RULES AND REGULATIONS RELATED TO THE MEDICAL MARIJUANA PROGRAM

[R21-28.6-MMP]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

March 2006 (E)

AS AMENDED:

July 2006 (E)

August 2006

January 2007 (re-filing in accordance with the provisions of §42-35-4.1 of the Rhode Island General Laws, as amended)

January 2008

March 2010

January 2012 (re-filing in accordance with the provisions of §42-35-4.1 of the Rhode Island General Laws, as amended)

December 2012

THIS PAGE INTENTIONALLY LEFT BLANK

INTRODUCTION

These amended *Rules and Regulations Related to the Medical Marijuana Program* [R21-28.6-MMP] are promulgated pursuant to the authority conferred under §21-28.6-5 of the General Laws of Rhode Island of, as amended, and are established for the purpose of adopting standards for the implementation of a medical marijuana program, including changes mandated pursuant to PL 2012-118 and PL 2012-242.

Pursuant to the provisions of §§42-35-3(a)(3) and (a)(4) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at the amended regulations: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations and (3) significant economic impact on small business. Based on the available information, no known alternative approach, duplication or overlap was identified.

These amended regulations shall supersede all previous *Rules and Regulations Related to the Medical Marijuana Program* promulgated by the Rhode Island Department of Health and filed with the Secretary of State.

TABLE OF CONTENTS

		Page
1.0	Definitions	1
2.0	General Requirements	3
3.0	Application for Registration Identification Cards and Fees	6
4.0	Issuance and Renewal of Registration Identification Cards	7
5.0	Registration and Operation of Compassion Centers	8
6.0	Protections for the Medical Use of Marijuana	18
7.0	Confidentiality Provisions	19
8.0	Scope of the Act	20
9.0	Penalties for Violations	20
10.0	Practices and Procedures	21
11.0	Severability	21

Section 1.0 **Definitions**

Wherever used in these Regulations the following terms shall be construed as follows:

- 1.1 "Act" means RIGL Chapter 21-28.6 entitled "The Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act."
- 1.2 "*Cardholder*" means a qualifying patient, a primary caregiver, or a principal officer, board member, employee, volunteer, or agent of a compassion center who has been issued and possesses a valid registry identification card.
- 1.3 "Compassion center" means a not-for-profit corporation subject to the provisions of RIGL Chapter 7-6, and registered under §21-28.6-12 of the Act that acquires, possesses, cultivates, manufactures, delivers, transfers, transports, supplies or dispenses marijuana, and/or related supplies and educational materials, to registered qualifying patients and/or their registered primary caregivers who have designated it as one of their primary caregivers.

1.4 "Debilitating medical condition" means:

- (a) Cancer, glaucoma, positive status for human immunodeficiency virus, acquired immune deficiency syndrome, Hepatitis C, or the treatment of these conditions;
- (b) A chronic or debilitating disease or medical condition or its treatment that produces one or more of the following: cachexia or wasting syndrome; severe, debilitating, chronic pain; severe nausea; seizures, including but not limited to, those characteristic of epilepsy; or severe and persistent muscle spasms, including but not limited to, those characteristic of multiple sclerosis or Crohn's disease; or agitation of Alzheimer's Disease; or
- (c) Any other medical condition or its treatment approved by the Department pursuant to §§2.5, 2.6 and 2.7 of these Regulations.
- 1.5 "Department" means the Rhode Island Department of Health or its successor agency.
- 1.6 "Marijuana" has the meaning given that term in RIGL §21-28-1.02(26) and is as follows: all parts of the plant (Cannabis sativa, L.), whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin, but shall not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of mature stalks, (except the resin extracted from it), fiber, oil or cake, or the sterilized seed from the plant which is incapable of germination.
- 1.7 "*Mature marijuana plant*" means a marijuana plant which has flowers or buds that are readily observable by an unaided visual examination.
- 1.8 "*Medical use*" means the acquisition, possession, cultivation, manufacture, use, delivery, transfer, or transportation of marijuana or paraphernalia relating to the consumption of marijuana to alleviate a registered qualifying patient's debilitating medical condition or symptoms associated with the medical condition.

- 1.9 "Paraphernalia", as used in these Regulations, means any equipment, product, or material of any kind that is primarily intended or designed for use in planting, propagating, growing, cultivating, harvesting, manufacturing, compounding, converting, producing, processing, preparing, inhaling, or otherwise introducing into the human body marijuana, including but not limited to: metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, or punctured metal bowls; water pipes, roach clips: meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand; bongs; ice pipes or chillers.
- 1.10 "Parent or legal guardian" means the custodial parent for a person under eighteen (18) years of age or the legal guardian with responsibility for health care decisions for a person of any age.
- 1.11 "*Practitione*" means a person who is licensed to practice medicine with authority to prescribe drugs pursuant to RIGL Chapter 5-37 or a physician licensed with authority to prescribe drugs in Massachusetts or Connecticut.
- 1.12 "*Primary caregiver*" means either a natural person who is at least twenty-one (21) years old or a compassion center. A natural person primary caregiver may assist no more than five (5) qualifying patients with their medical use of marijuana.
- 1.13 "Qualifying patient" means a person who has been diagnosed by a practitioner as having a debilitating medical condition and is a resident of Rhode Island.
- 1.14 "Registry identification card" means a document issued by the Department that identifies a person as a registered qualifying patient, a registered primary caregiver, or a registered principal officer, board member, employee, volunteer, or agent of a compassion center.
- 1.15 "*RIGL*" means the General Laws of Rhode Island, as amended.
- 1.16 "Seedling" means a marijuana plant with no observable flowers or buds.
- 1.17 "*These Regulations*" mean all parts of Rhode Island *Rules and Regulations Related to the Medical Marijuana Program* [*R21-28.6-MMP*].
- 1.18 "*Unusable marijuana*" means marijuana seeds, stalks, seedlings, and unusable roots.
- 1.19 "*Usable marijuana*" means the dried leaves and flowers of the marijuana plant, and any mixture or preparation thereof, but does not include the seeds, stalks, and roots of the plant.
- 1.20 "Written certification" means the qualifying patient's medical records, and a statement signed by a practitioner, stating that in the practitioner's professional opinion the potential benefits of the medical use of marijuana would likely outweigh the health risks for the qualifying patient. A written certification shall be made only in the course of a bona fide practitioner-patient relationship after the practitioner has completed a full assessment of the qualifying patient's medical history. The written certification shall specify the qualifying patient's debilitating medical condition or conditions.

Section 2.0 General Requirements

2.1 <u>Administration of the Program</u>. The Division of Environmental and Health Services Regulation within the Department shall be responsible for the administrative functions required to implement the provisions of the Act and these Regulations as they apply to the implementation of the medical marijuana program in Rhode Island.

Written Certifications

- 2.2 Practitioners shall provide written certifications for their patients on such forms as shall be provided by the Department.
- 2.3 The written certification shall specify the qualifying patient's debilitating medical condition or conditions.
- 2.4 A written certification shall be made only in the course of a bona fide practitioner-patient relationship after the practitioner has completed a full assessment of the qualifying patient's medical history.

Addition of Debilitating Medical Conditions

- 2.5 The Department shall accept a written petition from any person requesting that a particular disease or condition be included among the diseases and conditions that qualify as "debilitating medical conditions" contained in §1.4 of these Regulations.
- 2.6 The petitioner shall provide to the Department, as available:
 - (a) An explanation stating the reason(s) why the condition should be included;
 - (b) Any literature supporting the addition of the condition to the list;
 - (c) Letter(s) of support from physicians or other licensed health care professional knowledgeable about the condition and its treatment;
- 2.7 In considering such petitions, the Department shall include public notice of, and an opportunity to comment in a public hearing, upon such petitions.
 - 2.7.1 The Department shall, after hearing, approve or deny such petitions within one hundred eighty (180) days of submission.
 - 2.7.2 The approval or denial of such a petition shall be considered a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Superior Court.
 - 2.7.3 The denial of a petition shall not disqualify qualifying patients with that condition, if they have a debilitating medical condition as defined in subdivision 21-28.6-3(3) of the Act and §1.4 of these Regulations.
- 2.8 <u>Registered Primary Caregiver and Registered Qualifying Patient Possession Limits</u>. The following possession limits are established for each registered primary caregiver and registered qualifying patient:

- 2.8.1 Pursuant to RIGL §21-28.6-4(d), a registered primary caregiver may possess an amount of marijuana which does not exceed twelve (12) mature marijuana plants and two and one-half (2.5) ounces of usable marijuana for each qualifying patient to whom he or she is connected through the Department's registration process established pursuant to these Regulations.
- 2.8.2 Notwithstanding the provisions of §2.8.1 of these Regulations, and pursuant to RIGL §21-28.6-4(n), no primary caregiver other than a compassion center shall possess an amount of marijuana in excess of twenty-four (24) mature marijuana plants and five (5) ounces of usable marijuana for qualifying patients to whom he or she is connected through the Department's registration process established pursuant to these Regulations.
- 2.8.3 Pursuant to RIGL §21-28.6-4(a), a registered qualifying patient may possess an amount of marijuana which does not exceed twelve (12) mature marijuana plants and two and one-half (2.5) ounces of usable marijuana.
- 2.8.4 Pursuant to RIGL §21-28.6-4(e), registered primary caregivers and registered qualifying patients shall be allowed to possess a reasonable amount of unusable marijuana, including up to twelve (12) seedlings, which shall not be counted toward the limits established in §§2.8.1 and 2.8.3 of these Regulations.
- 2.9 <u>Compassion Center Possession Limits</u>. A compassion center shall not possess an amount of marijuana at any given time that exceeds the following limitations:
 - (a) One hundred fifty (150) marijuana plants of which no more than ninety-nine (99) shall be mature; and
 - (b) One thousand five hundred ounces (1,500 oz.) of usable marijuana.
- 2.10 **Primary Caregiver Eligibility.** A natural person may not serve as a primary caregiver if he or she has a felony drug conviction, unless the Department waives this restriction in respect to a specific individual at the Department's discretion. Additionally, the Department shall allow the person to serve as a primary caregiver if the Department determines that the offense was for conduct that occurred prior to the enactment of the Act or that was prosecuted by an authority other than the state of Rhode Island, and for which the Act would otherwise have prevented a conviction.
- 2.11 Compassion Center Principal Officer, Board Member, Agent, Volunteer or Employee Eligibility. A person shall not serve as a principal officer, board member, agent, volunteer or employee of a compassion center if he or she has been convicted of a felony drug offense or has entered a plea of *nolo contendere* for a felony drug offense and received a sentence of probation. Notwithstanding this requirement, the Department may allow a person to serve as a principal officer, board member, agent, volunteer or employee of a compassion center if the Department determines that the offense was for conduct that occurred prior to the enactment of the Act or that was prosecuted by an authority other than the state of Rhode Island, and for which the Act would otherwise have prevented a conviction.

- 2.12 <u>Compassion Center Authorized Activities</u>. A compassion center registered pursuant to §5.0 of these Regulations may acquire, possess, cultivate, manufacture, deliver, transfer, transport, supply, or dispense marijuana, or related supplies and educational materials, to registered qualifying patients and their registered primary caregivers who have designated it as one of their primary caregivers.
 - 2.12.1 A compassion center shall be considered a primary caregiver.
 - 2.12.2 Except as specifically provided to the contrary, all provisions in §21-28.6-1 through §21-28.6-11 of the Act shall apply to a compassion center unless they conflict with a provision contained in §21-28.6-12 of the Act.
- 2.13 **Emergency Notification.** A compassion center registered pursuant to §5.0 of these Regulations shall provide notification of emergency events to the Department and local law enforcement as outlined below.
 - 2.13.1 Immediately upon discovery of the event, provide telephone notification to the appropriate local law enforcement authorities regarding any of the following:
 - (a) An unplanned implementation of any portion of the compassion center's disaster plan;
 - (b) A failure/mechanical malfunction of the security alarm system that is expected to exceed an eight (8) hour period. [Ref: §5.1.7(e)(7) of these Regulations];
 - (c) An alarm activation or other event which requires response by public safety personnel; and
 - 2.13.2 Provide telephone notification to the Department within twenty-four (24) hours of discovery for any emergency event described in §2.13.1 of these Regulations;
 - 2.13.3 Submit a follow-up written report within five (5) business days for each telephone notification made pursuant to §2.13.2 of these Regulations. The written report shall include, as a minimum, a description of the event(s), identification of known or suspected cause(s) for the event(s), any corrective action(s) taken to prevent a recurrence, and the name and title of the individual preparing the report.
 - 2.13.4 **Notification**: Any notification required pursuant to §2.13.2 or §2.13.3 of these Regulations shall be made as follows:
 - (a) Written Notification:

Rhode Island Department of Health - Medical Marijuana Program 3 Capitol Hill - Room 104 Providence, RI 02908-5097

(b) **Telephone Notification:**

(401) 222-2828 [Monday-Friday 8:30 a.m. – 4:30 p.m.] (401) 272-5952 [24 hour number]

Section 3.0 Application for Registry Identification Cards and Fees

- 3.1 <u>Registry Identification Cards for Qualifying Patients and Primary Caregivers</u>. The Department shall issue registry photo identification cards to qualifying patients and primary caregivers who submit the following:
 - 3.1.1 Written certification as defined in §1.20 of these Regulations;
 - 3.1.2 Non-returnable, non-refundable application or renewal fee as set forth in the *Rules* and *Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* for each qualifying patient or primary caregiver of the qualifying patient identified on the application;
 - (a) Provided, however, for a qualifying patient or primary caregiver who submits satisfactory evidence to the Department of being a recipient of Medicaid, Supplemental Security Income (SSI), or Social Security Disability Insurance (SSDI), a non-returnable, non-refundable application or renewal fee as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* shall be submitted.
 - 3.1.3 Name, address, and date of birth of the qualifying patient. If the qualifying patient is homeless, no address is required.
 - 3.1.4 Name, address, and telephone number of the qualifying patient's practitioner; and
 - 3.1.5 Name, address, and date of birth of each primary caregiver, up to a maximum of two (2), of the qualifying patient, if any.
 - 3.1.6 Each applicant for qualifying patient registry identification card shall also indicate if he or she would like the Department to notify him or her of any clinical studies about marijuana's risk or efficacy.
- 3.2 <u>Registry Identification Cards for Minors</u>. The Department shall not issue a registry identification card to a qualifying patient under the age of eighteen (18) unless:
 - 3.2.1 The qualifying patient's practitioner has explained the potential risks and benefits of the medical use of marijuana to the qualifying patient and to a parent, guardian or person having legal custody of the qualifying patient; and
 - 3.2.2 A parent, guardian or person having legal custody consents in writing to:
 - (a) Allow the qualifying patient's medical use of marijuana;
 - (b) Serve as one of the qualifying patient's primary caregivers; and
 - (c) Control the acquisition of the marijuana, the dosage, and the frequency of the medical use of marijuana by the qualifying patient.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

Section 4.0 Issuance and Renewal of Registry Identification Cards

- 4.1 The Department shall verify the information contained in an application or renewal submitted pursuant to the Act, and shall approve or deny an application or renewal within fifteen (15) days of receiving it.
- 4.2 The Department shall issue registry identification cards within five (5) days of approving an application or renewal, which shall expire two (2) years after the date of issuance.
 - 4.2.1 If the Department fails to issue a valid registry identification card in response to a valid application submitted pursuant to the Act or these Regulations within thirty-five (35) days of its submission, the registry identification card shall be deemed granted and a copy of the registry identification application shall be deemed valid registry identification card.
 - 4.2.2 The department shall issue a registry identification card to each primary caregiver, if any, who is named in a qualifying patient's approved application, up to a maximum of two (2) primary caregivers per qualifying patient.
- 4.3 The Department may deny an application or renewal only if the applicant did not provide the information required pursuant to the Act, or if the Department determines that the information provided was falsified.
- 4.4 Rejection of an application or renewal is considered a final Department action, subject to judicial review. Jurisdiction and venue for judicial review are vested in the Superior Court.
- 4.5 A registry identification card shall not be transferable.
- 4.6 Registry identification cards shall contain:
 - 4.6.1 The date of issuance and expiration date of the registry identification card;
 - 4.6.2 A random registry identification number; and
 - 4.6.3 A photograph.

Requirements Related to Registry Identification Cards

- 4.7 Persons issued registry identification cards shall be subject to the following:
 - 4.7.1 A qualifying patient who has been issued a registry identification card shall notify the Department of any change in the qualifying patient's name, address, or primary caregiver; or if the qualifying patient ceases to have his or her debilitating medical condition, within ten (10) days of such change.
 - 4.7.2 If a registered qualifying patient has ceased to suffer from a debilitating medical condition, the card shall be deemed null and void and the person shall be liable for any other penalties that may apply to the person's non-medical use of marijuana.

- 4.7.3 A registered primary caregiver, principal officer, board member, employee, volunteer or agent of a compassion center shall notify the Department of any change in his or her name or address within ten (10) days of such change.
- 4.7.4 When a qualifying patient or primary caregiver notifies the Department of any changes listed in §4.7.1 of these Regulations, the Department shall issue the registered qualifying patient and each primary caregiver a new registry identification card within ten (10) days of receiving the updated information and a non-returnable, non-refundable fee as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* for each new registration card to be issued.
- 4.7.5 When a principal officer, board member, employee, volunteer or agent of a compassion center notifies the Department of any changes listed in §4.7.3 of these Regulations, the Department shall issue the cardholder a new registry identification card within ten (10) days of receiving the updated information and a fee as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* for each new registration card to be issued.
- 4.8 When a qualifying patient who possesses a registry identification card changes his or her primary caregiver, the Department shall notify the primary caregiver within ten (10) days. The primary caregiver's protections as provided in RIGL Chapter 21-28.6 as to that patient shall expire ten (10) days after notification by the Department.
- 4.9 If a cardholder loses his or her registry identification card, he or she shall notify the Department and submit a non-returnable, non-refundable fee as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* within ten (10) days of losing the card. Within five (5) days of receiving this notification, the Department shall issue a new registry identification card with new random identification number.

4.10 **[DELETED]**

Section 5.0 Registration and Operation of Compassion Centers

5.1 General Requirements for Operation of a Compassion Center.

- 5.1.1 A compassion center shall be operated on a not-for-profit basis for the mutual benefit of its patients. A compassion center need not be recognized as a tax-exempt organization by the Internal Revenue Services.
- 5.1.2 A compassion center shall not acquire, possess, cultivate, manufacture, deliver, transfer, transport, supply or dispense marijuana for any purpose except to assist registered qualifying patients with the medical use of marijuana directly or through the qualifying patient's other primary caregiver.
- 5.1.3 A compassion center shall not be located within one thousand (1,000) feet of the property line of a preexisting public or private school.

- 5.1.4 All principal officers and board members of a compassion center must be residents of the state of Rhode Island.
- 5.1.5 Each compassion center shall notify the Department in writing of the name, address, and date of birth¹ of any new principal officer, board member, agent, volunteer or employee and shall submit the fee established in §5.5 of these Regulations for a new registry identification card before that individual begins his or her relationship with the compassion center.
- 5.1.6 Each compassion center shall notify the Department in writing within ten (10) days of when a principal officer, board member, agent, volunteer or employee ceases to work at the compassion center. His or her registry identification card shall be deemed null and void and the individual shall be liable for any penalties that may apply to any nonmedical possession or use of marijuana by the individual.

5.1.7 **Security Requirements**:

- (a) Each compassion center shall implement appropriate security and safety measures to deter and prevent the unauthorized entrance into areas containing marijuana and the theft of marijuana.
 - (1) Access from outside the premises shall be kept to a minimum and be well-controlled;
 - (2) The outside perimeter of the premises shall be well-lighted; and
 - (3) Entry into area(s) where marijuana is held shall be limited to authorized personnel.
- (b) Each compassion center shall have a fully operational security alarm system at each authorized physical address that will provide suitable protection against theft and diversion. For the purpose of these Regulations, a fully operational security alarm system shall include, as a minimum:
 - (1) Immediate automatic or electronic notification to alert local or municipal law enforcement agencies to an unauthorized breach of security at the compassion center or at any other authorized physical address; and
 - (2) Immediate automatic or electronic notification to local or municipal public safety personnel of a loss-of-electrical support backup system.
- (c) When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (d) Each compassion center shall ensure that the storage of usable marijuana is in a locked area with adequate security. For purpose of these Regulations, "adequate security", as a minimum, should be assessed, established and maintained based on:

9

A compassion center is considered to be a primary caregiver. Therefore, any principal officer, board member, agent, volunteer or employee shall be at least twenty-one (21) years old.

- (1) Quantity of usable marijuana that will be kept on hand at each authorized location;
- (2) The compassion center's inventory system for tracking and dispensing usable marijuana;
- (3) The number of principal officers, board members, agents, volunteers or employees who have or could have access to the usable marijuana;
- (4) The geographic location of the compassion center (i.e., high or low crime area);
- (5) Scope and sustainability of the alarm system; and
- (6) Root cause analysis of any breach of security and/or inventory discrepancy for usable marijuana at that location.
- (e) Each compassion center, as a minimum, shall:
 - (1) Conduct an initial comprehensive inventory of all medical marijuana, including usable marijuana available for dispensing, mature marijuana plants and unusable marijuana, at each authorized location on the date the compassion center first dispenses medical marijuana.
 - (2) Conduct the comprehensive inventory required by §5.1.7(e)(1) of these Regulations at intervals not to exceed twenty-four (24) months from the date of the previous comprehensive inventory;
 - (3) Conduct a monthly inventory review of stored, usable marijuana;
 - (4) Within twenty-four (24) hours of discovery of the event, notify the Department and appropriate local law enforcement authorities by telephone of discrepancies identified during inventories conducted pursuant to §§5.1.7(e)(1), (e)(2) or (e)(3) of these Regulations.
 - (5) Establish a protocol for the testing and maintenance of the security alarm system;
 - (6) Conduct a maintenance inspection/test of the alarm system for each authorized location at intervals not to exceed thirty (30) days from the previous inspection/test and promptly make all necessary repairs to ensure the proper operation of the alarm system;
 - (7) In the event of a failure of the security alarm system, due to loss of electrical support or mechanical malfunction, that is expected to exceed an eight (8) hour period:
 - (i) Within twenty-four (24) hours of discovery of the event, notify the Department by telephone; and
 - (ii) Provide alternative security measures approved by the Department or close the authorized physical address(es) impacted by the failure/ malfunction until the security alarm system has been restored to full operation;

- (8) Maintain documentation in an auditable form² for a period of at least twenty-four (24) months after the event for:
 - (i) All inventories conducted pursuant to §§5.1.7(e)(1), (e)(2) or (e)(3) of these Regulations. The record shall include, as a minimum, the date of the inventory, a summary of the inventory findings and the name, signature and title of the individual who conducted the inventory;
 - (ii) All maintenance inspections/tests conducted pursuant to §5.1.7(e)(6) of these Regulations, and any servicing, modification or upgrade performed on the security alarm system. The record shall include, as a minimum, the date of the action, a summary of the action(s) performed and the name, signature and title of the individual who performed the action(s);
 - (iii) Any alarm activation or other event which requires response by public safety personnel; and
 - (iv) Any unauthorized breach(es) of security.
- (9) Request that the Rhode Island State Police (RISP) visit the compassion center to inspect the facility security and make any recommendations regarding the security of the facility and its personnel within ten (10) days prior to the initial opening of each compassion center.
 - (i) Said recommendations shall not be binding upon any compassion center, nor shall the lack of implementation of said recommendations delay or prevent the opening or operation of any center.
 - (ii) If the RISP do not inspect the compassion center within the ten (10) day period there shall be no delay in the compassion center's opening.
- 5.1.8 **Operations Manual**. Each compassion center shall develop, implement and maintain on the premises an operations manual which addresses, as a minimum, the following requirements:
 - (a) Procedures for the oversight of the compassion center;
 - (b) Procedures for safely dispensing medical marijuana to registered qualifying patients or their other registered primary caregiver:
 - (c) Procedures to ensure accurate record keeping, including protocols to ensure that quantities purchased do not suggest re-distribution;
 - (d) Employee security policies;
 - (e) Safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

11

² Any required record may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved for a period of at least twenty-four (24) months after the event which caused the record to be generated.

- (f) Personal safety and crime prevention techniques;
- (g) A job description or employment contract developed for all employees and agents and a volunteer agreement for all volunteers, which includes duties, responsibilities, authority, qualifications and supervision;
- (h) The compassion center's alcohol and drug free work place policy; and
- (i) A description of the compassion center's outreach activities to registered qualifying patients or their other registered primary caregiver which shall, as a minimum, include:
 - (1) Providing each new registered qualifying patient who visits the compassion center with a frequently asked questions sheet, designed by the Department, which explains the limitations on the right to use medical marijuana under state law;
 - (2) Ingestion options of useable marijuana provided by the compassion center;
 - (3) Safe smoking techniques that shall be provided to registered qualifying patients; and
 - (4) Potential side effects and how this information shall be communicated.
- (j) A description of the packaging of the useable marijuana that the compassion center shall be utilizing which shall, as a minimum, include:
 - (1) A label containing the name of the strain, batch and quantity; and
 - (2) A statement that the product is for medical use and not for resale.
- 5.1.9 **Required Training.** Each compassion center shall develop, implement and maintain on the premises an on-site training curriculum, or enter into contractual relationships with outside resources capable of meeting employee, agent and volunteer training needs. Each employee, agent or volunteer, at the time of his or her initial appointment, shall receive, as a minimum, training in the following:
 - (a) Professional conduct, ethics, and state and federal laws regarding patient confidentiality;
 - (b) Informational developments in the field of medical use of marijuana;
 - (c) The proper use of security measures and controls that have been adopted; and
 - (d) Specific procedural instructions for responding to an emergency, including robbery or violent accident.
- 5.1.10 **Personnel Records.** Each compassion center shall maintain a personnel record for each employee, agent or volunteer that includes, as a minimum, the following:
 - (a) An application for employment or to volunteer;
 - (b) A record of any disciplinary action taken;
 - (c) Documentation of all required training;

- (1) Documentation shall include a signed statement from the individual indicating the date, time and place he or she received said training and topics discussed, including the name and title of presenters; and
- (2) Documentation shall be maintained for a period of at least six (6) months after termination the individual's affiliation with the compassion center.
- 5.2 <u>Application for Operation of Compassion Center</u>. Applications shall only be accepted during an open application period announced by the Department. Each application for a compassion center shall be on forms provided by the Department and shall include:
 - 5.2.1 A non-refundable application fee, as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.
 - 5.2.2 The proposed legal name, articles of incorporation and bylaws of the compassion center.
 - 5.2.3 The proposed physical address of the compassion center, if a precise address has been determined. This shall also include the additional address to be used for the secure cultivation of medical marijuana (if applicable).
 - (a) Provide evidence of compliance with the local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana;
 - (b) Provide evidence that all of the physical addresses identified in §5.2.3(a) of these Regulations are not located within one thousand feet (1,000') of the property line of a preexisting public or private school; or
 - (c) If a precise address has not been determined, identify the general location(s) where it would be sited, and when.
 - 5.2.4 A description of the enclosed, locked facility that would be used in the cultivation of marijuana, including steps to ensure that the marijuana production shall not be visible from the street or other public areas.
 - 5.2.5 A description of how the compassion center will operate on a not-for-profit basis:
 - (a) Documentation of recognition as a tax-exempt organization by the US Internal Revenue Service; or
 - (b) Other written materials which will allow the Department to determine the compassion center's ability to comply with the review criteria contained in §21-28.6-12(c)(3)(iii) of the Act.
 - 5.2.6 The name, address, and date of birth of each principal officer and board member of the compassion center.
 - 5.2.7 A description of proposed security and safety measures which demonstrate compliance with §5.1.7 of these Regulations,
 - 5.2.8 A draft operations manual which demonstrates compliance with §5.1.8 of these Regulations.

- 5.2.9 A list of all persons or business entities having direct or indirect authority over the management or policies of the compassion center.
- 5.2.10 A list of all persons or business entities having five percent (5%) or more ownership in the compassion center, whether direct or indirect and whether the interest is in profits, land or building, including owners of any business entity which owns all or part of the land or building, and
- 5.2.11 The identities of all creditors holding a security interest in the premises, if any.
- 5.2.12 <u>Complete Application Required</u>. Only applications which the Department has determined to be complete (i.e., adequately address all requirements in §§5.2.1-5.2.11 of these Regulations) shall be eligible for review pursuant to §5.3 of these Regulations. An applicant who submits an incomplete applications shall receive written notification from the Department regarding the specific deficiencies and shall be allowed to resubmit additional material to address these deficiencies.
- 5.3 <u>Compassion Center Application Review Criteria</u>. The Department shall utilize the criteria specified in §21-28.6-12(c)(3) of the Act to review applications for a registration certificate to operate a compassion center.
- 5.4 <u>Issuance of Registration Certificate Authorizing Operation of a Compassion Center.</u>
 When an applicant to operate a compassion center is notified that its application has been approved by the Department, it shall submit the following additional items to the Department before the registration certificate authorizing operation of a compassion center will be issued:
 - 5.4.1 A certification fee, as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health;
 - 5.4.2 The legal name and articles of incorporation of the compassion center.
 - 5.4.3 The physical address of the compassion center. This shall include any additional address to be used for the secure cultivation of medical marijuana (if applicable).
 - (a) Provide evidence of compliance with the local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana.
 - (b) Provide evidence that all of the physical addresses identified in §5.4.3(a) of these Regulations are not located within one thousand feet (1,000') of the property line of a preexisting public or private school.
 - (c) It shall not be necessary to resubmit any information provided pursuant to §5.2.3(a) and/or §5.2.3(b) of these Regulations unless there has been a change in that information.
 - 5.4.4 The name, address and date of birth of each principal officer and board member of the compassion center.
 - 5.4.5 The name, address and date of birth of any person who will be an agent, employee or volunteer of the compassion center at its inception.

- 5.4.6 Any updates to previously submitted information regarding compliance with §§5.1.7 and 5,1.8 of these Regulations.
- 5.4.7 A current Certificate of Occupancy (or equivalent document) to demonstrate compliance with the provisions of RIGL §23-28.1 [Fire Safety Code] for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana.
- **Registry Identification Cards for Principal Officers, Board Members, Agents, Volunteers or Employees of a Compassion Center.** The Department shall issue registry photo identification cards to each principal officer, board member, agent, volunteer or employee of a compassion center who is identified by the compassion center pursuant to §5.4 of these Regulations, subject to the requirements in §5.5.1, §5.5.2 and §5.5.3.
 - 5.5.1 A non-returnable, non-refundable application or renewal fee as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health shall be submitted for each principal officer, board member, agent, volunteer or employee of the compassion center.
 - 5.5.2 The compassion center shall also submit the name, address and date of birth of any additional principal officer, board member, agent, employee or volunteer of the compassion center and a non-returnable, non-refundable application or renewal fee as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health for each individual.
 - 5.5.3 Pursuant to §21-28.6-12(c)(7)(i) of the Act, each compassion center principal officer, board member, agent, volunteer or employee shall apply³ to the Rhode Island State Police (RISP) for a national criminal identification records check that shall include fingerprints submitted to the Federal Bureau of Investigation (FBI) to demonstrate compliance with the eligibility requirements in §2.11 of these Regulations.
 - (a) (1) Upon the discovery of a felony drug offense conviction or a plea of *nolo* contendere for a felony drug offense with a sentence of probation, the RISP shall inform the applicant, in writing, of the nature of the felony and the RISP shall notify the Department, in writing, without disclosing the nature of the felony, that a felony drug offense conviction or a plea of *nolo* contendere for a felony drug offense with probation has been found;
 - (2) In those situations in which no felony drug offense conviction or plea of *nolo contendere* for a felony drug offense with probation has been found, the RISP shall inform the applicant and the Department, in writing, of this fact.

³ Applications shall only be submitted at Rhode Island State Police headquarters, ICU. Call (401) 444-1110 to arrange for an appointment..

- (b) Any expense associated with a national criminal identification records check that includes fingerprints submitted to the FBI shall be paid by the registry identification card applicant.
- (c) The Department shall notify the compassion center in writing of the purpose for denying the registry identification card.
- 5.5.4 The Department shall issue each principal officer, board member, agent, volunteer or employee of a compassion center a registry identification card within ten (10) days of receipt of the information required by §5.5.1 or §5.5.2, and §5.5.3. The registry identification card shall contain:
 - (a) The name, address and date of birth of the person;
 - (b) The legal name of the compassion center that the individual is affiliated with;
 - (c) The category of the person's affiliation (principal officer, board member, agent, volunteer or employee);
 - (d) The date of issuance and expiration date of the registry identification card;
 - (e) A random registry identification number; and
 - (f) A photograph.
- 5.5.5 Expiration Date. The registry identification card of a principal officer, board member, agent, volunteer or employee shall expire one (1) year after its issuance, upon the termination of the principal officer, board member, agent, volunteer or employee's relationship with the compassion center or upon the expiration of the compassion center's registration certificate, whichever occurs first.

5.6 <u>Expiration, Termination or Renewal of a Registration Certificate Authorizing Operation of a Compassion Center.</u>

- 5.6.1 A compassion center's registration shall expire two (2) years after its registration certificate is issued. The compassion center may submit a renewal application beginning sixty (60) days prior to the expiration of its registration certificate;
- 5.6.2 The Department shall grant a compassion center's renewal application within thirty (30) days of its submission if the following conditions are all satisfied:
 - (a) The compassion center submits the materials required under §5.4 of these Regulations, including a fee as set forth in the *Rules and Regulations* Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health;
 - (b) The Department has not ever suspended the compassion center's registration for violations of the Act or these Regulations;
 - (c) The Legislative Oversight Committee's report, if issued pursuant to \$21-28.6-12(j) of the Act, indicates that the compassion center is adequately providing patients with access to medical marijuana at reasonable rates; and

- (d) The Legislative Oversight Committee's report, if issued pursuant to §21-28.6-12(j) of the Act, does not raise serious concerns about the continued operation of the compassion center applying for renewal.
- 5.6.3 If the Department determines that any of the conditions listed in §§5.6.2(b), 5.6.2(c) or 5.6.2(d) of these Regulations have not been met, the Department shall begin an open application process for the operation of a compassion center. In granting a new registration certificate, the Department shall consider the review criteria listed in §21-28-12(c)(3) of the Act.
- 5.6.4 The Department shall issue a compassion center one (1) or more thirty (30) day temporary registration certificates after that compassion center's registration would otherwise expire if the following conditions are all satisfied:
 - (a) The compassion center previously applied for a renewal, but the Department had not yet come to a decision;
 - (b) The compassion center requested a temporary registration certificate; and
 - (c) The compassion center has not had its registration certificate revoked due to violations of the Act or these Regulations.

5.7. <u>Non-transferable Registration Certificate Authorizing Operation of a Compassion Center.</u>

- 5.7.1 A registration certificate authorizing operation of a compassion center shall not be transferred by assignment or otherwise to other persons or locations. Unless the compassion center applies for and receives an amended registration certificate authorizing operation of a compassion center, the registration certificate shall be void and returned to the Department when one (1) or more of the following situations occurs:
 - (a) A change in ownership of the compassion center;
 - (b) A change in one (1) or more authorized physical locations; or
 - (c) The compassion center discontinues its operation.
- 5.7.2 A compassion center shall provide the Department with a written notice of any change described in §5.7.1 of these Regulations at least sixty (60) days prior to the proposed effective date of the change. The Department may waive all or part of the required advance notice to address emergent or emergency situations.
- 5.7.3 Transactions which usually do not constitute a change of ownership include the following:
 - (a) Changes in the membership of a board of directors or board of trustees; or
 - (b) Two (2) or more legal entities merge and the entity to whom the registration certificate authorizing operation of a compassion center was issued survives.
- 5.7.4 Management agreements are generally not considered a change in ownership if the entity to whom the registration certificate authorizing operation of a compassion center was issued continues to retain ultimate authority for the operation of the compassion center. However, if the ultimate authority is

surrendered and transferred from the entity to whom the registration certificate authorizing operation of a compassion center was issued to a new manager, then a change of ownership has occurred.

5.8 <u>Maximum Amount of Usable Marijuana to be Dispensed.</u>

- 5.8.1 A compassion center or principal officer, board member, agent, volunteer or employee of a compassion center shall not dispense, deliver or otherwise transfer marijuana to a person other than a qualifying patient who has designated the compassion center as a primary caregiver or to such patient's other primary caregiver.
- 5.8.2 A compassion center or principal officer, board member, agent, volunteer or employee of a compassion center shall not dispense more than two and one half ounces (2.5 oz) of usable marijuana to a qualifying patient directly or through a qualifying patient's other primary caregiver during a fifteen (15) day period.
- 5.8.3 A compassion center or principal officer, board member, agent, volunteer or employee of a compassion center shall not dispense an amount of usable marijuana or marijuana plants to a qualifying patient or a qualifying patient's other primary caregiver that the compassion center, principal officer, board member, agent, volunteer or employee knows would cause the recipient to possess more marijuana than is permitted under the Act or these Regulations.
- 5.8.4 A person found to have violated §5.8.1 of these Regulations is not eligible to be an employee, agent, volunteer, principal officer or board member of any compassion center, and such person's registry identification card shall be immediately revoked.
- 5.9 <u>Inspection</u>. Compassion centers are subject to reasonable inspection by the Department's Office of Facilities Regulation. During an inspection, the Department may review the compassion center's confidential records, including its dispensing records, which shall track transactions according to qualifying patients' registry identification numbers to protect their confidentiality.

Section 6.0 Protections for the Medical Use of Marijuana

- 6.1 A practitioner shall not be subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including, but not limited to, civil penalty or disciplinary action by the Rhode Island Board of Medical Licensure and Discipline or by any other business or occupational or professional licensing board or bureau solely for providing written certifications or for otherwise stating that, in the practitioner's professional opinion, the potential benefits of the medical marijuana would likely outweigh the health risks for a patient.
- 6.2 A practitioner, nurse, or pharmacist shall not be subject to arrest, prosecution or penalty in any manner, or denied any right or privilege, including, but not limited to, civil penalty or disciplinary action by a business or occupational or professional licensing board or

- bureau solely for discussing the benefits or health risks of medical marijuana or its interaction with other substances with a patient.
- A registry identification card, or its equivalent, issued under the laws of another state, U.S. territory, or the District of Columbia to permit the medical use of marijuana by a patient with a debilitating medical condition, or to permit a person to assist with the medical use of marijuana by a patient with a debilitating medical condition, shall have the same force and effect as a registry identification card issued by the Department pursuant to the Act and these Regulations.
- 6.4 For the purposes of medical care, including organ transplants, a registered qualifying patient's authorized use of marijuana shall be considered the equivalent of the authorized use of any other medication used at the direction of a physician, and shall not constitute the use of an illicit substance.
- 6.5 No state employee shall be subject to arrest, prosecution or penalty in any manner, or denied any right or privilege, including, but not limited to, civil penalty, disciplinary action, termination, or loss of employee or pension benefits, for any and all conduct that occurs within the scope of his or her employment regarding the administration, execution and/or enforcement of the Act, and the provisions of RIGL §9-31-8 and §9-31-9 shall be applicable to this section.

Section 7.0 Confidentiality Provisions

- 7.1 Applications and supporting information submitted by qualifying patients, including information regarding their primary caregivers and practitioners, are confidential and protected under the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996, as amended.
- 7.2 The Department shall maintain a confidential list of the persons to whom the Department has issued registry identification cards.
 - 7.2.1 Individual names and other identifying information on the list:
 - (a) Shall be confidential and not be considered a public record pursuant to RIGL §38-2-2(4); and
 - (b) Shall not subject to disclosure, except to authorized employees of the Department as necessary to perform official duties of the Department.
- 7.3 The Department shall verify to law enforcement personnel whether a registry identification card is valid solely by confirming the random registry identification number.
- 7.4 All records maintained by a compassion center which pertain to one or more registered qualifying patients or other registered primary caregivers shall be considered:
 - 7.4.1 Confidential health care information under applicable Rhode Island law; and

- 7.4.2 Protected health care information for purposes of the Federal Health Insurance Portability and Accountability Act of 1996, as amended.
- 7.5 Pursuant to §21-28.6-6(j) of the Act, the Department may notify law enforcement personnel about falsified or fraudulent information submitted to the Department.

Section 8.0 Scope of the Act

- 8.1 The Act and these Regulations shall not permit:
 - 8.1.1 Any person to undertake any task under the influence of marijuana, when doing so would constitute negligence or professional malpractice;
 - 8.1.2 The smoking of marijuana:
 - (a) In a school bus or other form of public transportation;
 - (b) On any school grounds;
 - (c) In any correctional facility;
 - (d) In any public place;
 - (e) In any licensed drug treatment facility in this state; or
 - (f) Where exposure to the marijuana smoke significantly adversely affects the health, safety, or welfare of children.
 - 8.1.3 Any person to operate, navigate, or be in actual physical control of any motor vehicle, aircraft, or motorboat while under the influence of marijuana. However, a registered qualifying patient shall not be considered to be under the influence solely for having marijuana metabolites in his or her system.
- 8.2 Nothing in the Act or these Regulations shall be construed to require:
 - 8.2.1 A government medical assistance program or private health insurer to reimburse a person for costs associated with the medical use of marijuana; or
 - 8.2.2 An employer to accommodate the medical use of marijuana in any workplace.

Section 9.0 *Penalties for Violations*

- 9.1 Fraudulent representation to a law enforcement official of any fact or circumstance relating to the medical use of marijuana to avoid arrest or prosecution shall be punishable by a fine of five hundred dollars (\$500) which shall be in addition to any other penalties that may apply for making a false statement for the non-medical use of marijuana.
- 9.2 If a cardholder willfully violates any provision of the Act or these Regulations, as determined by the Department, his or her registry identification card may be revoked.
- 9.3 A registered qualifying patient who fails to notify the Department of any changes required pursuant to §4.7.2 of these Regulations shall be responsible for a civil infraction, punishable by a fine of no more than one hundred fifty dollars (\$150)

- 9.4 A primary caregiver, principal officer, board member, employee, volunteer or agent of a compassion center who fails to notify the Department of any changes required pursuant to \$4.7.3 of these Regulations shall be responsible for a civil infraction, punishable by a fine of no more than one hundred fifty dollars (\$150).
- 9.5 An employee, agent, volunteer, principal officer or board member of any compassion center found in violation of §21-28.6-12(i)(2) of the Act shall have his or her registry identification revoked immediately.
- 9.6 A compassion center's registry identification card shall be subject to revocation if the compassion center:
 - (a) Possesses an amount of marijuana exceeding the limits established by the Act or these Regulations;
 - (b) Is in violation of the laws of Rhode Island;
 - (c) Is in violation of other regulations issued by the Department; or
 - (d) Employs or enters into a business relationship with a medical practitioner who provides written certification of a qualifying patient's medical condition.

Section 10.0 Practices and Procedures

10.1 All hearings and reviews required under the provisions of RIGL Chapter 21-28.6 of the General Laws of Rhode Island, as amended, shall be held in accordance with the provisions of the Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health [R42-35-PP].

Section 11.0 Severability

11.1 If any provision of the Act or these Regulations or its application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the Act or these Regulations, which can be given effect without the invalid provision or application, and to this end the provisions of the Act and these Regulations are declared to be severable.

MedicalMarijuana_Final_December2012.doc Wednesday, 28 November 2012