State of Rhode Island and Providence Plantations
DEPARTMENT OF BUSINESS REGULATION
Medical Marijuana Program
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FINAL CONCISE EXPLANATORY STATEMENT FOR ADOPTION OF RULES AND REGULATIONS RELATED TO THE MEDICAL MARIJUANA PROGRAM ADMINISTERED BY THE DEPARTMENT OF BUSINESS REGULATION

A. Introduction. The Rhode Island Department of Business Regulation ("DBR") is hereby providing a final Concise Explanatory Statement for Rules and Regulations Related to the Medical Marijuana Program Administered by the Department of Business Regulation, 161-RICR-300-35-1, ERLID 8432 (the "Regulations") in accordance with the Rhode Island Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6. These Regulations are promulgated pursuant to the relevant statute, as adopted by the General Assembly, Chapter 21-28.6 of the Rhode Island General Laws entitled "The Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act," as amended, including amendment by the 2016 Public Laws, Chapter 142 (Budget Article 14)(the Act).

B. Statement of Purpose of the Regulation. These Regulations create a new regulatory framework for the medical marijuana program as administered by DBR in order to ensure program stability, increase safe and dependable access to medical marijuana, and increase oversight and accountability in the program to curtail diversion to the black and grey markets.

C. Summary of Regulatory Analysis. These Regulations have a large societal benefit to Rhode Island by creating tools to curtail the black market production and sale of marijuana, strengthening workplace safety for employees in the industry, and strengthening patient safety and consumer protections through new labeling and packaging standards, pesticide standards and setting the stage for future testing regulation by the Department of Health. These regulations also ensure a dependable and diverse supply of medicine for the state's medical marijuana patients. Requests for full regulatory analysis or supporting documentation may be emailed to DBR.MMPCompliance@dbr.ri.gov.

D. Summary of Post-Comment Changes and Associated Comments. Below is a summary of the changes between the text of the proposed rule contained in the notice of proposed rulemaking and the text of the final rule, which changes are all consistent with, and a logical outgrowth of, the rule proposed in the notice in compliance with R.I. Gen. Laws § 42-35-6.1. For the most logical presentation of the DBR's analysis in reviewing groups of related comments, related public comments are also addressed here, including those not resulting in the requested

changes. In addition to this summary of changes, a redlined document showing the exact changes in the full regulatory document will also be produced.

1. *Pesticide Provisions*

   In response to commentary received from the Rhode Island Department of Environmental Management, Division of Agriculture and Resource Marketing (DAG), the following changes were made:

   a. Sections 1.4(J)(9)(b)(6) and 1.7(I)(8)(b)(6) have been changed to delete the sentence "The product must be registered for sale in Rhode Island" and replace it with "The product must be a currently registered pesticide product eligible for sale in Rhode Island as determined by the Rhode Island Department of Environmental Management."

   b. New Sections 1.4(J)(9)(b)(7) and 1.7(I)(8)(b)(7) have been added to provide: "The product must be used in accordance with any and all use instructions on the label."

   c. Section 1.4(J)(9)(e) has been revised to read as follows: "*As a DBR record-keeping requirement,* compassion centers must keep detailed records of any pesticide products used and application regiments, including video recording during pesticide applications which must cease if there is a failure or disruption of the video surveillance system. *This record-keeping requirement is independent of that required of commercial pesticide applicators by the Rhode Island Department of Environmental Management, and is intended to apply in addition to that requirement, where relevant.*" The same change has been made to Section 1.7(I)(8)(e) for licensed cultivators.

   Also regarding the pesticide provisions, another commenter suggested using light as a proxy for determining whether the plant is at a stage during which pesticides should no longer be applied for safety reasons. Based on this comment, the second sentence was added to the following quoted provisions of 1.4(J)(9)(c) and 1.7(I)(8)(c): "No application of pesticides shall be made after the vegetative stage of growth of the cannabis plant. The vegetative stage of growth should be determined by visual buds or flower or by proxy of the plant receiving less than eighteen (18) hours of light in a twenty-four (24) hour period."

   Also regarding the pesticide provisions of the Regulations, the following specific public comments were received other than from the Rhode Island Department of Environmental Management that did not result in changes to the Regulations: a) requesting that neem oil be listed as a permitted pesticide product, b) suggesting a restriction be added that the label must indicate use for "leafy greens" and for products to be smoked, and c) suggesting persons applying pesticides be limited to DEM-licensed applicators. It is DBR's understanding that the Regulations, as

posted, would not prohibit use of neem oil so long as the usage complies with the applicable pesticide provisions of the Regulations. As for the other comments, DBR has determined that its Regulations, with changes suggested by DEM subject matter experts, reasonably address environmental concerns.

2. *Cultivator Micro-license.* In response to commentary criticizing high cultivator license costs and suggesting a smaller scale cultivator license, DBR changed the Regulations to include a micro-license which would have the following features: 0 – 2,500 sq. feet facility limit; $5000 non-refundable application fee; $5000 annual license fee; inventory limits of 50 mature plants and 50 seedlings until the Medical Marijuana Program Tracking System is in place; and an uncommitted inventory limit of 2.5 lbs. See Sections 1.5(C)(1), 1.5(E)(2), and 1.7(C)(1) as revised.

3. *Destruction of uncommitted inventory by licensed cultivators.* In response to commentary suggesting that the thirty (30) day period given for cultivators to sell or destroy excess uncommitted inventory was too short, DBR changed Section 1.7(C)(3)(c) to extend this period to forty-five (45) days. Relatedly, commentary was also received suggesting that cultivators be permitted to "give" excess uncommitted inventory to patients; however, this would be prohibited by the Act which in R.I. Gen. Laws § 21-28.6-16 provides that a cultivator may only deliver or transfer medical marijuana to a registered compassion center.

4. *Cooperative Cultivations.*

    a. Commentary was received advancing a differing interpretation of the Act with respect to how cooperative cultivations should be defined. The Act does not define "cooperative cultivation", "cooperative cultivation license" or "cooperatively cultivating" in statute but it does give DBR regulatory authority to promulgate regulations clarifying the licensing and operation of cooperative cultivations in R.I. Gen. Laws § 21-28.6-14(a)(10). DBR is confident that the cooperative cultivation regulations it has adopted under this statutory authority are reasonable and in furtherance of the intent of the Act. In reviewing this comment, DBR made a determination to simplify and clarify the definition of cooperative cultivation in Section 1.8(B)(1) which now reads as follows:

        "Cooperative cultivation" shall mean two (2) or more qualifying patient or primary caregiver cardholders that elect to cooperatively cultivate marijuana in the same dwelling unit or commercial unit within the limits and subject to the requirements of a cooperative cultivation license under the Act and these regulations. This excludes the situations of two (2) or more qualifying patient or primary caregiver cardholder(s) who are primary residents of the same dwelling unit where the medical marijuana plants are grown and who do not elect to grow together within the limits and subject to the requirements of a cooperative cultivation license under the Act and these regulations; provided nothing herein should be deemed to absolve persons in such a situation from

complying with the requirements that all medical marijuana plants must be properly tagged and not exceed the plant limits of R.I. Gen. Laws § 21-28.6-4(q)(if election to grow as a licensed cooperative cultivation is not made, no more than twenty-four (24) plants may be grown at a single dwelling unit or commercial unit). See also R.I. Gen. Laws § 21-28.6-14(entitled "Cooperative Cultivations"); R.I. Gen. Laws § 21-28.6-3(10)(defining "dwelling unit"); R.I. Gen. Laws § 21-28.6-3(3)(defining "commercial unit").

b. In response to commentary critical of the prohibition on firearms as a security measure for non-residential cooperative cultivations, Section 1.8(G)(4) was changed to permit use of security guards licensed by the Office of the Rhode Island Attorney General pursuant to R.I. Gen. Laws § 5-5.1-13 and who are under written contract to provide security services to the non-residential cooperative cultivation. Reasonable alternative security and safety measures in the Regulations, as posted, also include locks, lighting, written security and emergency plans, and coordination with law enforcement.

5. *Licensed Premises Siting Comments.*

a. In response to commentary requesting clarification as to how distance is to be measured for purposes of the restriction on siting a medical marijuana facility within 1000 feet of a preexisting public or private school, the following language was added to Sections 1.2(C)(2)(d)(2) and 1.5(D)(4)(b)(4): "For purposes of this paragraph, the 1000 foot distance shall be measured from the secured [compassion center/cultivator] premises, which shall include allotted outdoor areas (such as parking and loading areas), to the property line of the school, which shall include the school building, land, and appurtenances."

b. In response to commentary expressing concern with ambiguity in local zoning laws for licensed cultivator applicants, DBR added the following language to the Regulations in Section 1.5(D)(4): "With respect to local zoning, medical marijuana cultivation may fall within various zoning use categories including without limitation the following zoning use categories: agricultural uses (such as greenhouse and nursery), industrial uses (light and general), manufacturing and processing (such as factory) or specific medical marijuana related use categories. Whether medical marijuana cultivation is a permitted use, prohibited use or allowed by special use permit within these or any other use categories is determined by local zoning authorities." Relatedly, commentary was received suggesting that DBR pre-empt municipalities from banning cultivator licenses through zoning ordinances. While DBR has provided the above-cited guidance relative to zoning concerns, a request for complete municipal pre-emption would need to be addressed to the legislature. Also related, commentary was received indicating that the Regulations should require training of municipalities on issuance of local approvals for medical marijuana businesses such as zoning. DBR does not have the regulatory authority to require that municipalities undergo training.

Municipalities may contact DBR if they have any questions about the program.

6. *Licensed Premises Inspections.* In response to commentary suggesting the regulation provide for a regular frequency of inspections for compassion centers and cultivators at least on an annual basis and that annual renewals should include a recent inspection, DBR added Sections 1.2(H)(4) and Sections 1.5(H)(3) to read: "An annual inspection shall be part of the annual renewal process."

7. *Packaging and Labeling.* On the one hand, commentary was received opining that packaging and labeling requirements were overly restrictive. On the other hand, commentary was received suggesting more stringent and comprehensive labeling and packaging requirements.[1] DBR has determined that the Regulations, with the changes listed below, achieve a reasonable balance considering patient safety concerns and curtailing risk of use by minors and unauthorized individuals while recognizing that packaging and labeling requirements that are too restrictive may be cost-prohibitive and with respect labeling may prevent product recognition which can stifle the steady supply and variety of medicine and further achieve a balance of being sufficiently clear for compliance guidance while recognizing that not every conceivable packaging and labeling scenario can be addressed in regulatory language. Specifically the changes to the Regulation regarding packaging and labeling are as follows:

   a. Sections 1.4(I)(8)(e) and 1.7(H)(8)(e) were edited to grammatically clarify language posted with the clear intent that both the total estimated amount of THC and total estimated amount of CBD are required to be listed on the label.

   b. Sections 1.4(I)(8)(d) and 1.7(H)(8)(d), which require the label list the total weight in ounces and grams or volume as appropriate, were changed by adding: "Weight and volume must be determined using accurately calibrated equipment which equipment must also comply with any other applicable state laws."

   c. New Sections 1.4(H)(10) 1.7(H)(10) were added to read: "Notwithstanding any of the product labeling requirements set forth in this Section [1.4 (H)/1.7(H)], application may be made to DBR for approval to affix a two inch (2") by two inch (2") logo or graphic, which may be colored, for the purpose of identifying the compassion center selling and/or the cultivator producing the product."

   d. Sections 1.4(H)(5)(b) and 1.7(H)(5)(b) were amended by adding "or other similar sealing method pre-approved by DBR" to the requirement that "liquid

[1] For example, it was suggested that the patient name or identification number and the certifying practitioner be on the label. In addition to the potential of such a requirement being cost-prohibitive, it unnecessarily intrudes on patient privacy.

marijuana products may also be packaged in a bottle and sealed using a metal crown cork style bottle cap."

8. *Work place safety and sanitation at licensed premises*. Commentary was received expressing concerns over compassion center and licensed cultivator worker safety and sanitation. The following changes were made to the Regulations to address these concerns:

   a. New Section 1.4(J)(7)(m) was added to provide: "In addition to the safety and sanitary equipment including personal protective equipment that the compassion center is required to furnish its employees involved in marijuana manufacturing and extraction pursuant to Section 1.4(J)(4)(D) of these regulations, the compassion center must also furnish its employees with proper safety equipment for other types of work assigned as part of the compassion center operations." A corresponding change was made by adding Section 1.7(I)(6)(m).

   b. In response to a comment suggesting the compassion center and licensed cultivator manufacturing and extraction provisions expand the requirement that work surfaces where medical marijuana products are manufactured be non-porous, non-absorbent, and easily cleanable, Sections 1.4(J)(4)(f) and 1.7(I)(4)(g) were changed to add in "the walls and floors in the areas in which such products are manufactured."[2]

   c. With respect to medical conditions that may pose a risk of contamination to trigger compassion centers and licensed cultivators to exclude an employee from operations until the condition is cleared, commentary was received suggesting that the list of examples be expanded to specifically include the flu, colds, strep or pulmonary disease. In response to this commentary, DBR made technical amendments to Sections 1.4(J)(7)(k) and 1.7(J)(7)(k) to add additional clarity to the clear intent of the posted regulations to be a non-exhaustive list of medical conditions, changing the terms "include" to "include but not necessarily limited to." Compassion centers and licensed cultivators will have to use their best judgment with respect to these provisions as DBR Regulations cannot specifically account for every conceivable existing or future medical contamination threat nor does it have the subject matter expertise to do so.

   With these changes, DBR has determined that the Regulations adequately address work place safety and sanitation. Compliance monitoring includes inspection as well as video surveillance of the facilities. Furthermore, DBR will include a renewal application question regarding any Occupational Safety and

[2] DBR declines to specifically add in all equipment and furnishings; equipment and furnishings must be non-porous, non-absorbent, and easily cleanable if they constitute medical marijuana manufacturing "work surfaces." DBR also declines to add that these surfaces must be maintained in a manner consistent with FDA standards for any food product because the DOH medical marijuana program regulations provide that medical marijuana is not considered by DOH to be a food product.

Health Administration actions and address any such actions as appropriate in light of worker safety concerns.

9. *Authorized medical marijuana transports by licensees.* In response to commentary indicating alternatives to the two person per authorized transport vehicle requirement that were represented as recommended by security professionals, Sections 1.4(J)(3)(g) and 1.7(I)(3)(f) of the Regulations were amended to provide: "Authorized transports must be in compliance with one of the following minimum requirements: (i) an authorized transport may use a single authorized transport vehicle so long as it is operated/occupied by a minimum of two authorized transport cardholders and is subject to the requirement that at least one such cardholder shall remain in the authorized transport vehicle at all times; or (ii) an authorized transport may use two or more authorized transport vehicles that are operated/occupied by authorized transport cardholders provided the authorized transport vehicles are traveling together at all times during the authorized transport."

10. *Fine for failure of employee to return registry card when no longer employed.* In response to commentary suggesting that there be a penalty for failure of a compassion center employee to return his or her registry identification card within ten (10) days of termination of the employment, Section 1.3(H)(3) was changed by adding the following sentence: "In addition to being null and void, a penalty of up to one hundred and fifty dollars ($150) may be assessed for failure to return the card within the ten (10) day period." The $150 is consistent with the fine the legislature set for failure of a compassion center employee to update name and address information within ten days under R.I. Gen. Laws § 21-28.6-12(c)(9) and is a reasonable deterrent to prevent invalid cards from being in circulation. The same change was made for licensed cultivator employees for the same reasons. See Section 1.6(H)(2) as revised.

11. *Compassion center patient outreach activities.* In response to commentary suggesting editing Section 1.4(J)(5)(c) regarding required compassion center patient outreach activity so as not to specifically describe smoking techniques as "safe," the Regulations were changed to read as follows: "Providing applicable usage techniques and any corresponding safety information to registered qualifying patients." Furthermore, it should be noted that the Regulations, as posted, had also addressed concerns about smoking safety by requiring the following label warning in Sections 1.4(I)(9)(i) and 1.7(H)(9)(i): For product to be smoked, "Warning: Smoking is hazardous to your health."

12. *Compassion center customer service.* In response to commentary expressing concern about compassion centers refusing entry to registered patients, caregivers, and authorized purchasers, DBR changed the Regulation to add that the Operations Manual must include "customer service protocols." Compassion centers should be guided by such protocols and security policies when handling the issue of refusing entry. See Section 1.2(H)(2)(J).

13. *Illegal marijuana transaction advertising by holders of plant tags.* Commentary was received regarding advertising restrictions, including a request that DBR address the issue of patients and caregivers illegally selling marijuana online on Craigslist. In response, DBR has added Section 1.9(G)(6) to provide: "As a continuing condition of holding plant tags, plant tag holders may not pursue any marijuana transaction that is in violation of the Act, including pursuing such a transaction by online advertising."

14. *Plant Tag Fines.* In response to commentary expressing concern about DBR'S discretion to impose a fine between $25 and $5000 per plant for plant tag violations where the number of plants exceed the statutory limit, DBR developed the following tiered fine approach:

Number of plants exceeding the relevant possession limits of the Act	**Fine assessed per plant**
1 – 3 plants over limit	$25 assessed per plant
4 – 8 plants over limit	$100 assessed per plant
9 – 12 plants over limit	$250 assessed per plant
13 – 15 plants over limit	$1000 assessed per plant
16 – 24 plants over limit	$2500 assessed per plant
25 or more plants over limit	$5000 assessed per plant

5. Non-substantive changes included fixing punctuation and text formatting errors and adding several cross-references between related sections of the Regulations.

E. Summary of Comments Not Resulting in Regulatory Language Changes. Below is a summary of other public comments received (public hearing testimony and written public comments)[3] that did not result in changes to the text of the Regulation and a brief description of DBR's reason(s) for not making any such changes after due consideration.

1. *Comments Pertaining to Department of Health Regulatory Areas.* Commentary was received which pertained to Department of Health ("DOH") regulatory areas, such as practitioner certification, records, and responsibilities; medicinal forms, administration, dosage, and equivalency of medical marijuana; and product testing.

[3] Questions posed to the DBR during the public comment period do not require DBR response under the Administrative Procedures Act. See R.I. Gen. Laws § 42-35-2.8.

2. *Comments Otherwise Outside the Scope of DBR Regulatory Authority.*

   a. Commentary was received regarding the Legislative Oversight Committee. DBR does not have authority over this committee which was created by the legislature and by statute must be comprised of members appointed by the legislature.

   b. Commentary was received opining that the use of medical marijuana for religious purposes should be recognized. The Act is limited to scope to "medical use" of marijuana and DBR does not have jurisdiction to expand nor does it have any legislative charge or expertise to respond to comments opining about freedom of religion.

   c. Commentary was received regarding issues pertaining to employer-employee contracts, compensation and employment-related costs, collective bargaining, employment-related taxes, volunteer arrangements, employment discrimination, building contractor qualifications and rates, etc. Such issues are outside of the scope of DBR's jurisdiction.

3. *Comments Outside Scope of DBR Regulatory Language.*

   a. Commentary was received questioning the motives of the Act and Regulations. The Act provides the legislative purpose in R.I. Gen. Laws § 21-28.6-2 and DBR has declared the purpose of the Regulations in the Notice of Proposed Rulemaking which statement of purpose is also copied above.

   b. Commentary was received expressing dissatisfaction with the legislative and regulatory processes. Such commentary does not invite any specific changes to the language of the Regulation. DBR followed the Rhode Island Administrative Procedures Act, R.I. Gen. Laws § 42-35-1 et seq. governing rulemaking procedures and timelines in the adoption of these Regulations.

   c. Commentary was received suggesting the need for more medical marijuana scientific research. Such commentary does not invite any specific regulatory language changes to the Regulations nor does the Act mandate or fund such scientific research.

   d. Commentary was received expressing dissatisfaction with current compassion center operations. If citizens make a specific complaint about a specific compassion center violating a specific provision of the Act or the Regulations, DBR will review such complaints and take any appropriate action. However, no changes to the language in the Regulations were necessary from this set of commentary.

e. Commentary was received making suggestions about the DBR Medical Marijuana Program website. In accordance with the Rhode Island Administrative Procedures Act, R.I. Gen. § 42-35-1(19)(i) "a statement that concerns only the internal management of an agency" is not required to be documented in regulations. Website administration, including deciding what type of information to post and how frequently to update such information, is a matter of internal DBR management. As a general matter, the amendments to the APA in the 2016 legislative session subjects state agencies to publish certain information on their websites by December 31, 2018 and January 1, 2019. Also, DBR typically posts regulations, blank application forms, and final orders in enforcement actions, and periodic informational updates and guidance on its website.

4. *Comments Pertaining to Issues Governed Directly by Statute*. Comments were received which were directed at requirements that are set by the Act as adopted by the General Assembly. DBR does not have jurisdiction to change statutory provisions which can only be changed through the legislative process. Specifically:

   a. Commentary was received suggesting the term "marijuana" be changed to "cannabis" throughout the Regulations. The term "marijuana" is the controlling term of the Act.

   b. Commentary was received suggesting elimination and/or extension of the deadline for patients, caregivers, and cooperative cultivations to discontinue selling excess marijuana to compassion centers. The December 31, 2016 deadline is set by statute in R.I. Gen. Laws § 21-28.6-4(c) and (i). Similarly, commentary was received suggesting adoption of the Regulations be delayed until after the legislature reconvenes in January and/or until "more data" is collected. Due to the cited deadline and other statutory deadlines for the medical marijuana program, DBR cannot delay nor would it be in the best interest of the program to do so.

   c. Commentary was received opining that the statutory possession limits for patients and caregivers suffered from incongruence between plant numbers and usable weight which it was opined would result in a frequent need to destroy excess. Such possession limits are governed by the Act, but it should be noted that a patient or caregiver with higher yielding plants may of course self-limit how many plants he or she grows to avoid any need to destroy excess to comply with the maximum usable marijuana possession limits.

   d. Commentary critical of the number of compassion centers being limited to three was received. This number is set forth in the Act at R.I. Gen. Laws § 21-28.6-12.

e. Commentary was received suggesting compassion center registration and application fees be increased. The $250.00 application fee is set forth in R.I. Gen. Laws § 21-28.6-12 (c)(1)(i) and the $5,000.00 registration fee is set forth in R.I. Gen. Laws § 21-28.6-12 (c)(5)(i).

f. Commentary was received suggesting that the restriction on the siting of a compassion center within 1000 feet of a preexisting public or private school be extended to childcare facilities, DCYF group homes, licensed pre-schools and daycares, Boys & Girls Clubs, YMCAs, summer camps, playgrounds, and youth recreation centers. The restriction is limited to "public or private schools" by the Act, R.I. Gen. Laws § 21-28.6-12(f)(2). The term "public school" as it is generally understood would not include childcare facilities, DCYF group homes, licensed pre-schools, daycares, Boys & Girls Clubs, YMCAs, summer camps, playgrounds, nor youth recreation centers. Neither could the term "private school" both as generally understood and per the specific definition adopted by DBR verbatim to the legislative definition of the same term in the context of siting of liquor establishments in § 3-7-19(b) be so construed.

Note: As further described in discussion of comments in the preceding and following sections, many other comments pertained to issues that were directly or indirectly governed by the Act.

5. *Discussion of Other Substantive Comments Considered but not Resulting in Regulatory Language Changes.*

General Comment Responses

a. *Application of Regulations to Medical Marijuana Program Only.* Commentary was received suggesting that there could be confusion as to whether the Regulations apply to marijuana for non-medical use and also opining on recreational marijuana issues. DBR declines to make any changes based on this commentary because it is clearly stated not only in title of the Regulations but also in Section 1.1(B)(1) that the Regulations are limited to the medical marijuana program. For reference: "The scope of these DBR Regulations is limited to authorized activities under the Rhode Island Medical Marijuana Program and does not extend to any acquisition, possession, cultivation, manufacture, delivery, transfer, transportation, or sale for non-medical purposes. See R.I. Gen. Laws § 21-28.6-3(15)(defining "medical use") and R.I. Gen. Laws § 21-28.6-2(5)(legislative findings making distinction between medical and non-medical use)."

b. *Limitation of Rhode Island Medical Marijuana Program to Rhode Island Borders.* Commentary was received regarding activity beyond the borders of Rhode Island. DBR addresses such comments by pointing to Section 1.1(B)(2) of the Regulations which provides: "The protections and immunities for participation in the Rhode Island Medical Marijuana Program set forth in R.I. Gen. Laws §§ 21-

28.6-4 (patient and caregivers), 21-28.6-12(h)(compassion centers), and 21-28.6-16(m)(cultivators) do not apply to any activities beyond the borders of the state of Rhode Island."

c. *Outdoor Grows*. Commentary was received suggesting that medical marijuana should be permitted to be grown outdoors. DBR declines to make changes based on these comments because: (a) The Act does not contemplate outdoor marijuana grows; and (b) the Regulations do define secure indoor structures as any enclosed areas with four walls and a roof which would include secure greenhouses.

d. *Comments regarding price of medical marijuana*. On the one hand, commentary was received suggesting a prohibition on promotional deals, coupons, and discounts and/or restricting advertisement thereof. On the other hand, commentary was received that compassion center prices are too high, especially for disabled and low-income patients.[4] Recognizing both the need for medicine to be accessible and affordable and in light of the statutory dispensing limits of R.I. Gen. Laws § 21-28.6-12 which mitigate the risk of overuse by patients purchasing from compassion center(s), DBR determined that the Regulation should not be changed based on these sets of comments.

Comments Regarding Compassion Centers

e. Commentary was received expressing concerns with "vertical integration" generally and suggesting a limit as to the amount of marijuana a compassion center can grow for its own inventory. The Act permits a compassion center to grow as much of its own inventory as it deems appropriate so long as such inventory reflects the projected needs of qualifying patients and does not charge DBR with limiting the percentage of self-supply. See R.I. Gen. Laws § 21-28.6-12(i)(1).

f. Commentary was received regarding the issue of compassion center payment obligations to medical marijuana suppliers for fulfilled ordered. The Regulations, as posted, already addressed this issue in Section 1.4(B)(2)(e) and 1.7(B)(3)(e) by requiring that if the parties have not mutually agreed upon a payment date, the default payment date will be sixty (60) calendar days of delivery or pickup.

g. Commentary was received suggesting that the Regulation be more specific as to how compassion centers will ensure the neighboring community is not affected

[4] Relatedly, commentary was received that referenced the "ADA" in the context of pricing of medical marijuana for disabled patients. Assuming "ADA" refers to the Americans with Disabilities Act, DBR does not have jurisdiction over enforcement of the ADA and does not have any knowledge of ADA requiring medical marijuana states to regulate pricing. The Hawkins-Slater Act does provide for reduced patient registration and free medical marijuana plant tags for low-income and disabled individuals, eligibility for which is determined by DOH, which overall reduces program participation costs for those individuals.

by marijuana odor. DBR has determined that the Regulation, as posted, adequately addresses the issue of odor control by mandating ventilation and filtration systems and a written odor control and mitigation plan in Section 1.4(J)(8), compliance with which can be adequately monitored with routine and complaint-driven inspections and, if necessary, enforcement actions in accordance with Section 1.4(K).

h. Commentary was received expressing a concern with disruption of medicine to patients in circumstances such as a strike or lock-out, approved temporary shut-down, or during the period provided for start-up. DBR addresses such comments by stating that the underlying concern has already been addressed by Article 14 and the Regulation. Specifically, Article 14 removed the requirement that a patient designate a specific compassion center it would use. Therefore, if there were a disruption of operation at a particular compassion center, patients could still obtain medical marijuana at the other compassion centers. Concerns about the travel to a different compassion center than the patient's preferred center are mitigated by the Regulation's allowance of approved home delivery programs.

Comments Regarding Licensed Cultivators

i. Commentary was received suggesting licensed cultivators be restricted with a Rhode Island residency requirement. DBR's decision not to so restrict the pool of qualified candidates for cultivator licenses is supported by the determination that state interests are adequately protected by consideration during the cultivator application process of legal eligibility to do business in Rhode Island, payment of Rhode Island taxes, and relevant experience in Rhode Island.

Comments Regarding Cooperative Cultivations

j. Commentary critical of cooperative cultivation fees was received. R.I. Gen. Laws § 21-28.6-14(a)(10) charges DBR with promulgating regulations governing the licensing and operation of cooperative cultivations and specifically authorizes DBR to promulgate regulations that set a fee for a cooperative cultivation license, which by statute also includes mandatory tag fees set by § 21-28.6-15. Patient and caregivers who choose to cooperatively cultivate may receive the benefit of higher possession limits as compared to patients and caregivers growing individually and as a result of those increased possession amounts, cooperative cultivation licensing fees are needed to offset the cost of resources to process more complex applications and compliance inspections for cooperative cultivations.

Comments on Licensee Operational Requirements

k. *Prohibited Material Financial Interests.* Commentary was received suggesting expansion and clarification of the prohibited material financial interest rules in Section 1.2(E)(6)(c). DBR has determined that the Regulations, as posted, are

adequately clear in this respect. Questionable financial interests may need to be further reviewed on a case by case basis as not every conceivable scenario can be accounted for in regulatory language.

l. *Waste Disposal.* Regarding medical marijuana waste disposal, one comment was received indicating that waste disposal provisions were too onerous and another pointing out composting and fermentation processes as an option. The sections regarding "Safe Disposal of Medical Marijuana Waste and Safe Destruction of Usable Medical Marijuana," Sections 1.4(J)(10)(compassion centers), 1.7(I)(9)(licensed cultivators), and 1.8(N)(licensed cooperative cultivations), as posted, have in place avenues for DBR approval of alternatives to the DBR-mandated medical marijuana waste requirements. Through such approval processes, DBR may consider alternatives including composting and fermentation provided the processes ensure that unauthorized use does not occur through access to medical marijuana waste materials.

m. *Seed to Sale and Inventory Control Comments.* Commentary was received regarding seed to sale tracking processes. DBR responds to such commentary by pointing out that the Medical Marijuana Program Tracking System will involve system requirements and, where necessary, DBR guidance, to ensure proper use and integrity of the tracking system. Commentary was also received suggested more frequent "comprehensive inventories;" however, DBR has determined that the annual "comprehensive inventories" together with the continuous inventory tracking on the Tracking System will be adequate.

Comments Regarding Compassion Center and Cultivator Staff Requirements

n. Commentary was received regarding the criminal background provisions for compassion center and cultivator staff. The criminal background checks provisions for registrants under DBR's jurisdiction are governed by R.I. Gen. Laws § 21-28.6-12(c)(7)(compassion center registry identification card applicants and holders) and R.I. Gen. Laws § 21-28.6-16(k)(licensed cultivator registry identification card applicants and holders). Commentary included criticism of the disqualifying criteria; however, that is dictated by the cited statutory provisions, which DBR cannot change by regulation. Commentary was also directed at the frequency and timing of the criminal background checks for compassion center staff. The Regulation, as posted, Section 1.3(C)(10) provides: "DBR will not require a person subject to a national criminal background check under this subsection to undergo such a check more than once every two (2) years, unless a more frequent time frame is mandated and/or agreed to as part of a license disciplinary action." The Regulation, as posted, Section 1.3(E) provides: "Pursuant to R.I. Gen. Laws § 21-28.6-12(c)(8), compassion center registry identification cards shall expire one year after issuance." As such, the Regulation allows DBR to require each compassion center employee to submit to a criminal background check every other renewal period which period is tied to that individual employee's date of card issuance, not to the compassion center's registration issuance and renewal dates. DBR has determined that requiring a

criminal background check on a more frequent basis will create an undue burden on both the employees and on the law enforcement agencies processing the criminal background check requests. This determination is supported by the mitigation of the risk of disqualifying information occurring in the intervening years by Section 1.3(E) of the Regulation which provides: "Pursuant to R.I. Gen. Laws § 21-28.6-12(c)(13), a compassion center cardholder shall notify DBR of any disqualifying criminal convictions as defined in §21-4 28.6-12(c)(7). Such notification must be made in writing within ten (10) business days." The two year period is also consistent with the two year period for caregiver criminal background checks set by the legislature in the Act, R.I. Gen. Laws § 21-28.6-6(f)(3). The frequency and timing provisions and the rationale therefor are the same for licensed cultivator staff.

o. Commentary was received suggesting regulatory provisions that compassion center employees not have financial interests in any entity that helps to obtain or provides physician authorizations for medical marijuana. This issue is addressed by the Act, R.I. Gen. Laws § 21-28.6-12(d)(5)(iv).

p. Commentary was received suggesting that staff of compassion centers and cultivators be subject to mandatory annual training on the risks and harms of marijuana use. DBR's decision not to impose that specifically requested training requirement is supported by its determination that the certifying practitioner is primarily responsible for advising the patient on this topic and that the Regulation, as posted, adequately trains compassion center staff by including in the annual training, among other topics, general "informational developments in the field of medical use of marijuana." See Section 1.4(J)(6)(b).

q. Commentary was received suggesting that the Regulations prohibit compassion center employees from using marijuana. DBR has determined that the Regulation, as posted, strikes the appropriate balance on the issue of employee marijuana use by prohibiting use of marijuana on the compassion center premises (Section 1.4(J)(2)) and mandating a drug free work place policy be adopted by each compassion center (Section 1.4(H)(2)(f)).

r. Commentary was received suggesting that compassion center volunteers should be permitted to dispense medicine rather than being limited to volunteering services for educational programming. DBR declines to make such a change because dispensing medicine to patients requires access to point of sale systems containing confidential patient information which only employees and contracted agents authorized to use the system should have access to.

Inspection and Enforcement Comments

s. Commentary regarding DBR inspections of compassion centers and cultivators, access to their surveillance records, and information-sharing of surveillance recordings and plant tag data when authorized by law and particularly for

coordination with law enforcement, and law enforcement's independent authority to inspect these premises. At the outset, DBR notes that "Cole Memo" issued by the federal Department of Justice guides its position on these issues and is a pervasive theme in its approach to the medical marijuana program in general. The Cole Memo expresses an expectation that states permitting use of medical marijuana will have in place a "a strong and effective regulatory and enforcement system." Furthermore, it should be noted that broad inspection powers and cooperation with law enforcement are commonly understood features of entering such a highly regulated industry.

Regarding the inspections, as explained above, DBR changed the Regulations in response to commentary to specifically list an inspection be part of the annual renewal process. With respect to the term "reasonable" in the context of "reasonable inspection by DBR" for compassion centers and cultivators, commentary was received that the Regulations do not specify who determines what is "reasonable." As is understood for most administrative inspections of highly regulated industries, the inspecting agency makes an initial determination of reasonableness which an aggrieved party may choose to challenge through any available legal channels during which proceedings the inspecting agency would ask that its initial determination of reasonableness be afforded deference provided it is not arbitrary or capricious.

Commentary was also received suggesting that DBR be required to document the basis for any request for compassion center video surveillance recordings. It is DBR's determination that subjecting compassion centers to the requirement that video surveillance recordings be provided by DBR upon request, with or without documentation of the basis for such request, is a reasonable condition of licensure in a highly regulated industry and is a critical component of "a strong and effective regulatory and enforcement system."

Regarding information-sharing, commentary was received regarding the following provision: "DBR employees and representatives will hold video surveillance records and recordings of point-of-sale areas confidential except for authorized release in accordance with applicable law." Specifically, it was suggested DBR change "in accordance with applicable law" to "when required by applicable law." The language, as posted, requires that any release of the recordings not be in violation of any applicable law, which applicable law would certainly include the confidentiality provisions of the Act. Relatedly, commentary was received regarding Section 1.9(O)(4) of the Regulation which provides as follows: "Law enforcement may be granted access to the Medical Marijuana Program Tracking System to verify the validity of plant tags and tag data, or, if the System is not available, through other data sharing mechanisms, in accordance with applicable law." On the one hand, one commenter opined that it is "unclear what the 'applicable law' is that authorizes access to other unnamed data sharing mechanisms" and that "this section further fails to contain any restrictions regarding the confidentiality of data so obtained." On the other hand, commentary was received suggesting Section 1.9(O)(4) be amended to grant law

enforcement 24/7 access to the Medical Marijuana Program Tracking System. For the following reasons, DBR has determined that the Regulation, as drafted, reaches the appropriate balance on these issues. The language, as posted, requires that any release of plant tag data and verification information contained in other data sharing mechanisms before the Medical Marijuana Program Tracking System is available not be in violation of any applicable law, which applicable law would certainly include the confidentiality provisions of the Act and any applicable criminal law and procedure. Plant tag data is specifically limited in scope by the Regulations, Section 1.9(H), as posted, to data not protected by the patient confidentiality provisions of the Act. DBR has an appropriate level of discretion in the Regulation as to information-sharing that will include and working cooperatively with law enforcement while recognizing patient privacy concerns.

With respect to law enforcement's independent authority to inspect these premises, commentary was received suggesting a regulatory provision that would authorize local law enforcement to enter a licensed medical marijuana premises to conduct a compliance check. It is outside the scope of DBR's regulatory authority to make such an authorization.

t. Commentary was received suggesting the video surveillance recordkeeping requirement be reduced from 60 to 30 days. DBR declines to make this change because this length is reasonable and necessary for effective enforcement, *i.e.* if an issue is discovered during the flowering stage, the source of the issue may need to be identified as occurring during an earlier pesticide application and there could be breaches of security which are not realized until a pattern has been identified and which require access to surveillance of prior incidents in the pattern.

u. Commentary was received that the Regulations do not provide "standards for appealing a DBR [tag] revocation decision" or "for staying the required destruction requirement pending an appeal." The Section 1.1(E) of the Regulations, as posted, provides: "Enforcement hearings shall be handled in accordance with Department of Business Regulation Central Management Regulation 2 entitled Rules of Procedure for Administrative Hearings and the Rhode Island Administrative Procedures Act, R.I. Gen. Laws § 42-35-1 et seq."

Comments pertaining to localized concerns

v. Commentary was received suggesting restrictions on compassion center and cultivator signage including that no signage should be allowed in the windows or on exterior of the building other than the name of the compassion center. DBR has determined that each municipality is the more appropriate authority to address this issue through zoning or other local ordinances as it deems appropriate.

w. Commentary was received suggesting that a public hearing or public notice in a local paper be required for a cultivator license to allow the local community to express opposition or support for an application. DBR has determined that the most appropriate avenue for municipal residents to voice concerns about siting a cultivator within their municipal residents is through municipal approval processes such as zoning or other permitting. DBR has further determined that is without legislative authority/direction to mandate by regulation that a municipality incorporates newspaper notification or public hearings into such processes.

Miscellaneous Comments

x. Commentary was received advancing a differing interpretation of the Act's plant possession limits. DBR stands firmly by the interpretation it has used in formulating the maximum number of medical marijuana plant tags it will issue under its tagging regulations, Section 1.9.

y. Commentary was received suggesting DBR adopt a regulatory requirement that a patient must secure their supply of medical marijuana so as to prevent unauthorized use, such as by requiring a warning label to that effect and/or requiring such information be provided by the compassion center as part of its required outreach activities. The legislature did not vest DBR with jurisdiction over individual registrants' usable medical marijuana supply; however, it should be noted that pursuant to DBR's jurisdiction over medical marijuana plant tags, Section 1.9(G)(3)(b) of the Regulations, as posted, imposes basic requirements for preventing unauthorized access to medical marijuana plants as a continuing condition of plant tag issuance.

z. Commentary was received opining that the definitions of "wet" and "usable" marijuana required clarification. It is DBR's determination that the terms as defined in the Regulation, as posted, are clear and consistent with the statutory definitions in the Act which for ease of reference for the reader were clearly cited in the Regulation following each definition.

aa. Commentary was received requesting a label warning be mandated to specify that the use of medical marijuana for pets is prohibited. The Regulation, as posted, requires the following warning: "Warning: For medical use by a registered patient only." See Sections 1.4(I)(9)(g) and 1.7(H)(9)(g). Because patient registrations are never issued to animals, this warning can be reasonably understood to not promote use by an animal.

Director's Approval

Scottye Lindsey
Director

12/12/16
Date