Regulatory Analysis for 230-RICR-80-05-1

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

RHODE ISLAND DEPARTMENT OF BUSINESS REGULATION

November 2019 – Updated February 2020

Executive Summary

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 center, 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 operations requirements for the medical marijuana program in this state 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 DBR from DOH in 2019), product designation, advertising, quarantine/recall, enforcement and an equivalency table as required by statute.

Additionally, DBR 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.

Currently, the following number of licensees, caregivers and patients participate in the Medical Marijuana Program:

- Compassion Centers – 3 licensees (6 new licenses to be issued)
- Cultivators – 50 licensees
- Cooperative Cultivations – 2 licensees
- Registered Caregivers – Approximately 900 registrations
- Qualifying Patients –
    - Approximately 19,000 Rhode Island patient cardholders
    - Approximately 6,000 out of state patient cardholders

Note that the increases in application and licensing fees for compassion centers were enacted by statutory amendments in the FY 2020 budget. Therefore, those additional costs are neither attributable to nor result from these proposed regulatory amendments.

The below regulatory analysis is required by the Rhode Island Administrative Procedures Act, R.I. Gen. Laws 42-35-2.9.

As part of this analysis, DBR calculated a net benefit number per year, as seen in the table below. DBR then applied a range of discount rates, which yielded a **net present value** of **$(1,060,708)** (7% discount rate) to **$(1,124,316)** (3% discount rate). However, the reader is cautioned not to interpret these numbers as a comprehensive accounting of all relevant costs and benefits. The impacts of the non-quantifiable costs and benefits are likely to drive the true net benefit of the regulatory options under consideration. The lack of data prevents the Department from accurately predicting the full economic impacts, particularly in those areas related to benefits such as access to medical products, fair information sharing, safety, and equity for license consumers and patients.

Net Benefits by Year					
	Year 0	*Year 1*	*Year 2*	*Year 3*	*Year 4*
Quantifiable Net Benefit	$(356,470)	$(250,807)	$(216,247)	$(188,599)	$(166,481)

More information about the quantifiable and non-quantifiable costs and benefits can be found at the end of this analysis.

Regulatory Development

While constructing the proposed amended regulation**,** the Department considered a range of alternatives, including existing Rhode Island regulations and policies of similar subject matter, departmental experience, and industry best practice. This regulation considered other logistical methods and timeframes of information retention and protection.

Explanation of Significant Changes and Themes

Given the reorganization and consolidation of the original sections of the regulation, DBR has stricken the entirety of the existing language and proposed new language. The below chart crosswalks the original content in the existing regulation to the proposed regulation, explaining the original source of the content and what information has been relocated.

Original Section #	**Original Name**	**New Section #**	**New Name**	**Summary of Proposed Amendments**
1.1	General Provisions	**1.1**	**Definitions and Authority**	Expanded 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. Relocated definitions currently located elsewhere in the regulation:

Original Section #	Original Name	New Section #	New Name	Summary of Proposed Amendments
				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.
1.2	Compassion Center Application and Licensing	**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 including 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.

Original Section #	Original Name	New Section #	New Name	Summary of Proposed Amendments
1.3	Compassion Center Cardholder Registry Identification Card Provisions	**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	Compassion Center Operational Provisions	**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	Licensed Cultivator Application and Licensing Provisions	**1.5**	**Packaging and Labeling**	Language regarding packaging and labelling is 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	Licensed Cultivator Cardholder Registry Identification Card Provisions	**1.6**	**Operational Requirements for Marijuana Establishment Licensees**	Language regarding operational requirements for medical marijuana establishment licensees is 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

Original Section #	Original Name	New Section #	New Name	Summary of Proposed Amendments
				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	Licensed Cultivator Operational Provisions	**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 Cultivation Provisions	**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	Medical Marijuana Plant Tag Program	**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

Original Section #	Original Name	New Section #	New Name	Summary of Proposed Amendments
				amendments, particularly in the new § 1.4 for Registry Identification Cards.
1.10	Severability	**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**	This new section 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**	This new section expands upon and clarifies requirements for plant tag certificates located in § 1.9 of the existing regulation.
		1.13	**Enforcement**	This section 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.

Original Section #	Original Name	New Section #	New Name	Summary of Proposed Amendments
		1.14	**Marijuana Equivalency Table**	Added a new table in accordance with FY2020 amendments. This table was added to 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 table identifying the geographical zones in which the new compassion center licenses may be located.
		1.16	**Severability**	Formerly § 1.10, no changes.

Specific Changes Impacting Stakeholders

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.

I. Compassion Centers

A. Compassion Center Application, Licensing and Renewal

Section 1.2 includes proposed revisions to the application, licensing and renewal process for compassion centers.

1) Compliance Officer

Given the complexity of the requirements of the medical marijuana program, which allows the cultivation, manufacture, and sale of a federally illegal substance, DBR determined that each compassion center should designate a compliance officer under this regulation. DBR anticipates that the labor associated with compliance is already being performed by existing staff or by outside entities that are overseen by existing staff. The benefit from formalizing this designation is a marginal increase in DBR's ability to identify and communicate with compliance expertise within the state. The marginal cost of this designation is negligible given that the duties are currently performed. The alternative, to not require this designation, would decrease the ease of information flow between the department and the entities, but would not substantially decrease licensee costs.

2) Nonprofit Certification

Compassion centers have been and continue to be required by R.I. Gen. Laws § 21-28.6-12(f) to operate on a not-for-profit basis for the mutual benefit of its patients. The proposed amendment adds an additional requirement that all compassion centers certify both for initial and renewal applications that they are operating as a nonprofit in accordance with applicable state law.

Costs: It is estimated that it will take approximately 5 hours of time by a mid-level employee at each applicant/licensee to compile the information necessary to complete the certification given that it is all information that should already be maintained in the normal course of doing business. We assume an hourly wage of $40. Thus, the nonprofit certification requirement would cost applicants $200 per initial application and even less for renewal given a lower time commitment and also assuming operations continue to comply with the Act. Given an expectation of approximately 30 applicants, this would indicate an estimated total cost of $6,000 in the first year and potentially less in subsequent years.

Benefits: Requiring applicants to certify they are operating as a nonprofit ensures they are more likely to continue to be compliant with the statutory mandate of operating as a nonprofit, which also reduces potential violations that could hurt public welfare. However, as previously stated, this nonprofit requirement is part of state statute, and this analysis does not quantify the benefits of this requirement given its root in state law.

Alternative: The Secretary of State's office ("SOS") oversees all not-for-profit filings and the corporate structure of not-for-profit corporations under the state's not-for-profit requirements. Requiring a letter of good standing, or other confirmation from SOS to confirm compliance was considered. However, jurisdiction of SOS pertains to corporate filings and internal governance structure. SOS is not charged with overseeing the additional operational requirements, including operating for the mutual benefit of patients, which are placed on compassion centers through R.I. Gen. Laws § 21-28.6-12(f).

3) Geographic Zones

R.I. Gen. Laws § 21-28.6-12(c) requires the 6 new compassion center applicants to be selected and licenses issued considering convenience to patients from areas throughout the state, as well as the need and population of the location(s) where a license(s) would be operated. Application zones will be established by DBR based on existing medical marijuana cardholder access data and cardholder population size and density. These zones will ensure that applicants are selected, and licenses issued throughout the state, providing increased access in accordance with R.I. Gen. Laws § 21-28.6-12 and program need. DBR proposes to create 6 total zones, with 1 new center licensed in each zone.

Costs: The regulation allows applicants to submit an application for a compassion center license in multiples zones provided the applicant pays the statutory application fee of

$10,000 for each application. In addition to a fiscal cost to applicants, applicants may suffer a cost from the additional constraint of not being able to locate a compassion center in their ideal location and only being able to locate within an available predefined location. For applicants who are not able to locate in their preferred zone, or whose zone boundaries do not perfectly equate to the market they would prefer to serve, there may be a potential loss of sales or unrealized profits. Any lost sales experienced by one compassion center are likely to be realized by another, resulting in a net transfer and no impact to statewide revenue. This analysis does not quantify this cost due to a paucity of data.

Benefits: It is important that the compassion centers are made available to patients statewide and not all located in a single area of the state, given that access to the compassion centers functions as a basic public good for patients in need. The provision of public goods is based on equity of access and consumption rather than profit maximization. For example, the state heavily regulates the provision of electricity and natural gas services on the principle that these services are necessities, and equity in access and consumption should be elevated over profit maximization. The compassion center zones will function similarly in order to minimize travel times for patients which will ensure patient demand is effectively met. Furthermore, the increase in geographic distribution through pre-defined zones reduces any negative impacts on patients who suffer negative health impacts and may be unable to access a local compassion center. Additionally, an applicant's chances of being selected to hold a license is increased by the ability to be apply for a license in multiple zones.

Given the paucity of data related to patient need and access, and the inherent difficulty of analyzing equity issues in monetary terms, this analysis does not quantify the equity and access benefit of the zone approach. The equity benefit of this approach most closely aligns with the requirements of the Act.

Alternative 1: <u>Allowing qualified applicants to select their own location</u>
This approach would be inconsistent with the statutory mandate to meet patient need because applicants would most likely locate in areas based on potential profit maximization rather than equity of access for patients. Literature on location decisions for profit-maximizing firms suggests that compassion centers would locate in centrally-located, population-dense areas of the state such as Providence to maximize their exposure to potential patient markets.[1] However, this would substantively decrease accessibility for patients located outside of these regions, which would fail to satisfy the statutory mandate.

Alternative 2: <u>Issue licenses one at a time</u>.
This was considered as another alternative would require DBR to conduct new analysis as to where the next license should be awarded with consideration given to the placement of

[1] See Hotelling, Harold. (1929). Stability in Competition. Economic Journal, 39(153), 41–57. (Discussion of the Hotelling model which explores profit maximization for multiple firms in a linear city model with uniform population distribution. The incentive to locate in the center of the "city" is even larger when the population density is skewed toward the center.)

the previous one(s). While the final location distribution would likely be similar to the proposed geographic zone approach, this alternative would have a larger implementation burden. This alternative was also rejected because if a license was awarded in close proximity to another applicant's location, it would force the applicant(s) to abandon their proposed location and force them to spend time and resources to find a new location on revised analysis. This could happen repeatedly to applicants as more licenses are awarded rendering each revised application null and void. Establishing predefined zones where applicants can apply to and be selected addresses these issues and provides a stable and predictable licensing process for applicants.

Alternative 3: <u>Alternative methods of creating the zones.</u>
DBR also considered alternative methods of creating the zones. One such alternate method would be to draw the zone boundaries using overall population or adult population. Because the proposed regulation draws these boundaries using data about the location of current medical marijuana patients, the zones might be skewed to current patient need as opposed to considering both current and future patients. However, given that the Medical Marijuana Program has existed for almost 15 years, current patient data represents the best picture of the demand for medical marijuana. Drawing the zones using this patient data is the methodology best aligned with the legislative mandate that compassion centers adequately serve the patient population.

4) Applicant Selection & Approval Process

As part of the selection process to determine which applicant will be able to locate in each geographic zone, a randomized drawing will occur for each geographic zone.

Costs: There are two potential costs of the random selection approach. The first, more basic cost of the randomized drawing process is the time and resources it will take in order to produce an application in each zone. There is also the potential cost of awarding a license to an applicant who is less qualified than other applicants, and who might provide less efficient and more costly services to medical marijuana patients. However, because all applicants must be first deemed qualified to enter the randomized drawing the actual variance in applicant quality among these eligible applicants will be small and all applicants will be qualified to receive a license. DBR expects the application costs to remain consistent across the approximately 30 applicants. Relative to the alternatives below, the marginal costs are at worst minimal, because all application options involve similar administrative burden. The potential risk of awarding a license to an unqualified applicant is minimal and explained above.

Benefits: The random selection methodology is the preferred selection process when the demand for a good outweighs the supply of the good. This is the case here, where there are only 6 licensees but roughly 30 potential applicants. Additionally, random selection is the preferred methodology when the quality of applicants is expected to be above the threshold of acceptability. Given that applicants must qualify to enter the randomized drawing, this method works well for the population of potential applicants. A more limited

pool of applicants that are of higher quality means there is no clear way to distinguish which applicant would be the best suited for the license. Therefore, equity across which applicant will be selected is preferable to alternatives such as a first-come, first-serve basis. Furthermore, the random selection process gives applicants the opportunity to apply in multiple zones, increasing their likelihood of being selected.

Alternative 1: <u>Utilizing a first-come, first-serve selection process.</u>
The first-come, first-serve system is less equitable across applicants, showing particular bias toward applicants with the resources, monetary, informational, or otherwise, to apply quickly (but may not be indicative of actual applicant quality). Additionally, this system carries innate biases against minority-owned businesses, veteran-owned businesses and female-owned businesses which have a historically harder time raising capital quickly under time constraints than other businesses. As a result, these businesses would have a harder time being first to complete their application in each zone, leading to an unfair selection process. In contrast, the random selection process ensures all applicants that meet the necessary requirements have a sufficient time window regardless of location or other characteristic.

Alternative 2: <u>A competitive scoring process, utilizing a rubric</u>
In this alternative, priority of awards would be determined by how applicant's score on a rubric. However, the expected variance in applicant quality among those most qualified is expected to be low. Using such a scoring rubric might have the unintended consequence of creating an arbitrary cutoff and disqualifying some applicants who could have provided services as efficiently as applicants who scored in the top 6.

5) Business Plan

Additional requirements for a compassion center's proposed business plan were determined based on information sought during renewals of existing compassion centers, best practices from other states, and information necessary to establish that the applicant is capable of operating a compassion center.

Costs: The additional requirements are estimated to require 10 hours of mid-level employee's time at an hourly rate of $40, corresponding to $400 per application and a total cost of $12,000 assuming roughly 30 applicants. For renewal, costs would be de minimis because the business plan has already been developed.

Benefits: Although this proposal would increase upfront documentation and planning efforts for applicants, these efforts would also ensure a faster start-up if a license is issued which could significantly reduce costs down the line, likely more than offsetting the initial time costs of developing the additional requirements of the business plan.

Alternative: Not requiring a business plan was considered as an alternative, but the associated risks of not requiring a business plan were high because it would be more likely that approved applicants would not have the adequate capitalization for their proposed

activities. In fact, research shows that firms that develop business plans rather than jumping straight into a business tend to grow faster than counterparts without a business plan.[2] While compassion centers will be operating not-for-profit, this research suggests that developing a business plan may generate greater long-term efficiencies in addition to ensuring the financial viability of a business at the onset. Including a business plan and implementation timeline also provides insight into an applicant's ability to satisfy the timeline required to conduct licensed activities.

6) Security and Safety Plan

The proposed amendments clarify existing application requirements for security and safety plans which are currently required in relation to information about an applicant's proposed physical location.

Costs: Preparing a more detailed security and safety plan for the application is estimated to take 5 hours of a senior employee's time with an estimated hourly rate of $75 for a total cost of $375 per application and $11,250 across all applicants. For renewal, costs will be de minimis. A senior-level employee is required here because some or all of this information would be restricted and could only be accessed by employees authorized by management in accordance with § 1.6.5(F).

Benefits: A standard and more complete security and safety plan will benefit the compassion center be reducing security risk and would also benefit the health and safety of the public by ensuring that medical marijuana products located in a compassion center are protected from robberies which would result in diversion to illicit markets. Additionally, these efforts would also ensure a faster start-up if a license is issued which could significantly reduce costs down the line, likely more than offsetting the initial time costs of developing the additional requirements of the security and safety plan.

A 2011 study calculated the per unit cost of crime, looking at both the tangible costs (cost of illness) and intangible (pain and suffering). The study concluded that the unit crime cost of a theft is $3,532, while the cost of a robbery (theft with a person present) is $42,310.[3] This analysis does not predict and quantify a change in the incidence of compassion center thefts, but this study does suggest that if only one or two thefts were prevented, the benefits of the security and safety plan would outweigh the costs.

The more relevant benefit is a reduction in potential medical marijuana diversion to the illicit market. There is a paucity of data about diversion from Rhode Island's medical marijuana market. However, given the security protocols already in place at the state's 3

[2] See Brinckmann, J., Grichnik, D., & Kapsa, D. (2010). Should entrepreneurs plan or just storm the castle? A meta-analysis on contextual factors impacting the business planning–performance relationship in small firms. *Journal of Business Venturing, 25(1)*, 24-40.

[3] McCollister, K. E., French, M. T., & Fang, H. (2010). The cost of crime to society: new crime-specific estimates for policy and program evaluation. *Drug and alcohol dependence*, *108*(1-2), 98–109., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2835847/

compassion centers, there is likely little diversion from the Rhode Island retail medical marijuana market. As a result of the tripling in the number of compassion centers that will shortly occur, the risk of diversion increases as the amount of retail medical marijuana increases. This regulatory requirement for a security and safety plan will help forestall any potential diversion, although the paucity of data means this benefit is difficult to quantify.

Alternative: No additional application requirements for this item were considered as an alternative. However, the risks of burglary, theft and fire in this industry are high given the presence of high value, otherwise-illegal products and flammable materials for manufacturing processes. Therefore, it is in the best interests of the applicants to develop feasible and sufficient security and safety plans during the application process so DBR can review and ensure that are adequate for the concerns of this industry. Existing licensees have had attempted break-ins which support an earlier review of these procedures by DBR to ensure compliance and appropriate deterrent. This also benefits the community at large and any neighboring property owners resulting theft deterrent and increased safety.

7) Operations Manual

The current regulation requires licensees to maintain operations manuals for a variety of policies and procedures ensuring both public safety, production requirements, and workplace safety and management. The proposed amendments add the production of an operations manual to the application requirements and specifies what the manual should contain, such as: records retention, employee training, job descriptions, patient confidentiality, and procedures for recalls, etc.

Costs: Creating an operations manual to meet the standards set forth in the proposal is estimated to take 8 hours of a mid-level employee's time at an hourly rate of $40 for a total cost per application or renewal of $240. The total cost across all 30 applicants would be $7,200. For renewal, costs would be de minimis because the operations manual has already been developed.

Benefits: This will streamline employee training and will also help applicants and DBR track and approve changes to standard operating practices. Additionally, these efforts would also ensure a faster start-up if a license is issued which could significantly reduce costs down the line, likely more than offsetting the initial time costs of developing the additional requirements for operation of a compassion center.

Alternative: Not requiring an operations manual as part of the application was considered as an alternative, even though the creation and maintenance of such manual is an existing requirement for operations of both compassion centers and cultivators. However, earlier review during the application process enables DBR to better ascertain an applicant's ability to successfully startup and operate a compassion center in accordance with state law. Given the complexity and diversity of the information required to be maintained in the operations manual it is in best interest of applicants to develop these manuals earlier in the process, at the time of application. Waiting until a later time would result in extending the length of

time between issuance of license and commencing operations and retail sales.

8) Organizational Chart

This proposal clarifies the requirements for disclosure of all owners, key persons, and persons with managerial or operational control including requiring the submission of an organizational chart as part of the application.

Costs: It is estimated that it will take one hour of employee time per application or renewal to prepare and update the organizational chart. At an hourly rate of $40 for a mid-level employee's time, the cost per applicant would be $40 and the total cost across all applicants would be $1,200.

Benefits: The submission of an organizational chart would improve understanding of the ownership information provided in the application as well as ensure transparent operation of these nonprofit businesses. Furthermore, these updates were required to ensure compliance with new statutory language for divestiture and prohibited relationships.

Alternative: Given that these are complex organizations due to tax law, federal prohibitions, and nonprofit requirements, there is no clear alternative to requiring the submission of an organizational chart in the application. If we do not require the organizational chart, which is current practice and would not result in any additional costs or benefits, it is likely that an entity may receive a license which we later discover was not qualified. That would result in DBR initiating an enforcement action or other remedial actions at a greater cost of time and resources than would have otherwise been necessary.

II. Compassion Centers and Cultivators

A. Packaging and Labeling Requirements for Retail-Ready Medical Marijuana Products

The existing regulation contains provisions for packaging and labelling for compassion centers and cultivators. The proposed Section 1.5 consolidates existing content and incorporates best practices from other states to further the interests of public health, safety and welfare, and compliance with federal guidance, including the Cole Memo and FinCEN guidance.[4]

While these costs will impact all 9 compassion centers, the impact on cultivators is limited because not all cultivators produce all available products or are involved in packaging for retail-sales, which occur at compassion centers only. Therefore, cultivator costs for these changes will be calculated as an aggregate impact on 25% of the 50 licensed cultivators, which is 12.5. Most total impacts in this section will be based on a multiplier of 21.5 licensees (9 compassion centers + 12.5 cultivators) unless otherwise noted.

[4] Memorandum from James M. Cole, Deputy Attorney General, U.S. Department of Justice, for all U.S. Attorneys (Aug. 29, 2013), https://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf); FinCEN ("Financial Crimes Enforcement Network"), https://www.fincen.gov/.

1) Grace Period

The proposed regulation provides a 90-day grace period from the effective date of the regulation for compassion centers and cultivators to comply with the proposed packaging and labeling requirements.

Costs: Although existing licensees will have to purchase new compliant packaging, the regulation provides for a 90-day grace period from the effective date of the regulation which should provide sufficient changeover time and help minimize associated costs. Furthermore, given that existing inventory must be limited to patient need, it is unlikely that any existing licensee would have more than 90 days of inventory on hand, thereby limiting potential losses.

Benefits: The 90-day grace period provides a sufficient window for existing compassion centers and cultivators to change over their processes, limiting potential compliance risks that would occur under a shorter time frame. The 90-day timeframe will also keep impacted entities accountable to a reasonable timeline without given an unnecessary and inefficient excess of time to make the required changes.

Alternative 1: A shorter grace period of 30 days was considered as an alternative but given that changing production processes can take a variable amount of time depending on the producer, a shorter grace period may unfairly punish certain producers depending on their production techniques. The benefits of a short grace period would mean potentially greater compliance sooner compared to a longer grace period, but it is unlikely that compliance would be realized since it is unfeasible for firms to change over their production processes within a month given that these processes can be complex and multi-layered.

Alternative 2: A longer grace of 180 days was also considered as an alternative. While a longer grace period gives compassion centers and cultivators more time to become compliant, which reduces potential compliance costs for these entities, a longer grace period also creates incentives for these entities to delay changing their production processes for longer until they are closer to the end of the grace period. These unintended consequences make it possible that compliance will not be greater with a 180-day grace window, but there will be significant time costs resulting from several more months of the new packaging and labeling requirements not being in place as entities wait to make the bulk of the necessary changes. This would reduce the potential benefits from each of the proposed changes in the first year.

2) Child-Resistant Packaging

Currently, all packaging must be child resistant, but this proposal clarifies that packages must meet the federal child resistant standards.

Costs: Existing licensees will likely not need to purchase new compliant packaging as this standard is already in use throughout the majority of regulated jurisdictions, and compliant

packaging SKUs are already widely available and utilized. As such, licensees will not need to pay for the certification of new packages. There is also a phase in period to ensure package certification which will allow licensees to sell through current stock.

For those that will need to purchase new compliant packaging, the baseline cost of current packaging is approximately $0.38 per unit while packaging compliant with federal child-resistant standards costs approximately $0.70 per unit. This is a marginal increase of $0.32 per unit. Given that each licensee may purchase approximately 10,000 units per year, a cost increase of $0.32 per unit would total $3,200 per year per licensee. For all impacted licensees, the total cost would be $68,800 per year.

Benefits: Imposing these packaging requirements will benefit the public at large by preventing accidental consumption and overdose by minors. A study published in August 2019 on the "Incidence of Pediatric Cannabis Exposure Among Children and Teenagers Aged 0 to 19 years Before and After Medical Marijuana Legalization in Massachusetts" concluded that states should consider strengthening regulations to prevent unintentional exposure to young children, with particular attention to edible cannabis products and concentrated extracts.[5]

While it would be impossible to determine the positive health benefits of each proposed change ranging from packaging and labeling updates to advertising, the health benefits to children can be estimated given a reduction in the number of unintentional child-related medicine poisonings. According to Safe Kids Worldwide, there were 52,000 children aged 6 and under that were treated and released from U.S. emergency rooms for medication poisoning in 2017[6]. This represented a 32% declined from the 76,000 cases in 2010. At the same time, according to a Children's Safety Network 2016 resource guide, the average cost for treatment of children in emergency rooms was approximately $3,055 which is more than twice the average cost of an emergency room visit, which was $1,389 in 2017.[7] The cost is presumably higher given the sensitive and difficult nature of diagnosing and treating children. Assuming that Rhode Island's share of these medicine poisonings is consistent with Rhode Island's share of the total U.S. population and total U.S. GDP, estimated at 0.3%, the total number of Rhode Island medicine poisonings for children aged 6 and under would be 156 each year. Assuming that between 1% and 5% are related to medical marijuana exposure, the total number of cases would be between 2 and 8 each year. Assuming a reduction similar to the historic 32% reduction experienced previously indicates that additional packaging and labeling requirements would reduce the number of emergency room cases by between roughly 0.5 and 2.5 cases each year. Given the average cost of child treatment in an emergency room, this would generate benefits between $1,528 and $3,820 each year.

---

[5] Whitehill, J.M., Harrington, C., Lang, C.J., Chary, M., Bhutta, W.A., & Burns, MM. (2019). Incidence of Pediatric Cannabis Exposure Among Children and Teenagers Aged 0 to 19 Years Before and After Medical Marijuana Legalization in Massachusetts. JAMA Network Open.

[6] https://www.cnn.com/2019/03/14/health/medicine-poisonings-in-children-report/index.html

[7] https://www.childrenssafetynetwork.org/sites/childrenssafetynetwork.org/files/MedicinePoisoning.pdf, https://www.debt.org/medical/emergency-room-urgent-care-costs/

Alternative: <u>Allowing compassion centers the discretion to determine product packaging.</u> This alternative would likely result in inconsistent and unsafe packaging. The lack of a standard encourages a "race-to-the-bottom" approach to safety resulting from firms' competitive incentives. Given the substantial benefits of the proposed standards, this alternative was determined to not be in the best interest of the state. The nominal costs savings to licensees for not having to purchase child resistant packaging is outweighed by the overwhelming public benefit.

3) Maximum THC

The proposal sets a maximum of 10 milligrams (mgs) per serving of active THC in edible products and also sets a maximum amount of THC per package depending on the medical marijuana product form (i.e. edibles, ingestibles, liquids, or cartridges).

Costs: Existing licensees should be able to modify manufacturing techniques to comply with maximum serving dosages during the 90-day grace period, avoiding any non-compliance costs. Therefore, total costs for licensees will be borne during the initial period of modifying manufacturing procedures and recipes to comply with the maximum THC requirements. Given that many licensees already produce compliant products, they should not have to substantively deviate from existing practices which should temper upfront costs. While the THC amount per serving and per package will now be limited, the total allowable purchase limit is unchanged, so patients may still purchase the same amount of medical marijuana as before which suggests the limit should not impose any costs through this avenue. Additionally, there may be some financial costs to patients associated with buying more product separately which tends to mean higher per unit costs, but these impacts should also be marginal given that compassion centers do not typically engage in these volume-based discount pricing strategies which are more common in markets with many competitors. The biggest cost to consumers will likely be the production changeover costs borne by manufacturers which are subsequently passed on to consumers through higher prices.

Benefits: This new requirement is based on best practices in other states and will help avoid accidental overdose and ensure a minor or child's exposure to THC is limited should they gain access to a medical marijuana product. The imposed limits reflect a balance of the interests of patients being able to find relief from edible medical marijuana products (which are the most attractive to children) while still being low enough to be unlikely to cause lasting damage if accidentally or unknowingly ingested by a naïve user.[8] All states with regulated legal cannabis have some THC limit for manufactured products. States such as Oregon and Massachusetts have a limit of 5 mg of THC per serving, but those are adult use markets. Given that our program is limited to medical use, we have set a higher maximum of 10 mg of THC per serving because some patients may require increased doses.

[8] "Preventing Unintentional Ingestion of Marijuana by Children: A Health Impact Assessment of Packaging Regulations in Retail Marijuana Establishments in Colorado," August 2013. http://www.ucdenver.edu/academics/colleges/PublicHealth/research/ResearchProjects/piper/projects/Documents/HIA%20Final%20Report%208.20.2013.pdf

The imposition of maximum THC amounts and other labeling requirements will primarily benefit the end consumers of medical marijuana which are adult patients aged 18 and over. It is estimated that children aged 6 and younger comprise nearly half (45.2%) of poison exposures compared to 39.5% for adults.[9] As such, we can scale the number of child medicine poisonings by the ratio of adult to child incidence to get an estimate of the number of adult medicine poisonings each, which is approximately 45,422. Using a similar approach as above for child-resistant packaging, based on Rhode Island's share of medicine poisonings generates total adult Rhode Island cases of roughly 136 each year. Assuming a similar reduction in these cases as before and that marijuana constitutes between 1% and 5% of the cases suggests a total case reduction between approximately 0.5 and 2.5 each year, similarly to the number of child cases reduced. Using the average cost of an emergency room visit, which is likely to be more accurate for adults than children, indicates a recurring benefit between $695 and $3,473.

Alternative: DBR considered implementing a maximum THC per serving of 5 mg. Systematic reviews have demonstrated that users can develop tolerance to cannabis.[10] Many medical marijuana patients are frequent users who require larger doses or higher concentrations of marijuana to achieve the same effects as less frequent users. Additionally, there is a lack of data about the costs and benefits of a 5 mg threshold, which is more commonly seen in adult use markets. Given these facts, DBR chose to adopt the 10 mg serving size.

4) Labeling

The proposal includes additional labeling requirements to ensure patient education and consumer safety. Existing and new licensees will be required to develop more comprehensive labels in accordance with the proposal and apply such labels to future products.

Costs: The proposal modifies label content but does not impact existing processes for printing and adhering labels to packaging. As such, these labeling upgrades should be easily accomplished during the 90-day transition period at minimal costs to licensees while they sell through their existing stock of labeled products. All told, it is estimated that there will be an initial one-time cost for employees of 6 hours to develop the updated labels and templates. At an hourly rate of $20 for administrative-level employee, the total cost per license would be $120 and the total cost across all impacted licensees would be $2,580.

Benefits: The proposal, which is consistent with nationwide best practices, will ensure greater patient education and consumer safety, mitigating potential losses from uninformed consumer decision-making. The improved labeling requirements also provide additional transparency in pesticide use, solvent manufacturing, allergens, and other factors which are of special concern to patients, particularly those with severe and chronic medical

[9] https://www.poison.org/poison-statistics-national

[10] Colizzi, Marco & Bhattacharyya, Sagnik. (2018). Cannabis use and the develop of tolerance: a systematic review of human evidence. *Neuroscience & Biobehavioral Reviews, 93(10),* 1-25.

conditions.[11] The benefit of improved health outcomes for these individuals is especially large given their more serious health concerns and is driven by greater transparency. However, given that the health benefits are significant but the pool of people that will benefit the most from the revised labeling provisions are small, it is statistically too difficult to determine the total benefit to this cohort.

Alternative: DBR considered an alternative labeling structure which would not require producers to list intermediate production elements, most notably things like pesticides and solvents. The majority of the labeling requirements in the proposed regulation, which require notification of total THC/CBD, serving size, and ingredients and allergens, are typically required of food and medicine in general. This information is generally accepted as essential for consumers of these products. DBR then considered if asymmetrical information existed between producers and consumers regarding these other elements of production, and the value of mitigating that asymmetry with additional labeling requirements. Given the severity of the medical conditions that afflict many medical marijuana patients, and the unknown harms that might exist from these pesticides and solvents for this patient population, DBR determined that the benefits of correcting this information asymmetry through more stringent labeling outweighed any costs of unintended consequences.

5) Imprinting of the Universal Symbol

The proposal would require all manufacturers to imprint a universal symbol on each single standardized serving unit where practicable including, but not limited to, chocolate, soft confections, lozenges, hard confections, baked goods, pills, and capsules.

Costs: In order to implement this requirement, licensees must purchase edible ink printers, stamps, or new molds that contain the universal symbol established by DBR. Purchasing the molds imposes a one-time cost per edible type of approximately $70 per set of molds per product (i.e. hard candy, gummy, brownie, etc.) per licensee. Alternatively, depending on which method is more cost-effective, licensees may purchase an edible ink printer for $200 and edible ink for $15 per cartridge. On average, it is estimated that there would be roughly $500 in upfront expenditures to develop the necessary printing infrastructure. The total cost across all impacted licensees would be $10,750. Additionally, there would be recurring costs in subsequent years in the form of new and replacement molds or ink costs depending on the method. The recurring costs would total roughly $300 per licensee or $6,450 total each year.

Benefits: The proposal is a best practice to identify marijuana products and avoid accidental consumption if any serving unit is removed from its original packaging. The benefits of reduced accidental consumption would be captured in the benefit estimates from reduced emergency room visits for children and adults estimated previously. In addition to the health benefits of reducing accidental consumption, the requirement is also helpful to

[11] Orenstein, Daniel & Glantz, Stanton. (2018). Regulating Cannabis Manufacturing: Applying Public Health Best Practices from Tobacco Control, *Journal of Psychoactive Drugs*, *50(1)*, 19-32.

medical professionals when attempting to identify the type of product ingested by a patient which can reduce diagnostic costs and expedite patient recovery.

Alternative: There is no other alternative that makes a medical marijuana product identifiable after it is removed from its packaging. This is particularly important because most accidental consumption or overdoses occur when the product is removed from its packaging and the consumer does not know what they are ingesting. Any benefits realized from the reduction in accidental ingestion would be lessened under a proposal that does not include the universal symbol. Given the paucity of data about how much the packaging requirements would contribute to this reduction versus how much the universal symbol requirement would contribute, and considering the relatively low cost of implementation, DBR chose to adopt the universal symbol requirement.

6) Product Design Limitations and Prohibitions

Under the proposal, existing licensees will have to ensure that: (1) Products are not in the shape of a human, animal, fruit, cartoon characters, or any shape attractive to children; (2) Products do not imitate existing branded consumer products and marketed foods that do not contain marijuana; and (3) Products are not in the shape of a marijuana plant or leaf.

Costs: Any initial hourly costs to modify manufacturing procedures and recipes to comply with product design requirements will only be incurred in the first 90 days during the grace period. Most licensees already product compliant products, so they should not have to deviate substantively from existing practices. In addition, any molds of prohibited shapes or forms currently in use will have to be replaced to comply with the universal symbol requirement. As such, these requirements should not place any additional burden on licensees beyond those already accounted for in the universal symbol section.

There is a theoretical cost to compassion centers if consumers prefer these product designs and choose to purchase elsewhere. However, given that these limitations apply to all compassion centers, medical marijuana patients will have no in-state alternative. There might be some shift of sales to the Massachusetts adult use market; however, the lower tax rate in Rhode Island (11% compared to 20%) and convenience of Rhode Island compassion centers would indicate that any such shift would be de minimis. Finally, it can be presumed that medical marijuana patients are ultimately driven by the medicinal benefit rather than the product design, which also suggests that any shift in consumption would be small.

Benefits: These requirements will promote public safety by avoiding accidental ingestion by children or non-patients. Additionally, they also benefit licensees by ensuring they are not the subject of legal actions for intellectual property infringements for the imitation of existing trademarked or branded consumer products. The benefits to improved child safety would be included in the topline estimate provided earlier.

Alternative: Solely relying on packaging to obscure the product from the consumer, children or non-patients was considered as an alternative. However, this was rejected because the

proposed restrictions significantly reduce likelihood of attractiveness to children and accidental consumption by non-patients. The failure to regulate product forms would allow any and all product forms in the program, whether or not they have not been vetted by regulators or medical experts.

B. Product Designation

§ 1.7 establishes procedures for the designation of medical marijuana in accordance with the statutory requirement. In particular, if a product is not on DBR's pre-approved designation list of products, then the licensee will have to apply to DBR for the product to be designated as medical marijuana.

Costs: This mechanism is primarily to ensure that all products sold in compassion centers are designated as medical marijuana. Most flower products and concentrates with flavoring solely from cannabis will be on the pre-approved list. Additionally, edibles that are not appealing to children and contain the universal imprint will also likely be on the pre-approved list. Some products may have to be redesigned and submitted for approval, but this would be a one-time application per product type not on the pre-approved list.
As such, this provision should not impact the majority of products currently offered for sale by licenses, so the estimated costs to licensees should be minimal.

As discussed in the "Product Design Limitations and Prohibitions" section, there is arguably a cost that could be borne by producers if consumers shift their consumption given any mandated changes in product types and designs. But given the market dynamics in the medical marijuana market, combined with the expected lack of major changes in product types and designs, any such shift is expected to be minor.

Benefits: The purpose of product designation is to ensure that the products offered for retail sale are meant to be used as medicine and do not pose a risk to public safety or health. This protects patients from accidental consumption of products which may not only prove ineffective but also be detrimental to the wellbeing of the patient. The proposal ensures patients can reliably access the medicinal products that have been prescribed to them and not accidentally receive products that are not designated as medical marijuana. Therefore, the primary benefit of the provision is increased public safety and health outcomes.

Alternative: DBR considered allowing all products to be designated as medical marijuana unless otherwise revoked. However, this would mean that potentially dangerous products would be sold to patients and would have to be recalled after the harm to the public has already occurred. Failing to create a process by which medical marijuana products are designated as such would be contrary to the statute. The designation protects public health and safety. Furthermore, there are additional risks when ingesting medical marijuana through vaping or snorting, meter dosage through nasal cavity, or other devices which promote rapid consumption. Without a mechanism to vet and approve existing and future products and product forms, there is no oversight to ensure the safety of newly created products.

C. Advertising

§ 1.10 includes new advertising provisions which will only allow advertising which is not attractive to children and which is only targeted towards qualified patients and those who can legally possess and/or use medical marijuana.

Costs: Limiting advertising to people aged 21 and older and who are also patients will require licensee's websites to include the addition of an age/patient verification feature. This represents a one-time cost of between $100 to $300 per compassion center licensee for a total cost across licensees of between $900 to $2,700. Otherwise, the proposal is largely in line with current advertising practices and should not result in significant changes to licensed operations.

Benefits: The proposal is consistent with the medical marijuana program by only allowing advertising to relevant individuals, and furthers the interest of public health, safety, and welfare. It is well established that cigarette advertising was effective in promoting smoking habits and tobacco use among adolescents, with estimates suggesting that cigarette advertising increased the odds of teenagers moving from never smoking or using tobacco to experimental smoking and tobacco use by approximately 80%.[12] Assuming marijuana advertising is also effective, there is also a lower likelihood that children will be advertised to and more likely become adult marijuana users as well. As such, in addition to the benefits of fewer marijuana-related child incidents due to more focused advertising, there will be potentially fewer marijuana-related adult cases in the future too.

Alternative: Alternative advertising restrictions, such as the 70/30 rule applicable to tobacco products, were also considered. The 70/30 rule maintains that the text, typically warning text, on a package, billboard, or other advertising medium should take up 70% of the available space while the actual advertising would only take up the remaining 30% of space. This would ensure that the volume of warning text would exceed the actual advertising in physical terms, mitigating the effectiveness of the advertisement. While this would be more sensible for an adult use market because there may be public health implications of advertising increasing consumption, the Rhode Island medical marijuana market exists for the benefit of patients who need these products for their wellbeing. As such, advertising does not serve the purpose of bringing in new demand, but rather in shifting demand between providers of medical marijuana based on patient preference. Thus, the 70/30 rule would be an impractical standard for setting advertising limitations on the industry. Instead, given that medical marijuana is a federally illegal product only available for medical use to a limited number of citizens under state law, the proposal restricts the audience to patients only because the focus of advertising should be on the patients rather than the rest of the public.

[12] Shadel, W.G. & Tharp-Taylor, S. (2009). How Does Exposure to Cigarette Advertising Contribute to Smoking in Adolescents? The Role of the Developing Self-Concept and Identification with Advertised Models. *Addict Behavior*, *34(11)*, 932-937.

D. Quarantined Marijuana Products, Retests, Remediation and Recalls

1) Operations Manual Documentation

§ 1.6.6(B)(3) adds a requirement for establishing and maintaining policies and procedures to ensure that any voluntary or mandatory recalls of marijuana occur safely and efficiently.

Costs: The costs associated with this proposal relate to approximately two hours of a mid-level employee's time needed to develop new policies and procedures. At an hourly rate of $40, the total cost per licensee would be $80 initially as part of operations manual development and maintenance. A total for all licensees would be $4,720. Ongoing costs are de minimis.

Benefits: Licensees will be able to quickly respond to any public health or public safety concerns related to any dangerous products. This lowers the risk to the public and may limit a licensee's liability for negative consequences of selling dangerous or contaminated products.

Alternative: The failure to include these policies and procedures in the operations manual would result in an incomplete manual and the potential for inadequate training of employees to comply with the new provisions in § 1.11 for quarantine, remediation and recalls.

2) Quarantine, Remediation, Recalls and Destruction of Failed/Dangerous Products

§ 1.11 sets forth procedures for segregating and properly labeling products that will be tested under DOH's testing regulations and any product that may fail applicable tests for quality assurance and safety, including destruction of products deemed dangerous to public health and safety. Quarantine or recall defective or dangerous products is not provided for under the current regulation.

Costs: It is estimated that it will cost 3 hours of employee time to implement the costs. At an hourly rate of $20 for an administrative-level employee, the cost per licensee would be $60 and the total cost across all licensees (9 compassion centers and 50 cultivators) would be $3,540. Changes are limited to more specific labeling requirements and organization of inventory which should limit the potential cost. Furthermore, once the new practices are implemented, there will be no additional costs in time and effort, and the proposal would not require any additional equipment either.

However, along with the initial time costs, there is a direct cost to producers in the event that a recall or quarantine is issued at some point equivalent to the value of the lost inventory. Given that it is not possible to predict the frequency or size of a potential recall or quarantine in the marijuana industry, it is also not possible to explicitly estimate the costs to producers of a recall or quarantine in terms of lost product. That being said, compassion centers sold approximately $54 million in medical marijuana in fiscal year 2019. While sales

are not a direct measure of the cost of production given intermediate transportation and warehousing costs, between a 5% to 10% quarantine rate on the total sales volume would correspond to a total cost between $2.7M and $5.4M each year on the high end. Given the paucity of data concerning national medical marijuana quarantines, this analysis does not quantify the cost of quarantines and recalls, but merely provides these numbers as context.

Benefits: This proposal, which reflects best practices in the industry, will reduce risk around quarantine and recall processes by ensuring licensees have a standard process in place that can be followed as necessary. Quarantine reduces the risk of contaminating additional products and ensures that unsafe products are not released to patients, which is population at higher risk of suffering adverse health effects. Depending on the dangerousness of the product being quarantined or recalled, the potential benefits could be measured in lives saved. For instance, even saving a single life through a quarantine of defective or dangerous product would be worth $9.1 Million according to the Rhode Island Office of Management and Budget guidance on the value of a statistical life. In this case, the benefits of the quarantine would be nearly double the potential cost to producers of lost product. Again, given the unpredictability of quarantine/recall events, this analysis only provides these estimates for context rather than a formal quantification of benefits.

Alternative 1: DBR considered not allowing remediation of products which failed testing as an alternative. However, products which failed testing for mold, mildew or microbial contamination can be remediated under certain procedures. Allowing remediation through these procedures creates stability for the licensees and a greater supply of products for patients. Thus, the benefits of remediation in terms of market supply would significantly outweigh the potential cost of remediation.

Alternative 2: DBR also considered not requiring quarantine of products until after the state has confirmed that they failed to pass testing standards. However, this could mean that products could enter the supply chain which are later determined to be dangerous resulting in potential public harm and recalls. This would also result in greater expense to business when product is required to be recalled and destroyed because it would be further removed from the production source.

E. Authorized Transportation Vehicles

§ 1.6.8(A) clarifies existing requirements for the use of authorized transportation vehicles. The proposal adds the requirement that all authorized transport vehicles be equipped with an alarm system.

Costs: Most modern vehicles are sold with original equipment manufactured alarm systems. However, for any vehicles without an alarm can be adapted at a cost of approximately $500 per vehicle.

Benefits: This small expense, only if not already equipped, is outweighed by the great deterrent effect of an alarm against theft of a vehicle or its contents. In addition, these

vehicles are carrying medical marijuana products which are important to patient's health and welfare. Also, the existence of an alarm in a vehicle may reduce overall auto insurance rates.

Alternative: DBR considered not requiring vehicles with alarm systems as an alternative. However, the predominance of such alarms in most modern vehicles and the minimal cost to add one if necessary, greatly outweigh the risks of theft given the high value of the marijuana products being transported and likelihood of diversion to illicit markets.

F. Inventory Control

§ 1.6.4 establishes that compassion centers and cultivators cannot expand production without permission from DBR. This includes any compassion center licensed after July 1, 2019, which will be required to apply to DBR to engage in cultivation. Any newly licensed compassion center which formerly operated as a cultivator will be allowed to continue their current cultivation, but no new cultivation will be allowed before the completion of a market study.

R.I. Gen. Laws § 21-28.6-12(i)(1) states that compassion center inventory of medical marijuana must be in in line with projected patient need. These regulatory provisions are a logical outgrowth of this statutory requirement, and any costs and benefits related to these regulatory provisions are the result of the Act.

III. Caregivers

A. Registry Identification Cards – Transfer from DOH to DBR

Section 1.4 consolidates registry identification card provisions and also includes additional provisions to ensure compliance with caregiver specific provisions of the Act. This is consistent with the transfer of the issuance of registry identification cards for caregivers from DOH to DBR.

Transfer: Under this proposal, the fee for a caregiver registry identification card remains at $100 which is the same as the fee currently in place at DOH. This results in no change in costs or benefits. Additionally, the $25 fee charged by DOH for all caregivers who qualify for a reduced registration because of financial hardship for them or their patient would be eliminated. This results in a savings of $25 per year for caregivers that qualify for reduced registration but is offset by a reduction in revenue collected by the State of Rhode Island. As such, the fee change imposes a fiscal impact but represents a transfer and, therefore, has no impact on costs and benefits.

B. Cardholder Limitations – Patient No Longer Using Services of Caregiver

§ 1.4(B)(4)(D) of the proposed amendments states that DBR may deny a caregiver registry identification card application if the caregiver's designating patient has elected to grow

medical marijuana for themselves and/or has obtained a plant tag certificate under their own patient registration. Caregivers who are not also qualified as a patient themselves are not eligible for a registry identification card if they are not growing for a designated qualifying patient.

Costs: This requirement does not add any additional costs to the caregiver. Caregivers are only allowed to obtain a reimbursement for costs of goods produced, profit is not allowed. As the caregiver will no longer be able to grow marijuana, they must destroy any inventory not transferred to their patient which is already necessary for compliance with state law.

There is a potential cost to patients who currently grow and also have a caregiver, because those patients would no longer have a backup supplier of marijuana if their own grow failed. However, given that the retail marijuana market is going to triple in size in the near future, any patients whose grow fails will be able to transition to a competitive and convenient retail marketplace. Patients in this situation would see somewhat higher costs to due taxes and compassion center overhead (with a lower bound price increase of 11%, which is the overall tax rate). Given the paucity of data and inherent unpredictability of patients whose might find themselves shifted to the retail market given this regulatory proposal, DBR is unable to quantify the costs that might accrue to patients.

Benefits: Caregivers will no longer incur the costs resulting from growing marijuana for a patient or the annual $100 registry identification card fee. Patients who are already growing marijuana for themselves will no longer pay a caregiver for the expensive overhead of maintaining a second backup grow which may not end up being utilized by the patient, the marijuana produced from which may be diverted to the illicit market. They will have expanded period access to regulated medicine, as needed, through new compassion centers.

Alternative: Allowing patients who grow for themselves to also appoint a caregiver to grow for them was considered as an alternative. However, this redundancy further contributes to the supply of unregulated, home-grown marijuana which is not subject to the product safety and consumer protection mechanisms of medical marijuana which will now be more available through expanded compassion centers and home delivery programs. Unregulated home grows produce products that do not have proper warnings, or child resistant mechanisms and contribute to the illicit market. They are also the cause of dozens of fires across the state each year and produce nuisance odors to neighbors and community members. This alternative was also abandoned for the sake of public health and safety as home grows are also often the target of break-ins and other crimes. DBR also considered allowing patients who grow for themselves to appoint caregivers only after applying for permission with DBR. However, given the convenience and competition of the retail market (including authorized purchasers and home delivery), and the potential downsides of redundant marijuana production as described above, DBR did not find sufficient policy rationale to adopt this alternative.

C. Manufacturing Processes

§ 1.9 incorporates and clarifies existing provisions in the DOH regulations along with updated statutory requirements for caregivers. Under § 1.9.2(D), in addition to the existing prohibition on using solvent extraction processing for manufacturing that includes the use of a compressed, flammable gas solvent, caregivers must now seek approval from DBR for any other manufacturing method and must all receive approval from the Fire Marshall or local fire department for the use of any flammable/combustible material or heat source.

Costs: The approval requirement pertains only to caregivers who propose to engage in extraction activities, however, the majority of caregivers are not using these techniques. Accordingly, the associated costs of switching over to approved techniques and complying with the new requirement should be de minimis. Because the regulation itself does not prohibit any particular technique, caregivers will still able to be apply for permission if they believe a particular method is best suited to their patients.

Benefits: This requirement ensures the public health, safety and welfare of the caregiver and any neighboring members of the public due to the risks of using such products and processes outside of a regulated commercial setting. The use of flammable solvents and heat sources in unlicensed medical marijuana manufacturing has led to fires, explosions, and deaths in the past, and these dangerous forms of manufacturing would pose a persistent health risk. As such, the new regulation is proposed for the benefit of public health and safety and to ensure compliance with applicable building and fire codes. According to the U.S. Fire Administration, the loss from an average fire is around $10,000.[13] While this analysis does not quantify the potential benefit of prevented fires, this figure provides context for the scale of benefits that might be realized from this regulatory provision.

Alternative: There are no alternatives to proposal that would improve public health and safety as well as ensure compliance with building and fire codes.

IV. Caregivers & Cooperative Cultivations

A. Recordkeeping and Documentation of Reimbursements from Patients

§ 1.9.3 clarifies the updated and expanded statutory limitations on the costs and expenses for which a caregiver may receive reimbursement from their designating patient(s). The proposal also clarifies the documentation requirements for any such reimbursement. § 1.8(P) also establishes the same documentation requirements for licensed cooperative cultivations, whose members are either caregivers or patients.

Costs: The costs of complying with the updated provisions are estimated to be one hour of caregiver time per month valued at an hourly rate of $20 for a total cost per caregiver of

[13] https://www.usfa.fema.gov/data/statistics/#tab-1

$240 each year. The total cost among all 900 caregivers and 2 co-ops would be $216,480 in the first year. Between 2016 and 2019, the state saw a 75% drop in the number of caregivers (3,600 to 900). This analysis assumes that this structural trend continues and uses a conservative assumption of a 20% drop in the number of caregivers per year. Because caregivers are choosing to not renew their registrations, the same unit costs are spread over less caregivers, resulting in lower overall costs in subsequent years.

Benefits: These requirements ensure that the caregiver can demonstrate that they are operating within the requirements of the Act which provides protection for the cultivation and possession on an otherwise illegal substance. At the same time, these requirements also deter illicit market activity by tracking all transfers of product from caregiver to patient.

Alternative: DBR considered lesser documentation requirements, including requiring document retention for a period of 6 months instead of 1 year. However, because caregivers renew their registrations on a 1-year cycle, at least 1 year of documentation is needed to allow DBR to evaluate the compliance of that caregiver with the provision of the Act and the regulations.

V. Caregivers and Patients

A. Medical Marijuana Plant Tag Certificate Program

1) Summary

There are minimal changes to the plant tag certificate program in § 1.12 resulting in de minimis economic impacts upon patients and caregivers who elect to grow at home. In general, the proposed amendments streamlined and updated provisions to conform to the FY 2020 statutory amendments which clarify that DBR will issue a single certificate to each qualifying patient or registered primary caregiver whereas, previously, individual tags were issued for each plant set. The cost of the plant tag certificate remains at $25 per plant set up to the applicable possession limit. Additionally, the fee waivers for reduced registration patients and their caregivers remain unchanged.

2) Patients/Caregivers – Grow Location – Ownership or Permission

§ 1.12(C) requires patients and caregivers when applying for medical marijuana plant tag certificates to provide either: (1) proof of ownership of the premises where they will grow marijuana; or (2) documentation that shows they have permission from their landlord on the premises.

Costs: If the patient/caregiver does not own the premises where they will be growing marijuana, they will need to obtain written permission from their landlord to grow marijuana on the premises. This permission can be in the form of a letter or other approved correspondence from the landlord that is provided to DBR with the plant tag certificate application. These costs are de minimis.

There may be a subset of patient or caregivers who given these new documentation requirements are now unable to grow marijuana at their current premises. DBR is unable to estimate the size of this group due to a paucity of data.

Benefits: Given that the Act gives landlords discretion not to lease or continue to lease to a cardholder to grow, manufactures, processes, smokes or vaporizes medical marijuana in the leased premises (R.I. Gen. Laws § 21-28.6-4(d)), this will save the patient/caregiver time and money by establishing prior to investing in a grown operation whether or not it is permitted in their leased premises. It will also protect landlords by making sure their tenants seek prior approval, as growing often requires alteration to a building structure or HVAC, which may be undesirable. It will also protect patients and caregivers who grow marijuana as they will have documentation of their permission to grow on the premises.

Alternative: Not requiring permission or proof of ownership was considered but, consistent with the statutory provisions, the minimal time spent in obtaining pre-approval outweighs the significant costs resulting from eviction due to growing marijuana in leased premises without permission. Requiring that the permission document be notarized was considered but rejected due to the time and cost associated with the notarization process.

B. Administrative Penalties

§ 1.13(D) establishes a revised schedule of administrative penalties for violations of the Act and the regulations, including the possession of medical marijuana over the legal limit. The current regulation only establishes penalties for excess plants and uses a sliding scale between $25 and $5,000 per plant based on how many plants over the limit the patient or caregiver is. The proposed regulation establishes penalties for compassion center violations and simplifies the excess plant penalty to a maximum of $5,000 per plant per day.

Costs: As is standard practice, penalties are considered a transfer in that they are a cost to the violator but a benefit to the entity receiving the penalty.

Benefits: The main benefit of administrative penalties is through deterrence. In this case, deterrence takes the form of deterring possible diversion of medical marijuana to the illicit market. Given that the maximum penalty per plant is still the same as the status quo, and the proposed regulation gives DBR the discretion to vary the penalty amount, the benefits from this change are expected to be de minimis.

Alternative: DBR considered maintaining a penalty schedule but simplifying from the current 6 tiers to a 2- or 3-tiered structure. The difference between this approach and the chosen alternative was de minimis, and the proposed regulation strives for administrative simplicity in the absence of clear costs and benefits.

VI. Cooperative Cultivators

The application period for cooperative cultivators is closed, and language has been added to clarify the FY 2020 statutory amendments that the application period for cooperative cultivators is closed pursuant to R.I. Gen. Laws §21-28.6-14(d). Given that the license application period has closed, the proposal also removes references to residential cooperative cultivations which are no longer applicable. At this time, only individual patients and caregivers may grow in their residences subject to the requirements and limitations in the Act. Furthermore, there are currently only two licensed commercial cooperative cultivations that continue to operate.

Analysis

Quantifiable Costs

	Initial Costs to Comply	Renewal/Ongoing Costs
Compassion Center Application, Licensing and Renewal		
Nonprofit Certification	$200 per application	Less for renewals assuming operations continue to comply with the Act.
Business Plan	$400 per application	De minimis costs for renewal
Security & Safety Plan	$375 per application	De minimis costs for renewal
Operations Manual	$240 per application	$240 or less for renewal
Organizational Chart	$40 per application	$40 per renewal if there are updates or changes to the chart
Total per applicant/licensee	$1255	$500 or less
Total for approximately 30 Applicants	**$37,650**	**Total for 9 licensees: $4,500 or less**
Compassion Centers and Cultivators		
Packaging upgrade to federal child-resistant standard	$3,200 per year	$3,200 per year
Labeling	$120 per licensee to update label templates in accordance with amendments	N/A
Imprinting of Universal Symbol on Edibles	Option 1: $70 per set of molds, per product. Option 2 - $200 for edible ink printer plus $15 per edible ink cartridge. Estimate from either option, $500 up front	Option 1: As needed for new molds or new products. Option 2: $15 per edible ink cartridge. Annual ink cost: $300
Advertising – website changes	$100 to $300 one-time cost	N/A
Operations Manual Documentation – Quarantine products	$80 per licensee	Once implemented, requirements will be part of ongoing business practices.
Quarantine Products	$60, one-time cost	N/A
Alarm systems in vehicles	$500 (only if vehicles are not already equipped with alarm)	Once implemented, additional costs only if new vehicles without alarms are used.
Total per licensee	$4,760	$3,500

Total for 9 compassion centers and 12.5 Cultivators (assuming only 25% of cultivators are impacted)	**$102,340**	**$75,250**
Caregivers and Cooperative Cultivations		
Reimbursement and documentation requirements	Up to $240 per year	Up to $240 per year, decreasing by 20% (reflecting baseline trend in declining caregiver registration)
Total for all 900 caregivers and 2 Co-ops	**Up to $216,480 per year**	**Up to $216,480 per year, decreasing by 20% per year**

Non-Quantifiable Costs

There are non-quantifiable costs associated with new regulations for packaging, product labeling, product form, and product advertising. These new product safeguards are not widely utilized today, so it is difficult to quantify the costs of these proactive prohibitions. As noted above, these changes largely clarify and codify existing practices to protect consumers, vulnerable populations which do not have the legal protections to possess or use medical marijuana, and the public at large which has traditionally shouldered the costs of lack of and/or deficient regulation in the medical marijuana program.

Quantifiable Benefits

The estimated quantifiable benefits range between $2,223 and $7,293 depending on the level of reduction in child-related and adult emergency room visits related to medicine poisonings that the proposed amendments will generate. There is limited data on marijuana-related incidences and costs given that the industry is brand new and constantly evolving and changing which makes any meaningful estimation of benefits difficult. Furthermore, there is limited research on many of the proposed changes which makes quantifying specific components of the proposed amendments even more difficult. In reality, the bulk of the benefit from the proposed changes will derive from non-quantifiable benefits in terms of public health and safety. The analysis uses the lower end of this quantifiable benefits range when calculating a net present value. This analysis assumes that these benefits begin the accrue after the first year of implementation, after the licenses have been granted and the regulatory provisions are being enforced.

Non-Quantifiable Benefits

As a whole, these proposed changes work in concert to provide the medical marijuana program with greater oversight and accountability. They help further the legislative mandate of a well-regulated program for the state that safeguards public health and safety, as well as provide greater consumer protections for patients who rely on medical marijuana to treat their medical conditions. The proposed amendments also ensure that our most vulnerable populations are not targeted for commercial gain. They ensure that the public is properly educated about the risks associated with marijuana use, and that children are not able to obtain or mistakenly use marijuana products.

These regulations establish clear, transparent and fair application and licensing procedures including full disclosure and identification of licensees. They also help to diagnose and deter diversion to the illicit market. These functions are essential to complying with state and federal law, and federal guidance. Failure to ensure compliance with applicable state and federal law and federal guidance would compromise the program and remove protections from federal enforcement and intervention that currently allow the program to operate unimpeded.

Net Present Value

The overall quantifiable costs and benefits of this regulatory proposal are presented below.

Summary of Costs and Benefits					
	Year 0	*Year 1*	*Year 2*	*Year 3*	*Year 4*
Costs					
Compassion Center Application, Licensing and Renewal	$37,650	$4,500	$4,500	$4,500	$ 4,500
Compassion Centers and Cultivators	$102,340	$75,250	$75,250	$75,250	$75,250
Caregivers and Cooperative Cultivations	$216,480	$173,280	$138,720	$111,072	$88,954
Benefits					
Reduction in Emergency Room Visits	$-	$2,223	$2,223	$2,223	$2,223
Quantifiable Net Benefit	$(356,470)	$(250,807)	$(216,247)	$(188,599)	$(166,481)

As part of this analysis, DBR calculated a net benefit number per year, as seen in the table above. DBR then applied a range of discount rates, which yielded a **net present value** of **$(1,060,708)** (7% discount rate) to **$(1,124,316)** (3% discount rate). As noted earlier, the impacts of the non-quantifiable costs and benefits are likely to drive the true net benefit of the regulatory options under consideration. The lack of data prevents the Department from accurately predicting the full economic impacts, particularly in those areas related to benefits such as access to medical products, fair information sharing, safety, and equity for license consumers and patients.