing inspection of the pre-approved grower, processor, or dispensary are set forth in the regulations. The commission is authorized to issue a grower, processor, or dispensary license on determination that (1) all inspections demonstrate that the applicant’s entity and facility comply with the regulations; (2) the applicant’s entity and facility are ready to commence business in compliance with the regulations and application; and (3) financial and other background investigations have been completed and passed. The commission is required to refund the annual license fee promptly in the event that the commission does not issue a license.

The regulations clarify that the inventory control system used by a licensed grower, processor, or dispensary must be approved by the commission, and require that the inventory control system used by a licensed grower, processor, or dispensary identify and track the licensee’s stock of medical cannabis in a certain manner.

The regulations repeal the requirement that the independent testing laboratory have a standard operating procedure to test medical cannabis that is approved by a certain accreditation body and instead require that the laboratory be registered by the commission. The contents of the certificate of analysis issued by an independent testing laboratory is clarified by the regulations and an independent laboratory is also required to report to the commission each instance in which a batch of medical cannabis is out of compliance with the specification for the batch.

The regulations provide that if a certificate of analysis indicates that the levels of certain active ingredients as determined by the commission conform to the specifications for the variety, the licensed grower may assign an expiration date to the batch, release the batch for distribution, and revise the status of the batch in the inventory control. The regulations alter the process to be used by independent testing laboratories for product stability testing and retention sampling of

batches or lots of cannabis. Specifically, an independent testing laboratory must obtain from each batch or lot from each licensed grower and processor a sufficient number of samples to be available for testing of the lot or batch in the event follow-up testing is necessary after an adverse reaction report or other matter, and retain such samples for one year past the date of expiration of the batch or lot.

## **Legal Issues**

The regulations present no legal issues of concern.

## **Statutory Authority and Legislative Intent**

The Department of Health and Mental Hygiene cites §§ 13-3301 through 13-3303 and 13-3306 through 13-3312 of the Health – General Article as statutory authority for the regulations. More specifically, the regulations are authorized by §§ 13-3301, 13-3302, 13-3303, 13-3306, 13-3307, 13-3309, 13-3311, and 13-3312 of the Health-General Article. Section 13-3301(l) defines “processor agent”, § 13-3302(c) provides that one of the purposes of the Natalie M. LaPrade Medical Cannabis Commission is to develop regulations to implement programs to make medical cannabis available to qualifying patients in a safe and effective manner, and § 13-3303(g) authorizes the commission to set reasonable fees to cover the costs of operating the commission. Section 13-3306 requires the commission to license medical cannabis growers that meet all requirements established by the commission to operate in the State. Section 13-3307 requires medical cannabis dispensaries to be licensed by the commission and requires the commission to establish an application review process for granting dispensary licenses, while § 13-3309 requires a medical cannabis processor to be licensed by the commission. Section 13-3311 requires the commission to register at least one private independent testing laboratory to test cannabis and products containing cannabis that are to be sold in the State and requires the laboratory to meet the standards and requirements for accreditation, inspection, and testing established by the commission. Section 13-3312 sets forth the standards to be followed when applying for a criminal history records check. Sections 13-3308 and 13-3310 are not relevant to these regulations.

The relevant cited authority is correct and complete. The regulations comply with the legislative intent of the law.

## **Fiscal Analysis**

The regulations have no material fiscal impact on State or local agencies.

## **Agency Estimate of Projected Fiscal Impact**

The department advises that the regulations have no material fiscal impact on State or local governments. The Department of Legislative Services concurs. The fiscal and policy note for House Bill 490 (Chapter 251) of 2015, which expanded upon earlier medical cannabis legislation

in the State, did not anticipate any license fees being collected prior to issuing licenses. Thus, refunding annual licensing fees to applicants who paid the fee, but did not receive a license, does not have an overall impact on the revenue estimates for the Natalie M. LaPrade Medical Cannabis Commission. Further, the commission advises that, based on the current number of applicants, the commission could likely find another qualifying applicant in short order. Finally, the commission notes that it does not expect to issue many refunds on these license fees, if at all.

### **Impact on Budget**

There is no impact on the State operating or capital budget.

### **Agency Estimate of Projected Small Business Impact**

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

### **Contact Information**

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