

STATE OF CONNECTICUT
REGULATION
of the
DEPARTMENT OF CONSUMER PROTECTION
concerning
PALLIATIVE USE OF MARIJUANA

The Regulations of Connecticut State Agencies are amended by adding sections 21a-408-1 to 21a-408-70, inclusive, as follows:

(NEW) Sec. 21a-408-1. Definitions

As used in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Abuse of drugs" means the use of controlled substances solely for their stimulant, depressant or hallucinogenic effect upon the higher functions of the central nervous system and not as a therapeutic agent prescribed in the course of medical treatment or in a program of research operated under the direction of a physician or pharmacologist;

(2) "Act" means Sections 21a-408 to 21a-408q, inclusive, of the Connecticut General Statutes;

(3) "Administer" means the direct application of marijuana to the body of a qualifying patient by inhalation, ingestion or any other means;

(4) "Adulterated" has the same meaning as described in section 21a-105 of the Connecticut General Statutes;

(5) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana;

(6) "Agent" means an authorized person who acts on behalf of or at the direction of another person. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman;

(7) "Approved safe" has the same meaning as described in section 21a-262-1 of the Regulations of Connecticut State Agencies;

(8) "Approved vault" has the same meaning as described in section 21a-262-1 of the Regulations of Connecticut State Agencies;

(9) "Batch" means a specific harvest of marijuana or marijuana products that are identifiable by a batch number, every portion or package of which is uniform within recognized tolerances for the factors that were subject to a laboratory test and that appear in the labeling;

(10) "Board" means the Board of Physicians appointed under the provisions of section 21a-408l of the Connecticut General Statutes;

(11) "Bona fide physician-patient relationship" means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient's debilitating medical condition, or a symptom of the patient's debilitating medical condition, for which the physician has certified to the department that the patient would benefit from the palliative use of marijuana;

(12) "Commissioner" means the Commissioner of Consumer Protection;

(13) "Compounding" means to combine, mix or put together two or more ingredients and includes the preparation of a marijuana product in anticipation of a qualifying patient, primary caregiver or physician request;

(14) "Controlled substance" means a drug, substance, or immediate precursor listed in sections 21a-243-7 through 21a-243-11, inclusive, of the Regulations of Connecticut State Agencies;

(15) "Cultivation" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(16) "Debilitating" means a chronic medical condition that causes weakness or impairs the strength or ability of an individual and has progressed to such an extent that it substantially limits one or more major life activities of such individual. An assessment of whether a major life activity has been substantially limited shall be guided by interpretations of the term "disability" as set forth in 42 USC 12102(1)(A);

(17) "Debilitating medical condition" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(18) "Deliver" or "delivery" means the actual, constructive or attempted transfer from one person to another of marijuana, whether or not there is an agency relationship;

(19) "Department" means the Department of Consumer Protection;

(20) "Dietary supplement" has the same meaning as provided in 21 U.S.C. 321;

(21) "Dispensary" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(22) "Dispensary department" means that area within a dispensary facility where marijuana is stored, dispensed and sold. If a dispensary facility does not offer any products or services other than marijuana and paraphernalia, the entire dispensary facility is a dispensary department for purposes of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(23) "Dispensary facility" means a place of business where marijuana may be dispensed or sold at retail to qualifying patients and primary caregivers and for which the department has issued a dispensary facility license to an applicant under the Act and section 21a-408-14 of the Regulations of Connecticut State Agencies;

(24) "Dispensary facility backer" means, except in cases where the dispensary is the sole proprietor of a dispensary facility, any person with a direct or indirect financial interest in a dispensary facility, except "dispensary facility backer" does not include a

person with an investment interest in a dispensary facility provided the interest held by such person and such person's co-workers, employees, spouse, parent or child, in the aggregate, do not exceed five per cent of the total ownership or interest rights in such dispensary facility and such person does not participate directly or indirectly in the control, management or operation of the dispensary facility;

(25) "Dispensary facility manager" means the dispensary who has complete control and management over the dispensary facility;

(26) "Dispensary facility employee" means a dispensary, dispensary technician, dispensary facility staff and all other persons employed by a dispensary facility or who otherwise have access to the dispensary facility, including independent contractors who are routinely on the facility premises;

(27) "Dispensary technician" means an individual who has had an active pharmacy technician registration in Connecticut within the past five years, is affiliated with a licensed dispensary and is registered with the department in accordance with section 21a-408-24 of the Regulations of Connecticut State Agencies;

(28) "Dispense" or "dispensing" means those acts of processing marijuana for delivery or for administration for a qualifying patient pursuant to a written certification consisting of:

(A) Comparing the directions on the label with the instructions on the written certification, if any, to determine accuracy;

(B) the selection of the appropriate marijuana product from stock;

(C) the affixing of a label to the container; and

(D) the provision of any instructions regarding the use of the marijuana;

(29) "Dispensing error" means an act or omission relating to the dispensing of marijuana that results in, or may reasonably be expected to result in, injury to or death of a qualifying patient or results in any detrimental change to the medical treatment for the patient;

(30) "Disqualifying conviction" means a conviction for the violation of any statute or regulation pertaining to the illegal manufacture, sale or distribution of a controlled substance or controlled substance analog unless the violation resulting in the conviction occurred when the person held a valid license or registration certificate from the department and the violation was of a federal statute or regulation related to the possession, purchase or sale of marijuana that is authorized under the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(31) "Drug Control Division" means the division within the department responsible for overseeing the medical marijuana program;

(32) "Drug" has the same meaning as provided in section 20-571 of Connecticut General Statutes;

(33) "Electronic data intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices utilized by dispensaries with those used by physicians or the department in order to facilitate the secure transmission of qualifying patient or primary caregiver information;

(34) "Financial interest" means any actual, or a future right to, ownership, investment or compensation arrangement with another person, either directly or indirectly, through business, investment or family. "Financial interest" does not include ownership of investment securities in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by such person and such person's co-workers, employees, spouse, parent or child, in the aggregate, do not exceed one-half of one per cent of the total number of shares issued by the corporation;

(35) "Forms" means applications, registrations, written certifications or other documents prescribed by the commissioner in either hardcopy or electronic format;

(36) "Good standing" means a person has a license or registration with the department that is not on probation or subject to any other restriction or oversight by the department beyond others in the same class;

(37) "Label" means a display of written, printed or graphic matter upon the immediate container of any product containing marijuana;

(38) "Laboratory" means a laboratory located in Connecticut that is licensed by the department to provide analysis of controlled substances pursuant to section 21a-246 of the Connecticut General Statutes;

(39) "Legend drug" has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(40) "Manufacture" or "manufacturing" means any process by which marijuana is converted to a marijuana product and that involves heating, mixing marijuana with any other ingredient or otherwise altering the raw material;

(41) "Marijuana" has the same meaning as provided in section 21a-240 of the Connecticut General Statutes;

(42) "Marijuana product" means any product containing marijuana, including raw materials, that requires no further processing and that is packaged for sale to dispensaries, qualifying patients and primary caregivers;

(43) "One-month supply" means the amount of marijuana reasonably necessary to ensure an uninterrupted availability of supply for a thirty-day period for qualifying patients, which amounts, including amounts for topical treatments, shall be determined by the commissioner on the basis of practical administration of the Act, available research and recommendations from the Board of Physicians;

(44) "Palliative use" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(45) "Paraphernalia" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(46) "Person" includes any corporation, limited liability company, association or partnership, or one or more individuals, government or governmental subdivisions or agency, estate, trust, or any other legal entity;

(47) "Pesticide chemical" has the same meaning as provided in section 21a-92 of the Connecticut General Statutes;

(48) "Petition" means a written request submitted pursuant to the Act and section 21a-408-12 of the Regulations of Connecticut State Agencies that recommends adding a medical condition, medical treatment or disease to the list of debilitating medical conditions that qualify for the palliative use of marijuana;

(49) "Pharmaceutical grade marijuana" means marijuana or marijuana products that are not adulterated and are:

(A) processed, packaged and labeled according to the Food and Drug Administration's "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," 21 CFR 111;

(B) labeled with the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis and a pesticide chemical residue analysis which have been completed on a batch basis by a laboratory; and

(C) where each step of the production, cultivating, trimming, curing, manufacturing, processing and packaging method has been documented by using established standard operation procedures approved by the commissioner;

(50) "Pharmacist" has the same meaning as provided in section 20-571 of Connecticut's General Statutes;

(51) "Pharmacy technician" has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

(52) "Physician" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(53) "Prescription monitoring program" means the electronic prescription drug monitoring program established by section 21a-254(j) of the Connecticut General Statutes;

(54) "Primary caregiver" or "caregiver" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes for "primary caregiver";

(55) "Producer" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(56) "Producer backer" means any person with a direct or indirect financial interest in an entity licensed as a producer, except it shall not include a person with an investment interest in a producer, provided the interest held by such person and such

person's co-workers, employees, spouse, parent or child, in the aggregate, does not exceed five per cent of the total ownership or interest rights in such producer and such person does not participate directly or indirectly in the control, management or operation of the production facility;

(57) "Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, compounding, conversion or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of marijuana by a patient or caregiver for the patient's use;

(58) "Production facility" means a secure, indoor facility where the production of marijuana occurs and that is operated by a person to whom the department has issued a producer license under the Act and sections 21a-408-20 of the Regulations of Connecticut State Agencies;

(59) "Production facility employee" means any person employed by a producer or who otherwise has access to the production facility, including independent contractors who are routinely on the production facility premises;

(60) "Qualifying patient" or "patient" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(61) "Registration certificate" means an identification card or other document issued by the department that identifies a person as a registered qualifying patient or primary caregiver;

(62) "Sale" is any form of delivery, which includes barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor, agent, servant or employee;

(63) "State", when applied to a part of the United States, includes any state, district, commonwealth, territory or insular possession thereof, and any area subject to the legal authority of the United States of America;

(64) "Usable marijuana" has the same meaning as provided in section 21a-408 of the Connecticut General Statutes; and

(65) "Written certification" means a written or electronically submitted statement issued by a physician to the department certifying a patient for the palliative use of marijuana, which shall be submitted on a form and in a manner prescribed by the commissioner.

(NEW) Sec. 21a-408-2. Physician requirements for issuing written certifications to the department

(a) The department shall only accept written certifications from physicians for the palliative use of marijuana when the physician:

- (1) Holds an active license under chapter 370 of the Connecticut General Statutes and is in good standing;
- (2) Holds an active department controlled substance practitioner registration, is in good standing and is eligible to prescribe schedule II controlled substances;
- (3) Holds an active federal Drug Enforcement Administration controlled substance registration, is in good standing and is eligible to prescribe schedule II controlled substances;
- (4) Is registered with, and able to access, the Prescription Monitoring Program; and
- (5) Is not engaged in any conduct prohibited by the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(b) A physician issuing a written certification shall:

- (1) Have a bona fide physician-patient relationship with the qualifying patient;
- (2) Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history and current medical condition, including an in-person physical examination;
- (3) Diagnose the patient as having a debilitating medical condition;
- (4) Be of the opinion that the potential benefits of the palliative use of marijuana would likely outweigh the health risks of such use to the qualifying patient;
- (5) Have prescribed, or have had a reasonable basis for determining that it is not in the best interest of the patient to prescribe, prescription drugs to address the symptoms or effects for which the written certification is being issued;
- (6) Be reasonably available to provide follow-up care and treatment to the qualifying patient including, but not limited to, physical examinations, to determine the efficacy of marijuana for treating the qualifying patient's debilitating medical condition or the symptom of the debilitating medical condition for which the written certification was issued;
- (7) Comply with generally accepted standards of medical practice except to the extent such standards would counsel against certifying a qualifying patient for marijuana; and
- (8) Explain the potential risks and benefits of the palliative use of marijuana to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent, guardian or person having legal custody of the qualifying patient, prior to submitting the written certification.

(c) A physician shall not delegate the responsibility of diagnosing a patient or determining whether a patient should be issued a written certification. Employees under the direct supervision of the physician may assist with preparing a written certification so long as the final written certification is reviewed and approved by the physician before it is submitted to the department.

(d) If a physician provides instructions for the use of marijuana to the patient, or includes instructions as part of the written certification, the physician shall also securely transmit such instructions to the qualifying patient's designated dispensary facility.

(NEW) Sec. 21a-408-3. Physician requirements for maintaining patient medical records

(a) A physician shall maintain medical records, as described in section 19a-14-40 of the Regulations of Connecticut State Agencies, for all patients for whom the physician has issued a written certification.

(b) A physician shall make a copy of such medical records reasonably available to the commissioner or the commissioner's authorized representative, to other state agencies and to state and local law enforcement agencies for the purpose of enabling the department or other agency to ensure compliance with the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies or for the purpose of investigating or prosecuting a violation of any provision of the Connecticut General Statutes or the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-4. Physician prohibitions

(a) A physician that has issued or intends to issue a written certification shall not:

(1) Directly or indirectly accept, solicit, or receive anything of value from a dispensary, dispensary facility backer, dispensary facility employee, producer, producer backer, production facility employee, provider of paraphernalia or any other person associated with a dispensary facility or production facility, except as permitted by section 21a-70e of the Connecticut General Statutes;

(2) Offer a discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular primary caregiver, dispensary, dispensary facility or marijuana product;

(3) Examine a qualifying patient for purposes of diagnosing a debilitating medical condition at a location where marijuana or paraphernalia is acquired, distributed, dispensed, manufactured, sold, or produced; or

(4) Directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a physician from charging an appropriate fee for the patient visit.

(b) A physician that issues written certifications, and such physician's co-worker, employee, spouse, parent or child, shall not have a direct or indirect financial interest in a dispensary, dispensary facility, producer, production facility, provider of paraphernalia, or any other entity that may benefit from a qualifying patient's or primary caregiver's acquisition, purchase or use of marijuana, including any formal or informal agreement whereby a producer, dispensary, or other person provides compensation if the physician issues a written certification for a qualifying patient or steers a qualifying patient to a specific dispensary facility, paraphernalia provider, or marijuana product.

(c) A physician shall not issue a written certification for such physician or for the physician's family members, employees or co-workers.

(d) A physician shall not provide product samples containing marijuana other than those approved by the federal Food and Drug Administration.

(NEW) Sec 21a-408-5. Enforcement actions against physicians

(a) The commissioner may, after a hearing conducted pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, issue an order to revoke or suspend a physician's controlled substance practitioner registration or to restrict a physician's controlled substance practitioner registration so as to prohibit the physician from issuing written certifications if the physician has:

(1) Failed to comply with any provision of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Failed to comply with any provision of state statute or regulation concerning legend drugs or controlled substances; or

(3) Intentionally or negligently permitted another person to issue written certifications under the physician's name.

(b) If the commissioner has reason to believe that the public health, safety or welfare imperatively requires emergency action, the commissioner may issue an order restricting the physician's controlled substance practitioner registration to summarily prohibit the physician from issuing written certifications pending a hearing. Such hearing shall be conducted pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(c) The commissioner may enter into an agreement with a physician placing conditions on the physician's controlled substance practitioner registration that prohibit or restrict the issuing of written certifications.

(d) In addition to any other action permitted in this section, the commissioner may refer any case involving an alleged violation by a physician of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies,

to the Connecticut Medical Examining Board or to a Connecticut state or local law enforcement agency.

(NEW) Sec. 21a-408-6. Patient and primary caregiver registration

(a) A qualifying patient for whom a physician has issued a written certification, and the qualifying patient's primary caregiver where applicable, shall register with the department on forms, and in a manner, prescribed by the commissioner. For a registration application to be considered complete, the following items shall be submitted:

- (1) Written certification issued by a physician who meets the requirements set forth in the Act and section 21a-408-2 of the Regulations of Connecticut State Agencies;
- (2) Proof of residency of the qualifying patient acceptable to the department;
- (3) Proof of identity of the qualifying patient acceptable to the department;
- (4) Proof of the qualifying patient's age acceptable to the department;
- (5) A photograph of the qualifying patient meeting the following requirements:
 - (A) A current, digital, passport-size image, taken no more than thirty calendar days before the submission of the application;
 - (B) Taken against a plain white or off-white background or backdrop;
 - (C) At least two inches by two inches in size;
 - (D) In natural color;
 - (E) Provides a front, unobstructed view of the full face;
 - (F) Has between one and one and three-eighths inches from the bottom of the chin to the top of the head; and
 - (G) Is in "jpeg" format or such other format as the department may authorize;
- (6) A caregiver form, if applicable;
- (7) Proof of identity of the caregiver in a manner acceptable to the department;
- (8) Proof of the primary caregiver's age acceptable to the department;
- (9) A photograph of the caregiver meeting the requirements set forth in subsection (a)(5) of this section;
- (10) Permission for the department to determine whether the patient is an inmate confined in a correctional institution or facility under the supervision of the Department of Correction;
- (11) Permission for the department to conduct a background check of the primary caregiver for the purpose of determining if such applicant has been convicted of a violation of any law pertaining to the illegal manufacture, sale or distribution of a controlled substance;
- (12) Payment of the appropriate fees as set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies;

(13) The name, address and telephone number of the dispensary facility from which the qualifying patient or the patient's primary caregiver will purchase marijuana; and

(14) Such other information as the department may reasonably require to determine the applicant's suitability for registration or to protect public health and safety.

(b) If a registration application is determined to be inaccurate or incomplete, the department shall send the applicant a notice of deficiency. If the applicant corrects the deficiencies sixty days or less after receiving notice from the department, the department shall not charge any additional fees.

(c) The department shall deny an application if an applicant submits corrections or supplies the missing information more than sixty days after receiving a notice of deficiency from the department, or if the applicant fails to provide correct and complete information on their second attempt. Any such applicant may resubmit the registration application materials with all applicable fees for a new registration.

(d) A qualifying patient shall only designate, and the department shall only register, one primary caregiver for the patient at any given time.

(e) Absent permission from the commissioner for good cause shown, a qualifying patient may only change primary caregivers once per year at the time of renewal. A qualifying patient may change primary caregivers at the time of their registration renewal by requesting a different primary caregiver, who shall meet the requirements of the Act and this section, and be approved by the commissioner prior to the patient's registration certificate being renewed. If the qualifying patient requests permission to change primary caregiver prior to renewal, the qualifying patient shall submit a change of caregiver request form to the department, which shall set forth the reasons the qualifying patient seeks to change primary caregivers. If the department approves such change of primary caregiver request, the new primary caregiver shall register with the department and shall submit the non-refundable primary caregiver application fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies. The department shall approve a new primary caregiver only if such person meets the requirements of the Act and this section.

(f) A qualifying patient who lacked legal capacity at the time of the most recent application or renewal may not change primary caregivers unless:

(1) The qualifying patient provides a court order, or other proof acceptable to the department, indicating that the qualifying patient no longer lacks legal capacity, in which case the qualifying patient may change caregivers in accordance with subsection (e) of this section; or

(2) The primary caregiver is no longer willing or able to serve as a caregiver, in which case the qualifying patient's new primary caregiver applicant shall:

(A) Certify to the department that the current primary caregiver can no longer serve or no longer wishes to serve as a caregiver; and

(B) Submit an application and registration fee that meets the requirements of the Act and this section .

(NEW) Sec. 21a-408-7. Denial of a qualifying patient or primary caregiver registration application

(a) The department may deny an application or renewal of a qualifying patient's registration certificate if the applicant:

(1) Does not meet the requirements set forth in the Act or section 21a-408-6 of the Regulations of Connecticut State Agencies;

(2) Fails to properly complete the application form;

(3) Does not provide acceptable proof of identity, residency or age to the department;

(4) Provides false, misleading or incorrect information to the department;

(5) Fails to provide a photograph in accordance with section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies;

(6) Has had a qualifying patient's registration denied, suspended or revoked by the department in the previous six months;

(7) Has not paid all applicable fees as required by section 21a-408-28 of the Regulations of Connecticut State Agencies;

(8) Has a written certification issued by a physician who is not authorized to certify patients for marijuana; or

(9) Needs a primary caregiver according to the written certification issued by the physician and:

(A) The applicant has not designated a primary caregiver; or

(B) The department has denied the application of the primary caregiver designated by the qualifying patient.

(b) The department may deny an application or the renewal of a primary caregiver's registration certificate if the qualifying patient's physician has not certified the need for the patient to have a primary caregiver or if the primary caregiver applicant:

(1) Does not meet the qualifications set forth in the Act or section 21a-408-6 of the Regulations of Connecticut State Agencies;

(2) Has a disqualifying conviction;

(3) Fails to properly complete the primary caregiver application form;

(4) Does not provide acceptable proof of identity or age to the department;

(5) Fails to provide a photograph in accordance with section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies;

(6) Has not paid all applicable fees as required by section 21a-408-28 of the Regulations of Connecticut State Agencies;

(7) Provides false, misleading or incorrect information to the department;

(8) Has had a primary caregiver registration denied, suspended or revoked in the previous six months;

(9) Is already a primary caregiver, or has already applied to be a primary caregiver, for a different qualifying patient, unless the primary caregiver provides proof acceptable to the department demonstrating that the primary caregiver has a parental, guardianship, conservatorship or sibling relationship with each qualifying patient; or

(10) Is designated as a primary caregiver for a qualifying patient whose application is denied by the department or whose qualifying patient registration certificate has been suspended or revoked.

(c) If the commissioner denies an application or renewal of a qualifying patient applicant or primary caregiver applicant, the commissioner shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing.

(1) Upon receipt of such notice, the applicant may request a hearing, which request shall be submitted to the department in writing not more than twenty calendar days after the date of the notice.

(2) If the applicant makes a timely request for a hearing, the commissioner shall conduct a hearing in accordance with the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(3) If the applicant does not request a hearing in writing in a timely manner, the applicant shall be deemed to have waived the right to a hearing.

(NEW) Sec. 21a-408-8. Revocation or suspension of a qualifying patient or primary caregiver registration

(a) The commissioner may revoke or suspend the registration certificate of a qualifying patient, in accordance with the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, under the following circumstances:

(1) The qualifying patient becomes an inmate confined in a correctional institution or facility under the supervision of the Department of Correction;

(2) The qualifying patient's physician notifies the department that the physician is withdrawing the written certification submitted on behalf of the qualifying patient and, thirty days after the physician's withdrawal of the written certification, the patient has not obtained a valid written certification from a different physician;

- (3) The qualifying patient or primary caregiver provided false, misleading or incorrect information to the department;
- (4) The qualifying patient is no longer a resident of Connecticut;
- (5) The qualifying patient, together with the qualifying patient's caregiver where applicable, obtains more than a one-month supply of marijuana in a one-month period;
- (6) The qualifying patient provides or sells marijuana to any person, including another registered qualifying patient or primary caregiver;
- (7) The qualifying patient uses marijuana in a place or manner not permitted by the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;
- (8) The qualifying patient uses marijuana in a manner that puts others at risk or fails to take reasonable precautions to avoid putting others at risk;
- (9) The qualifying patient permits another person to use the qualifying patient's registration certificate;
- (10) The qualifying patient tampers, falsifies, alters, modifies or allows another person to tamper, falsify, alter or modify, the qualifying patient's registration certificate;
- (11) The qualifying patient's physician is no longer available to provide care to the patient and, after thirty days from the physician notifying the department of the physician's unavailability, the patient has not established a bona-fide relationship with a different physician;
- (12) The primary caregiver notifies the department that the primary caregiver is no longer willing to serve as a primary caregiver for the qualifying patient, or the primary caregiver's registration certification has been suspended or revoked, in which case the qualifying patient shall have thirty days to register an acceptable primary caregiver with the department before the department may commence an action to suspend or revoke the qualifying patient's registration;
- (13) The qualifying patient's registration certificate is lost, stolen or destroyed and the patient or the patient's primary caregiver fails to notify the department or notifies the department of such incident more than five business days after becoming aware that the registration certificate was lost, stolen or destroyed;
- (14) The qualifying patient fails to notify the department of a change in registration information or notifies the department of such change more than five business days after the change; or
- (15) The qualifying patient has violated any section of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.
- (b) The department may revoke or suspend the registration certificate of a primary caregiver, in accordance with the Uniform Administrative Procedures Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, under the following circumstances:

- (1) The registration certification of the qualifying patient has been revoked or suspended;
- (2) The qualifying patient's physician notifies the department that the qualifying patient is no longer in need of a primary caregiver;
- (3) The qualifying patient or primary caregiver provided false, misleading or incorrect information to the department;
- (4) The qualifying patient registers a different person to serve as the primary caregiver in accordance with the procedure set forth in section 21a-408-6 of the Regulations of Connecticut State Agencies;
- (5) The primary caregiver obtains more than a one-month supply of marijuana in a one-month period on behalf of a single qualifying patient;
- (6) The primary caregiver obtains marijuana for, or provides or sells marijuana to, any person other than the qualifying patient of the primary caregiver, including a different qualifying patient or primary caregiver;
- (7) The primary caregiver permits another person to use the primary caregiver's registration certificate;
- (8) The primary caregiver has tampered, altered, modified, falsified, or allowed any person to tamper, alter, modify or falsify, the primary caregiver's registration certificate or the registration certificate of the qualifying patient;
- (9) The primary caregiver has permitted the use of marijuana that endangers the health or well-being of a person other than the qualifying patient or primary caregiver;
- (10) The primary caregiver has a disqualifying conviction;
- (11) The primary caregiver's registration certificate is lost, stolen or destroyed and the primary caregiver fails to notify the department or notifies the department of such incident more than five business days after becoming aware that the registration certificate was lost, stolen or destroyed;
- (12) The primary caregiver fails to notify the department of a change in registration information or notifies the department of such change more than five business days after the change; or
- (13) The primary caregiver has violated any section of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-9. Reporting requirements for physicians, patients and caregivers

(a) A physician shall report to the department, in a manner prescribed by the commissioner, the death of a qualifying patient or change in status of a debilitating medical condition involving a qualifying patient for whom the physician has issued a written certification if such change may affect the patient's continued eligibility to use

marijuana. A physician shall report such death or change of status not more than five business days after the physician becomes aware of such fact.

(b) A qualifying patient or primary caregiver, who has been issued a registration certificate, shall notify the department of any change in the information provided to the department not later than five business days after such change. A qualifying patient or primary caregiver shall report changes that include, but are not limited to, a change in the qualifying patient's name, address, contact information, medical status, or status with the Department of Corrections. A qualifying patient or primary caregiver shall report such changes on a form, and in a manner, prescribed by the commissioner.

(c) A qualifying patient or primary caregiver may change the patient's designated dispensary facility no more than four times per year without good cause shown and prior approval by the commissioner or the commissioner's authorized representative. A qualifying patient or primary caregiver shall report the change on a form and in a manner prescribed by the commissioner. A change in the designated dispensary facility shall not be effective until five business days after the qualifying patient or primary caregiver notifies the department of such change. A qualifying patient or primary caregiver shall only purchase marijuana from the dispensary facility currently designated by the patient or caregiver with the department.

(d) If a qualifying patient's or primary caregiver's appearance has substantially changed such that the photograph submitted to the department does not accurately resemble such qualifying patient or primary caregiver, such person shall submit, in a timely manner, an updated photograph that meets the requirements set forth in section 21a-408-6(a)(5) of the Regulations of Connecticut State Agencies.

(e) If a qualifying patient has a primary caregiver, that primary caregiver may notify the department of any changes on behalf of the qualifying patient using the same forms and process prescribed for qualifying patients.

(f) If a qualifying patient or primary caregiver notifies the department of any change that results in information on the registration certificate being inaccurate or the photograph needing to be replaced, the qualifying patient or primary caregiver shall submit the fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies for a replacement registration certificate. The department shall thereafter issue the qualifying patient or primary caregiver a new registration certificate provided the applicant continues to satisfy the requirements of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies. Upon receipt of a new registration certificate, the qualifying patient or primary caregiver shall destroy in a non-recoverable manner the registration certificate that was replaced.

(g) If a qualifying patient or primary caregiver becomes aware of the loss, theft or destruction of the registration certificate of such qualifying patient or primary caregiver, the qualifying patient or primary caregiver shall notify the department, on a form and in a

manner prescribed by the commissioner, not later than five business days of becoming aware of the loss, theft or destruction, and submit the fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies for a replacement registration certificate. The department shall inactivate the initial registration certificate upon receiving such notice and issue a replacement registration certificate upon receiving the applicable fee provided the applicant continues to satisfy the requirements of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-10. Precautions for preventing the loss, theft or misuse of marijuana by patients and caregivers

(a) A qualifying patient and primary caregiver shall store marijuana in a secure location to prevent theft, loss or access by unauthorized persons.

(b) Qualifying patients and primary caregivers shall carry their registration certificate with them whenever they are in possession of marijuana.

(NEW) Sec. 21a-408-11. Proper disposal of marijuana by patients or caregivers

A patient or caregiver shall dispose of all usable marijuana in the patient's or caregiver's possession no later than ten calendar days after the expiration of the patient's registration certificate, if such certificate is not renewed, or sooner should the patient no longer wish to possess marijuana for palliative use. A patient or caregiver shall complete such disposal by one of the following methods:

(1) By rendering the marijuana non-recoverable in accordance with the department's proper disposal instructions, which are available on the department's Internet web site at www.ct.gov/dcp/drugdisposal;

(2) By depositing it in a Connecticut police department medication drop-box; or

(3) By disposing of the marijuana at a government-recognized drug take-back program located in Connecticut.

(NEW) Sec. 21a-408-12. Establishment of additional debilitating medical conditions, medical treatments or diseases

(a) The commissioner shall not add a medical condition, medical treatment or disease to the list of debilitating medical conditions under the Act unless the appropriateness of adding the condition, treatment or disease has been considered by the board, the board has submitted a written recommendation to the commissioner in accordance with this section and the commissioner has adopted a regulation in accordance with subsection (k) of this section.

(b) Persons seeking to add a medical condition, medical treatment or disease to the list of debilitating medical conditions under the Act shall submit a written petition to the commissioner and request that the commissioner present the petition to the board.

(c) Absent a showing of good cause, the commissioner shall only present a petition to the board if it includes the following information:

(1) The extent to which the medical condition, medical treatment or disease is generally accepted by the medical community and other experts as a valid, existing medical condition, medical treatment or disease;

(2) If one or more treatments for the condition, rather than the condition itself, are alleged to be the cause of a 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;

(3) The extent to which the condition or the treatments thereof cause severe or chronic pain, severe nausea, spasticity or otherwise substantially limits one or more major life activities of the patient;

(4) The availability of conventional medical therapies, other than those that cause suffering, to alleviate suffering caused by the condition or the treatment thereof;

(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 the treatment thereof;

(6) Any information or studies known to the petitioner regarding any beneficial or adverse effects from the use of marijuana in patients with the medical condition, medical treatment or disease that is the subject of the petition; and

(7) Letters of support from physicians or other licensed health care professionals knowledgeable about the condition, treatment or disease.

(d) If a medical condition, medical treatment or disease in a petition has been previously considered and rejected by the commissioner, or is determined by the commissioner to be substantially similar to such a rejected condition, treatment or disease, the commissioner may deny the petition without first submitting it to the board unless new scientific research supporting the request is included in the petition.

(e) If a written petition meets the requirements of this section, the commissioner shall refer the written petition to the board for a public hearing at the next board meeting that is at least sixty days after the date the petition was submitted and at which the board will be considering petitions.

(f) At least twice per year, the board shall conduct a public hearing to evaluate any petitions referred to it by the commissioner and to consider any other medical conditions, medical treatments or diseases that the board, on its own initiative, believes should be reviewed for possible inclusion on the list of debilitating medical conditions under the Act.

(g) No less than twenty days before each public hearing at which the board will consider petitions or the inclusion of debilitating conditions on its own initiative, the department shall publish on its Internet web site a list of the debilitating medical conditions, medical treatments and diseases that the board will be considering at its upcoming hearing so that the petitioner, where applicable, and other members of the public may offer public comments before the board.

(h) In addition to information provided in a petition, the board may examine scientific, medical or other evidence and research pertaining to the petition, and may gather information, in person or in writing, from other persons knowledgeable about the medical condition, medical treatment or disease being considered.

(i) Following the public hearing, the board shall consider the public comments and any additional information or expertise made available to the board for each proposed debilitating medical condition considered at the hearing. The board shall issue a written recommendation to the commissioner as to whether the medical condition, medical treatment or disease should be added to the list of debilitating medical conditions that qualify for the palliative use of marijuana. The board shall include in its recommendation the following:

- (1) Whether the medical condition, medical treatment or disease is debilitating;
- (2) Whether marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition, medical treatment or disease; and
- (3) Other matters that the board considers relevant to the approval or the denial of the petition.

(j) At least three members of the board, which shall constitute a quorum, shall consider each proposed debilitating medical condition. A majority of the board members present at the hearing where each proposed debilitating medical condition was presented for public comment shall concur in the recommendation submitted to the commissioner and that recommendation shall be considered the official recommendation of the board. Any board member who disagrees with the board's official recommendation may submit a dissenting or concurring recommendation to the commissioner.

(k) If, after receiving the board's official recommendation and any dissenting or concurring recommendation, the commissioner concludes that the medical condition, medical treatment or disease that was under consideration should be added to the list of debilitating medical conditions under the Act, the commissioner shall proceed to adopt regulations, in accordance with section 21a-408m of the Connecticut General Statutes and the Uniform Administrative Procedures Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, expanding the list of debilitating medical conditions accordingly.

(NEW) Sec. 21a-408-13. Number of dispensaries and dispensary facilities

(a) Only a dispensary at a dispensary department may dispense marijuana.

(b) The commissioner shall issue at least one dispensary facility license and may issue additional dispensary facility licenses upon a determination that additional dispensary facilities are desirable to assure access to marijuana for qualifying patients. Such determination shall be made based on the size and location of the dispensary facilities in operation, the number of qualifying patients registered with the department and the convenience and economic benefits to qualifying patients.

(c) Each dispensary facility may employ no more than five dispensaries at a time without prior approval from the commissioner, one of whom shall be designated as the dispensary facility manager.

(NEW) Sec. 21a-408-14. Dispensary facility license selection

(a) The department shall publish on its Internet web site, and in such other places as the department deems appropriate, a notice of open applications for dispensary facility licenses. Such notice shall include, but not be limited to:

- (1) The maximum number of licenses to be awarded;
- (2) Information on how to obtain an application;
- (3) The deadline for receipt of applications;
- (4) Acceptable methods for submitting an application;
- (5) The preferred locations, if any, for the dispensary facility licenses; and
- (6) The criteria that shall be considered in awarding the dispensary facility

licenses.

(b) Following the deadline for receipt of applications, the commissioner shall evaluate each complete and timely submitted application and award dispensary facility licenses on a competitive basis based on the criteria set out in the notice for applications. In the event the commissioner determines that there are an insufficient number of qualified applicants to award all of the dispensary facility licenses that the commissioner has determined are desirable, the department may republish, in accordance with this section, a notice of open applications for dispensary facility licenses.

(c) The commissioner shall consider, but is not limited to, the following criteria in evaluating dispensary facility license applications:

(1) The character and fitness of the dispensary, dispensary facility backers and any other person who may have control or influence over the operation of the proposed dispensary facility;

(2) The location for the proposed dispensary facility including, but not limited to:

(A) Its proximity to previously approved dispensary facilities or pending dispensary facility applications;

(B) Whether the registered patient population in the area proposed by the dispensary facility applicant justifies the need for a dispensary facility, or an additional dispensary facility, in that area;

(C) Whether the proximity of the proposed dispensary facility will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment;

(D) Whether the number of dispensary facilities in the locality is such that the granting of a license is detrimental to the public interest. In reaching a conclusion in this respect, the commissioner may consider the population of, the number of like licenses and number of all licenses existent in, the particular town and the immediate neighborhood concerned, the effect that a new license may have on such town or neighborhood or on like licenses existent in such town or neighborhood;

(3) The applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana;

(4) The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of marijuana; and

(5) The extent to which the applicant or any of the applicant's dispensary facility backers have a financial interest in another licensee, registrant or applicant under the Act or sections 21a-408-1 to 21a-408-70 of the Regulations of Connecticut State Agencies.

(6) Any other reason provided by Connecticut state or federal statute or Connecticut state or federal regulation that is not inconsistent with the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and that warrants consideration.

(d) The commissioner shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.

(e) The commissioner shall have the right to cancel a notice of open applications prior to the award of a dispensary facility license.

(f) The commissioner may disqualify any applicant who:

(1) Submits an incomplete, false, inaccurate or misleading application;

(2) Fails to submit an application by the published deadline; or

(3) Fails to pay all applicable fees;

(g) The decision of the commissioner not to award a dispensary facility license to an applicant shall be final.

(h) If an applicant has been awarded a dispensary facility license and has not commenced operation of such facility within one hundred twenty days of being notified of the dispensary facility license award, the commissioner may, in the commissioner's discretion, rescind such dispensary facility license, unless such delay was caused by a *force majeure*. A dispensary facility shall be deemed to have commenced operation if the dispensary facility is capable of operating in accordance with the dispensary facility applicant's approved application. In the event a dispensary facility license is rescinded pursuant to this subsection, the commissioner shall award a dispensary facility license by selecting among the qualified applicants who applied for the dispensary facility license subject to rescission. If no other qualified applicant applied for such dispensary facility license or satisfied the criteria for awarding a license, the department shall publish, in accordance with this section, a notice of open applications for dispensary facility licenses.

(NEW) Sec. 21a-408-15. Dispensary facility license applications

(a) Only a dispensary facility that has obtained a license from the department may sell marijuana to qualified patients and primary caregivers that have a registration certificate from the department.

(b) A dispensary facility license applicant shall submit an application form and the fees required by section 21a-408-28 of the Regulations of Connecticut State Agencies, as well as all other required documentation on forms prescribed by the commissioner.

(c) The applicant shall provide the following information and records in the application process:

(1) The name and address of the applicant, the applicant's dispensary facility backers, if any, and the person who will serve as the dispensary facility manager if the application is approved;

(2) The location for the dispensary facility that is to be operated under such license;

(3) A financial statement setting forth all elements and details of any business transactions connected with the application;

(4) A detailed description of any other services or products to be offered by the dispensary facility;

(5) Details regarding the applicant's plans to maintain adequate control against the diversion, theft or loss of marijuana;

(6) Details of any felony conviction or of any criminal conviction related to controlled substances or legend drugs of the applicant or applicant's backers;

(7) Documents sufficient to establish that the applicant is authorized to conduct business in Connecticut and that all applicable state and local building, fire and zoning requirements and local ordinances will be met;

(8) Permission for the department to conduct a background check on the applicant and the applicant's backers, if any, for the purpose of determining if such applicant and applicant's backers are suitable to own and operate a dispensary facility;

(9) Any business and marketing plans related to the operation of the dispensary facility or the sale of marijuana;

(10) Text and graphic materials showing the exterior appearance of the proposed dispensary facility and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;

(11) A blueprint of the proposed dispensary facility, which shall, at a minimum, show and identify:

(A) The square footage of the area which will constitute the dispensary department;

(B) The square footage of the overall dispensary facility;

(C) The square footage and location of areas used as storerooms or stockrooms;

(D) The size of the counter that will be used for selling marijuana;

(E) The location of the dispensary facility sink and refrigerator, if any;

(F) The location of all approved safes and approved vaults that will be used to store marijuana;

(G) The location of the toilet facilities;

(H) The location of a break room and location of personal belonging lockers;

(I) The location and size of patient counseling areas, if any;

(J) The locations where any other products or services will be offered; and

(K) The location of all areas that may contain marijuana showing the location of walls, partitions, counters and all areas of ingress and egress;

(12) Documents related to any compassionate need program the dispensary facility intends to offer; and

(13) Such other documents and information reasonably required by the department to determine the applicant's suitability for registration or to protect public health and safety.

(d) In the event any information contained in the application or accompanying documents changes after being submitted to the department, the applicant shall immediately notify the department in writing and provide corrected information in a timely manner so as not to disrupt the license selection process.

(e) The department may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to

operate a dispensary facility. The department may verify the information and assess the applicant's character and fitness by, among other things:

- (1) Contacting the applicant by telephone, mail, electronic mail or such other means as are reasonable under the circumstances;
- (2) Conducting an on-site visit of the proposed dispensary facility location or other dispensary facility locations associated with the applicant or the applicant's dispensary facility backers;
- (3) Conducting background checks or contacting references of the applicant, the applicant's dispensary facility backers and the dispensary facility backers' members, shareholders or investors;
- (4) Contacting state regulators in any other states where the applicant, the applicant's dispensary facility backers and the dispensary facility backers' members, shareholders or investors are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; and
- (5) Requiring a personal meeting with the applicant and the submission of additional information or documents.

(NEW) Sec. 21a-408-16. Dispensary facility employee licenses and registrations

(a) No person shall act as a dispensary without a license issued by the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(b) No person shall act as a dispensary technician without being registered with the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(c) No person shall be employed or retained as any other type of dispensary facility employee without being at least 18 years of age and being registered by the department under the Act and section 21a-408-24 of the Regulations of Connecticut State Agencies.

(d) Any dispensary facility backer, or other person who will exercise control over, or have management responsibility for, a dispensary facility shall be registered with the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies.

(e) Only a pharmacist who is in good standing and has an active pharmacist license issued by the department may apply for and receive a dispensary license.

(f) Only a person who has held an active pharmacy technician registration in Connecticut within the five years prior to the application, who is 18 years of age or older, and is currently in good standing, or was in good standing at the time his or her registration lapsed, may apply for and receive a dispensary technician registration.

(NEW) Sec. 21a-408-17. Notification of changes by dispensary facility

(a) Unless otherwise provided in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the dispensary facility manager shall provide any notification or information that is required from a dispensary facility pursuant to sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, except that if the notification or information relates to a change in the dispensary facility manager, or if the dispensary facility manager is otherwise not available to provide the notification or information to the department, a dispensary facility backer shall provide such notification or information.

(b) Prior to any person becoming affiliated with a dispensary facility, including any change associated with a change in ownership, such person shall comply with the licensing and registration requirements set forth in section 21a-408-16 of the Regulations of Connecticut State Agencies. No person shall commence such affiliation until approved by the commissioner.

(c) Prior to making any change to the dispensary facility name, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(d) Prior to changing a dispensary facility location, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(e) Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of a dispensary facility or a dispensary department, the dispensary facility shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change until approved by the commissioner.

(f) Prior to designating a new dispensary facility manager, the dispensary facility shall submit a change of dispensary facility manager form to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. No dispensary facility shall make such change in dispensary facility manager until approved by the commissioner. In the event of an emergency such that the designated dispensary facility manager is no longer able or willing to continue managing the dispensary department, the dispensary facility backer or current dispensary facility

manager shall immediately notify the department that the dispensary facility manager has ceased such management and shall immediately notify the department of the name, address and dispensary license number of the dispensary who assumes management of the dispensary facility. Such person shall serve as the acting dispensary facility manager until such time as the commissioner approves a new dispensary facility manager. The dispensary facility shall submit a change of dispensary facility manager form and accompanying fee to the department to designate a permanent dispensary facility manager not more than fifteen business days after the previously designated dispensary facility manager has ceased management responsibilities.

(g) The dispensary facility shall notify the department no later than ten business days after the date that a dispensary facility backer or dispensary facility employee ceases to work for, or be affiliated with, the dispensary facility.

(h) If a dispensary facility will be closing, the dispensary facility manager for the facility shall notify the department of the closing not less than fifteen days prior to the closing.

(NEW) Sec. 21a-408-18. Notification of changes by dispensary and dispensary technician

(a) Every dispensary and dispensary technician whose place of employment changes shall report to the department the following information regarding the dispensary or dispensary technician's new employment. Such notification shall be made, on a form prescribed by the commissioner, no less than five business days after the change in employment becomes effective.

(b) Any dispensary or dispensary technician whose name or home address changes shall notify the department of such change, on a form prescribed by the commissioner, no less than five business days after the change.

(NEW) Sec. 21a-408-19. Number of producers

(a) The department shall issue at least three, but no more than ten, producer licenses.

(b) Prior to issuing any additional producer licenses, the commissioner shall determine that additional producers are desirable to assure access to marijuana for qualifying patients, which determination shall be made based on the size and location of the production facilities in operation, the amount of marijuana each production facility is producing, the number of qualifying patients registered with the department and the convenience and economic benefits to qualifying patients or dispensary facilities.

(NEW) Sec. 21a-408-20. Producer selection

(a) The department shall publish on its Internet web site, and in such other places as the department deems appropriate, a notice of open applications for producer licenses. Such notice shall include, but not be limited to:

- (1) The maximum number of producer licenses to be awarded;
- (2) Information on how to obtain an application;
- (3) The deadline for receipt of applications;
- (4) Acceptable methods for submitting an application; and
- (5) The criteria that shall be considered in awarding the producer license.

(b) Following the deadline for receipt of applications, the department shall evaluate each complete and timely submitted application and award producer licenses on a competitive basis based on the criteria set out in the notice for applications. In the event the commissioner determines that there are an insufficient number of qualified applicants to award all of the producer licenses that the commissioner has determined are desirable, the department may republish, in accordance with this section, a notice of open applications for producer licenses.

(c) The department shall consider, but is not limited to, the following criteria in evaluating producer license applications:

(1) The location for the proposed production facility to be owned or leased and operated by the producer including, but not limited to:

(A) Whether the proximity of the proposed production facility will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment;

(B) Whether the number of production facilities in the locality is such that the granting of an additional license is detrimental to the public interest. In reaching a conclusion in this respect, the commissioner may consider the population of, the number of like licenses and number of all licenses existent in, the particular town and the immediate neighborhood concerned and the effect that a new license may have on such town or neighborhood or on like licenses existent in such town or neighborhood; and

(C) If the production facility is leased, whether the lease agreement limits access to the facility by the owner of the facility, or a representative or agent of the owner, except on conditions permitted by the Act and section 21a-408-53 of the Regulations of Connecticut State Agencies;

(2) The character and fitness of the producer, producer backers, and any other person who may have control or influence over the producer or production facility;

(3) Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a production facility;

(4) The applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana produced or manufactured at the production facility;

(5) The applicant's ability to produce pharmaceutical grade marijuana for palliative use in a secure, indoor facility;

(6) The applicant's expertise in agriculture and other production techniques required to produce pharmaceutical grade marijuana or to manufacture marijuana products;

(7) Proof acceptable to the commissioner that the applicant can establish and maintain an escrow account in a financial institution in Connecticut, a letter of credit drawn from a financial institution in Connecticut or a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner, in the secured amount of two million dollars. Any escrow account agreement, letter of credit or surety bond shall adhere to the terms and conditions set forth by the commissioner in the request for applications. The establishment of such escrow account, letter of credit or surety bond shall be required prior to issuance of a producer license;

(8) The extent to which the applicant or any of the applicant's producer backers have a financial interest in another licensee, registrant or applicant under the Act or sections 21a-408-1 to 21a-408-70 of the Regulations of Connecticut State Agencies; and

(9) Any other factors provided by Connecticut state or federal statute or Connecticut or federal regulation that are not inconsistent with the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and that warrant consideration.

(d) The commissioner shall have the right to amend the notice of open applications prior to the deadline for submitting an application. The commissioner shall publish such amended notice in the same manner as the original notice of open applications.

(e) The commissioner shall have the right to cancel a notice of open applications prior to the award of a producer license.

(f) The commissioner may disqualify any applicant who:

(1) Submits an incomplete, false, inaccurate or misleading application;

(2) Fails to submit an application by the published deadline; or

(3) Fails to pay all applicable fees.

(g) The decision of the commissioner not to award a producer license to an applicant shall be final.

(h) If an applicant has been awarded a producer license and has not commenced operation of a production facility within 180 days of being notified of the producer license award, the commissioner may, in the commissioner's discretion, rescind such producer license unless such delay was caused by *force majeure*. A producer shall be deemed to have commenced operation if the production facility is fully constructed and capable of operating in accordance with the producer's approved application. In the event a producer license is rescinded pursuant to this subsection, the commissioner shall award a producer license by selecting among the qualified applicants who applied for the producer license subject to rescission. If no other qualified applicant applied for such producer license or satisfied the criteria for awarding a license, the department shall publish, in accordance with this section, a notice of open applications for producer license.

(NEW) Sec. 21a-408-21. Producer applications

(a) A producer shall submit an application form and the fees required by section 21a-408-28 of the Regulations of Connecticut State Agencies, as well as all other required documentation on forms prescribed by the commissioner.

(b) The applicant shall provide the following information in the application process and maintain the following records, as applicable:

(1) The name and address of the applicant and the applicant's producer backers, if any;

(2) The location for the production facility that is to be operated under such producer license;

(3) A financial statement setting forth all elements and details of any business transactions connected with the application;

(4) Details of any felony conviction or of any criminal conviction related to controlled substances or legend drugs of the applicant or applicant's backers;

(5) Details regarding the applicant's plans to maintain adequate control against the diversion, theft or loss of marijuana;

(6) Documents sufficient to establish that the applicant is authorized to conduct business in Connecticut and that all applicable state and local building, fire and zoning requirements and local ordinances will be met; with regard to zoning, it shall be sufficient to establish that the proposed location is in a zone where a pharmaceutical manufacturing facility would be allowed;

(7) Permission for the department to conduct a background check on the applicant and the applicant's backers, if any for the purpose of determining if such applicant and applicant's backers are suitable to own and operate a producer or production facility;

(8) Any proposed business and marketing plans, including expected production capacity;

(9) Text and graphic materials showing the exterior appearance of the proposed production facility and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;

(10) A blueprint of the proposed production facility to be operated by the licensee, which shall, at a minimum, show and identify:

(A) The square footage of the areas where marijuana is to be grown;

(B) The square footage of the areas where marijuana is to be harvested;

(C) The square footage of the areas where marijuana is to be packaged and labeled;

(D) The square footage of the areas where marijuana is to be produced and manufactured;

(E) The square footage of the overall production facility;

(F) The square footage and location of areas to be used as storerooms or stockrooms;

(G) The location of any approved safes or approved vaults that are to be used to store marijuana;

(H) The location of the toilet facilities;

(I) The location of a break room and location of personal belonging lockers; and

(J) The location of all areas that may contain marijuana that shows walls, partitions, counters and all areas of ingress and egress. The blueprint shall also reflect all production, propagation, vegetation, flowering, harvesting, and manufacturing areas;

(11) Proof acceptable to the commissioner that the applicant can establish and maintain an escrow account in a financial institution in Connecticut, a letter of credit drawn from a financial institution in Connecticut or a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner;

(12) Documents related to any compassionate need program the producer intends to offer; and

(13) Such other documents and information reasonably required by the department to determine the applicant's suitability for licensing or to protect public health and safety.

(c) In the event any information contained in the producer license application or accompanying documents changes after being submitted to the department, the applicant shall notify the department in writing and provide corrected information in a timely manner so as not to disrupt the license selection process.

(d) The department may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to

operate a production facility. The department may verify the information and assess the applicant's character and fitness by, among other things:

(1) Contacting the applicant by telephone, mail, electronic mail or such other means as are reasonable under the circumstances;

(2) Conducting an on-site visit of the proposed production facility location or other production facility locations associated with the applicant or the applicant's producer backers;

(3) Conducting background checks or contacting references of the applicant, the applicant's producer backers and the producer backers' members, shareholders or investors;

(4) Contacting state regulators in any other states where the applicant, the applicant's producer backers and the producer backers' members, shareholders or investors are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; and

(5) Requiring a personal meeting with the applicant and the submission of additional information or documents.

(NEW) Sec. 21a-408-22. Production facility employee registrations

(a) A production facility employee shall be at least 18 years of age and shall be registered by the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies before being employed by a producer.

(b) Any producer backer or other person who will exercise control over, or have management responsibility for, a production facility shall be registered with the department pursuant to section 21a-408-24 of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-23. Notification of changes by producers

(a) Prior to adding any person as a producer backer or making any other change to the ownership of the production facility, the producer shall register such additional person, on forms prescribed by the commissioner, with the department pursuant to sections 21a-408-24 to 21a-408-25, inclusive, of the Regulations of Connecticut State Agencies, and pay the accompanying registration fee set forth for producer backers in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such addition or change until approved by the commissioner.

(b) Prior to making any change to the producer name or production facility name, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the

Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(c) Prior to changing a production facility location, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(d) Prior to any modification, remodeling, expansion, reduction or other physical, non-cosmetic alteration of a production facility, the producer shall submit an application, on a form prescribed by the commissioner, for such change to the department and pay the fee set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies. A producer shall not make such change until approved by the commissioner.

(e) The producer shall notify the department no later than ten business days after the date that a producer backer or production facility employee ceases to work for or be affiliated with the producer.

(f) The producer shall notify the department if the producer's production facility will be closing or if the producer does not intend to renew the producer's license immediately after such decision has been made. In no event shall such notification be given less than six months prior to the effective date of such closing.

(NEW) Sec. 21a-408-24 Licenses and registrations for dispensary facilities, dispensary facility employees, producers, producer backers and production facility employees

(a) Applicants for any of the licenses or registrations set forth in sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, shall be required to supply information to the department sufficient for the department to conduct a background check and determine the character and fitness of the applicant for the license or registration, which information may include, but is not limited to:

- (1) Name;
- (2) Address;
- (3) Social security number or federal employee identification number;
- (4) Date of birth or formation;
- (5) Name and address of the producer, production facility or dispensary facility that the applicant seeks to work for, invest in or otherwise be associated with;
- (6) Past employment history;
- (7) Pharmacist or pharmacy technician license or registration number, if applicable;
- (8) Previous or current involvement in the medical marijuana industry;

- (9) Personal references;
 - (10) Any criminal record;
 - (11) Whether the person has ever applied for a license or registration related to medical marijuana in any state and, if so, the status of that application, license or registration;
 - (12) Percent ownership or nature of the financial interest in the producer or dispensary facility, where applicable;
 - (13) Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a marijuana production facility or dispensary facility; and
 - (14) Such other information as the department may reasonably require to determine the applicant's suitability for licensing or registration or to protect public health and safety.
- (b) All licenses and registrations issued pursuant to sections 21a-408-13 to 21a-408-24 inclusive, of the Regulations of Connecticut State Agencies, shall expire one year after the date of issuance and annually thereafter if renewed.
- (c) Any person who receives a license or registration pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, shall notify the department of any changes to the information supplied on the application for such license or registration no later than five business days after such change.

(NEW) Sec. 21a-408-25. Department issuance of identification cards; expiration

- (a) The department shall issue each person licensed or registered pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies an identification card that shall expire one year after the date of issuance.
- (b) No person shall begin working at a dispensary facility or production facility prior to receiving their identification card.
- (c) All licensees and registrants shall conspicuously display the identification cards issued by the department while on the premises of a dispensary facility or production facility.
- (d) The dispensary facility manager or producer shall return to the department the identification card of any dispensary facility employee or production facility employee whose employment has been terminated no later than five business days after such termination.

(NEW) Sec. 21a-408-26. Non-transferability of licenses and registrations

No person issued a license or registration pursuant to 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies shall assign or transfer such license, or registration without the commissioner's prior approval.

(NEW) Sec. 21a-408-27. Renewal applications

(a) Every person issued a license or registration pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies shall file a renewal application and the proper fees as set forth in section 21a-408-28 of the Regulations of Connecticut State Agencies with the department at least 45 days prior to the date the existing license or registration expires.

(b) If a renewal application is not filed prior to the expiration date of the applicable license or registration, the license or registration shall expire and become void until the licensee or registrant files a renewal application and pays all applicable fees, and the renewal application is approved by the commissioner.

(c) If a renewal application and all applicable fees are submitted to the department more than thirty calendar days after the expiration of the license or registration, the commissioner shall not renew such license or registration and the applicant shall reapply for such license or registration.

(NEW) Sec. 21a-408-28. Fees

An applicant shall submit the following fees with each license and registration application submitted, in the form of a certified check or money order payable to the "Treasurer, State of Connecticut," or by such other means as approved by the commissioner:

(1) The non-refundable application fee and each renewal fee for each qualifying patient and for each primary caregiver application shall be twenty-five dollars. In addition, there shall be a non-refundable fee of seventy-five dollars for administrative costs for each qualifying patient application, for a total non-refundable fee of one hundred dollars per qualifying patient application and for each renewal.

(2) The non-refundable fee for a replacement registration certificate for a qualifying patient or primary caregiver whose information has changed or whose original registration certificate has been lost, stolen or destroyed shall be ten dollars;

(3) The non-refundable fee for a dispensary facility license application shall be one thousand dollars. In addition, upon approval of the applicant's dispensary facility license, the applicant shall pay an additional fee of five thousand dollars prior to receiving a license;

(4) The non-refundable fee for each renewal of a dispensary facility license shall be five thousand dollars;

(5) The non-refundable fee for a dispensary license and for each renewal shall be one hundred dollars;

(6) The non-refundable fee for a dispensary technician and dispensary employee registration and each renewal shall be fifty dollars;

(7) The non-refundable registration fee and each renewal fee for a dispensary facility backer shall be one hundred dollars;

(8) The non-refundable fee for an application to change a dispensary facility name shall be one hundred dollars;

(9) The non-refundable fee for a change of dispensary facility manager form shall be fifty dollars;

(10) The non-refundable fee for an application to expand or change the location of a dispensary facility shall be one thousand dollars. If the application is approved, the applicant shall pay an additional one thousand five hundred dollars upon such approval;

(11) The non-refundable fee for an application to make a physical, non-cosmetic alteration of a dispensary facility or a dispensary facility department, other than an expansion, shall be five hundred dollars;

(12) The non-refundable application fee for a producer license shall be twenty-five thousand dollars. In addition, if an application for a producer license is approved, the applicant shall pay a fee of seventy-five thousand dollars prior to receiving a license;

(13) The non-refundable fee for each renewal of a producer license shall be seventy-five thousand dollars per production facility location;

(14) The non-refundable application fee for a producer to open an additional production facility location shall be twenty-five thousand dollars. In addition, if an application for an additional location is approved, the applicant shall pay a fee of seventy-five thousand dollars prior to receiving permission to open an additional production facility.

(15) The non-refundable fee for a production facility employee registration and for each renewal shall be one hundred dollars;

(16) The non-refundable fee for a producer backer registration and for each renewal shall be one hundred dollars;

(17) The non-refundable fee for an application to change a producer name or production facility name shall be one hundred dollars;

(18) The non-refundable fee for an application to expand or change the location of a production facility shall be three thousand five hundred dollars. In addition, upon approval of the application, the applicant shall pay an additional fee of one thousand five hundred dollars;

(19) The non-refundable fee for an application to make a physical, non-cosmetic alteration of a production facility, other than an expansion, shall be five hundred dollars; and

(20) The non-refundable fee for a producer to register a marijuana brand name with the department shall be twenty five dollars per brand name.

(NEW) Sec. 21a-408-29. Escrow Account Terms

(a) The producer's two million dollar escrow account, letter of credit or surety bond shall be payable to the state of Connecticut in the event the commissioner determines, after a hearing pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, that the producer has failed to timely and successfully complete the construction of a production facility or to continue to operate such facility in a manner that provides a substantially uninterrupted supply to its usual dispensary facility customers during the term of the license.

(b) In addition to the other terms and conditions permitted by the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the commissioner shall permit the producer's two million dollar escrow account, letter of credit or surety bond to be reduced by five-hundred thousand dollars upon the successful achievement of each of the following milestones, resulting in a potential elimination in the escrow account, letter of credit or surety bond:

(1) A determination by the commissioner that the production facility is fully operational and able to commence production of marijuana as provided for in the license application of the producer;

(2) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for a one year period;

(3) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for an additional two consecutive years; and

(4) A determination by the commissioner that the production facility remained operational without substantial interruption and without any violation of the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies for a second period of two consecutive years.

(c) If a producer voluntarily chooses not to renew the producer license and provides notice of this decision in accordance with section 21a-408-23(f) of the Regulations of Connecticut State Agencies, the commissioner shall extinguish the obligations under the escrow account, letter of credit or surety bond at the end of the license term.

(NEW) Sec. 21a-408-30. Refusal to renew or issue a license or registration of a dispensary facility, dispensary facility employee, producer or production facility employee

(a) If the commissioner refuses to renew a dispensary facility license or producer license, the department shall, in accordance with the Uniform Administrative Procedure Act , sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes, notify the licensee of its refusal and set a day and place of a hearing thereon giving the licensee reasonable notice in advance thereof. If, at or after such hearing, the commissioner refuses to renew the license, the department shall promptly provide notice of such decision to such licensee.

(b) Upon refusal to issue or renew a license or registration required under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, other than dispensary facility licenses and producer licenses, the department shall provide the applicant, licensee or registrant with notice of the grounds for the refusal to issue or renew such person's license or registration and shall inform the person of the right to request a hearing.

(1) Upon receipt of such notice, the applicant, licensee or registrant may request a hearing, which request shall be submitted to the department in writing not more than ten calendar days after the date of the notice.

(2) If a request for a hearing is made within the ten-day period, the department shall conduct a hearing in accordance with the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(3) If the applicant, licensee or registrant does not request a hearing in writing within the ten-day period, the applicant shall be deemed to have waived the right to a hearing.

(NEW) Sec. 21a-408-31. Disciplinary action against dispensary facility, dispensary facility employee, producer or production facility employee

(a) For sufficient cause found in accordance with subsection (b) of this section, the commissioner may, in the commissioner's discretion, suspend, revoke or refuse to grant or renew a license or registration issued pursuant to sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies, or place such

license or registration on probation, place conditions on such license or registration, or take other actions permitted by statute or regulation. For purposes of this section, each instance of qualifying patient or primary caregiver contact or consultation that is in violation of any provision of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, shall be deemed a separate offense. Failure to renew any license or registration in a timely manner is not a violation for purposes of this section.

(b) Any of the following shall be sufficient cause for such action by the commissioner:

- (1) Furnishing of false or fraudulent information in any application;
- (2) Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the act subject to the conviction occurred when the person held a valid license or registration certificate issued pursuant to the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies and the conviction was based on a federal statute or regulation related to the possession, purchase or sale of marijuana that is authorized under the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;
- (3) Any civil action under any federal or state statute or regulation or local ordinance relating to the applicant's, licensee's or registrant's profession, or involving drugs, medical devices or fraudulent practices, including, but not limited to, fraudulent billing practices;
- (4) Failure to maintain effective controls against diversion, theft or loss of marijuana or other controlled substances;
- (5) Discipline by, or a pending disciplinary action or unresolved complaint, with regard to any professional license or registration of any federal, state or local government;
- (6) Abuse or excessive use of drugs or alcohol;
- (7) Possession, use, prescription for use or distribution of controlled substances or legend drugs, except for therapeutic or other proper medical or scientific purpose;
- (8) Failure to account for the disposition of marijuana;
- (9) Failure to keep accurate records of all marijuana dispensed, administered or sold to qualifying patients or primary caregivers;
- (10) Failure to keep accurate records of all marijuana produced, manufactured, packaged or sold to a dispensary or dispensary facility;
- (11) Denial, suspension or revocation of a license or registration, or the denial of a renewal of a license or registration, by any federal, state or local government or a foreign jurisdiction;
- (12) False, misleading or deceptive representations to the public or the commissioner or the commissioner's authorized representative;

- (13) Return to regular stock of any marijuana where:
- (A) The package or container containing the marijuana has been opened, breached or tampered with; or
 - (B) The marijuana has been sold to a patient or caregiver;
- (14) Involvement in a fraudulent or deceitful practice or transaction;
- (15) Performance of incompetent or negligent work;
- (16) Failure to maintain the entire dispensary facility or production facility and contents in a clean, orderly and sanitary condition;
- (17) Intentionally, or through negligence, obscuring, damaging, or defacing a license or registration card;
- (18) A determination by the commissioner that the applicant or holder of the license or registration has a condition, including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of dispensing, operation of a dispensary facility or activities as a dispensary, dispensary technician, dispensary facility employee, producer or production facility employee, provided the department shall not, in taking action against a license or registration holder on the basis of such a condition, violate the provisions of section 46a-73 of the Connecticut General Statutes, or 42 USC 12132 of the federal Americans with Disabilities Act;
- (19) Permitting another person to use the licensee's or registrant's license or registration;
- (20) Failure to cooperate or give information to the department, local law enforcement authorities or any other enforcement agency upon any matter arising out of conduct at a dispensary facility or production facility;
- (21) Discontinuance of business for more than sixty days, unless the commissioner approves an extension of such period for good cause shown, upon a written request from a dispensary facility or producer. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the dispensary facility or production facility;
- (22) A violation of any provision of the Connecticut General Statutes, or any regulation established thereunder, related to the person's profession or occupation; or
- (23) Failure to comply with any provision of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies.
- (c) No person whose application for a license or registration has been denied due to the applicant's character and fitness may make another application for a license or registration under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies for at least one year from the date of denial.

(d) No person whose license or registration has been revoked may make an application for a license or registration under sections 21a-408-13 to 21a-408-24, inclusive, of the Regulations of Connecticut State Agencies for at least one year from the date of such revocation.

(e) If a license or registration is voluntarily surrendered or is not renewed, the commissioner shall not be prohibited from suspending, revoking or imposing other penalties permitted by the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, on any such license or registration.

(NEW) Sec. 21a-408-32. Suspension of dispensary facility license or producer license

During the period of any suspension of a dispensary facility license or producer license as a result of disciplinary action by the department:

(1) No person issued a dispensary facility license shall alter the dispensary facility, unless the alterations have been expressly approved in writing by the commissioner, or attach to the exterior or any other part of the facility any sign indicating that the premises are “closed for repairs,” “closed for alterations” or any like signs.

(2) The dispensary facility manager shall place on the dispensary facility in the front window, or on the front door facing the street, a notice indicating the length of the suspension and the reasons therefor. The sign shall measure a minimum of eight inches in height by ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty by persons standing outside the dispensary facility. The dispensary facility manager shall maintain the sign in place until the period of suspension has terminated.

(3) A dispensary facility shall not offer, sell, order or receive marijuana products unless expressly approved by the commissioner.

(4) The dispensary facility manager shall close the entire dispensary facility for business and shall securely lock all marijuana products. Dispensary facility employees may visit the facility only for the necessary care and maintenance of the premises.

(5) A producer whose license has been suspended shall not sell, offer for sale, or deliver marijuana to any dispensary facility. Production facility employees may enter the premises of the production facility for the necessary care and maintenance of the premises and of any marijuana and marijuana products.

(6) The commissioner may, in the commissioner’s discretion, accept a monetary payment as an offer in compromise in lieu of, or so as to reduce a suspension, from a licensee or registrant whose license or registration is subject to a hearing that may result in a suspension or whose license or registration has been suspended after due

hearing. Such offer shall include a waiver of appeal and judicial review and a certified check in the amount designated by the commissioner.

(NEW) Sec. 21a-408-33. Confidentiality of information

(a) Except as provided by section 21a-408-50 of the Regulations of Connecticut State Agencies, a dispensary facility employee, producer, production facility employee, or any other person associated with a dispensary facility or producer, shall not disclose patient-specific information received and records kept pursuant to sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, except that such person shall disclose patient treatment or dispensing information to:

(1) The department or state and local law enforcement for purposes of investigating and enforcing the Act or sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Physicians, pharmacists or other dispensaries for the purpose of providing patient care and drug therapy management and monitoring controlled substances obtained by the qualifying patient;

(3) A qualifying patient but only with respect to information related to such patient;

(4) A primary caregiver, but only with respect to the qualifying patient of such primary caregiver;

(5) Third party payors who pay claims for dispensary services rendered to a qualifying patient or who have a formal agreement or contract to audit any records or information in connection with such claims;

(6) Any person, the state or federal government or any agency thereof pursuant to an order of a court of competent jurisdiction or pursuant to a search warrant; and

(7) Any person upon the express written consent of the patient and only with respect to information related to such patient. Such written consent shall clearly identify the specific person and purpose for which consent is being granted, but in no event shall such information be disclosed to an electronic data intermediary.

(b) An electronic data intermediary shall not have access to any data involving marijuana, qualifying patients, primary caregivers or other data from a dispensary facility or an agent of the dispensary facility.

(c) No electronic equipment utilized by a dispensary department shall collect patient-specific data for use outside the dispensary department, except that such data shall be disclosed to the commissioner or the commissioner's authorized representative for purposes of an inspection or investigation.

(NEW) Sec. 21a-408-34. Operation of dispensary facility

(a) No person may operate a dispensary facility without a dispensary facility license issued by the department.

(b) A dispensary facility shall not dispense marijuana from, obtain marijuana from, or transfer marijuana to, a location outside of the state of Connecticut.

(c) A dispensary facility shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:

(1) It may acquire marijuana from a producer; and

(2) It may dispense and sell marijuana to a qualifying patient or primary caregiver who is registered with the department pursuant to the Act and section 21a-408-6 of the Regulations of Connecticut State Agencies.

(d) No person at a dispensary facility shall provide marijuana samples or engage in marijuana compounding.

(e) A dispensary facility shall sell marijuana products only in the original sealed containers or packaging as delivered by the producer, except that a dispensary may remove the marijuana product from the producer's child-resistant container or package and place the marijuana product in a non-child-resistant, secure and light-resistant container upon a written request from the qualifying patient or primary caregiver so long as all original labeling is maintained with the product.

(f) Only a dispensary may dispense marijuana, and only a dispensary or dispensary technician may sell marijuana, to qualifying patients and primary caregivers who are registered with the department pursuant to the Act and section 21a-408-6 of the Regulations of Connecticut State Agencies. A dispensary technician may assist, under the direct supervision of a dispensary, in the dispensing of marijuana.

(g) A dispensary facility shall place all products sold to the qualifying patient or primary caregiver in an opaque package that shall not indicate the contents of the package, the originating facility or in any other way cause another person to believe that the package may contain marijuana.

(h) A dispensary facility shall not permit any person to enter the dispensary department unless:

(1) Such person is licensed or registered by the department pursuant to 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Such person's responsibilities necessitate access to the dispensary department and then for only as long as necessary to perform the person's job duties; or

(3) Such person has a patient or caregiver registration certificate, in which case such person shall not be permitted behind the service counter or in other areas where marijuana is stored.

(i) All dispensary facility employees shall, at all times while at the dispensary facility, have their current dispensary license, dispensary technician registration or dispensary facility employee registration available for inspection by the commissioner or the commissioner's authorized representative.

(j) While inside the dispensary facility, all dispensary facility employees shall wear name tags or similar forms of identification that clearly identify them to the public, including their position at the dispensary facility.

(k) A dispensary department shall be open for qualifying patients and primary caregivers to purchase marijuana products for a minimum of thirty-five hours a week, except as otherwise authorized by the commissioner.

(l) A dispensary department that closes during its normal hours of operation shall implement procedures to notify qualifying patients and primary caregivers of when the dispensary department will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs. If the dispensary department is, or will be, closed during its normal hours of operation for longer than two business days, the dispensary facility shall immediately notify the department.

(m) A dispensary facility that operates at times when the dispensary department is closed shall:

(1) Conspicuously post the hours of operation of the dispensary department at all entrances to the dispensary facility in block letters at least one-half inch in height; and

(2) Clearly state the hours of operation of the dispensary department in all advertising for the specific dispensary department or dispensary facility.

(n) A dispensary facility shall make publicly available the price of all marijuana products offered by the dispensary facility to prospective qualifying patients and primary caregivers. Such disclosure may include posting the information on the dispensary facility Internet web site.

(o) A dispensary facility shall provide information to qualifying patients and primary caregivers regarding the possession and use of marijuana. The dispensary facility manager shall submit all informational material to the commissioner for approval prior to being provided to qualifying patients and primary caregivers. Such informational material shall include information related to:

(1) Limitations on the right to possess and use marijuana pursuant to the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

(2) Safe techniques for proper use of marijuana and paraphernalia;

(3) Alternative methods and forms of consumption or inhalation by which one can use marijuana;

(4) Signs and symptoms of substance abuse; and

(5) Opportunities to participate in substance abuse programs.

(p) The dispensary facility shall establish, implement and adhere to a written alcohol-free, drug-free and smoke-free work place policy, which shall be available to the commissioner or the commissioner's authorized representative upon request.

(q) All deliveries from producers shall be carried out under the direct supervision of a dispensary who shall be present to accept the delivery. Upon delivery, the marijuana shall immediately be placed in an approved safe or approved vault within the dispensary department where marijuana is stored.

(NEW) Sec. 21a-408-35. Dispensary facility prohibitions

(a) No dispensary department shall be open or in operation, and no person shall be in the dispensary department, unless a dispensary is on the premises and directly supervising the activity within the dispensary department. At all other times, the dispensary department shall be closed and properly secured, in accordance with sections 21a-408-51 and 21a-408-62 of the Regulations of Connecticut State Agencies.

(b) No dispensary facility shall sell anything other than marijuana products and paraphernalia from the dispensary department.

(c) No marijuana shall be consumed on the premises of a dispensary facility.

(d) No food or beverages shall be consumed by qualifying patients or primary caregivers on the premises of a dispensary facility, except that complimentary food and non-alcoholic beverages may be available for qualifying patients and primary caregivers who are at the dispensary facility for a pre-scheduled education, counseling or therapy program.

(e) No person, except for a qualifying patient or primary caregiver, shall open or break the seal placed on a marijuana product packaged by a producer except that a dispensary may remove marijuana from a child-resistant container or package under the conditions set forth in sections 21a-408-34(e) of the Regulations of Connecticut State Agencies.

(f) Except as provided in subsection (g) of this section, no person, except a dispensary facility employee, or a production facility employee who is delivering marijuana products, shall be allowed on the premises of a dispensary facility without a qualifying patient or primary caregiver registration certificate issued by the department.

(g) (1) Upon prior written request, the commissioner or the commissioner's authorized representative may waive the provisions of subsection (f) of this section.

(2) All persons not permitted on the premises of a dispensary facility pursuant to subsection (f) of this section, but who have been authorized, in writing, to enter the facility by the commissioner or the commissioner's authorized representative shall obtain a visitor identification badge from a dispensary facility employee, prior to

entering the dispensary facility. A dispensary or dispensary technician shall escort and monitor such a visitor at all times the visitor is in the dispensary department. A visitor shall visibly display the visitor identification badge at all times the visitor is in the dispensary facility and shall return the visitor identification badge to a dispensary facility employee upon exiting the dispensary facility.

(3) All visitors shall log in and out. The dispensary facility shall maintain the visitor log, which shall include the date, time and purpose of the visit and which shall be available to the commissioner in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(4) If an emergency requires the presence of a visitor and makes it impractical for the dispensary facility to obtain a waiver pursuant to subsection (g)(1) of this section, the dispensary facility shall provide written notice to the commissioner as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A dispensary facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

(h) No person associated with a dispensary facility shall enter into any agreement with a certifying physician or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the dispensary facility at which the qualifying patient or primary caregiver will purchase marijuana.

(i) No marijuana shall be sold, dispensed or distributed via a delivery service or any other manner outside of a dispensary facility, except that a primary caregiver may deliver marijuana to the caregiver's qualified patient.

(j) Notwithstanding the requirements of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, members of the department, local law enforcement or other federal, state of Connecticut or local government officials may enter any area of a dispensary facility if necessary to perform their governmental duties.

(NEW) Sec. 21a-408-36. Procedures when dispensary department is closed

(a) During times that the dispensary department is closed, it shall be securely locked and equipped with an alarm system. Such alarm shall be activated and operated separately from any other alarm system at the dispensary facility and shall be able to immediately detect entrance to the dispensary department at times when it is closed. Keys and access codes to the alarm system shall be controlled in such a manner so as to prevent access to the dispensary department by other than authorized dispensary facility employees. Only a dispensary shall have the authority to deactivate the alarm system.

(b) A dispensary facility shall store marijuana in an approved safe or approved vault within the dispensary department and shall not sell marijuana products when the dispensary department is closed.

(NEW) Sec. 21a-408-37. Security of the dispensary department during momentary absences of a dispensary

During times when the dispensary leaves the dispensary department for a few moments, the dispensary shall take measures to ensure that adequate security of the dispensary department is provided and that entry by unauthorized persons is prevented or immediately detected. The presence of a dispensary technician in the dispensary department during these times shall be considered adequate security. If no such dispensary technician is available for this purpose, and the dispensary department is not within the view of the dispensary, the dispensary shall physically or electronically secure the dispensary department through the use of mechanisms such as a locked barrier or an alarm system that will prevent or immediately detect access to such department.

(NEW) Sec. 21a-408-38. Rights and responsibilities of dispensaries

(a) A dispensary, in good faith, may sell and dispense marijuana to any qualifying patient or primary caregiver that is registered with the department. Except as otherwise provided by sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, the dispensary dispensing the marijuana shall include the date of dispensing and the dispensary's signature or initials on the dispensary facility's dispensing record log.

(b) All dispensaries shall register with the department to access the prescription monitoring program.

(c) A dispensary shall review a qualifying patient's controlled substance history report within the prescription monitoring program before dispensing any marijuana to the qualifying patient or the qualifying patient's primary caregiver.

(d) A dispensary shall exercise professional judgment to determine whether to dispense marijuana to a qualifying patient or primary caregiver if the dispensary suspects that dispensing marijuana to the qualifying patient or primary caregiver may have negative health or safety consequences for the qualifying patient or the public.

(e) A dispensary may dispense a portion of a qualifying patient's one-month supply of marijuana. The dispensary may dispense the remaining portion of the one-month supply of marijuana at any time except that no qualifying patient or primary caregiver shall receive more than a one-month supply of marijuana in a one-month period.

(f) A dispensary, or dispensary technician, shall require the presentation of a registration certificate together with another valid photographic identification issued to a qualifying patient or primary caregiver, prior to selling marijuana to such qualifying patient or primary caregiver.

(g) A dispensary shall document a qualifying patient's self-assessment of the effects of marijuana in treating the qualifying patient's debilitating medical condition or the symptoms thereof. A dispensary facility shall maintain such documentation electronically for at least three years following the date the patient ceases to designate the dispensary facility and such documentation shall be made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-39. Dispensaries to assign serial number and maintain records. Transfer of records to another dispensary facility

(a) A dispensary shall assign and record a sequential serial number to each marijuana product dispensed to a patient and shall keep all dispensing records in numerical order in a suitable file, electronic file or ledger. The records shall indicate:

- (1) The date of dispensing;
- (2) The name and address of the certifying physician;
- (3) The name and address of the qualifying patient, or primary caregiver if applicable;
- (4) The initials of the dispensary who dispensed the marijuana; and
- (5) Whether a full or partial one-month supply of marijuana was dispensed.

(b) A dispensary facility shall maintain records created under this section and shall make such records available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(c) When a dispensary department closes temporarily or permanently, the dispensary facility shall, in the interest of public health, safety and convenience, make its complete dispensing records immediately available to a nearby dispensary facility and post a notice of this availability on the window or door of the closed dispensary facility. The dispensary facility shall simultaneously provide such notice to the commissioner.

(NEW) Sec. 21a-408-40. Labeling of marijuana products by dispensary

(a) A dispensary shall not dispense marijuana that does not bear the producer label required pursuant to section 21a-408-56 of the Regulations of Connecticut State Agencies.

(b) A dispensary, or a dispensary technician under the direct supervision of the dispensary, shall completely and properly label all marijuana products dispensed with all required information as follows:

- (1) The serial number, as assigned by the dispensary facility;
- (2) The date of dispensing the marijuana;
- (3) The quantity of marijuana dispensed;
- (4) The name and registration certificate number of the qualifying patient and, where applicable, the primary caregiver;
- (5) The name of the certifying physician;
- (6) Such directions for use as may be included in the physician's written certification or otherwise provided by the physician;
- (7) Name of the dispensary;
- (8) Name and address of the dispensary facility;
- (9) Any cautionary statement as may be required by Connecticut state statute or regulation; and
- (10) A prominently printed expiration date based on the producer's recommended conditions of use and storage that can be read and understood by the ordinary individual.

(c) The expiration date required by this section shall be no later than the expiration date determined by the producer.

(d) No person except a dispensary, or a dispensary technician operating under the direct supervision of a dispensary, shall alter, deface or remove any label so affixed.

(NEW) Sec. 21a-408-41. Responsibilities of dispensary facility manager

(a) A dispensary facility shall employ the dispensary facility manager at the dispensary facility for at least thirty-five hours per week, except as otherwise authorized by the commissioner.

(b) No person shall be a dispensary facility manager for more than one dispensary facility at a time.

- (c) The dispensary facility manager shall be responsible for ensuring that:
- (1) Dispensary technicians are registered and properly trained;
 - (2) All record-retention requirements are met;
 - (3) All requirements for the physical security of marijuana are met;
 - (4) The dispensary facility has appropriate pharmaceutical reference materials to ensure that marijuana can be properly dispensed;
 - (5) The following items are conspicuously posted in the dispensary department in a location and in a manner so as to be clearly and readily identifiable to qualifying patients and primary caregivers:

- (A) Dispensary facility license;
 - (B) The name of the dispensary facility manager; and
 - (C) The price of all marijuana products offered by the dispensary facility as identified by their registered brand name as set forth in section 21a-408-59 of the Regulations of Connecticut State Agencies; and
- (6) Any other filings or notifications required to be made on behalf of the dispensary facility as set forth in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, are completed.

(NEW) Sec. 21a-408-42. Dispensary technicians. Ratio. Supervision and responsibility

- (a) The ratio of dispensary technicians to dispensaries on duty in a dispensary department shall not exceed three dispensary technicians to one dispensary.
- (b) A dispensary whose license is under suspension or revocation shall not act as a dispensary technician.
- (c) The dispensary providing direct supervision of dispensary technicians shall be responsible for the dispensary technicians' actions. Any violations relating to the dispensing of marijuana resulting from the actions of a dispensary technician, or the use of dispensary technicians in the performance of tasks in a manner not in conformance with sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, shall constitute cause for action against the license of the dispensary. As used in this subsection, "direct supervision" means a supervising dispensary who:
 - (1) Is physically present in the area or location where the dispensary technician is performing routine marijuana dispensing functions; and
 - (2) Conducts in-process and final checks on the dispensary technician's performance.

(NEW) Sec. 21a-408-43. Dispensary technician limitations

- (a) Dispensary technicians shall not:
 - (1) Consult with a qualifying patient or the patient's primary caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or regarding any medical information contained in a patient medication record;
 - (2) Consult with the physician who certified the qualifying patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;
 - (3) Interpret the patient's clinical data or provide medical advice;
 - (4) Perform professional consultation with physicians, nurses or other health care professionals or their authorized agents; or

(5) Determine whether a different brand or formulation of marijuana should be substituted for the marijuana product or formulation recommended by the physician or requested by the qualifying patient or primary caregiver.

(b) Notwithstanding subsection (a) of this section, a dispensary technician may communicate with a physician who certified a qualifying patient, or the physician's agent, to obtain a clarification on a qualifying patient's written certification or instructions provided the supervising dispensary is aware that such clarification is being requested.

(NEW) Sec. 21a-408-44. Dispensary technician training

(a) Dispensary technicians shall complete initial training as determined by the dispensary facility manager of each dispensary facility. Such training shall include, but not be limited to:

(1) On-the-job and other related education, which shall be commensurate with the tasks dispensary technicians are to perform and which shall be completed prior to the regular performance of such tasks;

(2) Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and

(3) Developments in the field of the medical use of marijuana.

(b) The dispensary technician shall be registered as a dispensary technician with the department prior to the start of such training.

(c) The dispensary facility manager shall assure the continued competency of dispensary technicians through continuing in-service training designed to supplement initial training, which shall include any guidance specified by the department.

(d) The dispensary facility manager shall be responsible for maintaining a written record documenting the initial and continuing training of dispensary technicians, which shall contain:

(1) The name of the person receiving the training;

(2) The dates of the training;

(3) A general description of the topics covered;

(4) The name of the person supervising the training; and

(5) The signatures of the person receiving the training and the dispensary facility manager.

(e) When a change of dispensary facility manager occurs, the new manager shall review the training record and sign it, indicating that the new manager understands its contents.

(f) A dispensary facility shall maintain the record documenting the dispensary technician training and make it available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-45. Dispensary facility employee training. Employee records

(a) A dispensary facility shall provide to each dispensary facility employee, prior to the employee commencing work at the dispensary facility, at a minimum, training in the following:

(1) The proper use of security measures and controls that have been adopted for the prevention of diversion, theft or loss of marijuana;

(2) Procedures and instructions for responding to an emergency; and

(3) State and federal statutes and regulations regarding patient confidentiality.

(b) Each dispensary facility shall maintain and make available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies, a training record for each dispensary facility employee. Such record shall include, at a minimum, documentation of all required training, including:

(1) The name of the person receiving the training;

(2) The dates of the training;

(3) A general description of the topics covered;

(4) The name of the person supervising the training; and

(5) The signatures of the person receiving the training and the dispensary facility manager.

(NEW) Sec. 21a-408-46. Dispensary facility manager notifications

(a) A dispensary facility shall immediately notify the department whenever the dispensary facility manager ceases such management and shall immediately designate with the department the name, address and license number of the dispensary who assumes management of the dispensary facility. A dispensary facility shall file the notice of change in management of a dispensary on a form prescribed by the commissioner and shall pay the filing fee required in section 21a-408-28 of the Regulations of Connecticut State Agencies. The dispensary who ceases management of the dispensary facility shall also immediately notify the department of that fact.

(b) If a dispensary facility manager is absent from the dispensary facility for any reason for more than sixteen consecutive days, the dispensary facility shall immediately report such absence to the department. The dispensary facility shall provide the department with the name of the dispensary designated to be the acting dispensary facility manager no later than five days after the sixteenth consecutive day of the original dispensary facility manager's absence.

(c) If the absence of the dispensary facility manager exceeds forty-two consecutive days, such person shall be deemed to have ceased to be the dispensary

facility manager for the dispensary facility. In such case, the dispensary facility shall, in accordance with this section, immediately notify the department of the name, address and license number of the dispensary who is assuming management of the dispensary facility. A dispensary facility shall file the notice of change of dispensary facility manager on a form prescribed by the commissioner and shall pay the filing fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies. The dispensary who ceases management of the dispensary facility shall also immediately notify the department of that fact.

(NEW) Sec. 21a-408-47. Dispensing error reporting. Quality assurance program

(a) A dispensary facility shall display a sign concerning the reporting of dispensing errors in a conspicuous location visible to qualifying patients and primary caregivers. The sign shall measure a minimum of eight inches in height and ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty by consumers standing at the dispensary department. The sign shall bear the following statement: "If you have a concern that an error may have occurred in the dispensing of your marijuana, you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the Connecticut General Statutes)."

(b) A dispensary facility shall include the following printed statement on the receipt or in the bag or other similar packaging in which marijuana is contained: "If you have a concern that an error may have occurred in the dispensing of your marijuana, you may contact the Department of Consumer Protection, Drug Control Division, by calling (Department of Consumer Protection telephone number authorized pursuant to section 21a-2 of the Connecticut General Statutes)." The dispensary facility shall print such statement in a size and style that allows it to be read without difficulty by patients.

(c) A dispensary facility shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify and prevent dispensing errors. A dispensary facility shall provide to the commissioner a written copy of such quality assurance program, shall distribute it to all dispensary facility employees, and shall make it readily available on the premises of the dispensary facility. Such policies and procedures shall include:

(1) Directions for communicating the details of a dispensing error to the physician who certified a qualifying patient and to the qualifying patient, the patient's primary caregiver or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. Such communication shall describe methods of

correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

(2) A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

(d) A dispensary facility shall use the findings of its quality assurance program to develop dispensary systems and workflow processes designed to prevent dispensing errors.

(e) A dispensary facility manager shall inform dispensary facility employees of changes to dispensary facility policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

(NEW) Sec. 21a-408-48. Review of dispensing errors

(a) A dispensary facility manager shall notify all dispensary employees that the discovery or reporting of a dispensing error shall be relayed immediately to a dispensary on duty.

(b) A dispensary facility manager shall ensure that a dispensary performs a quality assurance review for each dispensing error. A dispensary shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered.

(c) A dispensary facility manager shall create a record of every quality assurance review. This record shall contain at least the following:

(1) The date or dates of the quality assurance review and the names and titles of the persons performing the review;

(2) The pertinent data and other information relating to the dispensing error reviewed;

(3) Documentation of contact with the qualifying patient, primary caregiver where applicable, and the physician who certified the patient as required by the quality assurance program implemented pursuant to section 21a-408-47 of the Regulations of Connecticut State Agencies;

(4) The findings and determinations generated by the quality assurance review; and

(5) Recommended changes to dispensary facility policy, procedure, systems, or processes, if any.

(d) A dispensary facility shall maintain quality assurance review records in an orderly manner and filed by date.

(e) A dispensary facility shall maintain a copy of the dispensary facility's quality assurance program and records of all reported dispensing errors and quality assurance

reviews and make such documents available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-49. Electronic system record-keeping safeguards

(a) If a dispensary facility uses an electronic system for the storage and retrieval of patient information or other marijuana records, the dispensary facility shall use a system that:

- (1) Guarantees the confidentiality of the information contained therein;
- (2) Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the dispensary; and
- (3) Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

(NEW) Sec. 21a-408-50. Dispensary reporting into the prescription monitoring program

(a) At least once per day, a dispensary shall transmit electronically to the Drug Control Division of the department the information set forth in the most recent edition of the Standard for Prescription Monitoring Programs established by the American Society for Automation in Pharmacy, a copy of which may be purchased from the American Society for Automation in Pharmacy on their Internet web site: www.asapnet.org.

(b) A dispensary shall transmit to the department, in a format approved by the department, the fields listed in this subsection, including, but not limited to, the following:

- (1) Drug Enforcement Administration Pharmacy number, which shall be populated by a number provided by the department;
- (2) Birth date;
- (3) Sex code;
- (4) Date order filled, which shall be the date marijuana is dispensed;
- (5) Order number, which shall be the serial number assigned to each marijuana product dispensed to a patient;
- (6) New-refill code;
- (7) Quantity;
- (8) Days supply;
- (9) National Drug Code number, which shall be provided by the department;
- (10) Drug Enforcement Administration Prescriber identification number;
- (11) Date order written, which shall be the date the written certification was issued;

- (12) Number of refills authorized;
- (13) Order origin code, which shall be provided by the department;
- (14) Patient last name;
- (15) Patient first name;
- (16) Patient street address;
- (17) State;
- (18) Payment code for either cash or third-party provider; and
- (19) Drug name, which shall be the brand name of the marijuana product.

(c) A dispensary shall transmit the information required pursuant to this section in such a manner as to insure the confidentiality of the information in compliance with all federal and Connecticut state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

(NEW) Sec. 21a-408-51. Security requirements for dispensary facilities

- (a) A dispensary facility shall:
 - (1) Not maintain marijuana in excess of the quantity required for normal, efficient operation;
 - (2) Store all marijuana in an approved safe or approved vault and in such a manner as to prevent diversion, theft or loss;
 - (3) Maintain all marijuana in a secure area or location accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;
 - (4) Keep all approved safes and approved vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana;
 - (5) Keep all locks and security equipment in good working order;
 - (6) Not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;
 - (7) Not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees;
 - (8) Keep the dispensary department securely locked and protected from entry by unauthorized employees; and
 - (9) Post a sign at all entry ways into any area of the dispensary facility containing marijuana, including a room with an approved safe or approved vault, which sign shall be a minimum of twelve inches in height and twelve inches in width which shall state: "Do Not Enter - Limited Access Area – Access Limited to Authorized Employees Only" in lettering no smaller than one-half inch in height.

(b) If a dispensary facility presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to diversion, theft or loss, the commissioner may require additional safeguards, including, but not limited to, a supervised watchman service.

(c) If diversion, theft or loss of marijuana has occurred from a dispensary facility, the commissioner shall determine the appropriate storage and security requirements for all marijuana in such dispensary facility, and may require additional safeguards to ensure the security of the marijuana.

(d) Any marijuana not stored in compliance with sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, or stored at a location other than that for which the dispensary facility license was issued, shall be subject to embargo or seizure by the department in accordance with section 21a-96 of the Connecticut General Statutes.

(e) Any dispensary facility whose license is revoked or not renewed shall dispose of its entire stock of marijuana in accordance with sections 21a-408-64 of the Regulations of Connecticut State Agencies.

(f) If a dispensary facility has provided other safeguards which can be regarded in total as an adequate substitute for some element of protection required of such facility, such added protection may be taken into account by the commissioner in evaluating overall required security measures.

(NEW) Sec. 21a-408-52. Operation of production facility

(a) Only a producer shall own and operate a production facility.

(b) A producer shall not:

(1) Produce or manufacture marijuana in any place except its approved production facility;

(2) Sell, deliver, transport or distribute marijuana from any place except its approved production facility;

(3) Produce or manufacture marijuana for use outside of Connecticut;

(4) Sell, deliver, transport or distribute marijuana to any place except a dispensary facility located in Connecticut;

(5) Enter into an exclusive agreement with any dispensary facility;

(6) Refuse to deal with any dispensary facility that is willing to deal with such producer on the same terms and conditions as other dispensary facilities with whom the producer is dealing; or

(7) Either directly or indirectly discriminate in price between different dispensary facilities that are purchasing a like, grade, strain, brand, and quality of marijuana or marijuana product, provided nothing herein shall prevent differentials which only make

due allowance for differences in the cost of manufacture, sale or delivery resulting from the differing methods or quantities in which such marijuana or marijuana products are sold or delivered to such dispensary facilities.

(c) A producer license shall permit the licensee to operate at a single production facility location. Prior to operating a production facility at a different location, a producer shall obtain an additional producer license in accordance with the producer license selection and application process set forth in sections 21a-408-20 to 21a-408-21 of the Regulations of Connecticut State Agencies, except that if the maximum number of producer licenses allowed under the Act have been issued, the commissioner may permit additional production facilities to be operated by a currently licensed producer.

(d) A producer shall establish and maintain an escrow account in a financial institution in Connecticut, obtain a letter of credit from a financial institution in Connecticut, or obtain a surety bond issued by a surety company licensed by the state of Connecticut Department of Insurance and of a capacity and rating acceptable to the commissioner, upon terms approved by the commissioner, in the amount of two million dollars. The money secured by the escrow account, letter of credit or surety bond shall be payable to the state of Connecticut in the event the producer fails to timely and successfully complete the construction of a production facility or to continue to operate such facility in a manner that provides an uninterrupted supply of marijuana or marijuana products to its usual dispensary facility customers during the term of the license. The commissioner may reduce or eliminate the escrow account, letter of credit or surety bond in accordance with the terms set forth in section 21a-408-29 of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-53. Minimum requirements for the storage and handling of marijuana by producers

(a) All production facilities shall:

(1) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for the production and manufacture of marijuana;

(2) Separate for storage, in a quarantined area, marijuana that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such marijuana is destroyed;

(3) Be maintained in a clean and orderly condition; and

(4) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Any area within the production facility where marijuana will be manufactured into an edible form shall comply with the Connecticut Food, Drug and Cosmetic Act, Connecticut General Statutes, sections 21a-91 to 21a-120, inclusive, and, Connecticut

General Statutes, sections 21a-151 to 21a-159, inclusive, regarding bakeries and food manufacturing establishments.

(c) A producer shall compartmentalize all areas in the production facility based on function and shall restrict access between compartments. The producer shall establish, maintain and comply with written policies and procedures, approved by the commissioner, regarding best practices for the secure and proper production and manufacturing of marijuana. These shall include, but not be limited to, policies and procedures that:

- (1) Restrict movement between production compartments;
- (2) Provide for different colored identification cards for production facility employees based on the production compartment to which they are assigned at a given time so as to ensure that only employees necessary for a production function have access to that compartment of the production facility;
- (3) Require pocketless clothing for all production facility employees working in an area containing marijuana; and
- (4) Document the chain of custody of all marijuana and marijuana products.

(d) Producers shall establish, maintain, and comply with written policies and procedures, approved by the commissioner, for the manufacture, security, storage, inventory, and distribution of marijuana. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft or loss, and for correcting all errors and inaccuracies in inventories. Producers shall include in their written policies and procedures, a process for the following:

(1) Handling mandatory and voluntary recalls of marijuana products. Such process shall be adequate to deal with recalls due to any action initiated at the request of the commissioner and any voluntary action by the producer to remove defective or potentially defective marijuana products from the market or any action undertaken to promote public health and safety by replacing existing marijuana products with improved products or packaging;

(2) Preparing for, protecting against, and handling any crises that affects the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(3) Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated marijuana is segregated from all other marijuana and destroyed. This procedure shall provide for written documentation of the marijuana disposition; and

(4) Ensuring the oldest stock of a marijuana product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(e) A producer shall store all marijuana in the process of manufacture, distribution, transfer, or analysis in such a manner as to prevent diversion, theft or loss,

shall make marijuana accessible only to the minimum number of specifically authorized employees essential for efficient operation, and shall return marijuana to its secure location immediately after completion of the process or at the end of the scheduled business day. If a manufacturing process cannot be completed at the end of a working day, the producer shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing marijuana inside an area or building that affords adequate security.

(f) No person, except production facility employees, local law enforcement, the commissioner or commissioner's authorized representative or other federal, state of Connecticut or local government officials, where necessary to perform their governmental duties, shall be allowed on the premises of a production facility, except that:

(1) Laboratory staff may enter a production facility for the sole purpose of identifying and collecting marijuana samples for purposes of conducting laboratory tests; and

(2) Upon prior written request, the commissioner or the commissioner's authorized representative may permit other persons to enter a production facility.

(g)(1) All persons who are not production facility employees, but who are permitted on the premises of a production facility pursuant to subsection (f)(1) or (2) of this section, shall obtain a visitor identification badge from a production facility employee, prior to entering the production facility. A production facility employee shall escort and monitor visitors at all times. A visitor shall visibly display the visitor identification badge at all times the visitor is in the production facility. A visitor shall return the visitor identification badge to a production facility employee upon exiting the production facility.

(2) The producer shall log all visitors in and out, and shall maintain a log that includes the date, time and purpose of the visit. A producer shall maintain such log and make it available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(3) If an emergency requires the presence of a visitor and makes it impractical to obtain permission pursuant to subsection (f)(2) of this section, the producer shall provide written notice to the commissioner as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A producer shall monitor the visitor and maintain a log of such visit as required by this subsection.

(NEW) Sec. 21a-408-54. Producer record keeping

Producers shall keep records of all marijuana produced or manufactured and of all marijuana disposed of by them. Such records shall be maintained and made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies and, in each case shall show:

- (1) The brand name, kind and quantity of marijuana involved;
- (2) The date of such production or removal from production;
- (3) A record of all marijuana sold, transported or otherwise disposed of;
- (4) The date and time of selling, transporting or disposing of the marijuana;
- (5) The name and address of the dispensary facility to which the marijuana was sold;
- (6) The name of the dispensary who took custody of the marijuana; and
- (7) The name of the production facility employee responsible for transporting the marijuana.

(NEW) Sec. 21a-408-55. Manufacturing of marijuana products

(a) A producer shall only manufacture or sell marijuana products in the following forms:

- (1) Raw material;
- (2) Cigarettes;
- (3) Extracts, sprays, tinctures or oils;
- (4) Topical applications, oils or lotions;
- (5) Transdermal patches;
- (6) Baked goods; and
- (7) Capsules or pills.

(b) No marijuana product shall:

- (1) Include alcoholic liquor, dietary supplements or any drug, except for pharmaceutical grade marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than one-half of one percent of alcohol by volume or ethanol-based tinctures with an alcohol level approved by the commissioner;
- (2) Be manufactured or sold as a beverage or confectionary;
- (3) Be manufactured or sold in a form or with a design that:
 - (A) Is obscene or indecent;
 - (B) May encourage the use of marijuana for recreational purposes;
 - (C) May encourage the use of marijuana for a condition other than a debilitating medical condition; or
 - (D) Is customarily associated with persons under the age of eighteen;

(4) Have had pesticide chemicals or organic solvents used during the production or manufacturing process, except that the commissioner may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of marijuana crops.

(c) Any marijuana product not in compliance with this section shall be deemed adulterated.

(NEW) Sec. 21a-408-56. Packaging and labeling by producer

(a) A producer shall individually package, label and seal marijuana products in unit sizes such that no single unit contains more than a one-month supply of marijuana.

(b) A producer shall place any product containing marijuana in a child-resistant and light-resistant package. A package shall be deemed child-resistant if it satisfies the standard for “special packaging” as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

(c) A producer shall label each marijuana product prior to sale to a dispensary and shall securely affix to the package a label that states in legible English:

(1) The name and address of the producer;

(2) The brand name of the marijuana product that was registered with the department pursuant to section 21a-408-59 of the Regulations of Connecticut State Agencies;

(3) A unique serial number that will match the product with a producer batch and lot number so as to facilitate any warnings or recalls the department or producer deem appropriate;

(4) The date of final testing and packaging;

(5) The expiration date;

(6) The quantity of marijuana contained therein;

(7) A terpenes profile and a list of all active ingredients, including:

(A) tetrahydrocannabinol (THC);

(B) tetrahydrocannabinol acid (THCA);

(C) cannabidiol (CBD);

(D) cannabidiolic acid (CBDA); and

(E) any other active ingredient that constitute at least 1% of the marijuana batch used in the product.

(8) A pass or fail rating based on the laboratory’s microbiological, mycotoxins, heavy metals and chemical residue analysis; and

(9) Such other information necessary to comply with state of Connecticut labeling requirements for similar products not containing marijuana, including but not limited to the Connecticut Food, Drug and Cosmetic Act, Connecticut General Statutes, sections

21a-91 to 21a-120, inclusive, and Connecticut General Statutes, sections 21a-151 to 21a-159, inclusive, regarding bakeries and food manufacturing establishments.

(d) A producer shall not label marijuana products as “organic” unless the marijuana plants have been organically grown as defined in section 21a-92 of the Connecticut General Statutes and the marijuana products have been produced, processed, manufactured and certified to be consistent with organic standards in compliance with section 21a-92a of the Connecticut General Statutes.

(NEW) Sec. 21a-408-57. Laboratory requirements

No laboratory shall handle, test or analyze marijuana unless such laboratory:

- (1) Is registered with the department as a controlled substance laboratory;
- (2) Is independent from all other persons involved in the marijuana industry in Connecticut, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a dispensary, dispensary facility, producer, production facility, certifying physician or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase or use of marijuana; and
- (3) Has employed at least one person to oversee and be responsible for the laboratory testing who has earned, from a college or university accredited by a national or regional certifying authority, at least a master’s level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or a bachelor’s degree in biological sciences and a minimum of four years of post-degree laboratory experience.

(NEW) Sec. 21a-408-58. Laboratory testing

(a) Immediately prior to manufacturing any marijuana product or packaging raw marijuana for sale to a dispensary, a producer shall segregate all harvested marijuana into homogenized batches.

(b) A producer shall make available each such batch at the production facility for a laboratory employee to select a random sample. The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy metals and pesticide chemical residue, and for purposes of conducting an active ingredient analysis.

(c) From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a dispensary facility, until the laboratory provides the results from its tests and analysis, the producer shall segregate and withhold from use the entire batch of marijuana, except the samples that have been removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent

the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a dispensary facility prior to the time that the laboratory has completed its testing and analysis and provided those results, in writing, to the producer or other designated production facility employee.

(d) A laboratory shall immediately return or dispose of any marijuana upon the completion of any testing, use, or research. If a laboratory disposes of marijuana, the laboratory shall comply with 21a-408-64 of the Regulations of Connecticut State Agencies.

(e) If a sample of marijuana does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, based on the standards set forth in this subsection, the producer shall dispose of the entire batch from which the sample was taken in accordance with section 21a-408-64 of the Regulations of Connecticut State Agencies.

(1) For purposes of the microbiological test, a marijuana sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia, which can be obtained at <http://www.usp.org>.

(2) For purposes of the mycotoxin test, a marijuana sample shall be deemed to have passed if it meets the following standards:

<u>Test</u>	<u>Specification</u>
Alfatoxin B1	<20 uG/KG of Substance
Alfatoxin B2	<20 uG/KG of Substance
Alfatoxin O1	<20 uG/KG of Substance
Alfatoxin O2	<20 uG/KG of Substance
Ochratoxin A	<20 uG/KG of Substance

(3) For purposes of the heavy metal test, a marijuana sample shall be deemed to have passed if it meets the following standards:

<u>Metal</u>	<u>Natural Health Products Acceptable limits uG/KG BW/Day</u>
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

(4) For purposes of the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR 180.

(f) If a sample of marijuana passes the microbiological, mycotoxin, heavy metal and pesticide chemical residue test, the laboratory shall release the entire batch for immediate manufacturing, packaging and labeling for sale to a dispensary facility.

(g) The laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, at the same time that it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results and make them available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(h) A producer shall provide to a dispensary facility the laboratory test results for each batch of marijuana used in a product purchased by the dispensary facility. Each dispensary facility shall have such laboratory results available upon request to qualifying patients, primary caregivers and physicians who have certified qualifying patients.

(NEW) Sec. 21a-408-59. Brand name

(a) A producer shall assign a brand name to each marijuana product. A producer shall register each brand name with the department, on a form prescribed by the commissioner, prior to any sale to a dispensary facility and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THCA);

(3) Cannabidiols (CBD);

(4) Cannabidiolic acid (CBDA); and

(5) Any other active ingredient that constitutes at least 1% of the marijuana batch used in the product.

(b) A producer shall not label two marijuana products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed within subsection (a)(1) to (4), inclusive, of this section within a range of 97% to 103%.

(c) The department shall not register any brand name that:

(1) Is identical to, or confusingly similar to, the name of an existing non-marijuana product;

(2) Is identical to, or confusingly similar to, the name of an unlawful product or substance;

(3) Is confusingly similar to the name of a previously approved marijuana product brand name;

(4) Is obscene or indecent;

- (5) May encourage the use of marijuana for recreational purposes;
- (6) May encourage the use of marijuana for a condition other than a debilitating medical condition;
- (7) Is customarily associated with persons under the age of 18; or
- (8) Is related to the benefits, safety or efficacy of the marijuana product unless supported by substantial evidence or substantial clinical data.

(NEW) Sec. 21a-408-60. Transportation of marijuana

- (a) Prior to transporting any marijuana or marijuana product, a producer shall:
 - (1) Complete a shipping manifest using a form prescribed by the commissioner;and
 - (2) Securely transmit a copy of the manifest to the dispensary facility that will receive the products and to the department at least twenty-four hours prior to transport.
- (b) The producer and dispensary facility shall maintain all shipping manifests and make them available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.
- (c) A producer shall only transport marijuana products:
 - (1) In a locked, safe and secure storage compartment that is part of the vehicle transporting the marijuana; and
 - (2) In a storage compartment that is not visible from outside the vehicle.
- (d) A production facility employee, when transporting marijuana, shall travel directly from the producer facility to the dispensary facility and shall not make any stops in between, except to other dispensary facilities.
- (e) A producer shall ensure that all delivery times and routes are randomized.
- (f) A producer shall staff all transport vehicles with a minimum of two employees. At least one delivery team member shall remain with the vehicle at all times that the vehicle contains marijuana.
- (g) A delivery team member shall have access to a secure form of communication with employees at the production facility at all times that the vehicle contains marijuana.
- (h) A delivery team member shall possess a department-issued identification card at all times when transporting or delivering marijuana and shall produce it to the commissioner, the commissioner's authorized representative or law enforcement official upon request.

(NEW) Sec. 21a-408-61. Security requirements for producers

- (a) A producer shall:

(1) Not produce, manufacture or maintain marijuana in excess of the quantity required for normal, efficient operation;

(2) Store all marijuana products in an approved safe or approved vault and in such a manner as to prevent diversion, theft or loss;

(3) Maintain all marijuana that is not part of a finished product in a secure area or location within the production facility accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;

(4) Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing or storage of marijuana, securely locked or protected from entry, except for the actual time required to remove or replace marijuana;

(5) Keep all locks and security equipment in good working order;

(6) Not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;

(7) Not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees; and

(8) Keep the production facility securely locked and protected from entry at all times.

(b) If a production facility presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to diversion, theft or loss, the commissioner may require additional safeguards such as a supervised watchman service.

(c) If a loss, theft, or diversion of marijuana has occurred from a production facility, the commissioner shall determine the appropriate storage and security requirements for all marijuana in such production facility, and may require additional safeguards to ensure the security of the marijuana.

(d) Any marijuana not stored in compliance with sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, or at a location other than that for which the producer license was issued, shall be subject to seizure in accordance with section 21a-96 of the Connecticut General Statutes.

(e) Any producer whose license is revoked or not renewed shall dispose of its entire stock of marijuana under conditions approved by the department.

(f) If a producer has provided other safeguards, which can be regarded in total as an adequate substitute for some element of protection required of such producer, such added protection may be taken into account by the commissioner in evaluating overall required security measures.

(g) No person shall be allowed access to any area within a production facility containing marijuana except laboratory employees and production facility employees whose responsibilities necessitate access to the area of the production facility containing marijuana and then for only as long as necessary to perform the person's job duties.

(h) Any area of a production facility containing marijuana, including a room with an approved safe or approved vault, shall have a sign posted at all entry ways, which shall be a minimum of twelve inches in height and twelve inches in width and shall state: "Do Not Enter - Limited Access Area – Access Limited to Authorized Employees Only" in lettering no smaller than one-half inch in height.

(i) Notwithstanding the requirements of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, members of the department, local law enforcement or other federal, state of Connecticut or local government officials may enter any area of a production facility if necessary to perform their governmental duties.

(NEW) Sec. 21a-408-62. Security alarm systems; minimum requirements for dispensary facilities and production facilities

(a) All dispensary facilities and production facilities shall have an adequate security system to prevent and detect diversion, theft or loss of marijuana utilizing commercial grade equipment, which shall, at a minimum, include:

(1) A perimeter alarm;

(2) Motion detector;

(3) Video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The dispensary facility or production facility shall direct cameras at all approved safes, approved vaults, dispensing areas, marijuana sales areas and any other area where marijuana is being produced, harvested, manufactured, stored or handled. At entry and exit points, the dispensary facility or production facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

(4) Twenty-four hour recordings from all video cameras, which the dispensary facility or production facility shall make available for immediate viewing by the commissioner or the commissioner's authorized representative upon request and shall retain for at least thirty days. If a dispensary facility or producer is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the dispensary facility or producer shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the

entity conducting the investigation or proceeding notifies the dispensary facility manager or producer that it is not necessary to retain the recording;

(5) Duress alarm, which for purposes of this subsection means a silent security alarm system signal generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system;

(6) Panic alarm, which for purposes of this subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;

(7) Holdup alarm, which for purposes of this subsection means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;

(8) Automatic voice dialer, which for purposes of this subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;

(9) A failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the dispensary facility or producer within five minutes of the failure, either by telephone, email, or text message;

(10) The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

(11) A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

(12) The ability to remain operational during a power outage.

(b) A dispensary facility or a production facility shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction or alterations.

(c) In addition to the requirements listed in subsection (a) of this section, each production facility shall have a back-up alarm system approved by the commissioner that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.

(d) A dispensary facility or a production facility shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, the commissioner or the commissioner's authorized representative, and others when approved by the commissioner. A dispensary facility and producer shall make available a current list of authorized employees and service employees that have access to the surveillance room to the

commissioner or the commissioner's authorized representative upon request. A dispensary facility and producer shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

(e) A dispensary facility and producer shall keep the outside perimeter of the dispensary facility and production facility premises well-lit.

(f) All video recording shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A dispensary facility and producer shall erase all recordings prior to disposal or sale of the facility.

(g) A dispensary facility and producer shall keep all security equipment in good-working order and shall test such equipment no less than two times per year.

(NEW) Sec. 21a-408-63. Dispensary and producer reportable events

(a) Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana or of any loss or unauthorized alteration of records related to marijuana or qualifying patients, a dispensary or producer shall immediately notify:

- (1) Appropriate law enforcement authorities; and
- (2) The Drug Control Division of the department.

(b) A dispensary or producer shall provide the notice required by subsection (a) of this section to the department by way of a signed statement which details the circumstances of the event, including an accurate inventory of the quantity and brand names of marijuana diverted, stolen, lost, destroyed or damaged and confirmation that the local law enforcement authorities were notified. A dispensary or producer shall make such notice no later than twenty-four hours after discovery of the event.

(c) A dispensary or producer shall notify the Drug Control Division of the department no later than the next business day, followed by written notification no later than ten business days, of any of the following:

- (1) An alarm activation or other event that requires response by public safety personnel;
- (2) A breach of security;
- (3) The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and
- (4) Corrective measures taken, if any.

(d) A dispensary and producer shall maintain and shall make available all documentation related to an occurrence that is reportable pursuant to subsections (a) through (c), inclusive, of this section in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-64. Disposal of marijuana

(a) A dispensary, producer, laboratory, law enforcement or court official or the commissioner or the commissioner's authorized representative shall dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded or deteriorated marijuana in the following manner:

(1) By surrender without compensation of such marijuana to the commissioner or the commissioner's authorized representative; or

(2) By disposal in the presence of an authorized representative of the commissioner in such a manner as to render the marijuana non-recoverable.

(b) The person disposing of the marijuana shall maintain and make available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies a separate record of each such disposal indicating:

(1) The date and time of disposal;

(2) The manner of disposal;

(3) The brand name and quantity of marijuana disposed of; and

(4) The signatures of the persons disposing of the marijuana, the authorized representative of the commissioner and any other persons present during the disposal.

(NEW) Sec. 21a-408-65. Inventory

(a) Each dispensary facility and production facility, prior to commencing business, shall:

(1) Conduct an initial comprehensive inventory of all marijuana at the facility. If a facility commences business with no marijuana on hand, the dispensary or producer shall record this fact as the initial inventory; and

(2) Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of marijuana, which shall enable the facility to detect any diversion, theft or loss in a timely manner.

(b) Upon commencing business, each dispensary facility and production facility shall conduct a weekly inventory of marijuana stock, which shall include, at a minimum, the date of the inventory, a summary of the inventory findings, the name, signature and title of the individuals who conducted the inventory, the date of receipt of marijuana, the name and address of the producer from whom received, where applicable, and the kind and quantity of marijuana received. The record of all marijuana sold, dispensed or

otherwise disposed of shall show the date of sale, the name of the dispensary facility, qualifying patient or primary caregiver to whom the marijuana was sold, the address of such person and the brand and quantity of marijuana sold.

(c) A complete and accurate record of all stocks or brands of marijuana on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the dispensary facility manager or producer may choose, so long as it is not more than one year following the prior year's inventory.

(d) All inventories, procedures and other documents required by this section shall be maintained on the premises and made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(e) Whenever any sample or record is removed by a person authorized to enforce the provisions of sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies or the provisions of the state of Connecticut food, drug and cosmetic statutes and regulations for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

(NEW) Sec. 21a-408-66. Marketing: prohibited conduct, statements and illustrations; commissioner review of advertisements

(a) A producer, production facility employee, producer backer, dispensary facility employee, dispensary facility backer or physician, in any combination, shall not cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or caregiver choice with regard to the selection of a physician, dispensary or marijuana product.

(b) An advertisement for marijuana or any marijuana product shall not contain:

(1) Any statement that is false or misleading in any material particular or is otherwise in violation of the Connecticut Unfair Trade Practices Act, sections 42-110a to 42-110q, inclusive, of the Connecticut General Statutes;

(2) Any statement that falsely disparages a competitor's products;

(3) Any statement, design, or representation, picture or illustration that is obscene or indecent;

(4) Any statement, design, representation, picture or illustration that encourages or represents the use of marijuana for a condition other than a debilitating medical condition;

(5) Any statement, design, representation, picture or illustration that encourages or represents the recreational use of marijuana;

(6) Any statement, design, representation, picture or illustration related to the safety or efficacy of marijuana, unless supported by substantial evidence or substantial clinical data;

(7) Any statement, design, representation, picture or illustration portraying anyone under the age of eighteen, objects suggestive of the presence of anyone under the age of eighteen, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of eighteen;

(8) Any offer of a prize, award or inducement to a qualifying patient, primary caregiver or physician related to the purchase of marijuana or a certification for the use of marijuana; or

(9) Any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the commissioner, department, the state of Connecticut or any person or entity associated with the state of Connecticut.

(c) Any advertisement for marijuana or a marijuana product shall be submitted to the commissioner at the same time as, or prior to, the dissemination of the advertisement.

(d) The submitter of the advertisement shall provide the following information in addition to the advertisement itself:

(1) A cover letter that:

(A) Provides the following subject line: Medical marijuana advertisement review package for a proposed advertisement for (Brand Name);

(B) Provides a brief description of the format and expected distribution of the proposed advertisement; and

(C) Provides the submitter's name, title, address, telephone number, fax number, and email address;

(2) An annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;

(3) Verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner and not a model or actor;

(4) Verification that a spokesperson who is represented as an actual patient is indeed an actual patient;

(5) Verification that an official translation of a foreign language advertisement is accurate;

(6) Annotated references to support disease or epidemiology information, cross-referenced to the advertisement summary; and

(7) A final copy of the advertisement, including a video where applicable, in a format acceptable to the commissioner.

(e) Advertising packages that are missing any of the elements in subsection (d) of this section, or that fail to follow the specific instructions for submissions, shall be considered incomplete. If the department receives an incomplete package, it shall so notify the submitter.

- (f) The commissioner may:
- (1) Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the commissioner determines that the advertisement would be false or misleading without such a disclosure; or
 - (2) Make recommendations with respect to changes that are:
 - (A) Necessary to protect the public health, safety and welfare; or
 - (B) Consistent with dispensing information for the product under review.
 - (3) If appropriate and if information exists, recommend statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific disease states, disease symptoms and population groups.

(NEW) Sec. 21a-408-67. Marijuana advertising; requirements for true statements and fair balance

(a) All advertisements for marijuana or marijuana products that make a statement relating to side effects, consequences, contraindications and effectiveness shall present a true statement of such information. When applicable, advertisements broadcast through media such as radio, television, or other electronic media shall include such information in the audio or audio and visual parts of the presentation.

(b) False or misleading information in any part of the advertisement shall not be corrected by the inclusion of a true statement in another distinct part of the advertisement.

(c) An advertisement does not satisfy the requirement that it present a “true statement” of information relating to side effects, consequences, contraindications, and effectiveness if it fails to present a fair balance between information relating to side effects, consequences, contraindications and effectiveness in that the information relating to effectiveness is presented in greater scope, depth, or detail than is the information relating to side effects, consequences and contraindications, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(d) An advertisement is false, lacking in fair balance, or otherwise misleading if it:

(1) Contains a representation or suggestion that a marijuana strain, brand or product is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other marijuana strains or products, unless such a claim has been demonstrated by substantial evidence or substantial clinical experience;

(2) Contains favorable information or opinions about a marijuana product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;

- (3) Uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;
 - (4) Uses a study on individuals without a debilitating medical condition without disclosing that the subjects were not suffering from a debilitating medical condition;
 - (5) Uses data favorable to a marijuana product derived from patients treated with a different product or dosages different from those approved in the state of Connecticut;
 - (6) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or
 - (7) Fails to provide adequate emphasis for the fact that two or more facing pages are part of the same advertisement when only one page contains information relating to side effects, consequences and contraindications.
- (e) No advertisement may be disseminated if the submitter of the advertisement has received information that has not been widely publicized in medical literature that the use of the marijuana product or strain may cause fatalities or serious damage to a patient.

(NEW) Sec. 21a-408-68. Marijuana marketing; advertising at a dispensary facility; producer advertising of prices

- (a) A dispensary facility shall:
- (1) Except as otherwise provided in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, restrict external signage to a single sign no larger than sixteen inches in height by eighteen inches in width;
 - (2) Not illuminate a dispensary facility sign advertising a marijuana product at any time;
 - (3) Not advertise marijuana brand names or utilize graphics related to marijuana or paraphernalia on the exterior of the dispensary facility or the building in which the dispensary facility is located; and
 - (4) Not display marijuana and paraphernalia so as to be clearly visible from the exterior of a dispensary facility.
- (b) A producer shall not advertise the price of its marijuana, except that it may make a price list available to a dispensary facility.

(NEW) Sec. 21a-408-69. Dispensary facility and producer records; furnishing of information; audits

- (a) Each dispensary facility and producer shall maintain a complete set of all records necessary to fully show the business transactions related to marijuana for a period of the current tax year and the three immediately prior tax years, all of which

shall be made available in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(b) The commissioner may require any licensee or registrant to furnish such information as the commissioner considers necessary for the proper administration of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, and may require an audit of the business of any dispensary facility or producer and the expense thereof shall be paid by such dispensary facility or producer.

(NEW) Sec. 21a-408-70. Inspection of records; entry on premises

(a) Every person required by sections 21a-408-1 to 21a-408-69, inclusive, of the Regulations of Connecticut State Agencies, to prepare, obtain or keep records, logs, reports or other documents, and every person in charge, or having custody, of such documents, shall maintain such documents in an auditable format for no less than three years. Upon request, such person shall make such documents immediately available for inspection and copying by the commissioner, the commissioner's authorized representative or others authorized by the Act or sections 21a-408-1 to 21a-408-69, inclusive, of the Regulations of Connecticut State Agencies, to review the documents. In complying with this section, no person shall use a foreign language, codes or symbols to designate marijuana types or persons in the keeping of any required document.

(b) For purposes of the supervision and enforcement of the medical marijuana program established pursuant to chapter 420f of the Connecticut General Statutes, the commissioner or the commissioner's authorized representative, is authorized:

(1) To enter, at reasonable times, any place, including a vehicle, in which marijuana is held, dispensed, sold, produced, delivered, transported, manufactured or otherwise disposed of;

(2) To inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein including records, files, financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls and facilities; and

(3) To inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished material.

Statement of Purpose:

(A) Purpose: These regulations establish the regulatory framework for the palliative use of marijuana pursuant to Chapter 420f of the Connecticut General Statutes.

(B) Summary: These new regulations set standards for the oversight of the medical marijuana industry with regard to:

- 1) Qualifying patients and primary caregivers;
- 2) Physician certifications that certify patients for the use marijuana;
- 3) Dispensaries, where marijuana is dispensed to patients;
- 4) Producers, where marijuana is grown and packaged for delivery to dispensaries;
- 5) Laboratories, where marijuana will be tested for safety and active ingredient analysis;
- 6) The confidentiality of information concerning patients;
- 7) Security requirements for handling and storing marijuana; and
- 8) The addition of debilitating medical conditions that can be treated with marijuana.

(C) Legal Effects: These regulations establish standards for the oversight and enforcement of the use, certification to use, sale and production of medical marijuana. If followed, these standards provide immunity from state criminal action for the production, possession, dispensing and use of medical marijuana. These regulations also establish legal standards for the suspension or revocation of licenses and registrations.