RHODE ISLAND GOVERNMENT REGISTER
PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF BUSINESS REGULATION (INCLUDES THE OFFICE OF THE HEALTH INSURANCE COMMISSIONER)

Title of Rule: Rules and Regulations Related to the Medical Marijuana Program Administered by the Office of Cannabis Regulation at the Department of Business Regulation

Rule Identifier: 230-RICR-80-05-1

Rulemaking Action: Proposed Amendment

Important Dates:
Date of Public Notice: 11/21/2019
Hearing Date: 12/06/2019
End of Public Comment: 12/21/2019

Authority for this Rulemaking:
R.I. Gen. Laws § 21-28.6-2, 21-28.6-4, 21-28.6-5, 21-28.6-6, 21-28.6-12, 21-28.6-14, 21-28.6-15, and 21-28.6-16.

Summary of Rulemaking Action:
The Department of Business Regulation, Office of Cannabis Regulation ("DBR") has proposed amendments to this regulation in accordance with the 2019 legislative changes to R.I. Gen. Laws Chapter 21-28.6 set forth in 2019 P.L Ch. 88, Art. 15, (the "Act"). These amendments add content to conform to new statutory requirements including, but not limited to: licensing of six (6) new compassion centers, the prohibition of issuing any new cultivator or cooperative cultivation licenses, and the transfer of caregiver registration from the Department of Health ("DOH") to DBR.

This regulation sets forth the licensing, registration and operational requirements for the medical marijuana program to ensure: a clear, transparent and fair application and licensing process; product safety, increased safe and dependable access to medical marijuana; and improved oversight and accountability in the program to curtail diversion to the illicit market consistent with federal guidance and to mitigate the potential for federal intervention and enforcement. With the proposed amendments, the regulation will apply to compassion centers and licensed cultivators, licensed cooperative cultivators, qualified patients (registered by DOH) and registered primary caregivers (transferred from DOH to DBR in 2019).

After conducting a comprehensive review of the existing regulation, DBR began by consolidating existing repetitive sections for operations and registry identification cards into new sections that apply to all applicable licensees and cardholders. This eliminated the need for existing repetitive sections. In addition, to increase clarity

and user-friendliness, original content was extracted from larger sections and relocated under its own section heading. For example, original language regarding packaging and labeling was extracted from the existing duplicative operations sections into its own expanded section. Additional sections were added for caregivers (transferred to from DOH to DBR in 2019), product designation, advertising, quarantine/recall, enforcement and an equivalency table.

DBR also reviewed its existing guidance documents/bulletins related to the Medical Marijuana Program and incorporated all relevant content into the regulation to give those provisions the force of law. This information includes compassion center: sales to out-of-state patients, home delivery procedures, and prohibited relationships with medical practitioners.

Given this restructuring, DBR has stricken the entirety of the existing language and proposed new language which begins on page 107 of the proposed regulation.

DBR is also seeking public comment on the license areas/application zones where new compassion centers will be licensed in accordance with § 1.2(C) and § 1.15.

Below is a summary of the amendments proposed in each section:

· § 1.1, Definitions and Authority – This expansion of the existing definitions section includes a more comprehensive list of definitions from R.I. Gen. Laws § 21-28.6-3 and updates consistent with FY2020 statutory changes. Definitions found elsewhere in the existing regulation have been consolidated into this section: volunteer, key persons/interest holders, related party transaction, cooperative cultivations, material financial interest or control, agents and testing agent. Added new definitions for terms such as: advertising, child resistant, DEM, related party transactions, print media, quarantine, radio, and television. Also added an incorporated materials section at § 1.1.7.

· § 1.2, Compassion Center Application, Licensing and Renewals - Edited and expanded upon the original § 1.2. Established and/or clarified application requirements, nonprofit requirements, divestiture requirements, variance procedures, and licensing requirements consistent with the FY2020 statutory amendments. Proposed amendments resulting in additional costs to compassions centers include: increased or new requirements for certification of non-profit compliance, business plan, operations manual, security and safety plan, submission of an organization chart, designation of a compliance officer and prohibited relationships with medical practitioners. In addition, the 6 new compassion center licenses will be issued by geographic zone as determined by DBR based upon patient need and public safety. The zones are set forth in § 1.15.

· § 1.3, Licensed Cultivator Applications, Licensing and Renewals - Relocated content from former § 1.5 (Cultivator Application and Licensing Provisions) to new § 1.3. Streamlined content to improve readability and reduce redundancy. Added

language regarding FY2020 statutory amendment prohibiting DBR from accepting applications for additional cultivator licenses. Edited language regarding divestiture and variance requests to improve clarity and for consistency with compassion center requirements.

· § 1.4, Registry Identification Cards - Combined provisions from current §§ 1.3 and 1.6, which were separate and repetitive sections for compassion center and cultivator ID cards. This new section § 1.4 applies to all relevant cardholders, including caregivers, which are now under the jurisdiction of DBR.

· § 1.5, Packaging and Labeling - Language regarding packaging and labelling was set forth twice in the current regulation, for compassion centers in § 1.4(I) and for cultivators in § 1.7(H). To limit redundancy, this language has been combined into this new and expanded section § 1.5, which is modeled after best practices from Canada and other US jurisdictions with programs in existence for over five years.

· § 1.6, Operational Requirements for Marijuana Establishment Licensees - Language regarding operational requirements for medical marijuana establishment licensees was set forth twice in the current regulation, for compassion centers in § 1.4 and cultivators in § 1.7. For the proposed amendments, DBR started with the existing language in § 1.4 for compassion centers and added references and applicable provisions for cultivators. Through the use of subsections, DBR added additional structure and clarity to this longer but comprehensive operations section. In addition, DBR included provisions from bulletins regarding home delivery and sales to out-of-state patients.

· § 1.7, Medical Marijuana Product Designation - Added a new section in accordance with FY2020 amendments, which clarifies requirements for the designation of medical marijuana consistent with the new statutory definition of "medical marijuana" set forth in R.I. Gen. Laws § 21-28.6-3(20).

· § 1.8, Cooperative Cultivations - Streamlined existing content in § 1.8 to improve clarity. Added provision that DBR will no longer accept cooperative cultivation applications in accordance with FY2020 amendments to R.I. Gen. Laws § 21-28.6-14(d). Removed references to residential co-ops because the only existing licensed co-ops are non-residential. Deleted repetitive content that exists elsewhere in the proposed amendments and replaced with internal cross-references (safe disposal of marijuana now in § 1.6, plant tag and possession limits now in § 1.12, and enforcement provisions now in § 1.13).

· § 1.9, Registered Primary Caregivers - Added a new section for caregivers in accordance with FY2020 amendments, R.I. Gen. Laws § 21-28.6-5(c). In addition, references to caregivers have been added throughout the proposed amendments, particularly in the new § 1.4 for Registry Identification Cards.

· § 1.10, Advertising - Added a new section in accordance with FY2020 amendments. This new section sets forth parameters for targeted advertising to registered patients. In addition, this new section establishes prohibitions with particular attention to not targeting or appealing to children.

· § 1.11, Quarantine Remediation Recall - Added new section which sets forth clear procedures for all marijuana and marijuana products that have not yet been deemed suitable for sale or have failed testing by a cannabis testing laboratory. In addition, there are also provisions for the recall and/or remediation of any medical marijuana or marijuana products if DBR or DOH identify any risks to public health, safety or welfare.

· § 1.12, Medical Marijuana Plant Tag Certificate Program – Added a new section which expands upon and clarifies requirements for plant tag certificates located in § 1.9 of the existing regulation.

· § 1.13, Enforcement – Added a new section which consolidates language from the current regulation regarding inspections, audits and penalties in addition to including updates consistent with the FY2020 statutory amendments. Specific grounds for the discipline of a licensee or cardholder were added consistent with other DBR licensing schemes.

· § 1.14, Marijuana Equivalency Table - Added a new section in accordance with FY2020 amendments. This will increase clarity regarding possession limits for compassion centers, patients and caregivers. This will also assist law enforcement.

· § 1.15, Compassion Center Application Zones - Added a new section identifying the geographical zones in which the new compassion center licenses may be located.

· § 1.16, Severability - Formerly § 1.10, no changes.

Additional Information and Comments:
All interested parties are invited to request additional information or submit written or oral comments concerning the proposed amendment until December 21, 2019 by contacting the appropriate party at the address listed below:

Erica Ferrelli
Department of Business Regulation (includes the Office of the Health Insurance Commissioner)
1511 Pontiac Ave, Bldg 68-1
Cranston, RI 02920
erica.ferrelli@dbr.ri.gov

Public Hearing:

A public hearing, in accordance with R.I. Gen. Laws § 42-35-2.8, to consider the proposed amendment shall be held on December 6, 2019 at 11:00 am at (Note the hearing is not at DBR), Gaige Hall, Rhode Island College, 600 Mt. Pleasant Ave, Providence, RI 02908 at which time and place all persons interested therein will be heard. The seating capacity of the room will be enforced and therefore the number of persons participating in the hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.

The place of the public hearing is accessible to individuals who are handicapped. If communication assistance (readers/interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-462-9551 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting.

Regulatory Analysis Summary and Supporting Documentation:
The regulatory analysis weighs costs and benefits around increasing general accountability, oversight and public safety in ensuring compliance with the enabling Act by medical marijuana licensees and registrants. The quantitative results were that the regulations would result in an approximately $357,000 in costs for implementation, reducing to approximately $167,000 by year 4. However, the qualitative benefits to public health, public safety, the population of medical marijuana patients and the public at large is significant and substantial.

In the development of the proposed amendment consideration was given to: (1) alternative approaches; (2) overlap or duplication with other statutory and regulatory provisions; and (3) significant economic impact on small business. No alternative approach would be as effective and less burdensome as the proposed regulation and no duplication, or overlap was identified based upon available information.

For full regulatory analysis or supporting documentation see agency contact person above.