

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Chapter 49A (16 Del.C. Ch. 49A)
16 DE Admin. Code 4470

PROPOSED

PUBLIC NOTICE

4470 State of Delaware Medical Marijuana Code

Preamble

The Secretary of Delaware Health and Social Services adopts these regulations in response to the authority vested in the Secretary by 16 Del.C. Ch. 49A, The Delaware Medical Marijuana Act. These regulations establish the standards for the procedures for issuing a certificate of registration to qualified patients and designated caregivers. These regulations provide a system of permitting and inspection, as well as governing confidentiality, payments of fees, and enforcement of these rules.

17 DE Reg. 738 (01/01/14)

Purpose

These regulations shall be liberally construed and applied to promote their underlying purpose of protecting the public's health.

1.0 State of Delaware Medical Marijuana Code

These regulations shall hereby be known as the "State of Delaware Medical Marijuana Code."

2.0 Definitions

The following words and terms, when used in these regulations, should have the following meaning, unless the context clearly indicates otherwise:

"Act" means the Delaware Marijuana Act, 16 Del.C. §§4901A *et seq.*

"Adulterated" means made impure or inferior by adding extraneous ingredients. Goods that are prepared in food establishments that are licensed facilities in response to 16 Del.C. §122(3)(u) and 16 Del.C. §134, and that contain marijuana for medical use by a registered patient, are not considered to be adulterated.

"Advisory board" means a nine-member committee established, chaired, and appointed by the General Assembly of Delaware to evaluate and make recommendations to the state legislature and the Department.

"Applicant" means any person applying to participate in the Delaware Medical Marijuana Program, hereinafter MMP.

"Background check" means any person required to obtain a background check under this chapter shall submit fingerprints and other necessary information to the State Bureau of Identification in order to obtain a report of the person's entire criminal history record from the State Bureau of Identification or a statement that the State Bureau of Identification Central Repository contains no such information relating to that person. The report will include the person's entire federal criminal history record from the Federal Bureau of Investigation pursuant to Federal Bureau of Investigation appropriation of Title II of Public Law 92-544 (28 U.S.C. § 534) or a statement that the Federal Bureau of Investigation's records contain no such information relating to that person. A person required to obtain a background check under this chapter is responsible for any costs associated with obtaining the background check.

"Batch" A batch is a collection of plants of the same strain and genetics, grown in the same room at the same time. The maximum batch size is five (5) pounds or 2268 grams.

"Bona fide physician-patient relationship" means a treatment or counseling relationship between a physician and patient in which all the following are present:

(1) The physician has reviewed the patient's relevant medical records and completed a full assessment of the patient's medical history and current medical condition, including a relevant, in-person, medical evaluation of the patient.

(2) The physician has created and maintained records of the patient's condition in accord with medically accepted standards.

(3) The patient is under the physician's continued care for primary medical care or the debilitating condition that qualifies the patient for the Medical Marijuana Program.

(4) The physician has a reasonable expectation that he or she will provide follow-up care to the patient to monitor the efficacy of the use of medical marijuana as a treatment of the patient's debilitating medical condition.

(5) The relationship is not for the sole purpose of certifying for medical marijuana.

"Butane Hash Oil" or "BHO" means a cannabis concentrate produced using an alkane or petroleum hydrocarbon.

"Cannabidiol" or "CBD" is a cannabinoid found in cannabis with mild psychoactive properties that does not induce a euphoric high.

"Cardholder" means a registered patient or a registered designated caregiver who has been issued and possesses a valid registry identification card.

"Compassion center agent" means a principal officer, board member, employee, or agent of a registered compassion center who is 21 years of age or older and has not been convicted of an excluded felony offense and has not been convicted of a drug misdemeanor within five years.

"Compassionate use card" means a card issued by the Department for conditions not covered in the Act or regulations. The compassionate use card has additional requirements for approval.

"Concentrate" means any product created when marijuana flowers are refined into something more pure and potent. This umbrella term includes any type of hash (water hash, pressed hash), dry sieve (kief), as well as hash oils (CO₂ oil, shatter, wax, and rosin) and indicates that these products are a concentrated form of cannabis, carrying a higher potency.

"Consumer" means a person who is a patient in the Medical Marijuana Program, takes possession of marijuana, and is not functioning in the capacity of an operator of a marijuana business.

"Debilitating medical condition" means one or more of the following:

(a) Terminal illness, cancer, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), decompensated cirrhosis (hepatitis C), amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease), post-traumatic stress disorder (PTSD), intractable epilepsy, autism with self-injurious or aggressive behavior, seizure disorder, glaucoma, chronic debilitating migraines, new daily persistent headache, and agitation of Alzheimer's disease or the treatment of these conditions;

(b) A chronic or debilitating disease medical condition or its treatment that produces one or more of the following: cachexia or wasting syndrome; severe, debilitating pain that has not responded to previously prescribed medication or

surgical measures for more than three months or for which other treatment options produced serious side effects; intractable nausea; seizures; or severe and persistent muscle spasms, including but not limited to those characteristic of multiple sclerosis;

(c) Pediatric qualifying conditions are limited to any of the following related to a terminal illness: pain, anxiety, or depression; seizure disorder; severe debilitating autism; or a chronic or debilitating disease or medical condition where they have failed treatment involving one or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; severe, painful and persistent muscle spasms; and chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions; or

(e)(d) Any other medical condition or its treatment added by the Department, as provided for in 16 Del.C. §4906A and Section 6.0 of this code.

“Delaware Enterprise Consolidated Cannabis Control System” or “DEC3S” is the statewide application which serves as patient registry, point of sale monitor, seed to sale inventory tracker and repository of medical marijuana product test results.

“Delaware Food Code” means the current State of Delaware Food Code, 16 Del.C. §4458A.

“Department” means the Delaware Department of Health and Social Services.

“Designated caregiver” means a person who:

- (a) Is at least 21 years of age unless the person is the parent or legal guardian of a minor who is a qualifying patient,
- (b) Has agreed to assist with a patient's medical use of marijuana
- (c) Has not been convicted of an excluded felony offense; and
- (d) Assists no more than five qualifying patients with their medical use of marijuana.

“Direct Sales” means sales of marijuana products within the State of Delaware directly to the registered patients without the use of an independent retailer or other intermediary.

“Division” means the Delaware Division of Public Health

“Drinking Water” means water that meets criteria as specified in 16 DE Admin. Code 4462 Public Drinking Water Systems Regulations. “Drinking water” is traditionally known as “potable water.”

“Employee” or “Agent” refers to an individual having supervisory or management duties, an individual on the payroll, a volunteer, an individual performing work under contractual agreement, or any other individual working in a marijuana business.

“Excluded felony offense” means:

- (a) A violent crime defined in 11 Del.C. §4201(c), that was classified as a felony in the jurisdiction where the person was convicted; or
- (b) A violation of a state or federal controlled substance law that was classified as a felony in the jurisdiction where the person was convicted, not including:
 - (1) An offense for which the sentence, including any term of probation, incarceration, or supervised release, was completed 10 or more years earlier; or
 - (2) An offense that consisted of conduct for which 16 Del.C. Ch. 49A would likely have prevented a conviction, but the conduct either occurred prior to July 1, 2011, or was prosecuted by an authority other than the State of Delaware.

“Food-Contact Surface” means a surface of equipment or a utensil with which food normally comes into contact; or a surface of equipment or a utensil from which food may drain, drip or splash into a food or onto; or a surface normally in contact with food.

“Food Equipment” means an article that is used in the operation of a marijuana-infused food establishment such as a freezer, grinder, hood, icemaker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, and table, temperature-measuring device for ambient air, vending machine, or ware washing machine. Equipment may be defined as a food-contact surface or non-food contact surface. “Equipment” does not include apparatuses used for handling or storing large quantities of packaged foods that are received from a supplier in a cased or overwrapped lot, such as hand trucks, forklifts, dollies, pallets, racks, and skids.

“Imminent Health Hazard” means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries and the nature, severity, and duration of the anticipated injury.

“Incidental amount of marijuana” means marijuana seeds, stalks and roots of the plant that are not included when calculating the allowable amounts of marijuana specified in these rules. This includes the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical ointment, food or drink.

“Intractable epilepsy” means an epileptic seizure disorder for which standard medical treatment does not prevent or significantly ameliorate recurring, uncontrolled seizures or for which standard medical treatment results in harmful side effects.

“Marijuana” means the same as defined in 16 Del.C. §4701 (23).

“Marijuana Infused Food Products” refers to a non-time/temperature controlled (non-TCS) for safety food as specified in these regulations that is offered for sale directly to consumers and only at a licensed Compassion Center.

“Marijuana Infused Food Establishment” refers to a licensed Compassion Center that has received an endorsement from the Department to make non-time/temperature controlled (non-TCS) marijuana infused food products.

“Marijuana paraphernalia” is limited to equipment, products and materials that are ordinarily used in planting, propagating, cultivating, growing, harvesting, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, ingesting, inhaling or otherwise introducing marijuana into the human body. It includes:

(a) Scales and balances used or intended for use in weighing or measuring marijuana;

(b) Separation gins and sifters, used or intended for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana;

(c) Envelopes and other containers used or intended for use in packaging small quantities of marijuana for medical use;

(d) Containers and other objects used or intended for use in storing medical marijuana; and

(e) Objects used or intended for use in ingesting, inhaling or otherwise introducing marijuana into the human body, including but not limited to:

(1) Metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens, hashish heads or punctured metal bowls;

(2) Water pipes;

(3) Carburetion tubes and devices;

- (4) Smoking and carburetion masks;
- (5) Roach clips, meaning objects used to hold burning marijuana cigarettes that have become too small or too short to be held in the hand;
- (6) Chamber pipes;
- (7) Carburetor pipes;
- (8) Electric pipes;
- (9) Air-driven pipes;
- (10) Chillums;
- (11) Bongs designed for marijuana and not for cocaine; or
- (12) Ice pipes or chillers.

"Medical marijuana oil" means a resinous matrix of cannabinoids obtained from the Cannabis plant by solvent extraction, formed into oil.

"Medical marijuana waste" means unused, surplus, returned, or out of date medical marijuana, recalled medical marijuana, and any plant debris, including dead plants, all unused plant parts, and roots.

"Medical use" means the acquisition, possession, use, delivery, transfer or transportation of marijuana or paraphernalia relating to the administration of marijuana to treat or alleviate a registered patient's debilitating medical condition or symptoms associated with the registered patient's debilitating medical condition.

"Nonfood-contact surface" means all exposed surfaces other than food and splash zones.

"Onsite assessment" means a visit by an employee of the Department for the purpose of ensuring compliance with the requirements of these rules.

"Pediatric Medical marijuana oil" means:

a. "Cannabidiol oil" which is a processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than seven percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of cannabidiol per milliliter but not more than seven percent tetrahydrocannabinol; and

b. "THC-A oil" which is a processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than seven percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of tetrahydrocannabinol acid per milliliter but not more than seven percent tetrahydrocannabinol; and

c. Any change in the oil formulation which is made by the Department based upon the recommendation of the advisory council Medical Marijuana Act Oversight Committee.

"Physician" means a properly licensed physician subject to 24 Del.C. Ch. 17, except as otherwise provided in this definition. If the qualifying patient is younger than 18 years of age, the physician must be a pediatric neurologist, pediatric gastroenterologist, pediatric oncologist, pediatric psychiatrist, developmental pediatrician or pediatric palliative care specialist.

"Poisonous and Toxic Materials" means substances that are not intended for ingestion, including cleaners and sanitizers; pesticides; necessary maintenance substances such as non-food grade lubricants; and personal care items such as medicines, first aid supplies, cosmetics and toiletries.

"Post-Traumatic Stress Disorder" means that a patient meets the diagnostic criteria for Post-Traumatic Stress Disorder (PTSD), per DSM-5 or subsequent current edition, including

symptoms of intense physical reactions such as tachycardia, shortness of breath, rapid breathing, muscle-tension, and sweating.

“Processing area” refers to the area of the marijuana business where marijuana is prepared, trimmed, packaged or food prep and other food service activities occur.

“Producer” refers to employees of the Marijuana Infused Food Establishment involved with the production of marijuana infused products.

“Qualifying patient” means an individual who meets the qualifications to receive a registry identification card under this chapter.

“Registration Holder” means the entity that is legally responsible for the operation of the marijuana compassion center such as the owner, the owner’s agent, or other person; and possesses a valid registration to operate a marijuana business.

“Registry identification card” means a document issued by the Department that identifies a person as a registered patient or registered designated caregiver.

“Regulatory Authority” means the Secretary, Delaware Department of Health and Social Services (DHSS), or authorized designee.

“Responsible Party” means the parent or legal guardian with responsibility and decision-making capability for a qualifying patient or applicant. The Responsible Party will have primary responsibility for purchase, handling and dispensing of the medical marijuana products for the person under the Responsible Party’s charge.

“Safety Compliance Facility” means a nonprofit organization permitted to test marijuana produced for medical use for potency and contaminants.

“Sanitization” refers to a heat or chemical treatment on cleaned food contact surfaces that is sufficient to yield a 99.999 percent reduction of the number of representative disease microorganisms of public health significance.

“Temperature Measuring Device” or **“TMD”** means a thermometer, thermocouple, thermistor or other device that indicates the temperature of food, air or water.

“Terminal Illness” means any disease, illness or condition sustained by any human being for which there is no reasonable medical expectation of recovery; which, as a medical probability, will result in the death of such human being regardless of the use or discontinuance of medical treatment implemented for the purpose of sustaining life or the life processes; and as a result of which, the human being’s health-care practitioner would not be surprised if death were to occur within 12 months.

“Tetrahydrocannabinol Delta 9” or **“THC”** is a decarboxylated cannabinoid found in cannabis with strongly psychoactive properties that induces a euphoric high.

“Time/Temperature Control for Safety Food” or **“TCS”** means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

“Tincture” means a mixture created from a concentrated extract of marijuana.

“Topical treatment” means a mixture or extract of marijuana made into a balm, lotion, ointment or rubbing alcohol solution, that is applied transcutaneously.

“Usable amount of medical marijuana for medical use” means six ounces or less of usable marijuana as defined below.

“Usable marijuana” means the dried leaves and flowers of the marijuana plant, and any mixture or preparation of those dried leaves and flowers, including but not limited to tinctures, ointments, and other preparations including medical marijuana oil, but does not include the seeds, stalks, and roots of the plant. It does not include the weight of any non-marijuana ingredients combined with marijuana, such as ingredients added to prepare a topical administration, food, or drink.

“Verification system” means a phone or web-based system established and maintained by the Department that is available to law enforcement personnel and compassion center agents on a twenty-four-hour basis for verification of registry identification cards.

“Written certification” means a document dated and signed by a physician, stating that in the physician’s opinion the patient is likely to receive therapeutic or palliative benefit from the medical use of marijuana to treat or alleviate the patient’s debilitating medical condition or symptoms associated with the debilitating medical condition. A written certification shall be made only in the course of a bona fide physician-patient relationship where the qualifying patient is under the physician’s care for the qualifying patient’s primary care or for the qualifying patient’s debilitating condition after the physician has completed an assessment of the qualifying patient’s medical history and current medical condition. The bona fide physician-patient relationship may not be limited to authorization for the patient to use medical marijuana or consultation for that purpose. The written certification shall specify the qualifying patient’s debilitating medical condition.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

3.0 Qualifying Patient Identification Card Application Requirements

3.1 The Department shall issue a registry identification card to an applicant for the purpose of participating in the medical marijuana program upon the written certification of the applicant’s physician, supporting application documents and a non-refundable application fee with a personal check or a cashier’s check made out “State of Delaware-MMP”. The following information shall be provided in the participant enrollment form submitted to the Department in order for a registry identification card to be obtained and processed.

3.2 An attached original written certification for patient eligibility form shall contain:

3.2.1 The name, address and telephone number of the applicant’s physician;

3.2.2 The physician’s clinical licensure;

3.2.3 The patient applicant’s name and date of birth;

3.2.4 The medical justification for the physician’s certification of the patient’s debilitating medical condition;

3.2.5 The physician’s signature and date;

3.2.6 The name and address of the applicant as they appear on the applicant’s government issued ID card, and date of birth of the applicant;

3.2.7 The name, address and date of birth of the applicant’s primary caregiver(s), if any;

3.2.8 A reasonable xerographic copy of the applicant’s Delaware driver’s license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; State of Delaware issued identification card must be available for inspection/verification;

3.2.9 The length of time the applicant has been under the care of the physician providing the medical provider certification for patient eligibility;

3.2.10 The applicant’s signature and date; and

3.2.11 A signed consent for release of medical information related to the patient’s debilitating medical condition, on a form provided by the medical marijuana program.

3.2.12 A designation of type of card: Adult Patient, Pediatric Patient, Compassionate Use Adult Patient, or Compassionate Use Pediatric Patient.

3.3 If the qualifying patient is under the charge of a Responsible Party as defined in these regulations:

3.3.1 The Responsible Party must be identified on the ~~initial~~ application.

- 3.3.2 If the qualifying patient is of an age where an ID to meet subsections 3.2.6 and 3.2.8 above has not been issued, the Responsible Party's ID shall be used. If the qualifying patient has a government issued ID, information and IDs for both individuals shall meet subsections 3.2.6 and 3.2.8 above.
- 3.3.3 If the patient is under the age of 18, the physician must be a pediatric neurologist, pediatric gastroenterologist, pediatric oncologist, pediatric psychiatrist, developmental pediatrician or pediatric palliative care specialist and certify that:
- 3.3.3.1 The qualifying patient has ~~intractable epilepsy~~ any of the following related to a terminal illness: pain, anxiety or depression; or
- 3.3.3.2 The qualifying patient has intractable epilepsy or seizure disorder;
- 3.3.3.2.3.3.3 The qualifying patient has a chronic or debilitating disease or medical condition where the patient has failed treatment involving 4 ~~one~~ or more of the following symptoms: cachexia or wasting syndrome; intractable nausea; ~~seizures~~; severe, painful and persistent muscle ~~spasms~~; or chronic debilitating migraines and new daily persistent headache that are refractory to conventional treatment and interventions; or
- 3.3.3.4 The qualifying patient has severe debilitating autism.
- 3.3.4 Patients under the age of 18 will have distinctive identifying banner on their patient identification card limiting the patient to marijuana oil purchases only.
- 3.3.5 Responsible Parties for qualifying patients under the age of 18 will be issued an identification card with the same type of 10-digit alphanumeric identifier provided to the minor in question.
- 3.4 The Department shall issue a compassionate use card to an eligible individual who submits all of the following:
- 3.4.1 A signed statement from the patient's physician that includes statements attesting to all of the following:
- 3.4.1.1 The patient has a severe and debilitating condition;
- 3.4.1.2 All current standard care practices and treatments have been exhausted and have been ineffective or the side effects are prohibitive with continued use;
- 3.4.1.3 The physician will re-evaluate and document the efficacy of medical marijuana treatment;
- 3.4.1.4 There are grounds supporting the potential for the patient to benefit from using medical marijuana;
- 3.4.1.5 The treating physician must detail how medical marijuana will be integrated into the patient's comprehensive treatment plan, identifying all wrap-around services including counseling, other medications, or specialty care. The Department will review the comprehensive treatment plan, including the re-evaluation interval.
- 3.4.1.6 If the patient is an adult, a signed statement from the patient acknowledging the patient's informed consent to treatment with medical marijuana and that the patient knows that there is limited or no evidence associated with medical marijuana's effectiveness in treating a condition that is not a debilitating medical condition under this chapter.
- 3.4.1.6.1 If the patient is under 18 years of age, a signed statement from the patient's parent or legal guardian acknowledging the patient's informed consent to treatment with medical marijuana and that the patient's parent or legal guardian knows that there is limited or no evidence associated with medical marijuana's effectiveness in treating a condition that is not a debilitating medical condition under this chapter.

3.4.2 The physician certifying a patient for a compassionate use card will re-evaluate the efficacy of medical marijuana treatment at the following intervals:

3.4.2.1 For substance use disorder diagnoses, re-evaluate after 15 days for the first 90 days, and every 30 days thereafter;

3.4.2.2 For mental health disorder diagnoses, re-evaluate every 30 days;

3.4.2.3 For autoimmune disease diagnoses, re-evaluate every 30 days for the first 90 days, and every 90 days thereafter; and

3.4.2.4 For other conditions, re-evaluate every 30 days, unless otherwise indicated or waived by the Department.

3.4.3 The timeframe for reevaluation begins on the date the card is issued.

3.4.4 The physician certifying a patient for a compassionate use card may require the re-evaluation of the patient at shorter intervals than listed if appropriate.

3.4.5 Updated documentation of the re-evaluations for the compassionate use card must be transmitted to the Department by the certifying practice within five business days of the re-evaluation interval to prevent the compassionate use card from entering a suspension status.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

4.0 Designated Caregiver Registry Identification Card Application Requirements

4.1 The Department shall issue a registry identification card to a primary designated caregiver applicant for the purpose of managing the well-being of one to five qualified patients, including themselves if caregiver is a qualified patient, in response to the requirements of this rule upon the completion and approval of the primary designated caregiver application form, available from the medical marijuana program, and a non-refundable application fee, in the form of a personal check, money order or a cashier's check made out to "~~Division of Public Health, Medical Marijuana Program~~". "State of Delaware-MMP". In order for a registry identification card to be obtained and processed, the following information shall be submitted to the medical marijuana program:

4.1.1 Proof that the applicant is at least ~~(24)~~ 21 years of age unless the person is the parent or legal guardian of a minor who is a qualifying patient;

4.1.2 A reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; State of Delaware issued identification card must be available for inspection/verification.

4.1.3 Written approval by the qualified patient(s) authorizing responsibility for managing the well-being of a qualified patient(s) with respect to the use of marijuana;

4.1.4 The name(s), address(es), telephone number(s) and date of birth of the qualified patient(s);

4.1.5 The name and address of the applicant as they appear on the applicant's government issued ID card, telephone number of the applicant; and

4.1.6 The applicant's signature and date.

4.2 Designated caregiver application requirements:

4.2.1 Criminal history screening requirements:

4.2.1.1 All designated caregiver applicants are required to consent to a nationwide and statewide criminal history screening background check every three years. All applicable application fees associated with the nationwide and statewide criminal history screening background check shall be paid by the designated caregiver applicant.

- 4.2.1.2 Individuals convicted of an excluded felony offense, as described in the definitions Section 2.0, and 16 Del.C. §4902A (7) are prohibited from serving as a designated caregiver. The applicant and qualified patient shall be notified by registered mail of his or her disqualification from being a designated caregiver.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

5.0 Registry Identification Cards

5.1 Department inquiry:

- 5.1.1 The Department may verify information on each application and accompanying documentation by the following methods:

- 5.1.1.1 Contacting each applicant by telephone, mail, or if proof of identity is uncertain, the Department shall require a face-to-face meeting and the production of additional identification materials;
- 5.1.1.2 Contacting the Delaware Division of Professional Regulation to verify that the physician is licensed to practice medicine in Delaware and is in good standing; and
- 5.1.1.3 Contacting the physician to obtain further documentation that the applicant's medical diagnosis and medical condition qualify the applicant for enrollment in the medical use marijuana program.

- 5.1.2 Upon verification of the information contained in an application submitted in response to this subsection, the Department shall approve or deny an application within 45 calendar days of receipt.

- 5.2 Department registry identification card: The Department shall issue a registry identification card within 30 calendar days of approving an application. A registry identification card shall contain a 10-digit alphanumeric identification, maintained by the Department, which identifies the qualified patient or designated caregiver. Unless renewed at an earlier date, suspended or revoked, or if the physician stated in the written certification that the qualifying patient would benefit from marijuana until a specified earlier date, a registry identification card shall be valid for a period of one year from the date of issuance and shall expire at midnight on the day indicated on the registry identification card as the expiration date.

5.3 Supplemental requirement:

- 5.3.1 A registered qualifying patient or registered designated caregiver who possesses a registry identification card shall notify the Department of any of the following within 10 calendar days of the change. An extension shall be granted by the medical marijuana program upon the showing of good cause.

- 5.3.1.1 A change in cardholder's name or address.
- 5.3.1.2 Knowledge of a change that would render the patient no longer qualified to participate in the program, such as a cure of the debilitating condition causing the need for Medical Marijuana.
- 5.3.1.3 Knowledge of a change that renders the patient's physician no longer a qualified "physician" as defined in Section 2.0 of these regulations; and
- 5.3.1.4 Knowledge of a change that renders the patient's caregiver no longer eligible as defined in these regulations.

- 5.3.2 Before a registered qualifying patient changes his or her designated caregiver, the qualifying patient must notify the Department in writing.

- 5.3.3 If a cardholder loses his or her registry identification card, he or she shall notify the Department in writing within 10 days of becoming aware the card has been lost. Upon notification, the Department shall issue a new registry identification card. Unless

documentation in the initial application has changed, the qualified patient or designated caregiver shall not be required to submit a new application.

- 5.3.4 When a cardholder notifies the Department of items listed in subsection 5.3 but remains eligible, the Department shall issue the cardholder a new registry identification card with a new random 10-digit alphanumeric identification number within 10 days of receiving the updated information and the cardholder shall pay a \$20 fee. If the person notifying the Department is a registered qualifying patient, the Department shall also issue his or her registered designated caregiver, if any, a new registry identification card within 10 days of receiving the updated information.
 - 5.3.5 If a registered qualifying patient ceases to be a registered qualifying patient or changes his or her registered designated caregiver, the Department shall promptly notify the designated caregiver by legal process server. The registered designated caregiver's protections under this chapter as to that qualifying patient shall expire 15 days after notification by the Department.
 - 5.3.6 A cardholder who fails to make a notification to the Department that is required by subsection 5.3 is subject to a civil infraction, punishable by a penalty of no more than \$150.00 and is also subject to the immediate revocation of the registry identification card and all lawful privileges provided under the act.
 - 5.3.7 If the registered qualifying patient's certifying physician notifies the Department in writing that either the registered qualifying patient has ceased to suffer from a debilitating medical condition or that the physician no longer believes the patient would receive therapeutic or palliative benefit from the medical use of marijuana, the card shall become null and void. However, the registered qualifying patient shall have 15 days to dispose of the patient's marijuana.
 - 5.3.8 When a registered qualifying pediatric patient attains 18 years of age, the patient may request a new patient card releasing them from the pediatric restrictions. The new patient ID card will be issued at the card replacement cost \$20 and maintain the original expiration date.
- 5.4 Registry identification card application denial: The DHSS Secretary or designee shall deny an application if the applicant fails to provide the information required, if the Department determines that the information provided is false, or if the patient does not have a debilitating medical condition eligible for enrollment in the program, as determined by the DHSS Secretary. A person whose application has been denied shall not reapply for six months from the date of the denial, unless otherwise authorized by the Department, and is prohibited from all lawful privileges provided by this rule and act.
- 5.4.1 The Department shall deny an application or renewal of a qualifying patient's registry identification card if the applicant:
 - 5.4.1.1 Did not provide the required information and materials;
 - 5.4.1.2 Previously had a registry identification card revoked; or
 - 5.4.1.3 Provided false or falsified information.
 - 5.4.2 The Department shall deny an application or renewal for a designated caregiver chosen by a qualifying patient whose registry identification card was granted if:
 - 5.4.2.1 The designated caregiver does not meet the requirements of Section subsection 4.2;
 - 5.4.2.2 The applicant did not provide the information required;
 - 5.4.2.3 The designated caregiver previously had a registry identification card revoked; or
 - 5.4.2.4 The applicant or the designated caregiver provides false or falsified information.

5.4.3 The Department shall notify the qualifying patient who has designated someone to serve as his or her designated caregiver if a registry identification card will not be issued to the designated caregiver.

5.4.4 Denial 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.

5.4.4.1 Denial of an application or renewal for a compassionate use registry identification card is not subject to judicial review.

5.5 Registry identification card renewal application: Each registry identification card issued by the Department is valid in accordance with subsection 5.2. A qualified patient or designated caregiver shall apply for a registry identification card renewal no less than 45 calendar days prior to the expiration date of the existing registry identification card in order to prevent interruption of possession of a valid (unexpired) registry identification card.

5.6 Non-transferable registration of registry identification card: A registry identification card shall not be transferred, by assignment or otherwise, to other persons or locations. Any attempt shall result in the immediate revocation of the registry identification card and all lawful privileges provided by this rule and act.

5.7 Automatic expiration of registry identification card by administrative withdrawal: Upon request the qualified patient or designated caregiver shall discontinue the medical marijuana program by an administrative withdrawal. A qualified patient or designated caregiver that intends to seek an administrative withdrawal shall notify the licensing authority in writing no less than 30 calendar days prior to withdrawal.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

6.0 Addition of Debilitating Medical Conditions

6.1 Any citizen may petition the Department to add conditions or treatments to the list of debilitating medical conditions listed in 16 Del.C. §4902A (3).

6.2 The Department shall not add a condition or treatment to the list of debilitating medical conditions unless it finds that (1) the medical condition or treatment is debilitating and (2) marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition or treatment.

6.3 Contents of the petition: In connection with any petition to add conditions or treatments to the list of debilitating medical conditions listed in 16 Del.C. §4902A (3), a petitioner shall provide the following information to the Department:

6.3.1 The extent to which the condition is generally accepted by the medical community and other experts as a valid, existing debilitating medical condition;

6.3.2 If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition;

6.3.3 The extent to which the condition or treatments cause severe suffering, such as severe or chronic pain or severe nausea or vomiting, or otherwise severely impair the patient's ability to carry on activities of daily living;

6.3.4 The ability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition or treatment;

6.3.5 The extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition or treatment; and

6.3.6 Letters of support from physicians or other licensed health care professionals knowledgeable about the condition or treatment.

6.3.7 The evidence must indicate the intended patient population and whether it is generally accepted for both adult and pediatric use or limited to a particular population.

6.4 Evaluation of a petition

6.4.1 Upon review of materials submitted in response to ~~Section~~ subsection 6.3 above, the Division of Public Health (DPH) shall make a determination as to whether the petition has merit.

6.4.2 A petition will be determined to have merit if it contains all of the material required in ~~Section~~ subsection 6.3 above and the debilitating condition that is the subject of the petition has not been considered through this process in the prior two years, unless significant, generally accepted, scientific discoveries have been made that are substantially likely to reverse the prior decision.

6.4.3 A decision that a petition does not have merit will be made in writing, stating the reason(s) it has been determined not to have merit and that it is the final decision, subject to judicial review.

6.4.4 A final decision on a petition determined to have merit will be made within 180 days of receipt of the petition in response to the following process.

6.4.4.1 DPH will post the complete petition on the Department's website for a 60-day public comment period.

6.4.4.2 DPH will post notice of a public hearing no fewer than 10 days prior to the public hearing

6.4.4.3 DPH will hold a public hearing within the 60-day public comment period.

6.4.4.4 After the public hearing and closure of the 60-day public comment period, DPH will review the petition and comments. During this review, DPH may conduct additional research, including consultation with additional experts.

6.4.4.5 DPH will draft a written decision on whether to grant the petition and add the debilitating medical condition for review and ultimate decision by the Department Secretary. This written decision will be detailed enough to provide the specific grounds and references to support the decision. The Department Secretary will issue the final decision on the petition.

6.4.4.6 If the petition to add a debilitating medical condition is granted, draft regulations adding the condition to Section 2.0 will be drafted and published in response to the Administrative Procedures Act Process.

6.5 The approval or denial of any petition is a final decision of the Department subject to judicial review. Jurisdiction and venue are vested in the Superior Court.

17 DE Reg. 738 (01/01/14)

7.0 Registration and operation of compassion centers

7.1 Requirements for operation of a compassion center.

7.1.1 General requirements

7.1.1.1 No person shall operate a compassion center without a Department-issued certificate of registration. The application and renewal requirements for a certificate of registration are in subsections 7.6 and 7.10 of these regulations.

7.1.1.2 A compassion center shall be operated on a not-for-profit basis. A compassion center need not be recognized as a tax-exempt organization by the Internal Revenue Service and is not required to incorporate in response to Title 8; however, a compassion center shall maintain appropriate documentation of its not-for-profit

status, and such documentation shall be available for inspection in response to subsection 7.2.7 of these regulations.

7.1.1.3 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 registered designated caregiver.

7.1.1.4 Use of pesticides is prohibited:

7.1.1.4.1 There are no pesticides authorized for use on marijuana; as such, a compassion center shall not apply pesticides in the cultivation of marijuana.

7.1.1.4.2 Prohibited pesticides include but are not limited to the following:

7.1.1.4.2.1 Organochlorines;

7.1.1.4.2.2 Organophosphates;

7.1.1.4.2.3 Caramates; and

7.1.1.4.2.4 Insecticidal, fungicidal or growth regulatory compounds.

7.1.1.5 Packaging of medical marijuana

7.1.1.5.1 All marijuana products shall be in tamper resistant packaging.

7.1.1.6 Labeling of medical marijuana

7.1.1.6.1 All medical marijuana product labels will contain these minimum requirements:

7.1.1.6.1.1 Name of the patient, patient number and date of sale.

7.1.1.6.1.2 Name of the strain, cannabinoid profile, and quantity of the medical marijuana dispensed.

7.1.1.6.1.3 A statement providing that "this product is for medical use only, not for resale" and indicating the medical marijuana is free of contaminants.

7.1.1.7 Labeling shall include recommendations and instructions for use, including daytime or nighttime use and dosing.

[7.1.1.8 Online advertising and marketing are permitted subject to the limitations listed in 16 De.C. Ch. 49A.]

7.1.2 Location of a compassion center: A compassion center shall not be located within ~~4,000~~ 500 feet of the property line of a preexisting public or private school.

7.1.3 Bylaws

7.1.3.1 A compassion center shall, as part of its initial application, provide to the Department a true, correct, and current copy of its bylaws, and shall maintain such bylaws in accordance with the Act and these regulations.

7.1.3.2 The bylaws of a compassion center shall include at a minimum:

7.1.3.2.1 The ownership structure of the compassion center;

7.1.3.2.2 The composition of the board of directors; and

7.1.3.2.3 Such provisions relative to the disposition of revenues to establish and maintain the not-for-profit character of the compassion center.

7.1.4 Maintenance of accurate books and records

7.1.4.1 Registered compassion centers shall keep detailed financial reports of proceeds and expenses.

7.1.4.2 Registered compassion centers shall maintain all inventory, sales and financial records in accordance with generally accepted accounting principles ("GAAP").

7.1.4.3 An annual financial audit must be conducted by an independent audit firm and submitted to the Department with the compassion center's annual report.

7.1.4.4 The Department or an audit firm contracted by the Department shall at all times have access to all books and records kept by any compassion center.

7.1.5 Disposal of Unusable Marijuana

7.1.5.1 The medical marijuana inventory system must be updated immediately when a plant is pulled out of inventory for destruction, starting the 72-hour destruction quarantine. The plant number, date and reason must be recorded. This information must be available for auditing by the department.

7.1.5.2 Medical marijuana waste must be stored, secured, and managed in accordance with these regulations and approved operations manual procedures. Medical marijuana waste must be made unusable prior to the waste leaving a registered facility.

7.1.5.3 Liquid waste from medical marijuana facilities shall be disposed of in compliance with the applicable County statutes and regulations including the International Plumbing Code.

7.1.5.4 Medical marijuana waste shall be rendered unusable through grinding and incorporating the medical marijuana waste with non-consumable, solid wastes listed below such that the resulting mixture is at least fifty percent non-marijuana waste:

7.1.5.4.1 Paper waste,

7.1.5.4.2 Plastic waste,

7.1.5.4.3 Cardboard waste,

7.1.5.4.4 Food waste,

7.1.5.4.5 Soil,

7.1.5.4.6 Grease or other compostable oil waste,

7.1.5.4.7 Other wastes approved by the Division of Public Health that will render the medical marijuana waste unusable.

7.1.5.5 After the medical marijuana waste is made unusable, ~~then~~ the solid waste shall be:

7.1.5.5.1 Disposed of as a solid waste at a solid waste site and disposal facility that has a Certificate of Designation from the local governing body,

7.1.5.5.2 Deposited at a compost facility that has a Certificate of Designation from the Department of Natural Resources and Environmental Control (DNREC), or

7.1.5.5.3 Composted on-site at a facility owned by the generator and operated in compliance with applicable County statutes and regulations.

7.2 Security requirements: A 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. Such measures shall include the following:

7.2.1 Exterior of premises: With respect to the exterior of a compassion center:

7.2.1.1 Access from outside the premises shall be kept to a minimum and be well controlled.

7.2.1.2 The outside perimeter of the premises shall be well lighted.

7.2.1.3 Entry into any area(s) where marijuana is held shall be limited to authorized personnel.

7.2.2 Alarm system:

- 7.2.2.1 A 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:
 - 7.2.2.1.1 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;
 - 7.2.2.1.2 Immediate automatic or electronic notification to local or municipal public safety personnel of a loss of electrical support backup system; and
 - 7.2.2.1.3 When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- 7.2.2.2 A compassion center shall conduct a maintenance inspection/test of the alarm system for each authorized location at intervals not to exceed 30 days from the previous inspection/test. A compassion center shall promptly make all necessary repairs to ensure the proper operation of the alarm system.
- 7.2.2.3 In the event of a failure of the security system, due to loss of electrical support or mechanical malfunction, that is expected to exceed an eight-hour period, a compassion center shall:
 - 7.2.2.3.1 Within 24 hours of discovery of the event, notify the Department by telephone; and
 - 7.2.2.3.2 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.
- 7.2.2.4 A compassion center shall maintain documentation in an auditable form for a period of at least 24 months after the event for:
 - 7.2.2.4.1 All maintenance inspections/tests conducted in response to subsection 7.2.2.2 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);
 - 7.2.2.4.2 Any alarm activation or other event which requires response by public safety personnel; and
 - 7.2.2.4.3 Any unauthorized breach(es) of security.
- 7.2.3 Video surveillance: A compassion center shall provide an appropriate video surveillance system that includes the following areas and access to recorded surveillance.
 - 7.2.3.1 Video surveillance should record access areas, customer service areas, growing areas, and anywhere the marijuana is handled, to include processing and packaging areas.
 - 7.2.3.2 Video footage will be digitally recorded and held for 90 days for routine footage or up to 36 months if video contains information of significance.
 - 7.2.3.3 A compassion center shall provide the Department with access to the video 24-hours a day, seven days a week through a secure internet connection.
- 7.2.4 Inventory controls
 - 7.2.4.1 Coding and computer interface: A compassion center shall:
 - 7.2.4.1.1 Employ a bar coding inventory control system to track batch, strain and amounts of marijuana in inventory and amounts sold, to include patients' card

registration numbers. All plants, regardless of stage of growth must have the strain and barcode label affixed to the plant or container for immature plants.

7.2.4.1.2 Be responsible for developing and hosting a secure computer interface to connect with DEC3S.

7.2.4.2 Storage of marijuana: A compassion center shall ensure that usable marijuana is stored in a locked area with adequate security. For purpose of these regulations "adequate security," at a minimum, should be assessed, established and maintained based on:

7.2.4.2.1 The quantity of usable marijuana that will be kept on hand at each authorized location;

7.2.4.2.2 The compassion center's inventory system for tracking and dispensing usable marijuana;

7.2.4.2.3 The number of principal officers, board members, agents, volunteers or employees who have or could have access to the usable marijuana;

7.2.4.2.4 The geographic location of the compassion center (i.e.: high-crime or low-crime area);

7.2.4.2.5 The scope and sustainability of the alarm system; and

7.2.4.2.6 The root cause analysis of any breach of security and/or inventory discrepancy for usable marijuana at that location.

7.2.5 Comprehensive and monthly inventories

7.2.5.1 A compassion center shall:

7.2.5.1.1 Notify the Department and local law enforcement within 24 hours any time there is a suspected loss of marijuana and shall cooperate fully with any investigation into the suspected loss.

7.2.5.1.2 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.

7.2.5.1.3 Conduct the comprehensive inventory required by subsection 7.2.5 of these regulations at intervals not to exceed 24 months from the date of the previous comprehensive inventory.

7.2.5.1.4 Conduct a monthly inventory review of stored, usable marijuana.

7.2.5.2 If an inventory conducted in response to subsection 7.2.5.1 of these regulations identifies a discrepancy, the Department and appropriate local law enforcement authorities will be notified of the discrepancy within 24 hours of discovery of the event.

7.2.5.3 Documentation of all inventories conducted in response to Section subsection 7.2.5.1 of these regulations 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(s) who conducted the inventory.

7.2.6 Maximum amount of compassion center inventory. A registered compassion center:

7.2.6.1 Shall grow an amount of marijuana sufficient to meet the qualifying patient population demands as determined by the Division.

7.2.6.2 Shall possess no more than 1,000 pounds of usable marijuana regardless of formulation unless a variance is approved by the OMM Director.

7.2.6.3 May not purchase usable marijuana or mature marijuana plants from any person other than another registered compassion center.

7.2.7 Compassion centers are subject to random inspection by the Department's Office of Medical Marijuana.

7.2.7.1 During an inspection, the Department may review the compassion center's confidential records, including its financial and dispensing records, which may track transactions according to qualifying patients' registry identification numbers to protect their confidentiality and its security protocols.

7.2.7.2 The Department will review the facility to ensure compliance with Section subsections 7.2 and Section 7.3 of these regulations.

7.2.7.3 The Department will inspect the facility for the presence of pesticides listed in Section subsection 7.1.1.4, fungus and molds.

7.2.7.4 The Department may collect samples for random quality sampling by a laboratory selected by the Department.

7.2.7.4.1 The compassion center will be invoiced for the cost of random sampling testing.

7.2.7.5 The Department will review the facility for compliance with applicable federal, state and local standards.

7.2.7.6 Hazard Chemical Storage

7.2.7.6.1 The Department will inspect the facility for the presence of butane, hexane, pentane, and propane; or extraction techniques that may produce hazardous conditions. Any form of alkane or petroleum hydrocarbon extraction is unauthorized in Delaware.

7.2.8 Dispensing marijuana

7.2.8.1 Design and security features of medical marijuana containers

7.2.8.1.1 Marijuana shall be dispensed in sealed, tamperproof containers clearly identified as having been issued by the compassion center and that meet the requirements in subsection 7.3.10 of these regulations.

7.2.8.1.2 Patients and designated caregivers should receive written instruction that the marijuana shall remain in this container when it is not being prepared for ingestion or being ingested.

7.2.8.2 No marijuana shall be dispensed unless or until the patient or caregiver identification card has been verified as valid in the computer system identified in subsection 7.2.4.1.2 of these regulations.

7.2.8.3 Maximum amount of usable marijuana to be dispensed.

7.2.8.3.1 A compassion center or principal officer, board member, agent, volunteer or employee of a compassion center

7.2.8.3.1.1 Shall not dispense, deliver or otherwise transfer marijuana to a person other than a qualifying patient or to such patient's other designated caregiver.

7.2.8.3.1.2 Shall not dispense more than three ounces of usable marijuana to a qualifying patient directly or through a qualifying patient's caregiver during a 14-day period.

7.2.8.3.1.3 Shall not dispense an amount of usable marijuana to a qualifying patient or a qualifying patient's 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.

7.2.8.3.1.4 Shall dispense pediatric medical marijuana oils as described in Section 2.0 of these regulations to qualified patients under the age of 18 years.

Patients under the age of 18 are restricted from purchasing products other than pediatric medical marijuana oil.

7.2.8.3.1.4.1 Any materials used in production of marijuana products will have Generally Recognized As Safe (GRAS) documentation and used as directed.

7.2.8.3.2 In addition to any other penalties that may be applicable under the Act or these regulations, any person found to have violated subsection 7.2.8 of these regulations is not eligible to be an employee, agent, principal officer or board member of any compassion center and such person's registry identification card shall be immediately revoked.

7.3 Operations manual. A compassion center shall, as part of its initial application, provide to the Department a true, correct and current copy of its operating manual, and shall maintain such operating manual in accordance with the Act and these regulations. Such manual shall include, as a minimum, the following requirements:

7.3.1 Procedures for the oversight of the compassion center including, but not limited to, documentation of the reporting and management structure of the compassion center;

7.3.2 Procedures for safely dispensing medical marijuana to registered qualifying patients or their registered designated caregiver;

7.3.3 Procedures to ensure accurate record keeping, including protocols to ensure that quantities purchased do not suggest re-distribution;

7.3.4 Employee security policies;

7.3.5 Safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

7.3.6 Personal safety and crime prevention techniques;

7.3.7 A job description or employment contract developed for all employees and a volunteer agreement for all volunteers which includes duties, responsibilities, authority, qualification and supervision;

7.3.8 The compassion center's alcohol and drug free work place policy;

7.3.9 A description of the compassion center's outreach activities to registered qualifying patients or their registered designated caregiver, which shall as a minimum include:

7.3.9.1 Providing each new registered patient who visits the compassion center with frequently asked questions, designed by the Department, that explain the limitations on the right to use medical marijuana under state law;

7.3.9.2 Ingestion options of usable marijuana provided by the compassion center;

7.3.9.3 Safe smoking techniques that shall be provided to registered qualifying patients; and

7.3.9.4 Potential side effects and how this information shall be communicated.

7.3.10 A description of the packaging of the useable marijuana that the compassion center shall be utilizing which shall, as a minimum, include:

7.3.10.1 The name of the strain, batch, and quantity;

7.3.10.2 The statement "this product is for medical use only, not for resale;" and

7.3.10.3 Details indicating (1) the medical marijuana is free of contaminants and (2) the levels of active ingredients in the product.

7.3.11 A description of the documentation that will accompany a registered compassion center agent when transporting marijuana on behalf of the registered compassion center. In response to 16 Del.C. §4918A(b), the documentation must specify, at least, the amount of marijuana being transported, the date the marijuana is being transported, the registry

identification number of the registered compassion center, and a contact number to verify that the marijuana is being transported on behalf of the registered compassion center.

7.3.12 Detailed procedures regarding the random sampling of medical marijuana. OMM staff will supervise selection of samples from the curing vessels with the Compassion Center staff.

7.3.12.1 Compassion Center staff will prepare additional barcode labels and tamper-proof containers for each plant scheduled to be sampled and develop a transportation manifest, initiating the chain of custody process for the batch of plants being tested;

7.3.12.2 The Compassion Centers will not sell or prepare products from the batch being tested until the Safety and Compliance Center enter the values into the DEC3S program, releasing the material for use or sale;

7.3.12.3 Any concentrates or other infused products must be sent to the Safety and Compliance Center for testing, using the manifest process listed above before the batch being tested is cleared for sale;

7.3.12.4 Sample results will be loaded into the DEC3S system by the Safety and Compliance Center allowing Compassion Centers to sell the material or incorporate it into other products; and

7.3.12.5 Compassion Centers will coordinate directly with the Safety and Compliance Center on invoicing and payment for testing services.

7.4 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 initial appointment, shall receive, as a minimum, training in the following:

7.4.1 Professional conduct, ethics, and state and federal laws regarding patient confidentiality;

7.4.2 Informational developments in the field of medical use of marijuana;

7.4.3 The proper use of security measures and controls that have been adopted; and

7.4.4 Specific procedural instructions for responding to an emergency, including robbery or violent accident.

7.5 Personnel

7.5.1 Records: Each compassion center shall maintain

7.5.1.1 A personnel record for each employee, agent or volunteer for a period of at least six months after termination of the individual's affiliation with the compassion center. The record shall include, as a minimum, the following:

7.5.1.1.1 An application for employment or to volunteer;

7.5.1.1.2 A record of any disciplinary action taken;

7.5.1.1.3 Documentation of all required training. Documentation shall include a signed statement from the individual indicating the date, time and place of said training and topics discussed, including the name and title of presenters;

7.5.1.2 A record of the source of any funds that will be used to open or maintain the compassion center, including the name, address, and date of birth of any investor contributing more than \$5,000; and

7.5.1.3 A record of any instances in which a business or not-for-profit that any of the prospective board members managed or served on the board of was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding.

7.5.2 Registry identification cards and background checks for principal officers, board members, agents, volunteers or employees of a compassion center.

- 7.5.2.1 In response to the requirements of this rule, and upon the approval of the submitted application, the Department shall issue a registry photo identification card to each principal officer, board member, agent, volunteer or employee of a compassion center who is associated with the compassion center and meets the requirements under these regulations. In order for a registry identification card to be obtained, the following items shall be submitted to the medical marijuana program.
- 7.5.2.1.1 Documentation verifying that the applicant is at least 21 years of age;
 - 7.5.2.1.2 A reasonable xerographic copy of the applicant's Delaware license or comparable State of Delaware or federal issued photo identification card verifying Delaware residence; identification card must be available for inspection/verification;
 - 7.5.2.1.3 A written and signed statement from an officer or executive staff member of the compassion center stating that the applicant is associated with the compassion center and in what capacity;
 - 7.5.2.1.4 The name, address and telephone number of the applicant;
 - 7.5.2.1.5 The name, address and telephone number of the compassion center with which the agent is associated;
 - 7.5.2.1.6 The applicant's signature and date;
 - 7.5.2.1.7 A non-refundable, non-returnable application or renewal fee of \$125 in the form of a check made out to "State of Delaware-MMP".
- 7.5.2.2 In response to 16 Del.C. §§4914A and 4915A, each principal officer, board member, agent, volunteer or employee of a compassion center shall consent to a full nationwide and statewide criminal history screening background check.
- 7.5.2.2.1 Each applicant shall submit a full State Bureau of Identification (SBI) criminal history screening check and a full nationwide criminal history screening check to demonstrate compliance with the eligibility requirements of these regulations.
 - 7.5.2.2.2 All applicable fees associated with the required criminal history screening background checks shall be paid by the compassion center or the applicant.
 - 7.5.2.2.3 In response to 16 Del.C. §4919A(n), individuals convicted of an excluded felony offense, as described in the definitions Section 2.0, and 16 Del.C. §4902A (7), within five years from the date of application, are prohibited from being a compassion center agent.
- 7.5.2.3 The Department may verify information on each application and the accompanying documentation as set forth in subsection 5.1 of these regulations.
- 7.5.2.4 The Department shall notify the compassion center in writing of the purpose for denying the registry identification card in accordance with § 4918A of the Act. The DHSS Secretary or designee shall deny an application if the applicant fails to provide the information required or if the Department determines that the information provided is false. Denial 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.
- 7.5.2.5 The Department shall issue each principal officer, board member, agent, volunteer or employee of a compassion center a registry identification card within 30 days of receipt of the information required by subsections 7.5.2.1 and 7.5.2.2. The registry identification card shall contain such information as set forth in §4911A of the Act and subsection 7.5.2 of these regulations.
- 7.5.2.6 Each compassion center shall notify the Department in writing within ten days of when a principal officer, board member, agent, volunteer or employee ceases to

work at the compassion center. The individual's registry identification card shall be deemed null and void and the individual shall be liable for any other penalties that may apply to the individual's nonmedical use of marijuana.

- 7.5.3 Expiration date of registry identification cards. The registry identification card of a principal officer, board member, agent, volunteer or employee shall expire one year after its issuance, or upon the expiration of the compassion center's registration certificate, whichever comes first.

7.5.3.1 Every principal officer, board member, agent, volunteer or employee of a compassion center must have a valid, unexpired registry identification card issued by the Office of Medical Marijuana.

- 7.6 Application for operation of a compassion center. Applicants shall only be accepted during an open application period announced by the Department and shall include the following items:

7.6.1 A non-refundable application fee, made payable to the Division of Public Health, Medical Marijuana Program, in the amount of \$5,000;

7.6.2 The proposed legal name, articles of incorporation and bylaws of the compassion center;

7.6.3 The proposed physical address(es) of the compassion center, including any additional address(es) to be used for the secure cultivation of medical marijuana, and with the following details:

7.6.3.1 If precise addresses are known, evidence of compliance to the following rules shall be included:

7.6.3.1.1 Compliance to the local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana;

7.6.3.1.2 Evidence that all of the physical addresses identified in this subsection are not located within 500 feet of a property line of a preexisting public or private school;

7.6.3.2 If precise addresses have not been determined, identification of the general location(s) where it would be sited, and when it would be established;

7.6.4 A description of the enclosed, locked facility, meeting all requirements of subsection 7.2 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;

7.6.5 Evidence of the compassion center's not-for-profit status, which can be:

7.6.5.1 Documentation of recognition as a tax-exempt organization by the United States Internal Revenue Service; or

7.6.5.2 Other written materials which will allow the Department to determine the compassion center's ability to comply with the revenue criteria contained in 16 Del.C. §4914A and §4915A.

7.6.6 The name, address, and date of birth of each principal officer and board member of the compassion center;

7.6.7 A description of proposed security and safety measures which demonstrate compliance with subsection 7.2 of these regulations;

7.6.8 A draft operations manual which demonstrates compliance with subsection 7.3 of these regulations;

7.6.9 An example of the design and security features of medical marijuana containers which demonstrates compliance with subsection 7.2.8 of these regulations;

7.6.10 A list of all persons or business entities having direct or indirect authority over the management or policies of the compassion center;

- 7.6.11 A list of all persons or business entities having 5.0% 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;
- 7.6.12 The identities of all creditors holding a security interest in the premises, if any.
- 7.7 Complete application required. Only applications which the Department has determined to be complete (i.e. adequately addresses all requirements in these regulations and 16 Del.C. §§4914A and 4915A) shall be eligible for review in response to § subsection 7.8 of these regulations.
- 7.8 Compassion center application review criteria. The Department shall evaluate applications for a compassion center registration certificate using an impartial and numerically scored competitive bidding process developed by the Department in accordance with 16 Del.C. §4914A(b) and these regulations. The Department shall consider the following criteria:
 - 7.8.1 Documentation of not-for-profit status, consistent with § subsection 7.6.5 of these regulations;
 - 7.8.2 The suitability of the proposed location or locations, including but not limited to compliance with any local zoning laws and the geographic convenience to patients from throughout the State of Delaware to compassion centers if the applicant were approved;
 - 7.8.3 The principal officer and board members' character and relevant experience, including any training or professional licensing related to medicine, pharmaceuticals, natural treatments, botany, or marijuana cultivation and preparation and their experience running business or not-for-profit entities;
 - 7.8.4 The proposed compassion center's plan for operations and services, including its staffing and training plans, whether it has sufficient capital to operate, and its ability to provide an adequate supply and variety of medical marijuana and medical marijuana-based products to the registered patients in the State;
 - 7.8.5 The sufficiency of the applicant's plans for record keeping;
 - 7.8.6 The sufficiency of the applicant's plans for safety, security, and the prevention of diversion, including proposed locations and security devices employed;
 - 7.8.7 The applicant's plan for making medical marijuana available on an affordable basis to registered qualifying patients enrolled in Medicaid or receiving Supplemental Security Income or Social Security Disability Insurance;
 - 7.8.8 The applicant's plan for safe and accurate packaging and labeling of medical marijuana, which shall include, without limitations, these minimum requirements for packaging and labeling:
 - 7.8.8.1 The name of the strain, batch, and quantity of the medical marijuana;
 - 7.8.8.2 A statement providing that "this product is for medical use only, not for resale";
 - 7.8.8.3 Details indicating the medical marijuana is free of contaminants;
 - 7.8.8.4 Details indicating the levels of active ingredients in the product;
 - 7.8.9 The applicant's ability to grow marijuana without use of pesticides.
- 7.9 Issuance of a registration certificate authorizing operation of a compassion center. When an applicant to operate a compassion center is notified that the Department has approved its application, it shall submit the following additional items to the Department before the registration certificate authorizing operation of a compassion center will be issued
 - 7.9.1 A certification fee, made payable to "State of Delaware-MMP" in the amount of \$40,000;
 - 7.9.2 The legal name, articles of incorporation, and bylaws of the compassion center;
 - 7.9.3 The physical address of the compassion center and any additional address(es) to be used for the secure cultivation of marijuana, including:

- 7.9.3.1 Evidence demonstrating the following:
 - 7.9.3.1.1 Compliance with all local zoning laws for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana; and
 - 7.9.3.1.2 That none of the physical addresses identified in subsection 7.9.3 of these regulations are located within 500 feet of the property line of preexisting public or private schools;
 - 7.9.3.2 It is not necessary to resubmit any information provided in response to subsection 7.6.3.1 of these regulations unless there has been a change in that information;
 - 7.9.4 Any updates to previously submitted information including, but not limited to, information about officers, principals, board members, agents, employees, and compliance with subsections 7.2 and 7.3 of these regulations;
 - 7.9.5 A current certificate of occupancy, or equivalent document, to demonstrate compliance with the provisions of the State Fire Code for each physical address to be utilized as a compassion center or for the secure cultivation of medical marijuana.
- 7.10 Expiration, termination, or renewal of a registration certificate authorizing operation of a compassion center.
- 7.10.1 Expiration: A compassion center's registration shall expire two years after its registration certificate is issued. The compassion center may submit a renewal application at any time beginning 90 days prior to the expiration of its registration certificate. Such renewal application must be submitted a minimum of 30 days prior to the expiration of its registration certificate to avoid suspension of the certificate.
 - 7.10.2 Renewal. The Department shall grant a compassion center's renewal application within 30 days of its submission if the following conditions are all satisfied:
 - 7.10.2.1 The compassion center submits materials required under subsection 7.9 of these regulations, including a summary annual report with financial audit attached, a comprehensive inventory with a cover letter and the \$40,000 fee, which shall be refunded if the renewal application is rejected;
 - 7.10.2.2 The Department has not ever suspended the compassion center's registration for violations of the Act or these regulations;
 - 7.10.2.3 Inspections conducted pursuant to the Act and these regulations do not raise any serious concerns about the continued operation of the registered compassion center applying for renewal; and
 - 7.10.2.4 The applicant continues to meet all of the requirements for the operation of a compassion center as set forth in the Act and in these regulations.
 - 7.10.3 Suspension: The Department will suspend a registration certificate authorizing the operation of a compassion center, with or without notice, for any violation of an applicable law or regulation.
 - 7.10.4 Termination: Upon receipt of written notice that a registration certificate has been terminated, the compassion center has 30 business days to request, in writing, a hearing, for the purpose of review of such action. The hearing process shall follow the procedures in subsections 9.4 through 9.5.10 of these regulations:
 - 7.10.4.1 A written decision will be issued by the Department within 30 days of the completion of the hearing. The decision will lift the suspension or terminate a registration certificate. The written decision will state with specificity the reasons for the decision.
 - 7.10.4.2 The termination of a registration certificate is a final decision of the Department, subject to judicial review. Jurisdiction and venue are vested in the Superior Court.
- 7.11 Non-transferable registration certificate authorizing operation of a compassion center.

- 7.11.1 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 or more of the following situations occur:
- 7.11.1.1 A change in ownership of the compassion center;
 - 7.11.1.2 A change in one or more authorized physical locations; or
 - 7.11.1.3 The compassion center discontinues its operation.
- 7.11.2 A compassion center shall provide the Department with a written notice of any change described in subsection 7.11 of these regulations at least 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.
- 7.11.3 Transactions which usually do not constitute a change of ownership include the following:
- 7.11.3.1 Changes in the membership of the board of directors or board of trustees; or
 - 7.11.3.2 Two or more legal entities merge and the entity to whom the registration certificate authorizing operation of a compassion center was issued survives.
- 7.11.4 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.

17 DE Reg. 738 (01/01/14)

19 DE Reg. 409 (11/01/15)

8.0 Registration and Operation of Safety Compliance Facilities

8.1 General Requirements for Operation of a Safety Compliance Facility

8.1.1 A Safety Compliance Facility may only operate if they have been issued a valid registration certificate from the Department.

8.1.2 A Safety Compliance Facility must be operated in accordance with the International Organization for Standardization 17025 (ISO 17025) standards as confirmed by accreditation by a third party accrediting body such as American Association for Laboratory Accreditation (A2LA) or ANSI-ASQ National Accreditation Board (ACLASS); or Certified under the Clinical Laboratory Improvement Act (CLIA) or a qualified auditing organization using ISO 17025 criteria approved by the Department.

8.2 Security Requirements

8.2.1 A Safety Compliance Facility shall implement appropriate security and safety measures to deter and prevent the unauthorized entrance into areas containing marijuana and the theft of marijuana. Such measures shall include the following:

8.2.1.1 Exterior of premises

8.2.1.1.1 With respect to the exterior of a Safety Compliance Facility:

8.2.1.1.1.1 Access from outside the premises shall be kept to a minimum and be well controlled;

8.2.1.1.1.2 The outside perimeter of the premises shall be well-lit; and

8.2.1.1.1.3 Entry into any area(s) where marijuana is held shall be limited to authorized personnel.

8.2.1.2 Alarm system

8.2.1.2.1 A Safety Compliance Facility shall have a fully operational security alarm system that will provide suitable protection against theft and diversion. For the purpose of these regulations, a fully operational security alarm system shall include:

8.2.1.2.1.1 Immediate automatic or electronic notification to alert local or municipal law enforcement agencies of an unauthorized breach of security at the Safety Compliance Facility or at any other authorized physical address;

8.2.1.2.1.2 Immediate automatic or electronic notification to local or municipal public safety personnel of a loss of electrical support backup system; and

8.2.1.2.1.3 When appropriate, the security system shall provide protection against tampering with computers or electronic records done to conceal theft or diversion.

8.2.1.2.2 A Safety Compliance Facility shall conduct a maintenance inspection/test of the alarm system for each authorized location at intervals not to exceed 30 days from the previous inspection/test. A Safety Compliance Facility shall promptly make all necessary repairs to ensure the proper operation of the alarm system.

8.2.1.2.3 In the event of a failure of the security system, due to loss of electrical support or mechanical malfunction, that is expected to exceed an eight-hour period, a Safety Compliance Facility shall:

8.2.1.2.3.1 Within 24 hours of discovery of the event, notify the Department by telephone; and

8.2.1.2.3.2 Provide alternative security measures approved by the Department or close the authorized physical address(es) affected by the failure/malfunction until the security alarm system has been restored to full operation.

8.2.1.2.4 A Safety Compliance Facility shall maintain documentation in an auditable form for a period of at least 24 months after the event for:

8.2.1.2.4.1 All maintenance inspections/tests conducted in response to subsection 8.2.1.2.4 of these regulations, and any servicing, modification or upgrade performed on the security alarm system. The record shall include, at 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);

8.2.1.2.4.2 Any alarm activation or other event which requires response by public safety personnel; and

8.2.1.2.4.3 Any unauthorized breach(es) of security.

8.2.1.3 Video surveillance

8.2.1.3.1 A Safety Compliance Facility shall provide an appropriate video surveillance system that includes the following areas and access to recorded surveillance.

8.2.1.3.1.1 Video surveillance should record access areas and anywhere the marijuana is handled;

8.2.1.3.1.2 Video footage will be digitally recorded and held for an appropriate time period consistent with the Division of Public Health's Records Retention Policy; and

8.2.1.3.1.3 A Safety Compliance Facility shall provide the Department with access to the video 24-hours a day, seven days a week through a secure internet connection.

8.2.1.4 Inventory controls

8.2.1.4.1 Coding and computer interface

8.2.1.4.1.1 A Safety Compliance Facility shall employ a bar coding inventory control system to track the source, strain, batch and weight of marijuana sample in inventory.

8.2.1.4.2 Storage of marijuana

8.2.1.4.2.1 A Safety Compliance Facility shall ensure that marijuana is stored in a locked area with adequate security. For purpose of these regulations "adequate security," at a minimum, should be assessed, established and maintained based on:

8.2.1.4.2.1.1 The quantity of marijuana present;

8.2.1.4.2.1.2 The geographic location of the Safety Compliance Facility (i.e.: high-crime or low-crime area); and

8.2.1.4.2.1.3 The scope and sustainability of the alarm system.

8.3 Operations Manual

8.3.1 A Safety Compliance Facility shall, as part of its initial application, provide to the Department a true, correct and current copy of its operations manual, and shall maintain such operations manual in accordance with the Act and these regulations. Such manual shall include, at a minimum, the following requirements:

8.3.1.1 Procedures for the oversight of the Safety Compliance Facility including, but not limited to, documentation of the reporting and management structure of the Safety Compliance Facility;

8.3.1.2 Procedures to ensure accurate record keeping;

8.3.1.3 Employee security policies;

8.3.1.4 Safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

8.3.1.5 Crime prevention techniques;

8.3.1.6 A job description or employment contract developed for all employees which includes duties, responsibilities, authority, qualification and supervision;

8.3.1.7 The Safety Compliance Facility's alcohol and drug free work place policy;

8.3.1.8 A description of the documentation that will accompany a registered Safety Compliance Facility agent when transporting marijuana on behalf of the registered Safety Compliance Facility. As required by 16 Del.C. §4918A(b), the documentation must specify, at least, the amount of marijuana being transported, the date the marijuana is being transported, the registry identification number of the registered Safety Compliance Facility, and a contact number to verify that the marijuana is being transported on behalf of the registered Safety Compliance Facility;

8.3.1.9 Detailed procedures regarding the testing of medical marijuana. As part of its initial application, a Safety Compliance Facility shall provide to the Department detailed procedures regarding the testing of medical marijuana, and shall adhere to such procedures in connection with the operation of the Safety Compliance Facility;

8.3.1.9.1 Each batch of medical marijuana harvested by a compassion center shall be tested in accordance with this regulation.

8.3.1.10 Such procedures shall include a description of how the marijuana will be tested including:

8.3.1.10.1 What tests are conducted;

8.3.1.10.2 What testing procedures are used;

8.3.1.10.3 How results are loaded into DEC3S;

8.3.1.10.4 How disposal of samples are tracked;

8.3.1.10.5 The selection process; and

8.3.1.10.6 The number of samples tested.

8.3.1.11 What equipment will be used to test and report on including:

8.3.1.11.1 Potency and cannabinoid profile;

8.3.1.11.2 Contaminates including mold, mildew and organic material;

8.3.1.11.3 Plant growth regulators;

8.3.1.11.4 Pesticides;

8.3.1.11.5 Microbiological contaminants and mycotoxins; and

8.3.1.11.6 Residual solvents.

8.3.1.12 What levels or combination of contaminants mandate elimination of a batch.

8.4 Required Training

8.4.1 Each Safety Compliance Facility 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 and agent training needs. Each employee or agent at the time of initial appointment, shall receive, as a minimum, training in the following:

8.4.1.1 Professional conduct, ethics, and state and federal laws;

8.4.1.2 The proper use of security measures and controls that have been adopted; and

8.4.1.3 Specific procedural instructions for responding to an emergency, including robbery or an accident resulting in injury, fire or damage to critical equipment.

8.5 Personnel Records

8.5.1 Each Safety Compliance Facility shall maintain a personnel record for each employee or agent for a period of at least six months after termination of the individual's affiliation with the Safety Compliance Facility. The record shall include, as a minimum, the following:

8.5.1.1 An application for employment or to volunteer;

8.5.1.2 A record of any disciplinary action taken;

8.5.1.3 Documentation of all required training. Documentation shall include a signed statement from the individual indicating the date, time and place of said training and topics discussed, including the name and title of presenters.

8.6 Application for Operation of a Safety Compliance Facility

8.6.1 A Safety Compliance Facility may only operate if they have been issued a valid registration certificate from the Department. When applying for a Safety Compliance Facility registration certificate, the applicant shall submit the following in accordance with these regulations:

8.6.1.1 The proposed legal name of the Safety Compliance Facility;

8.6.1.2 The proposed physical address of the Safety Compliance Facility;

8.6.1.3 The name, address, and date of birth of each principal officer and board member of the Safety Compliance Facility, provided that all such individuals shall be at least 21 years of age; and

8.6.1.4 Any information required by the Department to evaluate the applicant pursuant to the competitive bidding process.

8.7 Safety Compliance Facility Application Review Criteria

8.7.1 The Department shall evaluate applications for Safety Compliance Facility registration certificates using an impartial and numerically scored process developed by the Department in accordance with this chapter. The registration considerations shall consist of the following criteria:

- 8.7.1.1 The proposed principal officers' and board members' relevant experience, including any training or professional licensing related to analytical testing, medicine, pharmaceuticals, natural treatments, botany, or marijuana cultivation, preparation, and testing and their experience running businesses or not-for-profits;
 - 8.7.1.2 The suitability of the proposed location, including compliance with any local zoning laws and the geographic convenience to compassion centers throughout the state of Delaware;
 - 8.7.1.3 The sufficiency of the applicant's plans for safety, security, and the prevention of diversion, including proposed locations and security devices employed; and
 - 8.7.1.4 The proposed Safety Compliance Facility's plan for operations and services, including its staffing and training plans, and whether it has sufficient capital to operate.
- 8.8 Issuance of Registration Certificate Authorizing Operation of a Safety Compliance Facility
 - 8.8.1 An application for a Safety Compliance Facility registration certificate must be denied if any of the following conditions are met:
 - 8.8.1.1 Applicant failed to submit the materials required by this subsection, including if the plans do not satisfy the security, oversight, or recordkeeping regulations issued by the Department;
 - 8.8.1.2 Applicant would not be in compliance with local zoning regulations issued in accordance with 16 Del.C. §4917A; or
 - 8.8.1.3 Applicant does not meet the requirements of 16 Del.C. §4919A.
 - 8.8.2 After a Safety Compliance Facility is approved, but before it begins operations, it shall submit a registration fee paid to the Department in the amount of \$40,000 and, if a physical address had not been finalized when it applied, its physical address.
 - 8.8.3 The Department shall issue a renewable registration certificate with an identification number after a satisfactory compliance inspection by the Department.
- 8.9 Registry Identification Cards for Principal Officers, Board Members, Agents, Volunteers or Employees of a Safety Compliance Facility
 - 8.9.1 An application for a registry identification cards must be denied if any of the following conditions are met:
 - 8.9.1.1 If the prospective principal officer or board members has been convicted of an excluded felony offense;
 - 8.9.1.2 If the prospective principal officer or board members has served as a principal officer or board member for a registered Safety Compliance Facility or registered compassion center that has had its registration certificate revoked; or
 - 8.9.1.3 If the principal officer or board members is younger than 21 years of age.
 - 8.9.2 A record of the source of any funds that will be used to open or maintain the Safety Compliance Facility, including the name, address, and date of birth of any investor contributing more than \$5,000.
 - 8.9.3 A record of any instances in which a business or not-for-profit that any of the prospective board members managed or served on the board of was convicted, fined, censured, or had a registration or license suspended or revoked in any administrative or judicial proceeding.
- 8.10 Expiration Date
 - 8.10.1 A Safety Compliance Facility registration shall expire two years after its registration certificate is issued. The Safety Compliance Facility may submit a renewal application at any time beginning 90 days prior to the expiration of its registration certificate. Such renewal application must be submitted a minimum of 30 days prior to the expiration of its registration certificate to avoid suspension of the certificate.

8.11 Expiration, Termination or Renewal of a Registration Certificate Authorizing Operation of a Safety Compliance Facility

8.11.1 Registration certificates may be renewed every two years. The registered Safety Compliance Facility may submit a renewal application beginning 90 days prior to the expiration of its registration certificate. The Department shall grant a renewal application within 30 days of its submission if the following conditions are all satisfied:

8.11.1.1 The registered Safety Compliance Facility submits a renewal application and the required \$40,000 renewal fee, which shall be refunded if the renewal application is rejected;

8.11.1.2 The Department has not suspended the registered Safety Compliance Facility's registration certificate for violations of this chapter or regulations adopted pursuant to this chapter;

8.11.1.3 The inspections authorized by 16 Del.C. §4919A(u) do not raise serious concerns about the continued operation of the registered Safety Compliance Facility applying for renewal;

8.11.1.4 The Annual Report provided pursuant to 16 Del.C. §4922A, confirms a continued need for the facility;

8.11.1.5 The applicant continues to meet all of the requirements for the operation of a Safety Compliance Facility as set forth in the Act and in these regulations; and

8.11.2 Suspension

8.11.2.1 The Department may suspend a registration certificate authorizing the operation of a Safety Compliance Facility for any violation of an applicable law or regulation.

8.11.3 Termination

8.11.3.1 Upon receipt of written notice that a registration certificate has been terminated, the Safety Compliance Facility has 30 business days to request, in writing, a hearing, for the purpose of review of such action. The hearing process shall follow the procedures in subsections 9.4 through 9.5.10 of these regulations:

8.11.3.1.1 A written decision will be issued by the Department within 30 days of the completion of the hearing. The decision will lift the suspension or terminate a registration certificate. The written decision will state with specificity the reasons for the decision; and

8.11.3.1.2 The termination of a registration certificate is a final decision of the Department, subject to judicial review. Jurisdiction and venue are vested in the Superior Court.

8.12 Non-transferable Registration Certificate Authorizing Operation of a Safety Compliance Facility

8.12.1 A registration certificate authorizing operation of a Safety Compliance Facility shall not be transferred by assignment or otherwise to other persons or locations. Unless the Safety Compliance Facility applies for and receives an amended registration certificate authorizing operation of a Safety Compliance Facility, the registration certificate shall be void and returned to the Department upon one or more of the following occurrences:

8.12.1.1 A change in ownership of the Safety Compliance Facility;

8.12.1.2 A change authorized physical location; or

8.12.1.3 The Safety Compliance Facility discontinues its operation.

8.12.2 A Safety Compliance Facility shall provide the Department with a written notice of any change described in subsection 8.12.1 of these regulations at least 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.

8.12.3 Transactions which usually do not constitute a change of ownership include the following:

8.12.3.1 Changes in the membership of the board of directors or board of trustees; or

8.12.3.2 Two or more legal entities merge and the entity to whom the registration certificate authorizing operation of a Safety Compliance Facility was issued survives.

8.12.3.3 Management agreements are generally not considered a change in ownership if the entity to whom the registration certificate authorizing operation of a Safety Compliance Facility was issued continues to retain ultimate authority for the operation of the Safety Compliance Facility. However, if the ultimate authority is surrendered and transferred from the entity to whom the registration certificate authorizing operation of a Safety Compliance Facility was issued to a new manager, then a change of ownership has occurred.

8.13 Inspection

8.13.1 The Safety Compliance Facility will be available to State regulators for inspections, both scheduled and unscheduled, during normal business hours.

17 DE Reg. 738 (01/01/14)

9.0 Monitoring and Corrective Action Actions

9.1 On-site visits/interviews

9.1.1 The Department or its designee may perform on-site interviews of a qualified patient or designated caregiver to determine eligibility for the program. The Department may enter the premises of a qualified patient or designated caregiver during business hours for purposes of interviewing a program applicant. Twenty-four (24) hours' notice will be provided to the qualified patient or designated caregiver prior to an on-site interview.

9.1.2 All qualified patients or designated caregivers shall provide the Department or the Department's designee immediate access to any material and information necessary for determining eligibility with these requirements.

9.1.3 Failure by the qualified patient or designated caregiver to provide the Department access to the premises or information may result in action up to and including the revocation of the qualified patient or designated caregiver registry identification card and referral to state law enforcement.

9.1.4 Any failure to adhere to these rules, documented by the Department during an interview, may result in sanction(s), including suspension, revocation, non-renewal or denial of licensure and referral to state or local law enforcement.

9.1.5 The Department shall refer credible criminal complaints against a qualified patient or designated caregiver to the appropriate state or local authorities.

9.2 Corrective action

9.2.1 If violations of these requirements are cited as a result of monitoring or police contact, the qualified patient or primary caregiver shall be provided with an official written report of the findings within 30 days following the monitoring visit.

9.2.2 Unless otherwise specified by the Department, the qualified patient or designated caregiver shall correct the violation within 5 calendar days of receipt of the official written report citing the violation(s).

9.2.3 The violation shall not be deemed corrected until the Department verifies in writing after receiving notice of the corrective action that the corrective action is satisfactory.

9.2.4 If the violation has not been corrected, the Department may issue a notice of contemplated action to revoke the qualified patient's or designated caregiver's registry identification card.

9.2.5 Suspension of registry identification card without prior hearing

9.2.5.1 In accordance with the 16 Del.C. Ch. 49A, if immediate action is required to protect the health and safety of the general public, the Department may suspend the qualified patient or designated caregiver registry identification card without notice.

- 9.2.5.1.1 A qualified patient or designated caregiver whose registry identification card has been summarily suspended may request a record review no later than 30 calendar days after the registry identification card was summarily suspended.
- 9.2.5.1.2 The record review requested subsequent to a summary suspension shall be conducted by the Department.
- 9.2.5.1.3 The Department shall conduct the record review on the summary suspension by reviewing all documents submitted by both card holder and the Department.
- 9.2.5.1.4 The sole issue at a record review on a summary suspension is whether the card holder's registry identification card shall remain suspended pending a final adjudicatory hearing and ruling.
- 9.2.5.1.5 A card holder given notice of summary suspension by the Division may submit a written request to the Department for a record review. To be effective, the written request shall:
 - 9.2.5.1.5.1 Be made within 30 calendar days, as determined by the postmark, from the date of the notice issued by the Department;
 - 9.2.5.1.5.2 Be properly addressed to the medical marijuana program;
 - 9.2.5.1.5.3 State the applicant's name, address, and telephone number(s);
 - 9.2.5.1.5.4 Provide a brief narrative rebutting the circumstances of the suspension; and
 - 9.2.5.1.5.5 Additional documentation must be included with the request for a record review.
- 9.2.5.1.6 A card holder may request a hearing under subsection 9.4 following the record review.

9.3 Suspension, Revocation and Appeal Process

- 9.3.1 Participation in the medical marijuana program by a qualified patient or designated caregiver does not relieve the qualified patient or designated caregiver from:
 - 9.3.1.1 Criminal prosecution or civil penalties for activities not authorized in this rule and act;
 - 9.3.1.2 Liability for damages or criminal prosecution arising out of the operation of a vehicle while under the influence of marijuana; or
 - 9.3.1.3 Criminal prosecution or civil penalty for possession, distribution or transfers of marijuana or use of marijuana:
 - 9.3.1.3.1 In a school bus or public vehicle;
 - 9.3.1.3.2 On school grounds or property;
 - 9.3.1.3.3 In the workplace of the qualified patient's or designated caregiver's employment;
 - 9.3.1.3.4 At a public park, recreation center, youth center or other public place;
 - 9.3.1.3.5 To a person not approved by the Department pursuant to this rule;
 - 9.3.1.3.6 Outside Delaware or attempts to obtain or transport marijuana from outside Delaware; or
 - 9.3.1.3.7 That exceeds the allotted amount of usable medical use marijuana.
 - 9.3.1.4 Criminal prosecution or civil penalties related to growing or cultivating marijuana.
- 9.3.2 Revocation of registry identification card
 - 9.3.2.1 Violation of any provision of this rule may result in either the summary suspension of the qualified patient's or designated caregiver's registry identification card, or a

notice of contemplated action to suspend or revoke the qualified patient's or designated caregiver's registry identification card, and all lawful privileges under the act.

9.3.3 Grounds for revocation or suspension of registry identification card, denial of renewal application for registry identification card.

9.3.3.1 A registry identification card may be revoked or suspended, and a renewal application may be denied for:

9.3.3.1.1 Failure to comply with any provisions of these requirements;

9.3.3.1.2 Failure to allow a monitoring visit by authorized representatives of the Department;

9.3.3.1.3 The discovery of repeated related criminal misconduct or criminal law violations of these requirements during monitoring visits.

9.4 Request for hearing

9.4.1 A qualified patient or designated caregiver whose registry identification card has been summarily suspended, or who has received a notice of contemplated action to suspend or revoke, may request a hearing for the purpose of review of such action. A cardholder whose card was summarily suspended and who requested a record review under subsection 9.2.5 may request a hearing following the record review. The request for hearing shall be filed within 30 calendar days of the date the action is taken, the notice of contemplated action is received, or the record review decision is received. The request shall include the following:

9.4.1.1 A statement of the facts relevant to the review of the action;

9.4.1.2 A statement of the provision of the act and the rules promulgated under the act that are relevant to the review of the action;

9.4.1.3 A statement of the arguments that the qualified patient/designated caregiver considers relevant to the review of the action; and

9.4.1.4 Any other evidence considered relevant.

9.5 Hearing procedure

9.5.1 As soon as possible, but in no event later than 60 calendar days after the request for hearing is received, the Department shall convene a hearing.

9.5.2 Notice of the hearing shall be issued in accordance with §10122 of Title 29.

9.5.2.1 There shall be no public notice of the hearing in accordance with §4920A of Title 16.

9.5.3 An individual may request an expedited hearing.

9.5.3.1 The Department shall schedule the hearing on an expedited basis provided that the Department receives the individual's written request for an expedited hearing within five (5) calendar days from the date on which the individual received notification of the Department's decision to suspend the individual's card, or the date on which the individual received the final determination following the record review.

9.5.3.2 The Department shall convene an expedited hearing within 15 calendar days of the receipt by the Department of such a request.

9.5.3.3 The Department shall make a determination based upon the evidence presented.

9.5.3.4 A written copy of the determination and the reasons upon which it is based shall be sent to the individual within 30 calendar days.

9.5.4 Telephonic hearings

- 9.5.4.1 An individual cardholder may request a telephonic hearing at the time of the request for a hearing. Immediately after the parties agree to conduct the hearing by telephone, notice of the telephonic hearing shall be made to all parties and shall include all necessary telephone numbers.
- 9.5.4.2 Any party that has agreed to a telephonic hearing, but subsequently requests an in-person hearing shall do so in writing to the Department no later than 10 calendar days before the scheduled date of the hearing. The decision to grant or deny the request for an in-person hearing shall be at the discretion of the Department for good cause shown. The Department's decision to grant or deny the hearing shall be issued in writing and shall include the specific reasons for granting or denying the request. Should the Department grant the request, the hearing shall be rescheduled to a time convenient for all parties. Should the Department deny the request, the telephonic hearing shall proceed as scheduled.
- 9.5.4.3 The location or locations of the parties during the hearing shall have a speaker telephone and technology available so that all shall hear the proceedings and documents shall be transmitted between witnesses and the Department.
- 9.5.4.4 Failure to provide the correct telephone number or failure to be available at the commencement of the hearing shall be treated as a failure to appear and shall subject the petitioner to a default judgment.
- 9.5.4.5 The in-person presence of some parties or witnesses at the hearing does not prevent the participation of other parties or witnesses by telephone with prior approval of the Department.
- 9.5.5 During an administrative hearing:
- 9.5.5.1 The individual has the right to be represented by counsel.
- 9.5.5.2 All statements made shall be under oath.
- 9.5.5.3 The individual has the right to examine and cross-examine witnesses.
- 9.5.5.4 The individual has the right to present evidence.
- 9.5.6 A stenographic recording will be made by a qualified court reporter. At the request and expense of any party, such record shall be transcribed with a copy to the other party.
- 9.5.7 Following the hearing, the Department shall make a determination based upon the evidence presented.
- 9.5.8 Upon reaching its conclusion of law and determining an appropriate disciplinary action, the Department shall issue a written decision and order in accordance with §10128 of Title 29.
- 9.5.9 All decisions of the Department shall be final and conclusive. Where the individual is in disagreement with the action of the Department, the individual may appeal the Department's decision to the Superior Court within 30 days of service or of the postmarked date of the copy of the decision mailed to the individual. The appeal shall be on the record to the Superior Court and shall be as provided in §§10142 - 10145 of Title 29.
- 9.5.10 A written copy of the determination and the reasons upon which it is based shall be sent to the patient or caregiver cardholder within 30 calendar days.

10.0 General Provisions for the Production of Edible Marijuana Products

- 10.1 Delaware Department of Health and Social Services adopts these regulations pursuant to the authority vested by 16 Del.C. §122. These regulations establish registration procedures and standards of practice for conducting marijuana infused food processing operations in Compassion Center kitchens that safeguard public health and provide to consumers food that is tested for safety, potency and consistency. A marijuana infused food establishment that prepares, sells or dispenses edible marijuana products must:
- 10.1.1 Before preparing, selling or dispensing an edible marijuana product, obtain written authorization from the Division to prepare, sell or dispense edible marijuana products; and

- 10.1.2 If the marijuana business prepares edible marijuana products, ensure that the edible marijuana products are prepared according to the applicable requirements set forth in these regulations.
- 10.2 Each compassion center and facility for the production of edible marijuana products or marijuana-infused products shall, in consultation with the Division, cooperate to ensure that all edible marijuana products and marijuana-infused products offered for sale:
- 10.2.1 Are labeled clearly and unambiguously as medical marijuana;
- 10.2.2 Are not presented in packaging that is appealing to children. These requirements include:
- 10.2.2.1 Tamper or child-resistant packaging;
- 10.2.2.2 Opaque or plain in design;
- 10.2.2.3 Resealable for any product intended for more than a single use;
- 10.2.2.4 Prohibited from using bright colors, defined as colors that are "neon" in appearance;
- 10.2.2.5 Prohibited from imitating or having a semblance to any existing branded consumer products, including foods, beverages and toys;
- 10.2.2.6 Prohibited from using cartoons, cartoon-like font, caricatures, fruit, human or animal shapes, pictures/photographs images, or picture/photographs of product;
- 10.2.2.7 Prohibited from featuring a design, symbol, or celebrity brand or name that resembles a non-cannabis consumer product;
- 10.2.2.8 Prohibited from featuring images of minors or words that refer to products that are commonly associated with minors or marketed to minors; and
- 10.2.2.9 Each single serving of an edible contained in multiple serving package shall be marked, stamped or otherwise imprinted with the following symbol:



CONTAINS THC
NOT SAFE FOR KIDS OR PETS

- 10.2.3 Are regulated and sold on the basis of the concentration of THC and/or CBD in the products and not by weight; and
- 10.2.4 Are packaged and labeled in such a manner as to allow tracking by DEC3S.
- 10.3 Labeling
- 10.3.1 Products shall be properly labeled with the following: Name of Compassion Center, phone and website of compassion center that produced the edible, name of product, net weight, date of production / lot number, barcode, refrigeration of the product if required and cannabinoid profile.
- 10.3.2 Labels shall include a list of ingredients in decreasing order by weight, serving size and how many servings per package, batch, serial number and bar codes.
- 10.3.3 Labels shall include the following statement: "This food is made in a Marijuana Infused Food Establishment and is NOT subject to routine Government Food Safety Inspections" with a seal stating "tested for contaminants".
- 10.3.4 Labels shall be printed in at least **[10-point type 6-point type, as long as the information can be easily read using standard reading glasses.]** in a color that provides a clear contrast to the background label.
- 10.3.5 Additional information as required by the Division must be made available for review upon request from the consumer, including the following:

- 10.3.5.1 The date on which the product was manufactured;
- 10.3.5.2 If the product is perishable, a suggested use-by date;
- 10.3.5.3 The total milligrams of active cannabinoids and terpenoids in the product, as provided by the independent testing laboratory that tested the product;
- 10.3.5.4 A list of all ingredients including amount in grams of sodium, sugar, carbohydrates and total fat per serving and all major food allergens as identified in 21 U.S.C. §§343;
- 10.3.5.5 A warning that states: "Caution: When eaten or swallowed, the intoxicating effects of this drug may be delayed by 2 or more hours."
- 10.3.5.6 If a marijuana extract was added to the product, a disclosure of the type of extraction process and any solvent, gas or other chemical used in the extraction process, or any other compound added to the extract;
- 10.3.5.7 A warning that states: "This product may have intoxicating effects and may be habit forming."
- 10.3.5.8 The statement: "This product is unlawful outside of the State of Delaware."
- 10.3.5.9 A medical marijuana dispensary must provide with all edible marijuana products and marijuana-infused products sold at retail accompanying material that discloses any products applied to the marijuana plants and growing medium during production of the marijuana used to create the extract added to the edible marijuana products or marijuana-infused products and the type of extraction method used, including, without limitation, any solvents, gases or other chemicals or compounds used to produce or that are added to the extract, and contains the following warnings:
 - 10.3.5.9.1 "The impairment effects of edible products may be delayed by two hours or more. This product has not been analyzed or approved by the FDA to treat, cure, or prevent any disease. There is limited information on the side effects of using this product, and there may be associated health risks.
 - 10.3.5.9.2 "This product contains or is infused with marijuana or active compounds of marijuana.";
 - 10.3.5.9.3 "This product should not be used by women who are pregnant or breast feeding."
 - 10.3.5.9.4 "For use only by the person named on the label of the dispensed product. Keep out of the reach of children."
 - 10.3.5.9.5 "Products containing marijuana can impair concentration, coordination and judgment. It is against the law drive or operate a vehicle or machinery under the influence of this product."
 - 10.3.5.9.6 "FOR USE BY ADULTS 18 and OLDER, KEEP THIS PRODUCT AWAY FROM CHILDREN."

10.4 Packaging

- 10.4.1 The immediate food contact surface of any product packaging material shall be food grade in quality, and therefore meet the food safety requirements of 16 Del.C. Ch. 33.
- 10.4.2 Any product containing marijuana must be packaged in child-resistant packaging in accordance with 16 C.F.R. §1700.
- 10.4.3 Marijuana-infused products must be packaged in plastic which is 4 millimeters or more in thickness and must be heat-sealed without an easy-open tab, dimple, and corner or flap so that it is difficult for a child to open and as a tamperproof measure.
- 10.4.4 Any container or packaging containing usable marijuana, edible marijuana products or marijuana-infused products must protect the contents from contamination and must not impart any toxic or deleterious substance to the usable marijuana or marijuana product.

10.5 Exemptions

10.5.1 Establishments registered as marijuana infused food establishments in Delaware shall be exempt from the Cottage Food Regulations.

10.5.2 Establishments registered under these regulations shall be exempt from the Delaware Food Code.

10.6 Inspections

10.6.1 The Division may conduct one or more preoperational inspections to verify that the marijuana infused food establishment is:

10.6.1.1 Constructed and equipped in accordance with the registration application;

10.6.1.2 Has established standard operating procedures as specified; and

10.6.1.3 Is otherwise in substantial compliance with these regulations.

10.6.2 Additional inspections both scheduled and no-notice will be conducted at the discretion of the Division and as deemed necessary by the Division.

11.0 Limitations

11.1 Registration

11.1.1 Marijuana Infused Food Establishments are only permitted to engage in direct sales with consumers in the State of Delaware.

11.1.2 Online sales are not permitted. Online advertising and marketing are permitted subject to the limitations listed in 16 Del.C. Ch. 49A.

11.1.3 Wholesale or other sales to resellers or food establishments are not permitted by a Marijuana Infused Food Establishment.

11.1.4 A Marijuana Infused Food Establishment shall only produce those specific food products listed on their registration.

11.1.5 Approved sources of non-marijuana ingredients:

11.1.5.1 Each facility for the production of edible marijuana products or marijuana-infused products shall ensure that it obtains non-marijuana ingredients for edible marijuana products or marijuana-infused products from sources that comply with the requirements of federal and state law and regulations and are approved by the Division, including, without limitation, commercial and retail businesses.

11.1.6 The production of edible marijuana products or marijuana-infused products for sale shall not use non-marijuana ingredients prepared or stored in a private home.

11.2 Allowable Products

11.2.1 Products produced in a Marijuana Infused Food Establishment are limited to non-TCS baked goods and candy.

11.2.2 The manufacturing of baked goods shall be allowed in a Marijuana Infused Food Establishment to include cookies, muffins and brownies.

11.2.3 Bakery items which as a finished product contain components such as fruit filling, cream filling or meat are prohibited.

11.2.4 Candy products including, but not limited to chewables, fudge, lollipops, chocolates, and hard candy, are allowed to be manufactured in a Marijuana Infused Food Establishment provided the final products are non-TCS.

11.2.5 All labeling requirements set forth in subsection 16.2 must be met before the product is sold.

11.2.6 Products may not exceed 10mg of THC-Delta 9 or 25mg of CBD per serving.

11.2.7 Marijuana infused products are limited to five servings per package.

11.2.8 Products infused with THC, must have the letters "THC" molded into the product.

11.3 Application

11.3.1 Compassion Centers seeking registration as a Marijuana Infused Food Establishment must submit to the Division an application demonstrating that they meet the requirements set forth in these regulations. The application shall include:

11.3.1.1 The name, mailing address, e-mail address, telephone, and signature of the person applying for the registration and the name, mailing address, and physical address of the Marijuana Infused Food Establishment;

11.3.1.2 Information about products and processes including but not limited to products to be made, ingredients, example labels, processes and products;

11.3.1.3 Floor plan of the processing area identifying appliances to be used, food contact surfaces (types of materials used for contact surfaces must be described,) areas for refrigeration and dry good storage, and restroom facilities;

11.3.1.4 Proof of completion of training that satisfies Section 13.0; and

11.3.1.5 A statement signed by the applicant that:

11.3.1.5.1 Attests to the accuracy of the information provided in the application;

11.3.1.5.2 Affirms that the applicant will comply with these regulations; and

11.3.1.5.3 Allow the Division access to the establishment as specified under subsection 10.6 and to the records specified under subsection 7.5.

11.3.2 Compassion Centers may first apply to the Division for an endorsement as a Marijuana Infused Food Establishment on or after July 1, 2020.

11.3.3 Following the submission of an application demonstrating that all requirements of these regulations have been met, up to and including the on-site inspection, the producer may begin sales to consumers in accordance with these regulations.

11.3.4 Upon registration by the Division, a Marijuana Infused Food Establishment and associated activities shall comply with the standards established by these regulations.

11.3.5 It shall be a violation of these regulations to operate in Delaware as a Marijuana Infused Food Establishment, as defined by these regulations, if not registered with the Division.

11.3.6 Registration with the Division does not exempt the Marijuana Infused Food Establishment from other state, county or local codes unless specifically listed in subsection 10.5.

11.3.7 If the proposed Marijuana Infused Food Establishment uses a private well as a source of potable water the well must be in compliance with State of Delaware Regulations Governing Public Drinking Water Systems.

11.3.7.1 Private wells shall comply with chemical and bacteriological standards; a satisfactory analysis is required before a registration may be issued. Completion of any required sampling is the responsibility of the Compassion Centers.

11.3.7.2 Tests conducted within 60 days of the date of the initial or renewal application will be accepted to demonstrate compliance.

11.3.8 Establishments served by a public water supply and sewage systems do not require further evaluation.

11.4 Renewal

11.4.1 Registration must be renewed bi-annually.

11.4.1.1 Marijuana Infused Food Establishments must maintain a Medical Marijuana Compassion Center License through the Division.

12.0 Marijuana Infused Food Establishment Endorsement Requirements

12.1 Conditions of the Marijuana Infused Food Establishment Endorsement

12.1.1 Upon acceptance of the endorsement to operate a Marijuana Infused Food Establishment issued by the Division the Compassion Center shall:

- 12.1.1.1 Allow representatives of the Division access to the Marijuana Infused Food Establishment during hours of operation and other reasonable times. After the Division representative presents official credentials and an intent to conduct an inspection the producer shall allow the Division representative to determine if the Marijuana Infused Food Establishment is in compliance with these regulations by allowing access to the establishment, allowing inspection, and providing information and records to which the Division is entitled according to law;
- 12.1.1.2 Comply with Division directives including time frames for corrective actions specified in inspection reports and other directives issued by the Division regarding the Marijuana Infused Food Establishment. Comply with the conditions of a granted variance, and conditions of approved facility plans and specifications;
- 12.1.1.3 Accept notices issued and served by the Division according to the law. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with the regulations or Division directives, including time frames for corrective actions specified in inspection reports;
- 12.1.1.4 Immediately discontinue operations and notify the Division if an imminent health hazard may exist because of an emergency such as fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger health;
- 12.1.1.5 Immediately contact the Division to report an illness of an employee who is diagnosed with Norovirus, Salmonella typhi (Typhoid fever), Shigella spp., Shiga toxin-producing E. Coli including 0157:H7, Hepatitis A virus or nontyphoidal salmonella;
- 12.1.1.6 Replace existing facilities and equipment with facilities and equipment that comply with the Code if:
 - 12.1.1.6.1 The Division directs the replacement because the surfaces and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the surfaces and equipment were accepted; or
 - 12.1.1.6.2 The Division directs the replacement of the facilities and equipment because of a change of ownership.
- 12.1.1.7 Prepare and maintain a current written contingency plan for use in initiating and affecting a product recall.

12.2 Safe Production of Marijuana Infused Products

- 12.2.1 Each facility for the production of edible marijuana products or marijuana-infused products shall ensure that:
 - 12.2.1.1 Pasteurized eggs or egg products are substituted for raw eggs in the preparation of edible marijuana products or marijuana-infused products.
 - 12.2.1.2 Marijuana products and ingredients only have contact with the surfaces of:
 - 12.2.1.2.1 Equipment and utensils that are cleaned and sanitized; or
 - 12.2.1.2.2 Single-service and single-use articles that have not previously been used.
 - 12.2.1.3 All ingredients must be cooked thoroughly to a safe temperature for the proper time.

12.3 Quality Control Unit

- 12.3.1 Each facility for the production of edible marijuana products or marijuana-infused products shall have a quality control unit that:
 - 12.3.1.1 Has the responsibility and authority to approve or reject all components, product containers, closures, in-process materials, packaging materials, labeling and marijuana or marijuana products;

12.3.1.2 Has the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated and resolved;

12.3.1.3 Is responsible for approving or rejecting marijuana or marijuana products manufactured, processed, packaged or held under contract by another Compassion Center;

12.3.1.4 Is responsible for approving or rejecting all procedures or specifications which may impact the identity, strength, quality and purity of the marijuana or marijuana products.

12.3.2 Each Compassion Center or Marijuana Infused Food Establishment shall:

12.3.2.1 Set forth the responsibilities and procedures applicable to the quality control unit in writing; and

12.3.2.2 Follow the written responsibilities and procedures set forth pursuant to subsection 7.3.12.3.

13.0 Training Requirements

At least one employee during hours of operation shall be on location and have shown proficiency in food safety through passing a test that is part of a program approved by the Office of Food Protection.

14.0 Producer Requirements

14.1 The producer shall ensure that:

14.1.1 Only approved food items shall be made in the Marijuana Infused Food Establishment;

14.1.2 Only persons necessary to the Marijuana Infused Food Establishment shall be allowed in the food preparation, food storage or ware washing areas during operation;

14.1.3 Producers and employees are effectively cleaning their hands, by routinely hand washing per specifications provided by the Division;

14.1.4 Producers or employees are properly cooking TCS ingredients, being particularly careful in cooking those foods known to cause severe foodborne illness and death, and routinely monitor cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated;

14.1.5 Producers or employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing per specifications provided by the Division;

14.1.6 Producers and employees shall prevent cross-contamination of ready to eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single use gloves, or dispensing equipment; and

14.1.7 Producers and employees are informed in a verifiable manner of their responsibility to report to the producer, information about their health and activities as they relate to diseases that are transmissible through food.

15.0 Facility Requirements

15.1 Indoor Areas

15.1.1 Materials that are smooth, durable and easily-cleanable shall be installed in the following areas:

15.1.1.1 Food preparation

15.1.1.1.1 Each facility for the production of edible marijuana products or marijuana-infused products shall ensure that:

15.1.1.1.1.1 The surfaces of equipment and utensils that have direct contact with marijuana products are clean to sight and touch;

15.1.1.1.1.2 The surfaces of cooking equipment and pans that have direct contact with marijuana products are kept free of encrusted grease deposits and other soil accumulations;

15.1.1.1.1.3 The surfaces of equipment that do not have direct contact with marijuana products are kept free of an accumulation of dust, dirt, residue and other debris.

15.1.1.2 Food preparation area surfaces

15.1.1.2.1 Each facility for the production of edible marijuana products or marijuana-infused products shall ensure that the surfaces of equipment and utensils that have direct contact with marijuana products are cleaned;

15.1.1.2.1.1 Each time there is a change from working with raw marijuana products to working with finished marijuana products;

15.1.1.2.1.2 Between uses with potentially hazardous marijuana products and ingredients, using the appropriate time and temperature controls to ensure the safety of the marijuana products;

15.1.1.2.1.3 At any time during operation when contamination may have occurred;

15.1.1.2.1.4 If they come into contact with potentially hazardous marijuana products or ingredients, surfaces and utensils are cleaned throughout the day at least once every 4 hours.

15.1.1.2.1.5 The surfaces of utensils and equipment that have direct contact with marijuana products or ingredients that are not potentially hazardous are cleaned;

15.1.1.2.1.5.1 At any time when contamination may have occurred;

15.1.1.2.1.5.2 At a frequency specified by the manufacturer; or

15.1.1.2.1.5.3 If the manufacturer does not specify a frequency, at a frequency necessary to prevent the accumulation of soil or mold.

15.1.1.3 Dry food storage

15.1.1.3.1 All elements involved in the production of marijuana infused products will be stored at least 12 inches off the floor on shelving or other generally recognized food storage container.

15.1.2 Carpeting of any kind, shall not be used in the following areas:

15.1.2.1 Food preparation; or

15.1.2.2 Dry food storage.

15.1.3 Utility lines shall be installed inside walls, above ceiling or below floors, where possible.

15.1.4 Insect control devices shall not be installed over food preparation surfaces.

15.2 Artificial Interior Lighting

15.2.1 Provide minimum illumination intensities

15.2.1.1 At least 50-foot candles at a surface where a producer or employee is working with food or working with utensils or equipment such as knives, slicers, and grinders or where the producer or employee safety is a factor.

15.3 Animals

15.3.1 No animals/pets shall be permitted in the kitchen area of a Marijuana Infused Food Establishment during the preparation, packaging, or handling of any marijuana infused food products. [Employees with service animals, as defined by the Americans with Disabilities Act, must comply with state and federal food codes regarding the presence of service animals in food establishments.]

15.4 Poisonous and Toxic Materials

15.4.1 Toxic substances shall be stored so they cannot contaminate food preparation or cooking equipment in kitchen areas.

15.4.2 Rodent bait shall be contained in covered, tamper-resistant bait stations. Toxic tracking powders shall not be used as a pesticide and nontoxic tracking powders shall not contaminate food, equipment or utensils.

15.4.3 All medicines and first aid supplies shall be labeled and stored in a kit or container out of food preparation areas.

15.5 Plumbing in a Marijuana Business

15.5.1 The plumbing shall meet the requirements of all municipal, county or state codes.

15.5.2 Marijuana Infused Food Establishments shall have convenient access to permanent restroom facilities equipped with running potable water, paper towels and soap.

15.6 Sewage Disposal

15.6.1 Individual sewage disposal systems require the approval of the Department of Natural Resources and Environmental Control prior to operating the establishment.

15.7 Temperature Measuring Devices (TMD)

15.7.1 In mechanically refrigerated food storage units, TMD shall be located to measure the air temperature in the warmest part of the unit.

15.7.2 TMD shall be readily accessible for use in ensuring attainment and maintenance of required food temperatures.

15.7.3 TMD shall be accurate to $\pm 1^{\circ}$ Celsius or $\pm 2^{\circ}$ Fahrenheit to measure food temperatures.

15.7.4 TMD shall not have sensors constructed of glass, except if encased in shatterproof coating.

15.8 Refrigeration and Cold Holding Equipment

15.8.1 Freezer units shall be capable of maintaining stored food solidly frozen.

15.8.2 Refrigeration and cold holding units shall be capable of maintaining stored foods at 41° Fahrenheit or below.

16.0 Product Requirements

16.1 Testing

16.1.1 All batches of food are required by the Division to be laboratory tested through the Safety Compliance Facility for safety and cannabinoid profile. Testing of food products shall be the financial responsibility of the Compassion Center.

16.2 Recall Plan

16.2.1 The Marijuana Infused Food Establishment shall:

16.2.1.1 Prepare and maintain a current written contingency plan for use in initiating and affecting a recall of products;

16.2.1.2 Use sufficient coding of regulated products to make possible positive identification and to facilitate effective recall of all violated lots;

16.2.1.3 Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records shall be maintained for 3 years.

16.3 Reporting and Records

16.3.1 A Marijuana Infused Food Establishment must maintain records for each batch of product indicating type of finished product, date of production, lot number, and date and location of sales. These records shall be maintained for 3 years.

17.0 Compliance and Enforcement Procedures

17.1 A person may not operate a Marijuana Infused Food Establishment without a valid endorsement to operate issued by the Division.

17.2 If the Division determines that a Marijuana Infused Food Establishment is operating without a valid endorsement; that one or more conditions exist which represent an imminent health hazard; or that serious violations, repeat violations, or general unsanitary conditions are found to exist, administrative action may occur.

17.2.1 Administrative action on the Marijuana Infused Food Establishment will be conducted in accordance with the following:

17.2.1.1 Operation without an endorsement

17.2.1.1.1 Immediate Closure Order

17.2.1.1.1.1 If a Marijuana Infused Food Establishment is found operating without an endorsement as required by subsection 7.1 of this regulation, the Division shall order the establishment immediately closed.

17.2.1.1.2 Notice of Closure

17.2.1.1.2.1 The closure shall be effective upon receipt of a written notice by the producer or employee of the Marijuana Infused Food Establishment. A closure notice statement recorded on the inspection report by a representative of the Division constitutes written notice.

17.2.1.1.3 Duration of Closure

17.2.1.1.3.1 The Marijuana Infused Food Establishment shall remain closed until an endorsement application; applicable fees and any required plans have been received and approved by the Division.

17.2.1.2 Imminent Health Hazard(s)

17.2.1.2.1 Endorsement suspension without hearing

17.2.1.2.1.1 If some condition is determined to exist in a Marijuana Infused Food Establishment which presents an imminent health hazard to the public, or for any violation of an applicable law or regulation, the Division may suspend the endorsement of the Marijuana Infused Food Establishment without a prior hearing. The suspension shall be effective upon receipt of written notice by the producer or employee of the marijuana establishment. A suspension statement recorded on an inspection report by the Division constitutes written notice.

17.2.1.3 Serious Violations, Repeat Violations and General Unsanitary Conditions

17.2.1.3.1 When conditions exist in a marijuana establishment that represent serious violations, repeat violations or general unsanitary conditions, the Division may initiate a corrective action plan.

17.2.2 In response to the order to close, the facility may:

17.2.2.1 Take no action, in which case the order to close shall remain in effect.

17.2.2.1.1 Take action to correct the unsafe and unsanitary practices identified during the survey.

17.2.2.1.1.1 The facility may submit evidence through a written plan of correction showing that the deficient practices, identified during the investigation, have been addressed and corrected.

17.2.2.1.1.2 A change of location for the facility does not nullify an order to close and an acceptable plan of correction must still be submitted.

17.2.2.1.1.3 The Department shall determine if the plan of correction is acceptable.

17.2.2.1.1.4 Once accepted, the Department shall schedule a revisit as soon as possible.

17.2.2.2 Request, in writing, an administrative hearing with the Department to contest the order to close.

17.2.2.2.1 Such request must be received within 10 calendar days from the date on which the order to close was issued.

17.2.2.2.1.1 As soon as possible, but in no event later than 60 calendar days after the issuance of the closure order, the Department shall convene a hearing on the reasons for closure.

17.2.2.2.1.2 The Department shall make a determination based upon the evidence presented.

17.2.2.2.1.2.1 A written copy of the determination and the reasons upon which it is based shall be sent to the facility within 30 calendar days of the hearing.

17.2.2.2.2 During an administrative hearing:

17.2.2.2.2.1 The facility has the right to be represented by counsel;

17.2.2.2.2.2 All statements made shall be under oath;

17.2.2.2.2.3 The facility has the right to examine and cross-examine witnesses and present evidence;

17.2.2.2.2.4 A stenographic record will be made by a qualified court reporter. At the request and expense of any party, such record shall be transcribed with a copy to the other party; and

17.2.2.2.2.5 The decision of the Department shall be based upon sufficient legal evidence. If the charges are supported by such evidence, the Department may continue, modify or revoke the closure order.

17.2.2.2.3 Upon reaching its conclusion of law and determining an appropriate disciplinary action, the Department shall issue a written decision and order in accordance with §10128 of Title 29.

17.2.2.2.4 All decisions of the Department shall be final and conclusive. Where the facility is in disagreement with the action of the Department, the facility may appeal the Department's decision to the Superior Court within 30 days of service or of the postmarked date of the copy of the decision mailed to the facility. The appeal shall be on the record to the Superior Court and shall be as provided in §§10142 - 10145 of Title 29.

17.2.3 Examination of Food

17.2.3.1 Food may be examined or tested by the Division contract lab as often as necessary for enforcement of this regulation.

17.2.3.2 All food shall be wholesome and free from spoilage. Food that is spoiled or unfit for human consumption shall not be kept on the premises.

17.3 Penalties

17.3.1 Operation in Violation of Regulation

17.3.1.1 Any person who violates a provision of this regulation, and any person who is the holder of a permit or who otherwise operates a food establishment that does not comply with the requirements of this regulation shall be subject to the penalties found in 16 Del.C. §4914 and these regulations.

17.4 Injunction

17.4.1 The Division may seek to enjoin violations of the regulation.

18.0 Random Sampling Procedures

18.1 Compassion Centers will coordinate with the Office of Medical Marijuana (OMM) for collection of samples by State Regulators, who will supervise randomly chosen samples of each batch for testing by the Testing Center. Sample results will be loaded into the DEC3S system by the testing center allowing Compassion Centers to sell the material or incorporate it into other products.

18.2 Sampling

18.2.1 Compassion centers may create any size batch they deem appropriate, but not more than five (5) pounds.

18.2.2 The minimum sample size is set at 0.5% of batch weight. A one (1) pound batch would require a two (2) gram sample and a five (5) pound batch would require an 11-gram sample. The minimum sample size for testing is one (1) gram.

18.2.3 All medical marijuana products will be tested as directed in subsection 18.3 of these regulations.

18.3 Compassion Center's Responsibility:

18.3.1 Compassion Centers will coordinate harvest schedules with the Office of Medical Marijuana (OMM) and the Testing Center.

18.3.1.1 After the marijuana has been harvested, dried and cured, the OMM staff will supervise selection of random samples from the curing vessels with the Compassion Center staff.

18.3.1.2 Compassion Center staff will prepare additional barcode labels and tamper-proof containers for each batch and develop a transportation manifest, initiating the chain of custody process for the batch of plants being tested.

18.3.2 The Compassion Centers will not sell or prepare products from the batch being tested until the testing centers enter the values into the DEC3S program, releasing the material for use or sale.

18.3.3 Compassion Centers will be invoiced for payment of testing services directly from the Testing Center.

18.3.4 All concentrates or other infused products must be sent to the Testing Center using the process listed above before they are cleared for sale.

18.4 Testing Facility Responsibility:

18.4.1 The testing center will receive samples from the Office of Medical Marijuana (OMM) staff and co-sign the sample manifest after verification of sample barcodes. The testing center will enter the samples into the lab portion of DEC3S. The Testing Center will process the samples for the following profile, terpenes and contaminants:

18.4.1.1 Tetrahydrocannabinol (THC).

18.4.1.2 Tetrahydrocannabinolic Acid (THCA).

18.4.1.3 Cannabidiol (CBD).

18.4.1.4 Cannabidiolic Acid (CBDA).

18.4.1.5 Cannabigerol (CBG).

18.4.1.6 Cannabinol (CBN).

18.4.1.7 That the presence of contaminants does not exceed the levels in the most current version of the American Herbal Pharmacopoeia Monograph or the guidance from the Division of Public Health.

18.4.2 Contaminants include, but are not limited to all of the following:

18.4.2.1 Residual solvent or processing chemicals.

- 18.4.2.2 Foreign material, including, but not limited to, hair, insects, or similar or related adulterant.
- 18.4.2.3 Microbiological impurity, including total aerobic microbial count, total yeast mold count, P. aeruginosa, aspergillus spp., s. aureus, aflatoxin B1, B2, G1, G2, or ochratoxin A, E. coli, and coliforms.
- 18.4.2.4 Residual levels of volatile organic compounds shall be below the lesser of either the specifications set by the United States Pharmacopeia (U.S.P. Chapter 467) or those set by the Division of Public Health.
- 18.4.3 Terpenes described in the most current version of the cannabis inflorescence monograph published by the American Herbal Pharmacopoeia. Terpene testing will be done as required by the compassion centers to inform patients of the products formulization.
- 18.4.4 After the sample testing has been completed.
 - 18.4.4.1 Testing Center will update DEC3S with the values associated with the tests. If the samples pass all tests, the barcode is unlocked, and Compassion Centers will be able to sell or use the marijuana in making other products or concentrates.
 - 18.4.4.2 Testing Center will certify destruction of the sample after DEC3S is updated.
- 18.5 Delaware Consolidated Cannabis Control System (DEC3S) Actions:
 - 18.5.1 The Delaware Consolidated Cannabis Control System (DEC3S) will be used throughout the sample collection, manifest and barcode verification procedures.
 - 18.5.2 Batches will be listed as unavailable for sale until the Testing Center completes the sample testing and enters the results into DEC3S, unlocking them for sale.
 - 18.5.3 The cannabinoid profile values will be available for the Compassion Centers to list on the packaging of the medical marijuana product.
 - 18.5.4 If a sample tested fails one or more of the listed standards, the DEC3S will lockout those barcodes until remediation action is completed and the batch is resubmitted for testing.
 - 18.5.4.1 If remediation is not possible, the compassion center will coordinate with the Office of Medical Marijuana on the batches disposition or the batch must be scheduled for destruction.

19.0 Severability

In the event any particular clause or section of these regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full effect.

20.0 Variance

- 20.1 A licensee may seek a variance from these regulations by making a request for variance to the Division. The Division may grant a variance by modifying or waiving the requirements of these regulations if, in the opinion of the Division, a health hazard or nuisance will not result from the variance
- 20.2 A variance shall not be transferable from person to person, nor from location to location.
- 20.3 If a variance is granted, the Division shall retain the information specified below in its records for the variance:
 - 20.3.1 A statement of the proposed variance of the requirement of these regulations, citing the relevant section of these regulations;
 - 20.3.2 An analysis of the rationale for how the potential public health hazards or nuisances will be alternatively addressed by the proposal; and
 - 20.3.3 Any other information requested by the Division that may be deemed necessary to render judgment.

20.4 A variance is rendered void upon occurrence of one or more of the following: the physical facility is demolished; a remodeling project in the facility includes the area(s) addressed in the variance.