STATE OF CONNECTICUT

Regulation of

Department of Consumer Protection

Concerning

Palliative Use of Marijuana

Section 1. Sections 21a-408-1 to 21a-408-15, inclusive, of the Regulations of Connecticut State Agencies are amended to read as follows:

Sec. 21a-408-1. Definitions

As used in sections 21a-408-1 to 21a-408-[72] 59, 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)](1) "Act" means Chapter 420f of the Connecticut General Statutes;

[(3)](2) "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)](3) "Advanced practice registered nurse" or [("APRN")] has the same meaning as provided in chapter 378 of the Connecticut General Statutes;

[(6)](4) "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 or use of [marijuana by qualifying patients]cannabis or [primary caregivers]; cannabis-related services, as defined in section 21a-421j-1 of the Regulations of Connecticut State Agencies.

[(7)](5) "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;

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

[(9)](7) "Approved vault" [has the same meaning as described]means a vault that complies with the requirements prescribed in section 21a-262-1 of the Regulations of Connecticut State Agencies, or such other vault approved by the department;

[(10) "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;]

[(11)](8) "Backer" has the same meaning as provided in section 21a-420 of the Connecticut General Statutes;

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

[(12)](10) "Bona fide healthcare professional-patient relationship" means a relationship in which the physician, physician assistant, or APRN 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,

physician assistant, or APRN has certified to the department that the patient would benefit from the palliative use of marijuana;

[(13)](11) "Cannabis establishment" has the same meaning as provided in section 21a-420 of the Connecticut General Statutes;

(12) "Commissioner" means the Commissioner of Consumer Protection or the commissioner's designee;

[(14)](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, physician assistant, or APRN request;

[(15)](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;

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

[(17)](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);

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

[(19)](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;

[(20)](19) "Department" means the Department of Consumer Protection;

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

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

[(23)](22) "Dilute" or "dilution" means to make thinner or weaker by adding water or another solvent to the product;

[(24)](23) "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;

[(25)](24) "Dispensary facility" has the same meaning as provided in Chapter 420f of the Connecticut General Statutes; [means a place of business where marijuana may be dispensed, sold or distributed in accordance with Section 21a-408-35 of the Regulations of Connecticut State Agencies 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;

(26) "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;

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

(28) "Dispensary facility employee" means a dispensary, dispensary technician, dispensary facility staff, a person who does not have a personal ownership interest in a dispensary facility, but sits on a board of a company with such an ownership interest, 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;]

[(29)](25) “Dispensary technician" has the same meaning as provided in section 21a-420 of the Connecticut General Statutes; [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 sections 21a-408-24 and 21a-408-25 of the Regulations of Connecticut State Agencies;]

[(30)](26) “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;

[(31)](27) “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;

[(32) “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-408-72, inclusive, of the Regulations of Connecticut State Agencies;]

[(33)](28) “Drug Control Division” means the division within the department responsible for overseeing the medical marijuana program;

[(34)](29) “Drug” has the same meaning as provided in section 20-571 of Connecticut General Statutes;

[(35) "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;

(36) “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;]

(30) “Employee” has the same meaning as provided in section 21a-420 of the Connecticut General Statutes;

(31) “Financial interest" has the same meaning as provided in section 21a-420 of the Connecticut General Statutes;

[(37)](32) “Forms” means applications, registrations, written certifications or other documents prescribed by the commissioner in either hardcopy or electronic format;

[(38)](33) “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;

(34) “Key Employee” has the same meaning as provided in section 21a-420 of the Connecticut General Statutes;

[(39)](35) “Label" means a display of written, printed or graphic matter upon the immediate container of any product containing marijuana;

[(40) “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;

(41)](36) “Legend drug” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

[(42)](37) “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;] has the same meaning as provided in section 21a-420 of the Connecticut General Statutes;

[(43)](38) “Marijuana” or “cannabis” has the same meaning as provided in section 21a-240 of the Connecticut General Statutes;

[(44) “Marijuana product” means any product containing marijuana, including raw materials, that requires no further processing and that is packaged for sale or for research purposes;]

(39) “Medical marijuana product” has the same meaning as provided in section 21a-420 of the Connecticut General Statutes;

[(45)](40) "Minor" means a person who is under 18 years of age and is not an emancipated minor;

[(46) “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 shall be determined by the commissioner on the basis of available research and recommendations from the Board of Physicians;]

[(47)](41) “Palliative use” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

[(48)](42) “Paraphernalia” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

[(49)](43) “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;

[(50)](44) “Pesticide chemical” has the same meaning as provided in section 21a-92 of the Connecticut General Statutes;

[(51)](45) “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;

[(52)](46) “Pharmaceutical grade marijuana” means marijuana or marijuana products that are not adulterated, as defined in section 21a-105 of the Connecticut General Statutes, 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;] produced, packaged and labeled in accordance with chapter 420h of the Connecticut General Statutes and the regulations promulgated thereunder.

[(53)](47) “Pharmacist” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

[(54)](48) “Pharmacy technician” has the same meaning as provided in section 20-571 of the Connecticut General Statutes;

[(55)](49) “Physician” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

(50) “Physician Assistant” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

[(56)](51) “Prescription monitoring program” means the electronic prescription drug monitoring program established by section 21a-254(j) of the Connecticut General Statutes;

[(57)](52) [“Primary caregiver” or “caregiver] “Caregiver” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes [for “primary caregiver”];

[(58)](53) “Producer” has the same meaning as provided in section 21a-408 of the Connecticut General Statutes;

[(59) "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;

(60)](54) "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, dispensary or caregiver for the patient's use;

[(61)](55) "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;

[(62) "Production facility employee" means any person employed by a producer, any person who does not have a personal ownership interest in a producer, but sits on a board of a company with such an ownership interest, or any person who otherwise has access to the production facility, including independent contractors who are routinely on the production facility premises;]

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

[(64)](57) "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;

(58) "Responsible and Equitable Regulation of Adult-Use Cannabis Act" or "RERACA" has the same meaning as provided in section 21a-420 of the Connecticut General Statutes;

[(65)](59) "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; and

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

(67)](60) "Written certification" means a written or electronically submitted statement issued by a physician, physician assistant, or an APRN 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.

Sec. 21a-408-2. Requirements for issuing written certifications to the department

(a) The department shall only accept written certifications for the palliative use of marijuana when the physician, physician assistant, or APRN:

(1) Holds an active license under chapter 370 or 378 of the Connecticut General Statutes, which license [and] is in good standing;

(2) Holds an active [department] controlled substance practitioner registration issued by the department that 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 reviews a patient's prescription history in the Prescription Monitoring Program; and

(5) Is not engaged in any conduct prohibited by the Act [or], sections 21a-408-1 to 21a-408-[72]59, inclusive, of the Regulations of Connecticut State Agencies, RERACA, and any regulations, and Policies and Procedures promulgated thereunder.

(b) A physician, physician assistant, or APRN issuing a written certification shall:

(1) Have a bona fide health care professional-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, physician assistant, or APRN 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, physician assistant, or APRN may assist with preparing a written certification so long as the final written certification is reviewed and approved by the physician, physician assistant, or APRN before it is submitted to the department.

(d) If a physician, physician assistant, or APRN provides instructions for the use of marijuana to the patient, [or includes]such instructions shall be included as part of the written certification, [the physician or APRN]and a pharmacist shall [also securely transmit]abide by such instructions [to the qualifying patient's designated dispensary facility.]and any variation therefrom shall be discussed with the certifying physician, physician assistant, or APRN.

Sec. 21a-408-3. Requirements for maintaining patient medical records

(a) A physician, physician assistant, or APRN 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, physician assistant, or APRN has issued a written certification.

(b) A physician, physician assistant, or APRN shall make a copy of such medical records reasonably available to the commissioner, 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-[72]59, 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.

Sec. 21a-408-4. Prohibited acts of Physicians, Physician Assistants, and APRNs

(a) A physician, physician assistant, or APRN who has issued or intends to issue a written certification, and such person's employee, spouse, parent, or child shall not:

(1) Directly or indirectly accept, solicit, or receive anything of value from, or have a [dispensary, dispensary facility]direct or indirect financial interest in, a backer, [dispensary facility employee, producer, producer backer, production facility]employee, [provider of paraphernalia or]cannabis establishment, any [other]person that may benefit from a qualifying patient's or caregiver's acquisition, purchase, or use of cannabis, or any person associated

with a [dispensary facility or production facility]cannabis establishment, except [as]for a retailer, product packager, delivery service, transporter, or a paraphernalia provider, or as otherwise 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]cannabis establishment, type of cannabis, or medical marijuana product;

(3) Examine a qualifying patient, either in person or through means of telehealth, for purposes of diagnosing a debilitating medical condition at or from a location where marijuana, cannabis, medical marijuana products 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, physician assistant, or APRN from charging an appropriate fee for the patient visit.

(b) [A physician or APRN who issues written certifications, and such physician's or APRN'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 or APRN 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, physician assistant, or APRN shall not issue a written certification for such physician, physician assistant, or APRN or for [the physician's or APRN's]such person's [family members] spouse, parent, child, employee[s] or co-worker[s].

[(d)] (c) A physician, physician assistant, or APRN shall not provide product samples containing marijuana other than those approved by the federal Food and Drug Administration.

Sec. 21a-408-5. Enforcement actions against physicians [or], Physician Assistants, and APRNs

(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 place conditions upon, revoke or suspend a physician's or APRN's controlled substance practitioner registration or to restrict a physician's, physician assistant or APRN's controlled substance practitioner registration so as to prohibit the physician, physician assistant, or APRN from issuing written certifications if the physician, physician assistant, or APRN has:

(1) Failed to comply with any provision of the Act or sections 21a-408-1 to 21a-408-[72]59, inclusive, of the Regulations of Connecticut State Agencies, RERACA, and any Policies and Procedures promulgated thereunder;

(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 or APRN's name.

(b) If the [commissioner has reason to believe]department finds that the public health, safety or welfare imperatively requires emergency action, the commissioner may issue an order restricting the physician's or APRN's controlled substance practitioner registration to summarily prohibit the physician, physician assistant, or APRN 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, physician assistant, or APRN placing conditions on the physician's or APRN'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, physician assistant, or APRN of the Act or sections 21a-408-1 to 21a-408-[72]59, inclusive, of the Regulations of Connecticut State Agencies, RERACA, and any Policies and Procedures promulgated thereunder. to the Connecticut Medical Examining Board, Connecticut Board of Examiners for Nursing or to a Connecticut state or local law enforcement agency.

Sec. 21a-408-6. Patient and [primary] caregiver registration

(a) A qualifying patient for whom a physician, physician assistant, or APRN 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.

(b) The form prescribed by the commissioner may require the qualifying patient or [primary] caregiver to grant permission for the department to[:(1)Determine]determine whether the patient is an inmate confined in a correctional institution or facility under the supervision of the Department of Correction.[; and

(2) 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.]

(c) When the qualifying patient is a minor, the commissioner shall require:

(1) An acknowledgement from the custodial parent, guardian or other person having legal custody of such person indicating that:

(A) The custodial parent, guardian or other person having legal custody will serve as a [primary] caregiver for the qualifying patient; and

(B) The custodial parent, guardian or other person having legal custody will control the acquisition and possession of marijuana and any related paraphernalia for palliative use on behalf of the minor patient.

(2) An acknowledgment from both the qualifying patient's primary care provider and a physician who is board certified in an area of medicine involved in the treatment of the debilitating condition for which the qualifying patient was certified which confirms that the palliative use of marijuana is in the best interest of the qualifying patient; and

(3) A certification that a written certification has been issued pursuant to section 21a-408-2 of the Regulations of Connecticut State Agencies.

(d) If [a registration]an application of a qualifying patient applicant or caregiver applicant is determined to be inaccurate or incomplete, the department may send the applicant a notice of deficiency. If the applicant corrects the deficiencies within sixty days or less after receiving notice from the department, the department shall not charge any additional fees.

(e) The department may deny an application of a qualifying patient applicant or caregiver applicant 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 such applicant's second attempt. Any such applicant may resubmit the registration application materials with all applicable fees for a new registration.

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

(g) [Absent]A qualifying patient may change caregivers more than once per year only upon permission from the [commissioner]department 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 the [primary] caregiver [prior to renewal], the qualifying patient shall submit a change of caregiver request form to the department. If a caregiver change is requested more than once per year, such request shall set forth the reasons the qualifying patient seeks to change [primary] caregivers[. If], and 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-408-29 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.

(h) 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 (g) 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.

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;

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

(6) Has not paid all applicable fees as required by section 21a-408-29 of the Regulations of Connecticut State Agencies;

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

(8) Is a minor or 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)](3)

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

[(5)] (4) Has not paid all applicable fees as required by section 21a-408-29 of the Regulations of Connecticut State Agencies;

[(6)] (5) Provides false, misleading or incorrect information to the department;

[(7)] (6) Has had a [primary] caregiver registration denied, suspended or revoked in the previous six months;

[(8)] (7) 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

[(9)] (8) 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.

Sec. 21a-408-8. Revocation or suspension of a qualifying patient or [primary] caregiver registration

(a) The commissioner may place conditions upon, 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, physician assistant, or APRN notifies the department that the physician, physician assistant, or APRN is withdrawing the written certification submitted on behalf of the qualifying patient and, thirty days after the physician's or APRN's withdrawal of the written certification, the patient has not obtained a valid written certification from a different physician, physician assistant, or APRN;

(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]the possession limit set forth in RERACA;

(6) The qualifying patient provides or sells a medical marijuana product to any person, [including another registered qualifying patient] or [primary caregiver;] sells cannabis to any person without the appropriate cannabis establishment license;

(7) The qualifying patient uses marijuana in a place or manner not permitted by the Act or sections 21a-408-1 to 21a-408-[72]59, 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, physician assistant, or APRN is no longer available to provide care to the patient and, after thirty days from the physician, physician assistant, or APRN notifying the department of the physician's or APRN's unavailability, the patient has not established a bona-fide healthcare professional-patient relationship with a different physician, physician assistant, or APRN;

(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-[72]59, inclusive, of the Regulations of Connecticut State Agencies.

(b) The department may place conditions upon, 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, physician assistant, or APRN 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]the possession limit set forth in [a one-month period]RERACA on behalf of a single qualifying patient;

(6) The [primary] caregiver obtains marijuana for, or provides or sells [marijuana to,]a medical marijuana product to, or sells cannabis without the appropriate cannabis establishment license 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)] (11) 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)] (12) The [primary] caregiver has violated any section of the Act or sections 21a-408-1 to 21a-408-[72] 59, inclusive, of the Regulations of Connecticut State Agencies.

Sec. 21a-408-9. Reporting requirements for physicians, APRNs, patients and caregivers

(a) A physician, physician assistant, or APRN 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, physician assistant, or APRN has issued a written certification if such change may affect the patient's continued eligibility to use marijuana. A physician, physician assistant, or APRN 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 Correction. 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. 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 approved by the department. A qualifying patient or primary caregiver shall only purchase marijuana from the dispensary facility currently designated by the patient or caregiver with the department.

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 prescribed by the commissioner.

(e)] (c) 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)] (d) 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-408-29 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-[72]59, 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)] (e) 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-408-29 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 section 21a-408-1 to 21a-408-[72]59, inclusive, of the Regulations of Connecticut State Agencies.

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

(a) Qualifying patients and [primary] caregivers 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.

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

A patient or caregiver shall dispose of all [usable] medical marijuana products 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 medical marijuana products 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;

[(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].

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, and 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 (i) 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 on a form prescribed by the commissioner and request that the commissioner present the petition to the board.

(c) The commissioner may deny a request to present a petition to the board if it does not include all of the information required on the form prescribed by the commissioner.

(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, a quorum of the] The board shall convene as necessary to conduct [a] public [hearing]hearings 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) 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.

(h) 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.]

(i) If, after receiving the board's recommendation, which may include any dissenting or concurring opinions, 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.] post that medical condition, medical treatment or disease to the Department's Internet website and said medical condition, medical treatment or disease shall be deemed approved and effective without further action on the date such medical condition, medical treatment or disease is posted on the Department's Internet website.

Sec. 21a-408-12a. Additional Debilitating Medical Conditions

In accordance with the procedures set forth in section 21a-408a-12 of the Regulations of Connecticut State Agencies, the following medical conditions, medical treatments or diseases shall be added to the list of debilitating medical conditions:

(a) For patients eighteen years of age or older:

(1) Sickle cell disease;

(2) Post laminectomy syndrome with chronic radiculopathy;

(3) Severe psoriasis and psoriatic arthritis;

(4) Amyotrophic lateral sclerosis;

(5) Ulcerative colitis;

(6) Complex regional pain syndrome, Type 1 and Type II;

(7) Spasticity or Neuropathic Pain Associated with Fibromyalgia;

(8) Severe Rheumatoid Arthritis;

(9) Post Herpetic Neuralgia;

(10) Muscular Dystrophy;

(11) Hydrocephalus with Intractable Headache;

(12) Intractable Headache Syndromes;

(13) Neuropathic Facial Pain;

(14) Osteogenesis Imperfecta;

(15) Chronic Neuropathic Pain Associated with Degenerative Spinal Disorders;

(16) Interstitial Cystitis;

(17) Intractable Neuropathic Pain that is unresponsive to standard medical treatments;

(18) Median Arcuate Ligament Syndrome;

(19) Tourette Syndrome;

(20) Vulvodynia and vulvar burning;

(21) Chronic Pain of at least 6 months' duration associated with a specified underlying chronic condition refractory to other treatment intervention; [and]

(22) Ehlers-Danlos Syndrome associated with Chronic Pain[.]; and

(23) Chronic Pancreatitis.

(b) For patients under eighteen years of age:

(1) Muscular Dystrophy;

(2) Osteogenesis Imperfecta;

(3) Intractable Neuropathic Pain that is unresponsive to standard medical treatments; [and]

(4) Tourette Syndrome for patients who have failed standard medical treatment[.]; and

(5) Chronic Pancreatitis for patients whose pain is recalcitrant to standard medical management.

(c) All other medical conditions, treatments or diseases posted on the Department's website in accordance with section 21a-408-12 of the Regulations of Connecticut State Agencies.

Sec. 21a-408-13. Number of 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 and hybrid retailers in operation, the number of qualifying patients registered with the department and the convenience and economic benefits to qualifying patients.

[(c)] (b) Each dispensary facility may employ no more than fifteen [dispensaries]licensed pharmacists at a time without prior approval from the commissioner, at least one of whom shall be designated and licensed as [the dispensary facility manager] a key employee.

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; and

(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;

(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-[72]59, inclusive, of the Regulations of Connecticut State Agencies; and

(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-[72]59, 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 may award a dispensary facility license by selecting among the qualified applicants who applied for the dispensary facility license subject to rescission.

Sec. 21a-408-15. Dispensary facility license applications

(a) A dispensary facility license applicant shall submit an application form and the fees required by section 21a-408-29 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 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(s) who will serve as [the dispensary facility manager] key employee(s) 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 of the area where dilution may occur;

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

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

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

(G) The location of all approved safes and approved vaults that will 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;

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

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

(L) 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.

(c) 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.

(d) The department may verify information contained and investigate claims made, 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] key employees;

(4) Contacting state regulators in any other states where the applicant, and the applicant's [dispensary facility backers and the dispensary facility backers' members, shareholders or investors]backers are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana [program]or adult use cannabis programs; and

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

Sec. 2. Sections 21a-408-19 to 21a-408-21, inclusive, of the Regulations of Connecticut State Agencies are amended to read as follows:

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.

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; and

(2) 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-408-55]21a-421j-8 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 medical 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)] (7) 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-[72]59 of the Regulations of Connecticut State Agencies; and

[(9)] (8) 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-[72]59, 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 may award a producer license by selecting among the qualified applicants who applied for the producer license subject to rescission.

Sec. 21a-408-21. Producer applications

(a) A producer shall submit an application form and the fees required by section 21-408-29 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 applicant, 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)] (11) Documents related to any compassionate need program the producer intends to offer; and

[(13)] (12) 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, investigate claims made by the applicant, 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 or adult use cannabis market; and

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

Sec. 3. Sections 21a-408-27 to 21a-408-29, inclusive, of the Regulations of Connecticut State Agencies are amended to read as follows:

Sec. 21a-408-27. Non-transferability of licenses and registrations

No person issued a license or registration pursuant to 21a-408-1 to 21a-408-[72]59, inclusive, of the Regulations of Connecticut State Agencies shall assign or transfer such license or registration without the commissioner's prior approval.

Sec. 21a-408-28. Renewal applications

(a) Every person issued a license or registration pursuant to sections 21a-408-14 to 21a-408-25, inclusive, of the Regulations of Connecticut State Agencies shall file a renewal application and the proper fees as set forth in section 21a-408-29 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.

Sec. 21a-408-29. 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, primary caregiver and research program subject 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;

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 thirty-five dollars;

(3) The non-refundable fee to be designated as a medical marijuana laboratory shall be two hundred dollars;

The non-refundable fee for each renewal of a medical marijuana laboratory designation shall be two hundred dollars;

(5) The non-refundable fee for a research program shall be two hundred dollars upon approval of the research program under section 21a-408t of the Connecticut General Statutes;

(6) The non-refundable fee for a license for a dispensary, dispensary technician, dispensary employee, dispensary backer, producer employee, producer backer, laboratory employee and research program employee, and for each renewal, shall be one hundred dollars;

(7)] (2) The non-refundable fee for a dispensary facility license application shall be five 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;

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

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

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

(11) 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 fee of one thousand five hundred dollars upon such approval;

(12) 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;

(13)] (4) 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;

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

[(15)] (6) 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[;].

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

(17) 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;]

(18) 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]

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

Sec. 4. Section 21a-408-59 of the Regulations of Connecticut State Agencies is amended to read as follows:

Sec. 21a-408-59. Laboratory requirements.

(a) 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]cannabis and hemp [industry]industries 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 cannabis establishment, as defined in section 21a-420 of the general statutes, an infused beverage manufacturer, as defined in section 21a-425a of the general statutes, a moderate-THC product vendor, as defined in section 21a-426 of the general statutes, or a manufacturer, as defined in section 22-61*l* of the general statutes[dispensary, dispensary facility, producer, production facility, certifying physician, certifying APRN, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase or use of marijuana]; and

[(3)](2) 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 has a minimum of two years of post-degree laboratory experience, or earned a bachelor's degree in biological sciences and has a minimum of four years of post-degree laboratory experience.

[(4)](3) Has provided proof to the department of accreditation in testing and calibration in accordance with the most current version of the International Standard for Organization and the International Electrotechnical Commission ("ISO/IEC") 17025 or proof that the laboratory has applied for accreditation in testing and calibration in the most current version of ISO/IEC 17025. Any testing and calibration method utilized to perform a medical marijuana analysis shall be in accordance with the laboratory's ISO/IEC 17025 accreditation. The accrediting body shall be recognized by International Laboratory Accreditation Cooperation.

(A) A laboratory applying for authorization to provide medical marijuana analytical tests shall receive ISO/IEC 17025 accreditation within eighteen months from the date the laboratory applied for ISO/IEC 17025 accreditation. A laboratory may request, and the commissioner may grant for good cause shown, additional time for the laboratory to receive ISO/IEC 17025 accreditation.

(B) [A laboratory shall send proof of ISO/IEC 17025 accreditation to the department for all medical marijuana related analytical test methods for which it has received ISO/IEC 17025 accreditation no later than five business days after the date in which the accreditation as received.]

[(C)] A laboratory may use non-accredited analytical test methods so long as the laboratory has commenced an application for ISO/IEC 17025 accreditation for analytical test methods for medical marijuana analysis. No laboratory shall use non-accredited analytical test methods for medical marijuana analysis if it has applied for and has not received ISO/IEC 17025 accreditation within eighteen months. The laboratory may request and the commissioner may grant for good cause shown additional time for the laboratory to utilize non-accredited analytical test methods for medical marijuana analysis.

[(D)](C) At such time that a laboratory loses its ISO/IEC 17025 accreditation for any medical marijuana related analytical test methods, it shall inform the department within twenty-four hours. The laboratory shall immediately stop handling, testing or analyzing marijuana.

[(b) A laboratory that transports medical marijuana to or from itself, a producer, dispensary facility or research program location shall have a transportation protocol approved by the commissioner.]

Sec. 5. Sections 21a-408-16 through 21a-408-18, inclusive, of the Regulations of Connecticut State Agencies are repealed.

Sec. 6. Sections 21a-408-22 through 21a-408-26, inclusive, of the Regulations of Connecticut State Agencies are repealed.

Sec. 7. Sections 21a-408-30 through 21a-408-58, inclusive, of the Regulations of Connecticut State Agencies are repealed.

Sec. 8. Sections 21a-408-60 through 21a-408-72, inclusive, of the Regulations of Connecticut State Agencies are repealed.

Statement of Purpose

This proposed revision to the palliative use of marijuana regulations reflects the enactment of Chapter 420h of the general statutes, Regulation of Adult-Use Cannabis, and the regulations promulgated thereunder, which are set to become effective on or around the same time as these proposed revisions. Whereas the adult-use cannabis statutes and regulations cover many of the same areas of regulation as the existing palliative use of marijuana regulations. This proposed regulation language removes inconsistent and incongruent provisions, and streamlines the subject matter to only those provisions that apply solely to the palliative use of marijuana.