DEPARTMENT OF HEALTH

Amendment and Compilation of Chapter 11-850 (Interim Rules)
Hawaii Administrative Rules

April 1, 2022

SUMMARY

Chapter 11-850 (Interim Rules), Hawaii Administrative Rules, entitled "Medical Cannabis Dispensaries", is amended and compiled.

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HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 850

MEDICAL CANNABIS DISPENSARIES

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SUBCHAPTER 1

GENERAL PROVISIONS

§11-850-1 Purpose and applicability. (a) The purpose of this chapter is to regulate a statewide dispensary system to ensure safe and legal access to medical cannabis for qualifying patients and qualifying out-of-state patients.

(b) The requirements of this chapter shall apply as indicated; provided that, for cannabis and manufactured cannabis products that are being produced and dispensed as of February 24, 2022:

(1) Until December 31, 2022, the application of subchapters 7 and 8 shall be limited to the extent that a licensee may continue to produce and dispense the cannabis and manufactured cannabis products in the same manner as they are then currently being produced, as long as the requirements of sections 11-850-110, 11-850-111(c), 11-850-112(b)(3), (4), and (8), 11-850-113, 11-850-114, and 11-850-126 are met; and

(2) The remaining requirements of subchapters 7 and 8 shall apply to all cannabis and manufactured cannabis products as of January 1, 2023. [Eff 12/14/15; am and comp 2/24/22; am and comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9,

329D-10, 329D-11, 329D-27) (Imp: HRS §§329D-1 to 329D-27; SLH 2017, Act 170, §3)

§11-850-2 Definitions. As used in this chapter:

"Accreditation body" means an impartial organization that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement for Testing and which requires laboratories to conform to ISO/IEC 17025, the general requirements for the competence of laboratories established by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

"Actual yield" means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular manufactured cannabis product.

"Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

"Allergen cross-contact" means the unintentional incorporation of an allergen into cannabis or a manufactured cannabis product.

"Applicant" means an individual applicant and applying entity who are applying for a dispensary license pursuant to chapter 329D, Hawaii Revised Statutes (HRS).

"Applying entity" means a business registered with the department of commerce and consumer affairs applying for a dispensary license pursuant to chapter 329D, HRS.

"Batch" means a specific quantity of cannabis or manufactured cannabis product that is intended to be uniform and that is produced during a specified time period covered by a single batch production record during the same production cycle. A batch of cannabis shall contain only cannabis of an identical strain that has been grown and harvested together and exposed to substantially similar conditions throughout cultivation.

"Batch number" means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the production, packaging, labeling, and storage of a batch of cannabis or manufactured cannabis products can be determined.

"Blanching" means a pre-packaging heat treatment for an adequate time and at an adequate temperature to partially or completely inactivate naturally occurring enzymes and to effect other physical or biochemical changes.

"Business days" means Monday through Friday, excluding State holidays.

"Cannabinoids" means any of the various naturally occurring, biologically active, chemical constituents of cannabis that bind to or interact with receptors of the endogenous cannabinoid system.

"Cannabis" has the same meaning as defined in section 329-121, HRS.

"Caregiver of a qualifying out-of-state patient" has the same meaning as defined in section 329-121, HRS.

"Certificate of accreditation" means a certificate issued by an accreditation body for a laboratory facility, entity, or site to be registered in Hawaii.

"Certified laboratory" means a laboratory that is certified by the department to analyze cannabis and manufactured cannabis products for content, contamination, and consistency as provided in this chapter.

"Component" means any substance intended for use in the production of a manufactured cannabis product, including those that may not appear in the finished batch of the manufactured cannabis product.

"Contact surface" means any surface that contacts cannabis, a component, or a manufactured cannabis product, and those surfaces from which drainage onto the cannabis, component, or manufactured cannabis product, or onto surfaces that contact the cannabis, component, or manufactured cannabis product, occurs during the normal course of operations. Examples of

contact surfaces include containers, utensils, tables, surfaces of equipment, and packaging.

"Contamination" means microbiological, chemical, radiological, or physical substances that either develop in or are added to cannabis, manufactured cannabis products, or ingredients and are capable of causing cannabis or manufactured cannabis products to be:

(1) Unsafe for consumption or topical use, as intended; or

(2) In violation of a regulatory standard.

"Days" as used in this chapter means calendar days unless otherwise specified.

"Department" means the state department of health.

"Director" means the director of the state department of health or the director's designee.

"Dispensary facility" means all property designated by a dispensary licensee as a medical cannabis production center or a retail dispensing location, including all property designated by the licensee as a subcontracted medical cannabis production center or a subcontracted retail dispensing location.

"Dispensary licensee" means an individual applicant and an applying entity who are issued a license by the department and includes their officers, employees, or agents.

"Dispense" or "dispensing" has the same meaning as defined in section 329D-1, HRS.

"Edible cannabis products" has the same meaning as defined in section 329D-10(c), HRS.

"Enclosed indoor facility" has the same meaning as defined in section 329D-1, HRS.

"Final form" means the form cannabis or a manufactured cannabis product is in when it is available for sale at a retail dispensing location. For pre-filled and sealed containers used to aerosolize and deliver cannabis orally, this is the final form of the cannabis, cannabis oils, or cannabis extracts that will be placed into the sealed containers.

"Gummy" or "gummies" means a chewable soft confection made primarily from sugar with gelatin or another gelling agent such as starch or pectin.

"Hemp" has the same meaning as defined in section 328G-1, HRS.

"Hemp product" has the same meaning as defined in section 328G-1, HRS.

"Individual applicant" means an individual authorized by an applying entity to apply for a dispensary license pursuant to chapter 329D, HRS, who shall be the primary point of contact with the department during the application process and after licensing.

"Ingredient" means any substance that is used in the manufacture of a manufactured cannabis product and that is intended to be present in the finished batch of the manufactured cannabis product.

"Manufacture" has the same meaning as defined in section 329D-1, HRS, except that it excludes chemical synthesis of cannabis or its psychoactive constituents.

"Manufactured cannabis product" has the same meaning as defined in section 329D-1, HRS, except that it excludes chemically synthesized cannabis or its psychoactive constituents.

"Medical cannabis dispensary" or "dispensary" has the same meaning as defined in section 329D-1, HRS.

"Medical cannabis production center" or "production center" has the same meaning as defined in section 329D-1, HRS.

"Medical use" has the same meaning as defined in section 329-121, HRS.

"Microorganisms" means yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern. This definition includes species that:

(1) May have public health significance;

(2) May cause cannabis, a component, or a manufactured cannabis product to decompose; or

(3) Indicate that the cannabis, component, or manufactured cannabis product is contaminated.

"Pathogen" means a microorganism of public health significance.

"Person" has the same meaning as defined in section 329D-1, HRS.

"Pest" means any objectionable insect or other animal including birds, rodents, flies, mites, and larvae.

"Playground" has the same meaning as defined in section 329D-22(b), HRS.

"Primary caregiver" has the same meaning as defined in section 329-121, HRS.

"Product complaint" means any communication that contains any written, electronic, or oral allegation expressing concern with the quality of cannabis or a manufactured cannabis product for any reason. Examples of product complaints are: Foul odor, off taste, illness or injury, disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a cannabis or manufactured cannabis product container, improper packaging, mislabeling, or cannabis or manufactured cannabis products that are superpotent, subpotent, or contain the wrong ingredient, or contain a drug or other contaminant (e.g., bacteria, pesticide, mycotoxin, glass, lead).

"Production" or "produce" has the same meaning as defined in section 329D-1, HRS.

"Psychoactive" means that a chemical substance changes nervous system function and results in alterations in perception, mood, consciousness, cognition, or behavior.

"Qualified individual" means a person who has the education, training, or experience (or a combination thereof) necessary to produce, package, or store clean and safe cannabis or manufactured cannabis products as appropriate to the individual's assigned duties.

"Qualifying out-of-state patient" or "registered qualifying out-of-state patient" has the same meaning as defined in section 329-121, HRS.

"Qualifying patient" has the same meaning as defined in section 329-121, HRS.

"Quality" means that the cannabis or manufactured cannabis product consistently meets established specifications for content, consistency, and limits on contaminants, and has been produced, packaged, labeled, and stored under conditions to prevent contamination.

"Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent cannabis or manufactured cannabis products from being contaminated.

"Quality control personnel" means any person, persons, or group within a medical cannabis production center designated to be responsible for its quality control operations.

"Registered employee of a dispensary" or "authorized employee of a dispensary" means an individual employed by a dispensary licensee or a dispensary subcontractor, who meets all of the requirements of this chapter for dispensary employees and whose name has been provided to the department by the dispensary licensee.

"Representative sample" means a sample that consists of an adequate number of increments that are drawn based on rational criteria, such as random sampling, and that are intended to ensure that the sample accurately portrays the material being sampled.

"Reprocessing" means using, in the production of cannabis or a manufactured cannabis product, cannabis, manufactured cannabis products, or components that have been previously removed from production and that have been made suitable for use in the production of cannabis or a manufactured cannabis product.

"Reserve sample" means a representative sample of cannabis or manufactured cannabis product that is held for a designated period of time.

"Retail dispensing location" has the same meaning as defined in section 329D-1, HRS.

"Rework" means manufactured cannabis products or components that have been removed from production and

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that have been successfully made suitable for use as or in manufactured cannabis products.

"Safe moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the cannabis or manufactured cannabis product under the intended conditions of production and storage. The safe moisture level for a manufactured cannabis product is related to its water activity (a_w). An a_w will be considered safe if adequate data are available that demonstrate that the manufactured cannabis product or component at or below the given a_w will not support the growth of undesirable microorganisms.

"Sanitize" means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.

"School" has the same meaning as defined in section 329D-22(b), HRS.

"Scope of accreditation" means a document issued by an accreditation body which describes the methodologies, range, and parameters for analyzing products for which the accreditation has been granted.

"Standard operating procedure" means written instructions on how to perform tasks and descriptions of the approved or required procedures for accomplishing specific quality assurance objectives.

"Subcontractor" or "contractor" has the same meaning as defined in section 329D-1, HRS.

"Synthetic cannabinoid" has the same meaning as defined in section 328G-1, HRS.

"Theoretical yield" means the quantity that would be produced at any appropriate step of manufacture or packaging of a particular manufactured cannabis product, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

"Time/temperature control for safety product" means a manufactured cannabis product that:

(1) Requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation; and
(2) If regulated as a food, would meet the definition of a "time/temperature control for safety food" in the U.S. Food and Drug Administration 2017 Food Code (9th edition).

"Total tetrahydrocannabinol" or "total THC" means the sum of the percentage by weight of:
(1) Delta-9-tetrahydrocannabinolic acid (D9-THCA) multiplied by 0.877; and
(2) Delta-9-tetrahydrocannabinol (D9-THC).

"Water activity" or "a_w" is a measure of the free moisture in cannabis, a component, or a manufactured cannabis product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature. [Eff 12/14/15; am and comp 2/24/22; am and comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-10, 329D-11, 329D-27) (Imp: HRS §§329-121, 329D-1 to 329D-27; SLH 2017, Act 170, §3)

§11-850-3 Severability. If any provision of this chapter or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable. [Eff 12/14/15; comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-1 to 329D-27)

§11-850-4 Disclaimer. Nothing in this chapter is intended to represent anything about the legality of the use or possession of cannabis pursuant to federal law. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-1 to 329D-27; SLH 2017, Act 170, §3)

§11-850-5 Number of licenses per county. (a) The department may issue eight dispensary licenses statewide including three licenses for the city and county of Honolulu, two licenses for the county of Hawaii, two licenses for the county of Maui, and one license for the county of Kauai. No dispensary license shall be issued for the county of Kalawao.

(b) Beginning October 1, 2018, the department may issue dispensary licenses in addition to those authorized by subsection (a), based on qualifying patient need; provided that:

(1) No more than one license may be issued per five hundred qualifying patients residing in any single county;

(2) In considering whether to award a new license, the department shall consider an applicant's capability to serve and supply medical cannabis to qualifying patients in a rural or underserved geographical area of a county; and

(3) A "rural or underserved geographical area" shall be determined by considering the number of registered qualifying patients that reside within a certain zip code compared to the quantity of medical cannabis that the closest production center and retail dispensing location have the capability to provide.

(c) The number of licenses the department issues is subject to the availability of qualified applicants in each county. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-2, 329D-7)

§11-850-6 Number of production centers per license; allowable number of plants. (a) A

dispensary licensee shall be allowed to operate up to two production centers.

(b) Each production center shall be limited to no more than three thousand cannabis plants; provided that the department may determine whether a dispensary licensee shall be allowed an additional two thousand cannabis plants at a licensee's production center. No more than five thousand plants shall be allowed at a single production center. For purposes of this section, "plant" means a cannabis plant that is greater than twelve vertical inches in height from where the base of the stalk emerges from the growth medium to the tallest point of the plant, or greater than twelve horizontal inches in width from the end of one branch to the end of another branch; provided that multiple stalks emanating from the same root ball or root system shall be considered part of the same single plant.

(c) If two production centers are located on the same property at the same address they shall be in physically separated and individually identifiable structures with no shared exterior walls to ensure compliance with the limit on the number of plants allowed at each production center. [Eff 12/14/15; am and comp2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §329D-2)

§11-850-7 Number of retail dispensing locations per license. (a) A dispensary shall be allowed to operate up to two retail dispensing locations; provided that the department may determine whether a dispensary licensee shall be allowed one additional retail dispensing location.

(b) No more than one retail dispensing location may be located at the same address. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §329D-2)

§11-850-8 Restrictions. (a) A person shall not be granted more than one dispensary license.

(b) A dispensary license shall not be sold or otherwise transferred from one person to another person, except with the prior written approval of the department following notice given in accordance with section 329D-5.5, HRS.

(c) A dispensary facility shall not be permitted within seven hundred fifty feet of the real property comprising a playground or school. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-2, 329D-3, 329D-5.5, 329D-6, 329D-22)

§11-850-9 Subcontractors. (a) The provisions of this chapter and chapter 329D, HRS, shall apply to a subcontractor in the same manner as to a dispensary licensee.

(b) A dispensary licensee shall not subcontract with any person who is subcontracted to another dispensary licensee for the production or dispensing of cannabis or manufactured cannabis products. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-1 to 329D-27; SLH 2017, Act 170, §3)

§11-850-10 (Reserved).

SUBCHAPTER 2

LICENSING

§11-850-11 License required. No person shall operate a medical cannabis dispensary unless the

person has a license issued by the department pursuant to this chapter. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-2, 329D-5, 329D-6; SLH 2017, Act 170, §3)

§11-850-12 Application. (a) An application for a dispensary license shall include both an individual applicant and an applying entity and they shall apply to the department on a form and in a manner prescribed by the department.

(b) The department shall establish an open application period for available licenses.

(c) The department shall publish notice of the open application period no less than thirty days prior to the start of the open application period. The notice shall include but not be limited to:

(1) The date and time the open application period begins and ends;

(2) Where and how to obtain an application form;

(3) Where and how to submit an application form;

(4) Where to obtain a copy of the rules; and

(5) Information about the merit scoring system.

(d) The department shall post on its website the names of all individual applicants and applying entities.

(e) Information and statements provided in an application shall become conditions of a license if the application is selected, and failure to satisfy the conditions will be cause for revocation or denial of renewal. [Eff 12/14/15; comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-4)

§11-850-13 Minimum qualifications for individual applicant. An individual applicant shall:

(1) Be not less than twenty-one years of age;

(2) Be a legal resident of the State for not less than five years preceding the date of application;
(3) Not have any felony convictions or any other disqualifying background history in accordance with this chapter; and
(4) Be authorized by the applying entity to submit an application for a dispensary license, and act as the primary point of contact with the department. [Eff 12/14/15; comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-3, 329D-7)

§11-850-14 Documentation and information for individual applicant. (a) An individual applicant shall provide the following required information and documents:
(1) Legal name, date of birth, legal residence, last four digits of the applicant's social security number, mailing address, and principal residence address if different from the mailing address, phone number, facsimile number, email address, whether the individual applicant was convicted of a felony, the person's authority to act on behalf of the applying entity, and date of start of residency in the State of Hawaii; and
(2) The following supporting documents shall be submitted at the time of application:
(A) To establish legal name an applicant must present at least one of the following source documents:
(i) Certified copy of a birth certificate or marriage certificate filed with a state office of vital statistics or equivalent agency in the

individual's state of birth or marriage;

(ii) Valid, unexpired U.S. passport or U.S. passport card;

(iii) Consular report of birth abroad Form FS-240, DS-1350 or FS-545 issued by the U.S. Department of State;

(iv) Valid, unexpired permanent resident card (Form I-551) issued by the Department of Homeland Security (DHS) or the U.S. Citizenship and Immigration Services (USCIS);

(v) Unexpired employment authorization document issued by the DHS, Form I-766 or Form I-688B;

(vi) Unexpired foreign passport with the following: a valid, unexpired U.S. visa affixed, and an approved I-94 form documenting the applicant's most recent admittance into the United States or a DHS admittance stamp on the passport;

(vii) Certificate of naturalization issued by DHS, Form N-550 or Form N-570;

(viii) Certificate of citizenship, Form N-560 or Form N-561, issued by DHS

(ix) Court-issued, certified copy of a divorce decree; or

(x) Certified copy of a legal change of name order;

(B) To establish date of birth an applicant must present at least one of the following source documents:

(i) At least one document included in clauses (i) through (viii) of subparagraph (A) of this paragraph; or

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(ii) Valid, unexpired driver's license or government issued photo identification card;

(C) To establish residency in the State of not less than five years preceding the application, an applicant must present at least one of the following source documents:

(i) State of Hawaii tax return Form N-11 for each of the five years preceding the application without schedules, worksheets, or attachments, and redacted to remove all financial information and all but the last four digits of the individual's social security number;

(ii) Evidence of voter registration;

(iii) Ownership, lease, or rental documents for place of primary domicile;

(iv) Billing statements including utility bills; or

(v) Vehicle registration;

(D) To establish proof of no felony convictions or other disqualifying background information, an individual applicant shall provide the following documentation:

(i) Report and validation code from an eCrim report generated by the Hawaii Criminal Justice Data Center not more than 60 days prior to the date of application; and

(ii) Consent to a background check including fingerprinting; and

(E) Documentation of the authority of the individual to act on behalf of the applying entity.

(b) The information and documents shall be submitted in a manner prescribed by the department in the notice of open application, and all of the

original documents or certified copies shall be retained on file by the applicant and be subject to physical inspection by the department as part of the application evaluation process. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-3, 329D-4, 329D-7, 329D-12)

§11-850-15 Minimum qualifications for applying entity. An applying entity shall:

(1) Be organized under the laws of the State;

(2) Have a Hawaii tax identification number;

(3) Have a department of commerce and consumer affairs business registration division number and suffix;

(4) Have a federal employer identification number;

(5) Not be less than fifty-one percent held by Hawaii legal residents or entities wholly controlled by Hawaii legal residents who have been legal residents for not less than five years immediately preceding the date the application was submitted;

(6) Have financial resources under its control of not less than $1,000,000 for each license applied for, plus not less than $100,000 for each retail dispensing location allowed under the license applied for, in the form of bank statements or escrow accounts, and those financial resources shall have been under the control of the applying entity for not less than ninety days immediately preceding the date the application was submitted; and

(7) Be composed of owners, principals, or members, each of whom is not less than twenty-one years of age and has no felony convictions or any other disqualifying background history in accordance with section 11-850-17. [Eff 12/14/15; am and

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comp 2/24/22; comp] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-3, 329D-7)

§11-850-16 Documentation and information for applying entity. (a) An applying entity shall provide the following required information and documents:

(1) Name of the applying entity and any other name under which the applying entity does business; street address, telephone number, facsimile number, email address; date the applying entity was organized under the laws of Hawaii; Hawaii tax identification number; federal employer identification number; names of owners and percentage of ownership for each; designation of the county for which the applicant is applying for a license; and

(2) The following supporting documents shall be submitted at the time of application:

(A) To establish that not less than fifty-one percent of an entity applicant is held by Hawaii legal residents or entities wholly controlled by individuals who have been legal residents for not less than five years immediately preceding the date of application an applying entity shall present the source documents listed in section 11-850-14(a)(2)(C) for each owner whose shares count toward the fifty-one percent ownership requirement;

(B) A tax clearance certificate issued by the department of taxation dated not more than thirty days prior to the date of the application;

(C) A certificate of good standing and business registration division number

and suffix from the department of commerce and consumer affairs;

(D) Copies of the entity's bank statements for the twelve months prior to the date of application;

(E) A certified copy of the organizing documents of the applying entity;

(F) A copy of the applying entity's bylaws;

(G) To establish that the applying entity has financial resources under its control of not less than $1,000,000 for each license applied for, plus not less than $100,000 for each retail dispensing location allowed under the license applied for, and that the financial resources have been under the control of the applying entity for not less than ninety days prior to the date of application an applying entity shall present the following:

(i) Copies of bank statements; or

(ii) Escrow accounts;

(H) To establish legal name and date of birth for each owner, principal, or member, an applying entity shall submit any of the documents listed in section 11-850-14(a)(2)(A) and any of the documents listed in section 11-850-14(a)(2)(B); and

(I) To establish proof of no felony convictions for each individual listed in section 11-850-17(a)(2), an applying entity shall provide the following documentation for each:

(i) Report and validation code from an eCrim report generated by the Hawaii Criminal Justice Data Center not more than 60 days prior to the date of application; and

(ii) Consent to a background check including fingerprinting.

(b) The information and documents shall be submitted in a manner prescribed by the department in the notice of open application, and all of the original documents or certified copies shall be retained on file by the applicant and be subject to physical inspection by the department as part of the application evaluation process. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-3, 329D-4, 329D-7, 329D-12)

§11-850-17 Background checks. (a) The following are subject to background checks conducted by the department or its designee:

(1) The individual applicant or licensee;

(2) All officers, directors, members of a limited liability corporation, shareholders with at least twenty-five percent ownership interest in a corporation, and managers of an entity applicant or licensee;

(3) Each employee of a dispensary;

(4) Each subcontractor of a dispensary;

(5) All officers, directors, members of a limited liability corporation, shareholders with at least twenty-five per cent ownership interest in a corporate owner, and managers of a subcontracted production center or retail dispensing location;

(6) Each employee of a subcontracted production center or retail dispensing location;

(7) Any person permitted to enter or remain in a dispensary facility pursuant to section 329D-15(a)(4) or 329D-16(a)(3), HRS; and

(8) Agents of any of the above persons.

(b) A person subject to background checks as provided in subsection (a) shall be disqualified as an individual applicant or licensee, be disqualified as an entity applicant or licensee, be prohibited from entering a dispensary, and be prohibited from having

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any responsibility for operating a dispensary, if the person:

(1) Has a conviction related to use, possession, or distribution of drugs or intoxicating compounds;

(2) Has a conviction for a crime involving violence;

(3) Has a conviction for a crime involving a firearm;

(4) Has a conviction for a crime involving theft, or business or commercial fraud; or

(5) Has any other background history that the department finds would pose a risk to the health, safety, or welfare of the public, a qualifying patient, or a qualifying out-of-state patient, considering the nature of the offense, the time elapsed since the offense occurred, and evidence of rehabilitation.

(c) A dispensary licensee shall deny employment to any individual who has been convicted of:

(1) Murder in any degree;

(2) A class A or class B felony; or

(3) A class C felony involving trafficking, distributing, or promoting a schedule I or II controlled substance other than cannabis within the last ten years.

(d) A dispensary licensee may deny employment to any individual who has been convicted of a class C felony involving:

(1) Fraud, deceit, misrepresentation, embezzlement, or theft; or

(2) Endangering the welfare of a minor.

(e) A person subject to background checks pursuant to section 329D-12(a)(5), HRS, shall be disqualified to enter the premises of a dispensary facility if the person has a felony conviction;

(f) Each person undergoing a background check shall provide written consent and all applicable processing fees to the department or its designee to conduct the background check.

(g) All dispensary licensees shall have written policies and procedures on conducting and maintaining

current background checks on all of the persons listed in subsection (a) which shall include but not be limited to notifying the department immediately of any arrest or conviction for an offense listed in subsections (b) to (e). [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27, 846-2.7) (Imp: HRS §§329D-3, 329D-6, 329D-7, 329D-12, 329D-15, 329D-16)

§11-850-18 Application fee. (a) Each application for a dispensary license shall include a non-refundable application fee of $5,000 by certified check or cashier's check payable to State of Hawaii Department of Health, delivered or mailed by certified mail, return receipt requested, to: Department of Health, Medical Cannabis Dispensary Licensing Section, 601 Kamokila Blvd., Rm. 337, Kapolei, HI, 96707.

(b) The application fee must be received by the department or postmarked by 4:30 pm HST on the last day of the open application period.

(c) An application is not complete and will not be considered unless the application fee is timely received by the department as stated in subsection (b). [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-4, 329D-7)

§11-850-19 Verification of application. (a) After receipt of an application, the department shall verify that the application and supporting documentation is complete, and the information submitted in the application is true and valid, and meets the requirements of section 329D-3, HRS.

(b) Applications that meet the requirements of section 329D-3, HRS, shall be placed into the pool of applicants for further review and selection based on merit, and the department shall notify the applicant in writing.

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(c) Applications that do not meet the requirements of section 329D-3, HRS, shall be denied pursuant to section 11-850-24, and the department shall notify the applicant in writing. [Eff 12/14/15; comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-3, 329D-4, 329D-5, 329D-7)

§11-850-20 Selection process and criteria based on merit. (a) The department shall consider the following criteria based on merit to evaluate applications verified pursuant to section 11-850-19:

(1) Ability to operate a business, including but not limited to education, knowledge, and experience with:
   (A) Regulated industries;
   (B) Agriculture or horticulture;
   (C) Commercial manufacturing;
   (D) Pharmaceutical companies;
   (E) Operating or working in a medical cannabis dispensary business;
   (F) Creating and implementing a business plan, including a timeline for opening a business;
   (G) Creating and implementing a financial plan;
   (H) Retail sales;
   (I) Secure inventory tracking and control;
   (J) Protecting confidential customer information;
   (K) Owning or managing a business that required twenty-four hour security monitoring; and
   (L) Any other experience the applicant considers relevant;

(2) Plan for operating a medical cannabis dispensary in the county for which the applicant is seeking a license, including but not limited to a timeline for opening a retail dispensing location;

(3) Proof of financial stability and access to financial resources, including but not limited to:
   (A) Legal sources of finances immediately available to begin operating a dispensary;
   (B) A summary of financial statements in businesses previously or currently owned or operated by the applicant;
   (C) A financial plan for operating a medical cannabis dispensary in Hawaii;
   (D) Good credit history; and
   (E) History of bankruptcy by the applicant or entities owned or operated by the applicant;
(4) Ability to comply with the security requirements of this chapter and section 329D-7, HRS;
(5) Capacity to meet the needs of qualifying patients and qualifying out-of-state patients, including but not limited to:
   (A) Educating patients on how cannabis can be used to assist patients with debilitating medical conditions and about the cannabis and manufactured cannabis products that will be available in the applicant's retail dispensing locations;
   (B) Producing and maintaining a supply of cannabis that is sufficient to meet the needs of qualifying patients and qualifying out-of-state patients;
   (C) Providing safe, accessible retail dispensing locations; and
   (D) Measuring and improving customer satisfaction;
(6) Ability to comply with criminal background check requirements pursuant to this chapter and sections 329D-6, 329D-12, and 846-2.7, HRS;
(7) Ability to comply with the requirements in this chapter and chapters 329 and 329D, HRS,

for inventory tracking, security, and sales limits for qualifying patients and qualifying out-of-state patients;

(8) Ability to maintain confidentiality of a qualifying patient's or qualifying out-of-state patient's medical condition, health status, and purchases of cannabis or manufactured cannabis products;

(9) Ability to comply with the requirements for certified laboratory analysis of cannabis and manufactured cannabis products pursuant to this chapter;

(10) Ability to comply with requirements for signage, packaging, labeling, and chain of custody of products;

(11) A plan for secure disposal or destruction of cannabis and manufactured cannabis products;

(12) Ability to ensure product safety, in accordance with this chapter; and

(13) No history of having a business license revoked.

(b) Each merit criterion will be worth a number of points announced by the department in the notice of open application period.

(c) The department shall group the applications according to the county of proposed licensure.

(d) A review panel comprised of members designated by the department who have relevant expertise shall evaluate the applications and award points for each merit criterion. The points shall be totaled for each application and the applications ranked from the highest total score to the lowest total score within each group.

(e) In order to be awarded a license based on merit criteria, an applicant must be able to show the ability to operate a dispensary.

(f) The department shall award a dispensary license to the highest scoring applicant or applicants within each group. The department shall notify in writing each of the applicants of their respective score and ranking for their respective group. The

department shall post on its website the total score for each applicant.

(g) The department shall hold unselected applications in reserve to offer a license to the next highest scoring applicant if the highest scoring applicant fails to pay the licensing fee in accordance with section 11-850-21. When all available licenses within each group have been issued, the department shall remove all unselected applications from its list of reserved applications in that group and notify all applicants. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-5, 329D-7; SLH 2017, Act 170, §3)

§11-850-21 Licensing fee and issuance of license. (a) Within seven days of receiving written notice of selection from the department, the selected applicant shall submit to the department a dispensary license fee of $75,000 by certified or cashier's check made payable to: State of Hawaii Department of Health.

(b) If the dispensary license fee is not timely paid, the selected applicant will be disqualified, and the department shall select the next highest scoring applicant within the segregated group of applications in accordance with section 11-850-20.

(c) Upon issuance of a dispensary license, the dispensary licensee may begin operations; provided that it may not begin producing or dispensing cannabis or manufactured cannabis products until it receives a written notice to proceed from the department for each phase of production and for dispensing, following inspections to determine compliance with this chapter and chapter 329D, HRS. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-4, 329D-5, 329D-6, 329D-7; SLH 2017, Act 170, §3)

§11-850-22 Narcotics enforcement division certificate. (a) Upon award of a license pursuant to section 11-850-21, a dispensary licensee shall apply to the department of public safety narcotics enforcement division (NED) and obtain a certificate to possess and handle cannabis and manufactured cannabis products.

(b) A dispensary licensee shall provide proof of the NED certificate to the department within seven days of obtaining the certificate.

(c) The dispensary licensee shall maintain the certificate throughout the licensing period, and shall notify the department immediately if the NED certificate is suspended or revoked. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329-33, 329D-9; SLH 2017, Act 170, §3)

§11-850-23 Term. A license shall be valid for one year from the date issued unless suspended or revoked by the department, or unless surrendered by the dispensary licensee. [Eff 12/14/15; comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-4, 329D-21)

§11-850-24 Denial of application for or renewal of a license. (a) The department may deny an application for or renewal of a license for any of the following reasons:

(1) Failure to provide the information required in sections 11-850-13 through 11-850-17;
(2) Failure to meet the requirements set forth in this chapter or chapter 329D, HRS;
(3) Provision of misleading, incorrect, false, or fraudulent information;
(4) Failure to pay all applicable fees as required;

(5) Receipt of an application evaluation score lower than the successful applicants for the respective county;

(6) An applicant has a background history that indicates the applicant does not have a reputable and responsible character or would pose a risk to the health, safety, or welfare of the public, qualifying patients, or qualifying out-of-state patients; or

(7) Any other ground that serves the purpose of this chapter or chapter 329D, HRS.

(b) If the department denies an application for or renewal of a license, the department shall notify the applicant in writing of the department's decision, including the reason for the denial.

(c) A person aggrieved by a decision made pursuant to this section may appeal in accordance with this chapter. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-3, 329D-4, 329D-5, 329D-6, 329D-12, 329D-15, 329D-16)

§11-850-25 License renewal process and fee. (a) A license may be renewed if the dispensary licensee:

(1) Submits to the department a renewal application on a form and in a manner prescribed by the department at least sixty days prior to the expiration date on the license;

(2) Continues to meet all the requirements of this chapter and chapter 329D, HRS; and

(3) Submits the renewal fee to the department as required in subsection (c).

(b) Before renewing a license, the department may require further information and documentation and may conduct additional background checks to determine that the licensee continues to meet the requirements of this chapter and chapter 329D, HRS.

(c) After receiving written notice from the department that its renewal application has been

approved, the dispensary licensee shall pay the annual renewal fee of $50,000 by certified or cashier's check payable to: State of Hawaii Department of Health prior to the expiration date on the license.

(d) A dispensary licensee whose license is not renewed shall cease all operations immediately upon expiration of the license, return the license to the department, and destroy all cannabis and manufactured cannabis products in the dispensary licensee's possession pursuant to this chapter. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-2, 329D-3, 329D-4, 329D-6, 329D-7; SLH 2017, Act 170, §3)

§11-850-26 Surrender of license. (a) A dispensary may voluntarily surrender a license to the department at any time.

(b) If a dispensary voluntarily surrenders a license, the dispensary shall:

(1) Return the license to the department;

(2) Submit a report to the department including the reason for surrendering the license; contact information following the close of business; the person or persons responsible for the close of the business; and where business records will be retained; and

(3) Destroy all cannabis and manufactured cannabis products in its possession pursuant to this chapter.

(c) No portion of the licensing fee shall be returned to the dispensary licensee if the license is voluntarily surrendered prior to the expiration of the license. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-2, 329D-4, 329D-6, 329D-7, 329D-18; SLH 2017, Act 170, §3)

§11-850-27 Change in information. (a) The dispensary licensee shall notify the department of any changes in contact information.

(b) The dispensary licensee shall notify the department in writing no less than fourteen days in advance of any change that may affect the licensee's qualifications for licensure, and submit to the department supporting documentation to prove the dispensary licensee continues to be qualified. In the event of a change for which a dispensary licensee does not have prior notice, the licensee shall notify the department immediately upon learning of the change. [Eff 12/14/15; comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-3, 329D-4)

§§11-850-28 to 11-850-30 (Reserved).

SUBCHAPTER 3

OPERATIONS

§11-850-31 Dispensary operations. (a) In all dispensary facilities, only the individual licensee, authorized employees of the dispensary, authorized employees of the subcontracted dispensary facilities, employees of a certified laboratory for analysis purposes, state employees authorized by the director, and law enforcement and other government officials acting in their official capacity shall be permitted to touch or handle any cannabis or manufactured cannabis products; provided that a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient may receive cannabis or manufactured cannabis products at

a retail dispensing location following completion of a sale.

(b) A retail dispensing location shall not be at the same location as a production center. Considerations for determining whether locations are the same include proximity and whether there are separate buildings, entrances, and parking areas.

(c) No dispensary licensee, including a dispensary licensee's officers, employees, agents, or anyone with any financial interest in a licensed dispensary shall provide written certification pursuant to chapter 329, HRS, for the medical use of cannabis for any person.

(d) A dispensary licensee shall not transfer any cannabis or manufactured cannabis products to any other dispensary.

(e) A dispensary licensee shall not accept any cannabis or manufactured cannabis products from any other dispensary.

(f) A dispensary licensee shall maintain and follow all policies and procedures required by this chapter. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-2, 329D-6, 329D-7, 329D-17, 329D-18; SLH 2017, Act 170, §3)

§11-850-32 Production centers. (a) Not less than thirty days prior to producing or manufacturing any cannabis or manufactured cannabis products at a licensed production center, a dispensary licensee shall provide the department with the address, tax map key number, and a copy of the premises title or lease, as applicable, of the proposed location of that production center and allow the department to inspect the premises to determine the dispensary's ability to comply with the requirements of this chapter and chapter 329D, HRS.

(b) Until the department approves its facility, the dispensary shall not possess cannabis or begin

producing or manufacturing cannabis or manufactured cannabis products.

(c) Production centers shall:

(1) Remain secured pursuant to this chapter at all times;

(2) Be in an enclosed indoor facility;

(3) Be accessible to authorized individuals only as identified in this chapter;

(4) Maintain a twenty-four hour security system pursuant to this chapter and chapter 329D, HRS; and

(5) Display a copy of the current, valid dispensary license and current, valid narcotics enforcement division certificate at all times.

(d) Production centers shall not allow the entry of animals, except service animals as defined in section 347-2.5, HRS, guard dogs or pest-detecting dogs allowed under section 11-850-113(c), and beneficial insects. Service animals shall:

(1) Be allowed only if a health or safety hazard will not result from the presence or activities of the service animal; and

(2) Not be allowed to enter areas where cannabis, manufactured cannabis products, or components are exposed or where equipment or utensils are washed.

(e) Hemp shall not be produced, handled, stored, or processed in a medical cannabis production center. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-2, 329D-6, 329D-7, 329D-18; SLH 2017, Act 170, §3)

§11-850-33 Retail dispensing locations. (a) Not less than sixty days prior to opening a licensed retail dispensing location for business, a dispensary licensee shall provide the department with the address, tax map key number, and a copy of the premises title or lease, as applicable, of the

proposed location of that retail dispensing location and allow the department to inspect the premises to determine the dispensary's ability to comply with the requirements of this chapter and chapter 329D, HRS.

(b) Until the department approves its facility, the retail dispensing location shall not possess or dispense cannabis or manufactured cannabis products.

(c) Retail dispensing locations shall:

(1) Remain locked at all times;

(2) Not be open for dispensing before 8:00 a.m. or after 8:00 p.m., Hawaii-Aleutian Standard Time, Monday through Sunday;

(3) Be in an enclosed indoor facility;

(4) Be accessible to authorized individuals only as identified in this chapter;

(5) Maintain a twenty-four hour security system pursuant to this chapter;

(6) Require a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient to present a valid government-issued photo identification and a valid medical use of cannabis registration card issued by the department pursuant to chapter 329, HRS, before entering the premises;

(7) Record the name and entry and exit date and time of all persons entering the retail dispensing location in accordance with subsection 11-850-51(a)(5);

(8) Display a copy of the current, valid dispensary license, current, valid narcotics enforcement division certificate, and any other required permits or licenses at all times;

(9) Store all cannabis or manufactured cannabis products behind a counter or other barrier to ensure that a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient does not have direct access to the product prior to sale.

(d) Retail dispensing locations shall not:

(1) Provide free samples of cannabis or manufactured cannabis products;
(2) Dispense cannabis or manufactured cannabis products as premade or manufactured cigarettes or in any form prepared specifically for smoking or inhaling, except for forms specifically designed for use in devices that provide safe pulmonary administration pursuant to subsection 11-850-72(a)(4) to (5);
(3) Make available for sale or as gifts or premiums any supplies or paraphernalia that provide for the use of medical cannabis in smokable or inhalable form, except for devices that provide safe pulmonary administration pursuant to subsection 11-850-72(a)(4) to (5);
(4) Dispense cannabis or manufactured cannabis products to a qualifying patient or qualifying out-of-state patient who is under the age of eighteen years; or
(5) Allow the entry of animals, except for service animals as defined in section 347-2.5, HRS. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329-122, 329D-2, 329D-6, 329D-7; SLH 2017, Act 170, §3)

§11-850-34 Dispensary employees. (a) A dispensary licensee shall establish and maintain written policies and procedures governing the qualifications, recruitment, hiring, and training of operators, employees, or subcontractors of production centers and retail dispensary locations.

(b) No person under the age of twenty-one shall be employed by a dispensary facility.

(c) Operators, employees, and subcontractors shall wear an identification badge issued by the dispensary with the photograph and name of the wearer

in a visible location at all times when on the premises of a dispensary facility.

(d) A dispensary licensee shall provide training upon hire and annually to each employee. The training shall include, but not be limited to the following:

(1) Health, safety, and sanitation standards in accordance with this chapter;

(2) Security pursuant to this chapter;

(3) Prohibitions and enforcement pursuant to this chapter;

(4) Confidentiality pursuant to this chapter; and

(5) All other provisions of this chapter and chapter 329D, HRS, that apply to that person's scope of employment.

(e) The dispensary licensee shall provide the names of all employees and subcontractors to the department and shall immediately notify the department in writing of any change in the employment status of any of its employees or subcontractors. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-15, 329D-16, 329D-17, 329D-18, 329D-19)

§11-850-35 Employee records. (a) A dispensary licensee shall have available at each dispensary facility a time clock or other adequate method to record the month, day, year, and time that each employee arrives at and leaves the facility.

(b) Time record entries shall be made at the time an employee reports for duty and again when the employee goes off duty and at any time the employee leaves and returns to the premises for any reason.

(c) A dispensary licensee shall maintain all employee records, including the specific employee training provided and hours worked in accordance with section 11-850-41. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9,

329D-7, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-15, 329D-16, 329D-17, 329D-18, 329D-19)

§11-850-36 Transport. (a) A dispensary may transport cannabis and manufactured cannabis products between its facilities, and between its facilities and a laboratory for analysis.

(b) Only employees designated by the dispensary licensee, who are trained and knowledgeable on the transportation protocols required by this chapter, shall transport cannabis and manufactured cannabis products. Every transport of cannabis and manufactured cannabis products shall be accompanied by at least two employees.

(c) Each time cannabis and manufactured cannabis products are transported, the dispensary licensee shall prepare a manifest on a form prescribed by the department that lists the elements required by the department's tracking system.

(d) A dispensary licensee shall only transport cannabis or manufactured cannabis products that are listed on the manifest.

(e) A dispensary licensee shall transport cannabis or manufactured cannabis products in secured containers. The dispensary licensee shall include a copy of the manifest in the interior and on the exterior of the container.

(f) For transport between or among dispensary facilities, a transport container shall be packed, secured, and loaded and unloaded and unpacked in full view of security surveillance cameras. For transport from a dispensary facility to a laboratory, a transport container shall be packed, secured, and loaded in full view of security surveillance cameras.

(g) Cannabis and manufactured cannabis products shall be transported under conditions that maintain their quality and safety.

(h) Upon receipt of cannabis and manufactured cannabis products the dispensary licensee or the laboratory shall:

(1) Unpack the transported cannabis or manufactured cannabis products and verify the container contents against the associated manifest within twenty-four hours of receipt;
(2) Immediately report to the department any discrepancies between what is received and what is on the manifest;
(3) Immediately initiate an investigation into any discrepancies found; and
(4) Submit a written report of the discrepancy, investigation, and resolution to the department within three calendar days of the initial report.

(i) The designated employees transporting cannabis and manufactured cannabis products shall not stop at a location not listed on the manifest.

(j) The dispensary licensee shall transport cannabis and manufactured cannabis products using routes that reduce the possibility of theft or diversion.

(k) A dispensary licensee shall not transport cannabis or manufactured cannabis products:
(1) Off site to qualifying patients, primary caregivers, qualifying out-of-state patients, or caregivers of qualifying out-of-state patients;
(2) To another county or another island, unless solely for the purposes of laboratory analysis pursuant to subchapter 9 and subject to all tracking requirements in subchapter 5; and with the understanding that state law and its protections do not apply outside of the jurisdictional limits of the State; or
(3) To, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government. [Eff 12/14/15; am and comp2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-27) (Imp:

HRS §§329D-6, 329D-7, 329D-8, 329D-17, 329D-18, 329D-19; SLH 2017, Act 170, §3)

§11-850-37 Inspections. (a) Each dispensary licensee shall be subject to an annual announced inspection and unlimited unannounced inspections by the department, and inspections by any other government employee or official acting in an official capacity. Inspections for license renewals shall be unannounced in accordance with section 329D-23(a)(1), HRS.

(b) A dispensary licensee shall permit entry to the department for the purposes of any inspection.

(c) A dispensary licensee shall give the department access to all parts of the dispensary property, equipment, records, documents, and any other substance, material, or information relevant to ensure the dispensary licensee's compliance with this chapter, upon request.

(d) A dispensary licensee shall not refuse to allow inspection at any of its dispensary facilities, and its employees and personnel shall not delay or interfere with any inspection.

(e) Upon completion of the inspection, the department shall provide written notice to the dispensary licensee of its findings and if applicable shall proceed in accordance with subchapter 11. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-4, 329D-6, 329D-7, 329-10, 329-13, 329D-15, 329D-16, 329-17, 329D-18, 329-19, 329D-23)

§11-850-38 Reports. (a) A dispensary licensee shall submit quarterly reports on January 31, April 30, July 31, and October 31. If the due date for submitting a quarterly report falls on a Saturday, Sunday, or State holiday, the report will be on time if it is submitted on the next day that is not a

Saturday, Sunday, or State holiday. Reports shall be submitted on a form and in a manner prescribed by the department.

(b) Reports shall include:

(1) Records of entry and exit for all individuals who entered a dispensary facility;

(2) Amounts by category of cannabis produced and manufactured cannabis products manufactured and offered for sale;

(3) Amounts by category of cannabis and manufactured cannabis products sold;

(4) A list of all cannabis, manufactured cannabis products, or unusable cannabis materials that have been destroyed or will be destroyed;

(5) A summary financial statement;

(6) Laboratory results of all analyses conducted;

(7) Description of any breach or halt in its security system and tracking system;

(8) An updated list of employees; and

(9) Any other information requested by the department. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-9, 329D-10, 329D-18, 329D-19, 329D-23; SLH 2017, Act 170, §3)

§11-850-39 Audits. (a) A dispensary licensee shall annually obtain an independent financial audit from a licensed certified public accountant of all dispensary operations and assets in compliance with generally accepted auditing standards, at the dispensary licensee's expense, and shall provide a copy of the audit's findings to the department.

(b) The report of the audit's findings shall be completed and submitted to the department no later than sixty days prior to the end of the license

expiration date, or at another time as the department may direct.

(c) When a license is revoked, suspended, surrendered, or expires, a dispensary licensee shall file a final report thirty days following revocation, suspension, surrender, or expiration. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-7, 329D-21, 329D-23)

§11-850-40 Confidentiality of information. (a) A dispensary licensee shall safeguard and keep confidential from public disclosure any personally identifying information and the medical condition of a qualifying patient or qualifying out-of-state patient.

(b) A dispensary licensee shall prohibit photography or video recording inside a dispensary facility by anyone other than the dispensary licensee, the department, law enforcement personnel, or persons approved in writing by the department. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §329D-7)

§11-850-41 Recordkeeping. (a) A dispensary licensee shall maintain business operation records including but not limited to:

(1) Inventory tracking including transport of cannabis and manufactured cannabis products;
(2) Sales and compliance with dispensing limitations for each qualifying patient, primary caregiver, qualifying out-of-state patient, and caregiver of a qualifying out-of-state patient;
(3) Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
(4) Logs of entry and exit for dispensary facilities; and

(5) Employee records.

(b) Records required by this chapter shall:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;

(2) Contain the actual values and observations obtained during monitoring and verification activities;

(3) Be accurate, indelible, and legible;

(4) Be created concurrently with performance of the activity documented;

(5) Be as detailed as necessary to provide history of work performed; and

(6) Include:

(A) Information adequate to identify the facility (e.g., the name and, when necessary, the location of the facility);

(B) The date and, when appropriate, the time of the activity documented;

(C) The signature or initials of the person performing the activity; and

(D) Where appropriate, the identity of the product and the batch number.

(c) A dispensary licensee shall retain all security recordings for a minimum of fifty days.

(d) Records pertaining to cannabis or manufactured cannabis products shall be retained for six years beyond the date of distribution of the last batch of cannabis or manufactured cannabis products associated with those records. Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, shall be retained at the facility for at least six years after their use is discontinued.

(e) Except as provided in subsections (c) and (d), all records required by this chapter shall be retained at the facility for at least six years after the date they were prepared. Offsite storage of

records is permitted if such records can be retrieved and provided onsite within twenty-four hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(f) If reduction techniques, such as microfilming, are used, the dispensary shall make suitable reader and photocopying equipment readily available to the department. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-9, 329D-13, 329D-15, 329D-16, 329D-18, 329D-19, 329D-20, 329D-23; SLH 2017, Act 170, §3)

§11-850-42 Allowed quantities for dispensing. (a) A dispensary licensee may dispense to a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient any combination of cannabis or manufactured cannabis products that shall not exceed four ounces of cannabis during a period of fifteen consecutive days, and shall not exceed eight ounces of cannabis during a period of thirty consecutive days.

(b) Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of cannabis or manufactured cannabis products purchased by a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient from any other licensed dispensary within the state and shall not sell any amount of cannabis or manufactured cannabis products to that qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient that exceeds the limits identified in this chapter. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329-122, 329D-6, 392D-7, 329D-13, 329D-14, 329D-17, 329D-18; SLH 2017, Act 170, §3)

§11-850-43 Disposal or destruction. (a) A dispensary licensee or laboratory certified by the department to analyze cannabis and manufactured cannabis products shall dispose of or destroy unused, unsold, contaminated, or expired cannabis or manufactured cannabis products, or waste products resulting from the cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the cannabis or manufactured cannabis product does not become available to unauthorized persons and is documented as subtracted from inventory.

(b) A dispensary licensee shall destroy or dispose of unused, unsold, contaminated, or expired cannabis or manufactured cannabis products by a means prescribed by the department or the department of public safety narcotics enforcement division administrator.

(c) A dispensary licensee shall establish written policies and procedures to be followed by all of its employees for the disposal or destruction of unused, unsold, contaminated, or expired cannabis and manufactured cannabis products. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-8, 329D-18, 329D-19; SLH 2017, Act 170, §3)

§11-850-44 Solvents and processing practices. (a) Solvents used in producing manufactured cannabis products shall be of the highest purity, with the minimum standard being solvent intended to be safe for use in manufacturing a product for human consumption.

(b) The following solvents shall not be used in the production of manufactured cannabis products:

(1) Benzene;

(2) Carbon tetrachloride;

(3) 1,2-Dichloroethane;
(4) 1,1-Dichloroethene; and
(5) 1,1,1-Trichloroethane.

(c) Cannabis shall not be processed using butane in an open system where fumes are not contained nor by use of any other method of processing the department determines poses a risk to health and safety. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §§329D-9)

§§11-850-45 to 11-850-50 (Reserved).

SUBCHAPTER 4

SECURITY

§11-850-51 Required security in all dispensary facilities. (a) All dispensary facilities shall have the following security features:

(1) A video surveillance system professionally installed that allows for twenty-four hour continuous video monitoring and recording of all dispensary facilities as follows:
   (A) All video equipment used in a dispensary facility shall have back up capability;
   (B) All recorded images must clearly and accurately display the time and date;
   (C) The surveillance system storage device and the cameras must be internet protocol (IP) compatible;
   (D) The video surveillance system shall have minimum camera resolution to allow for the clear and certain identification of any person and activities in any area of a dispensary

facility where cannabis and manufactured cannabis products are produced, moved, or stored; all point of sale areas; any room used to pack or unpack a secured container used to transport cannabis or manufactured cannabis products; any room or area storing a surveillance system storage device; and all exits and entrances to a dispensary facility from both indoor and outdoor locations;

(E) The surveillance system video recording storage device shall be secured in a lockbox, cabinet, or closet, or secured in another manner that limits access to protect the system from tampering or theft; and

(F) The dispensary licensee shall make video recordings available to the department upon request;

(2) An alarm system to detect unauthorized entry and allow notification of law enforcement in an emergency. The alarm system shall be:

(A) Electronic with a backup power source for a minimum of four hours;

(B) Connected to a security response organization or to law enforcement;

(C) Activated twenty-four hours a day every day; and

(D) Professionally installed;

(3) A locked entry point to screen individuals for authorized entry to the facility. Only the following may be authorized to enter dispensary facilities:

(A) Persons included on a current department-approved list provided to the department by the licensee of those persons who are allowed into that dispensary's facilities for a specific purpose for that dispensary in accordance with section 329D-15(a)(4) or 329D-16(a)(3), HRS;

(B) Other approved individuals, with government issued photo identification, including:
(i) A government employee or official acting in the person's official capacity; and
(ii) Dispensary employees; and
(C) For retail dispensing locations only, with valid government issued photo identification and valid medical cannabis card issued pursuant to chapter 11-160:
(i) Qualifying patients;
(ii) Primary caregivers;
(iii) Qualifying out-of-state patients;
(iv) Caregivers of qualifying out-of-state patients;

(4) All entrances, exits, windows, and other points of entry shall be equipped with commercial-grade, non-residential locks or other functioning mechanical or electrical security devices; and

(5) A system to record the names of persons listed in paragraph (3) entering the dispensary facility and the date and time of entry to and exit from the dispensary facility; provided that the dispensary licensee's electronic tracking system pursuant to subsection 11-850-61(b) shall be used to record the name and date and time of entry to and exit from the dispensary facility for a qualifying patient, primary caregiver, qualifying out-of-state patient, and caregiver of a qualifying out-of-state patient.

(b) In the event of a breach or failure of its security system, a dispensary licensee shall immediately suspend operations and secure the affected dispensary facility until the security system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations. [Eff 12/14/15; am

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and comp 2/24/22; comp] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-15, 329D-16, 329D-18, 329D-19, 329D-20; SLH 2017, Act 170, §3)

§11-850-52 Required security in production centers. In addition to other security features required in this chapter and chapter 329D, HRS, all production centers shall have the following security features:

(1) Secure fencing that surrounds the premises sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any cannabis in any form;

(2) All cannabis and manufactured cannabis products shall be secured in a locked room, vault, or locked container securely affixed to a wall or floor. [Eff 12/14/15; am and comp 2/24/22; comp APR 2 9 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §329D-6, 329D-7, 329D-16, 329D-18, 329D-19, 329D-20; SLH 2017, Act 170, §3)

§11-850-53 Required security in retail dispensing locations. In addition to the other security features required in this chapter and chapter 329D, HRS, all retail dispensing locations shall have the following security features:

(1) A protocol for admitting qualifying patients, primary caregivers, qualifying out-of-state patients, or caregivers of qualifying out-of-state patients with valid government issued photo identification and medical cannabis registration cards issued pursuant to chapter 329, HRS, prior to allowing them access to the secured room for sales;

(2) A separate secured room for sales which shall include secured and locked display cases for cannabis and manufactured cannabis products;
(3) A maximum occupancy limit ratio in the secured sales room of two customers to every one retail dispensing location employee;
(4) All cannabis and manufactured cannabis products shall be secured in a locked room, vault, or locked container securely affixed to a wall or floor; and
(5) Exterior lighting that illuminates all entries and exits to allow for the clear and certain identification of any person and activities. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-15, 329D-18; SLH 2017, Act 170, §3)

§§11-850-54 to 11-850-60 (Reserved).

SUBCHAPTER 5

TRACKING REQUIREMENTS

§11-850-61 Tracking requirements. (a) A dispensary licensee shall track electronically the dispensary's inventory of cannabis and manufactured cannabis products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory. A dispensary licensee shall also track

electronically inventory that is quarantined, recalled, returned, or reprocessed.

(b) A dispensary licensee shall track electronically all sales of cannabis and manufactured cannabis products to qualifying patients, primary caregivers, qualifying out-of-state patients, and caregivers of qualifying out-of-state patients from all dispensaries in the State and shall have a sales system that automatically prohibits sales in excess of the legal limits, as set out in section 11-850-42, and that cannot be overridden manually.

(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system and permit the department to access such data in event the department's computer software tracking system is inoperable or is not functioning properly and sales are made pursuant to an alternate tracking system under subsection (e).

(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

(e) In the event the department's computer software tracking system is inoperable or is not functioning properly, the department may implement an alternate tracking system to temporarily enable qualifying patients, primary caregivers, qualifying out-of-state patients, or caregivers of qualifying out-of-state patients to purchase medical cannabis or manufactured cannabis products from a licensed dispensary. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8,

329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-8, 329D-13, 329D-14, 329D-18, 329D-19; SLH 2017, Act 170, §3)

§§11-850-62 to 11-850-70 (Reserved).

SUBCHAPTER 6

PRODUCTS AND PRODUCT STANDARDS

§11-850-71 Cannabis. (a) A dispensary licensee may dispense cannabis only in the form of dried matured processed flowers of female cannabis plants. A dispensary licensee shall not add any other ingredient to cannabis in any way.

(b) A dispensary licensee shall establish and maintain written standard operating procedures for the production, manufacture, analysis, sale, security, storage, inventory tracking, transportation, and disposal of cannabis that includes but is not limited to:

(1) Safe and appropriate use of equipment;

(2) Effective training and monitoring of employees and subcontractors who participate in the production or sale of cannabis;

(3) Adequate protocols for laboratory analysis of cannabis pursuant to this chapter; and

(4) Safe and appropriate storage and disposal or destruction of cannabis at all stages of production and sale.

(c) The director may require quarantine, removal, or modification of cannabis determined to present a potential health hazard. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-1, 321-9, 329D-7, 329D-8, 329D-9, 329D-10, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9, 329D-10; SLH 2017, Act 170, §3)

§11-850-72 Manufactured cannabis products. (a) A dispensary licensee may manufacture cannabis products limited to:

(1) Edible cannabis products as specified in section 11-850-76;
(2) Ointments and skin lotions;
(3) Transdermal patches;
(4) Pre-filled and sealed containers used to aerosolize and deliver cannabis orally, such as with an inhaler or nebulizer; provided that the containers need not be manufactured by the licensed dispensary but:
    (A) Shall be filled only with cannabis, cannabis oils, or cannabis extracts manufactured by the dispensary licensee;
    (B) Shall not contain nicotine, hemp, hemp-derived cannabinoids, tobacco-related products or any non-cannabis derived products; and
    (C) Shall be designed to be used with devices used to provide safe pulmonary administration of manufactured cannabis products; and
(5) Devices that provide safe pulmonary administration; provided that:
    (A) The heating element of the device, if any, is made of inert materials such as glass, ceramic, or stainless steel, and not of plastic or rubber;
    (B) The device is distributed solely for use with single-use, pre-filled, tamper-resistant, sealed containers that do not contain nicotine, other tobacco products, hemp, or hemp-derived cannabinoids;
    (C) The device is used to aerosolize and deliver cannabis by inhalation, such as an inhaler, medical-grade nebulizer, or

other similar medical grade volatilization device;

(D) There is a temperature control on the device that is regulated to prevent the combustion of cannabis oil; and

(E) The device need not be manufactured by the licensed dispensary.

(b) A dispensary licensee shall establish and maintain written standard operating procedures for the manufacturing, analysis, sale, security, storage, inventory tracking, transportation, and disposal of manufactured cannabis products that includes but is not limited to:

(1) Safe and appropriate use of manufacturing equipment;

(2) Safe and appropriate storage of materials used to produce manufactured cannabis products;

(3) Effective training and monitoring of employees and subcontractors who participate in the manufacturing or dispensing of manufactured cannabis products;

(4) Adequate protocols for laboratory analysis of manufactured cannabis products pursuant to this chapter; and

(5) Safe and appropriate storage and disposal or destruction of manufactured cannabis products at all stages of production and sale.

(c) A dispensary licensee shall report to the department prior to producing any manufactured cannabis products:

(1) Strains of cannabis to be used by the dispensary to produce manufactured cannabis products;

(2) Types of manufactured cannabis products that the dispensary will produce; and

(3) The manufacturing process or processes the dispensary will use in producing manufactured cannabis products.

(d) Prohibited ingredients.

(1) Except for alcohol in tinctures and caffeine naturally occurring in chocolate, no manufactured cannabis product shall contain nicotine, caffeine, alcohol, or any other substance not derived from cannabis that:
   (A) Is psychoactive; or
   (B) Would increase the potency, toxicity, or addictive potential of the product or create a potentially unsafe combination with cannabinoids.
(2) No manufactured cannabis product shall contain:
   (A) Synthetic cannabinoids; or
   (B) Cannabinoids created through isomerization, including delta-8-tetrahydrocannabinol and delta-10-tetrahydrocannabinol.
(3) No aerosolizeable manufactured cannabis product shall contain zirconium.
(4) No manufactured cannabis product shall contain:
   (A) Any color additives not listed in subpart A or C of 21 C.F.R. part 73, published by the U.S. Government Publishing Office, as amended as of April 1, 2021;
   (B) Bithionol;
   (C) Vinyl chloride;
   (D) Halogenated salicylanilides listed in 21 C.F.R. section 700.15, published by the U.S. Government Publishing Office, as amended as of April 1, 2021;
   (E) Chloroform;
   (F) Methylene chloride;
   (G) Prohibited cattle material, as defined in 21 C.F.R. section 700.27, published by the U.S. Government Publishing Office, as amended as of April 1 , 2021;
   (H) Mercury compounds;
   (I) Hexachlorophene;
   (J) Ephedrine alkaloids; or

(K) Any ingredient the department determines would render the product injurious or hazardous to health.

(e) Prohibited components. Except for ointments intended for topical application, skin lotions, and transdermal patches, manufactured cannabis products shall not be manufactured with any components that are not intended to be safe for use in manufacture of a product for human consumption. Additives used as components in the production of manufactured cannabis products, except for ointments intended for topical application, skin lotions, and transdermal patches, shall be limited to those allowed for use in food in section 11-29-8.

(f) A dispensary licensee shall not produce manufactured cannabis products with an appearance, flavor, or smell designed to appeal to minors.

(g) The director may require quarantine, removal, or modification of a manufactured cannabis product determined to present a potential health hazard. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-1, 321-9, 329D-7, 329D-8, 329D-9, 329D-10, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9, 329D-10, 329D-17; SLH 2017, Act 170, §3)

§11-850-73 Manufacturing permits or licenses. (a) A dispensary licensee shall determine the manufacturing activities required to produce the products intended for sale and shall obtain and maintain as current all required state and county permits or licenses for a particular manufacturing activity.

(b) A dispensary licensee shall provide the department with proof of possession of all state or county permits or licenses necessary for a particular manufacturing activity prior to dispensing any manufactured cannabis products and upon request.

(c) A dispensary licensee shall post at the dispensary licensee's facilities a copy of all current

state and county permits or licenses necessary for manufacturing.

(d) Upon suspension or revocation of a state or county permit or license necessary for a particular manufacturing activity, the dispensary licensee shall immediately cease production or manufacture of the particular product covered by the relevant state or county permit or license and shall notify the department. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-9, 329D-10; SLH 2017, Act 170, §3)

§11-850-74 Equivalent weights for manufactured cannabis products. A dispensary licensee that produces manufactured cannabis products shall calculate the equivalent physical weight of the cannabis that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured cannabis product the equivalency calculations and the formulas used. [Eff 12/14/15; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329-122, 329D-7, 329D-9, 329D-13; SLH 2017, Act 170, §3)

§11-850-75 Repealed. [Eff 12/14/15; R 2/24/22] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-76 Edible cannabis products. (a) A dispensary licensee may manufacture edible cannabis products limited to the product types listed in subsection (b) and subject to all requirements and prohibitions in this section. A dispensary may manufacture product test batches as necessary to produce the documentation required in subsection (e)

prior to meeting the requirements in subsections (c) and (d), but shall not dispense an edible cannabis product until all requirements of this section are met for that product.

(b) Allowable edible cannabis products are limited to the following types:

(1) Capsules;
(2) Lozenges;
(3) Pills;
(4) Infused oils and butters; provided that oils and butters shall not contain garlic or peppers;
(5) Oil extracts and concentrates;
(6) Tinctures; provided that tinctures shall:
  (A) Have a maximum volume of two ounces; and
  (B) Be labeled for intended use measured in drops or dropperfuls.
(7) Gummies;
(8) Hard molded confections made primarily from sugar or syrup;
(9) Chocolates;
(10) Cookies;
(11) Brownies;
(12) Honey;
(13) Beverages;
(14) Powdered beverage mixes or beverage additives; and
(15) Syrup beverage mixes or beverage additives.

(c) An edible cannabis product shall:

(1) Not be a time/temperature control for safety product; and
(2) Be homogenous to ensure uniform distribution of cannabinoids.

(d) A dispensary manufacturing an edible cannabis product shall ensure that a laboratory certified by the department under subchapter 9:

(1) Is able to meet the requirements of section 11-850-135(a) and (b) for the product; and
(2) Has the appropriate certifications and accreditations to perform an analytical

method or methods applicable to the product matrix.

(e) A dispensary manufacturing an edible cannabis product shall maintain records documenting compliance with subsections (c) and (d) in accordance with section 11-850-41. The records documenting compliance with subsections (c)(2) and (d) shall include an attestation by a certified laboratory and documentation of analytical results from the same laboratory for samples of product test batches and quality control samples.

(f) Edible cannabis products shall not be designed to resemble commercially available candy or other products marketed to children. The words "candy" and "candies" shall not be used on packaging, labeling, advertising, product lists, or product menus. Edible cannabis products shall not be in the shape of or contain a depiction of a human, animal, or fruit, or a shape or depiction that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.

(g) Edible cannabis products shall be manufactured and packaged with one of the following aids to guide portioning:

(1) Single-serving packaging;

(2) Scoring that guides and assists with breaking a multi-serving product into single-serving portions; or

(3) The inclusion of a measuring device that is designed, sized, or clearly marked to measure a single serving. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-10, 329D-11, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9, 329D-10, 329D-11, 329D-17, 329D-19)

§11-850-77 Hemp products; use of hemp products as ingredients in manufactured cannabis products.

(a) A hemp product used as an ingredient in a manufactured cannabis product shall be in compliance with all applicable requirements of chapter 11-37.

(b) A hemp product shall not be used as an ingredient in a pre-filled and sealed container for use with a device that provides safe pulmonary administration or as an ingredient in a device that provides safe pulmonary administration.

(c) A retail dispensing location may offer for sale hemp products that are compliant with chapter 11-37. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-9, 329D-10, 329D-27) (Imp: HRS §§329D-7, 329D-9, 329D-10)

§§11-850-78 to 11-850-109 (Reserved).

SUBCHAPTER 7

CURRENT GOOD MANUFACTURING PRACTICE

§11-850-110 General health and safety standards. (a) A dispensary licensee shall ensure that all cannabis and manufactured cannabis products it dispenses are safe for use or consumption by qualifying patients and qualifying out-of-state patients.

(b) A dispensary licensee shall comply with State and county health, safety, and sanitation regulations and may be subject to inspection to confirm that no health or safety concerns are present which may contaminate the products. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-111 Personnel. (a) The management of a medical cannabis production center shall ensure that all individuals who produce cannabis or manufactured cannabis products are qualified to perform their assigned duties.

(b) Each individual engaged in production of cannabis or manufactured cannabis products (including temporary and seasonal personnel) or in the supervision thereof shall:

(1) Be a qualified individual, as that term is defined in section 11-850-2; and

(2) Receive training in the principles of hygiene and safety, including the importance of employee health and personal hygiene, as appropriate to the cannabis or manufactured cannabis product, the facility, and the individual's assigned duties.

(c) The management of the medical cannabis production center shall take reasonable measures and precautions to ensure the following:

(1) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel shall be instructed to report such health conditions to their supervisors.

(2) Cleanliness. All persons working in direct contact with cannabis, manufactured cannabis products, components, contact surfaces, and packaging materials shall conform to

hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of cannabis or manufactured cannabis products. The methods for maintaining cleanliness include:

(A) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of cannabis manufactured cannabis products, components, contact surfaces, or packaging materials;

(B) Maintaining adequate personal cleanliness;

(C) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated;

(D) Removing all unsecured jewelry and other objects that might fall into cannabis, manufactured cannabis products, components, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which cannabis, manufactured cannabis products, or components are manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials;

(E) Maintaining gloves, if they are used in handling cannabis, manufactured cannabis products, or components, in an intact, clean, and sanitary condition;

(F) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints;

(G) Storing clothing or other personal belongings in areas other than where cannabis, manufactured cannabis products, or components are exposed or where equipment or utensils are washed;

(H) Confining the following to areas other than where cannabis, manufactured cannabis products, or components may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco; and

(I) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

(d) Responsibility for ensuring compliance by individuals with the requirements of this subchapter shall be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe cannabis and manufactured cannabis products.

(e) Records that document training required by subsection (b)(2) shall be established and maintained subject to the requirements of section 11-850-41. [Eff and comp 2/24/22; comp APR 29 2022] (Auth:

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HRS §§321-9, 329D-7, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-9, 329D-19)

§11-850-112 Facility and grounds. (a) Grounds. The grounds about a production center under the control of the dispensary shall be kept in a condition that will protect against the contamination of cannabis or manufactured cannabis products. The methods for adequate maintenance of grounds shall include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the facility that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where cannabis, manufactured cannabis products, or components are exposed;

(3) Adequately draining areas that may contribute contamination to cannabis, manufactured cannabis products, or components by seepage, foot-borne filth, or providing a breeding place for pests;

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where cannabis, manufactured cannabis products, or components are exposed; and

(5) If the facility grounds are bordered by grounds not under the dispensary's control and not maintained in the manner described in paragraphs (1) to (4), care shall be exercised in the facility by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of contamination.

(b) Facility construction and design. The facility shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for cannabis and manufactured cannabis product production purposes (i.e., production and storage). The facility shall:

(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe cannabis and manufactured cannabis products;

(2) Permit the taking of adequate precautions to reduce the potential for mix-ups and allergen cross-contact and for contamination of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate safety controls and operating practices and effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means;

(3) Be constructed in such a manner that:

(A) Floors, walls, and ceilings may be adequately cleaned, kept clean, and kept in good repair;

(B) Drip or condensate from fixtures, ducts, and pipes does not contaminate cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials; and

(C) Aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against

contaminating cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials with clothing or personal contact;

(4) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where cannabis, manufactured cannabis products, or components are examined, produced, packed, or stored and where equipment or utensils are cleaned;

(5) Provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed cannabis, manufactured cannabis products, or components in any step of preparation, or otherwise protect against contamination in case of glass breakage;

(6) Provide adequate ventilation or control equipment to minimize dust, odors, and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate cannabis, manufactured cannabis products, or components;

(7) Locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating cannabis, manufactured cannabis products, components, contact surfaces, and packaging materials; and

(8) Provide, where necessary, adequate screening or other protection against pests. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-113 Sanitary operations. (a) General maintenance. Buildings, fixtures, and other physical facilities shall be maintained in a clean and sanitary

condition and shall be kept in repair adequate to prevent cannabis or manufactured cannabis products from becoming contaminated. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against allergen cross-contact and against contamination of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials.

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a medical cannabis production center:

(A) Those required to maintain clean and sanitary conditions;

(B) Those necessary for use in laboratory testing procedures;

(C) Those necessary for facility and equipment maintenance and operation; and

(D) Those necessary for use in the facility's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified and stored in a manner that protects against contamination of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials.

(c) Pest control. Pests shall not be allowed in any area of a production center. Guard, guide, or pest-detecting dogs may be allowed in some areas of a production center if the presence of the dogs is

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unlikely to result in contamination of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials. Effective measures shall be taken to exclude pests from the production and storage areas and to protect against the contamination of cannabis, manufactured cannabis products, or components on the premises by pests. The use of pesticides to control pests in the production center is permitted only under precautions and restrictions that will protect against the contamination of cannabis, manufactured cannabis products, components, contact surfaces, and packaging materials.

(d) Sanitation of contact surfaces. All contact surfaces, including utensils and contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of cannabis, manufactured cannabis products, or components.

(1) Contact surfaces used for producing and storing cannabis or low-moisture manufactured cannabis products or components shall be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into cannabis, manufactured cannabis products, or components, all contact surfaces shall be cleaned and sanitized before use and after any interruption during which the contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) shall be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials.

(e) Sanitation of non-contact surfaces. Non-contact surfaces of equipment used in the operation of a production center shall be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of cannabis, manufactured cannabis products, components, contact surfaces, and packaging materials.

(f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with contact surfaces and utensils shall be stored in a location and manner that protects contact surfaces from allergen cross-contact and from contamination. [Eff and comp 2/24/22; comp APR 2 9 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-114 Sanitary facilities and controls. Each medical cannabis production center shall be equipped with adequate sanitary facilities and accommodations including:

(1) Water supply. The water supply shall be adequate for the operations intended and shall be derived from an adequate source. Any water that contacts cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the production of cannabis and manufactured cannabis products, for the

cleaning of equipment, utensils, and packaging materials, or for employee sanitary facilities;

(2) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:

(A) Carry adequate quantities of water to required locations throughout the facility;

(B) Properly convey sewage and liquid disposable waste from the facility;

(C) Avoid constituting a source of contamination to cannabis, manufactured cannabis products, components, water supplies, equipment, or utensils or creating an unsanitary condition;

(D) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and

(E) Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for cannabis or manufactured cannabis product production;

(3) Sewage disposal. Sewage shall be disposed of into an adequate sewerage system or disposed of through other adequate means;

(4) Toilet facilities. Each medical cannabis production center shall provide employees with adequate, readily accessible toilet facilities. Toilet facilities shall be kept clean and shall not be a potential source of contamination of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials;

(5) Hand-washing facilities. Each medical cannabis production center shall provide hand-washing facilities designed to ensure

that an employee's hands are not a source of contamination of cannabis, manufactured cannabis products, components, contact surfaces, or packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature; and

(6) Rubbish disposal. Rubbish shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of cannabis, manufactured cannabis products, components, contact surfaces, packaging materials, water supplies, and ground surfaces. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-115 Equipment and utensils. (a) All medical cannabis production center equipment and utensils used in production and storage of cannabis or manufactured cannabis products shall be so designed and of such material and workmanship as to be adequately cleanable and shall be adequately maintained to protect against allergen cross-contact and against contamination.

(b) Equipment and utensils shall be designed, constructed, and used appropriately to avoid the contamination of cannabis, manufactured cannabis products, or components with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(c) Equipment shall be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(d) Contact surfaces shall be corrosion-resistant.

(e) Contact surfaces shall be made of non-toxic materials and designed to withstand the environment of their intended use and the action of cannabis, manufactured cannabis products, and components, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(f) Contact surfaces shall be maintained to protect cannabis, manufactured cannabis products, and components from allergen cross-contact and from being contaminated by any source.

(g) Seams on contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(h) Equipment that is in areas where cannabis or manufactured cannabis products are produced, packed, or stored and that does not come into contact with cannabis, manufactured cannabis products, or components shall be so constructed that it can be kept in a clean and sanitary condition.

(i) Production, conveyance, and storage systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(j) Each freezer and cold storage compartment used to store cannabis, manufactured cannabis products, or components capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(k) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in cannabis, manufactured cannabis products, or components shall be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(l) Compressed air or other gases mechanically introduced into cannabis, manufactured cannabis products, or components or used to clean contact surfaces or equipment shall be treated in such a way that cannabis, manufactured cannabis products, or components are not contaminated.

(m) Equipment and utensils used in measuring, mixing, or weighing shall be:

(1) Of suitable size and accuracy for measuring, mixing, and weighing operations;

(2) Calibrated regularly or checked according to a written standard operating procedure with results documented, where appropriate; and

(3) Removed from use if they are defective, do not meet recommended tolerances, or cannot be repaired and calibrated immediately.

[Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-116 Processes and controls. (a) General.

(1) All operations in the production and storage of cannabis, manufactured cannabis products, and components shall be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations shall be employed to ensure that cannabis and manufactured cannabis products are suitable for human consumption or for topical application to the skin or hair, as applicable, and that packaging materials are safe and suitable.

(3) Overall sanitation of the facility shall be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions shall be taken to ensure that production procedures do not

contribute to allergen cross-contact or to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible allergen cross-contact and contamination.

(6) All cannabis, components, and in-process materials that have become contaminated shall be rejected, or if appropriate and allowed under section 11-850-135(j)(1), treated or processed to eliminate the contamination.

(b) Ingredients.

(1) Ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into manufactured cannabis products and shall be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Ingredients shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying cannabis, manufactured cannabis products, or components shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying cannabis, manufactured cannabis products, or components if it does not cause allergen cross-contact or increase the level of contamination of the cannabis, manufactured cannabis product, or component.

(2) Ingredients shall either not contain levels of microorganisms that may render the manufactured cannabis product injurious to the health of humans, or they shall be treated during manufacturing operations so that they no longer contain levels that would cause the product to be contaminated.

(3) Ingredients susceptible to contamination with aflatoxins or other natural toxins shall not be contaminated before these ingredients are incorporated into a manufactured cannabis product.

(4) Ingredients and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall be examined and, based on examination results, shall not be contaminated before these ingredients are incorporated into a manufactured cannabis product.

(5) Ingredients and rework shall be stored in bulk or in containers designed and constructed so as to protect against mix-ups, allergen cross-contact, and contamination and shall be stored at such temperature and relative humidity and in such a manner as to prevent the ingredients or manufactured cannabis product from becoming contaminated. Material scheduled for reprocessing shall be identified as such.

(6) Frozen ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the ingredients from becoming contaminated.

(7) Liquid or dry ingredients received and stored in bulk form shall be stored in a manner that protects against allergen cross-contact and against contamination.

(8) Ingredients that are allergens, and rework that contains allergens, shall be identified and stored in a manner that prevents allergen cross-contact.

(9) Water used as an ingredient shall be:

(A) Of a defined quality;

(B) Unaffected by materials used in the water treatment equipment;

(C) Tested or monitored regularly to verify that it meets applicable chemical,

physical, and microbiological specifications for quality; and

(D) Supplied by a system set up to avoid stagnation and risks of contamination that is routinely cleaned and sanitized according to an appropriate standard operating procedure that ensures no biofilm build-up.

(c) Manufacturing operations.

(1) Equipment, utensils, and containers shall be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All cannabis and manufactured cannabis product production and storage shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination, and deterioration.

(3) Components that can support the rapid growth of undesirable microorganisms shall be stored at temperatures that will prevent the component from becoming contaminated during production and storage.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms shall be adequate under the conditions of production, storage, and distribution to prevent cannabis, manufactured cannabis products, or components from being contaminated.

(5) Work-in-process and rework shall be handled in a manner that protects against allergen cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures shall be taken to protect cannabis and manufactured cannabis products

from allergen cross-contact and from contamination by ingredients, other components, or refuse. When ingredients, other components, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contamination of cannabis or manufactured cannabis products. Cannabis, manufactured cannabis products, or components transported by conveyor shall be protected against allergen cross-contact and against contamination as necessary.

(7) Equipment, containers, and utensils used to convey or store cannabis, components, work-in-process, rework, or other manufactured cannabis products shall be constructed, handled, and maintained during production and storage in a manner that protects against allergen cross-contact and against contamination.

(8) Adequate measures shall be taken to protect against the inclusion of metal or other extraneous material in cannabis or manufactured cannabis products.

(9) Cannabis, manufactured cannabis products, and components that are contaminated:

(A) Shall be disposed of in a manner that protects against the contamination of other cannabis, manufactured cannabis products, and components; or

(B) If the contaminated cannabis, manufactured cannabis product, or component is allowed to be reprocessed under section 11-850-135(j)(1), it may be:

(i) Reprocessed using a method that has been proven to be effective; or

(ii) Reprocessed and reexamined and subsequently found not to be contaminated before being

incorporated into other manufactured cannabis products.

(10) All operations in the production and storage of cannabis, manufactured cannabis products, and components shall be performed so as to protect cannabis, manufactured cannabis products, and components against allergen cross-contact, contamination, and growth of undesirable microorganisms. Cannabis, manufactured cannabis products, and components shall be protected from contaminants that may drip, drain, or be drawn into them.

(11) Heat blanching, when required in the preparation of manufactured cannabis products or components capable of supporting microbial growth, shall be effected by heating the manufactured cannabis product or component to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling it or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers shall be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Cannabis and manufactured cannabis products and components that rely principally on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level.

(13) Manufactured cannabis products and components that rely principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below.

(14) When ice is used in contact with cannabis, manufactured cannabis products, or

components, it shall be made from water that is safe and of adequate sanitary quality in accordance with section 11-850-114(1) and manufactured in accordance with current good manufacturing practice. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-117 Warehousing and distribution. Storage and transportation of cannabis, manufactured cannabis products, and components shall be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of cannabis, manufactured cannabis products, or components as well as against deterioration of the cannabis, manufactured cannabis product, or component and the container. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§§11-850-118 to 11-850-120 (Reserved).

SUBCHAPTER 8

QUALITY CONTROL

§11-850-121 Standard operating procedures. (a) A medical cannabis dispensary shall establish written processing and control standard operating procedures for the production of cannabis and manufactured cannabis products (for example, formulations, processing procedures, in-process control methods,

packaging procedures, procedures for operating equipment).

(b) Standard operating procedures shall include provisions to ensure that:

(1) The selection, weighing, and measuring of ingredients and the determination of finished yield are reviewed by a second individual;

(2) Major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification, stage of processing, and control status;

(3) There are appropriate measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material;

(4) There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing;

(5) The theoretical yield for a production batch is compared with the actual yield;

(6) The storage and handling of packaging materials that are intended to come into direct contact with the product prevent mix-ups and microbiological or chemical contamination; and

(7) Finished product packages bear permanent, meaningful, unique batch numbers.

(c) Documentation of standard operating procedures shall be sufficient to prevent errors of interpretation and loss of information.

(d) Documentation of standard operating procedures shall be established and maintained subject to the requirements of section 11-850-41. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9, 329D-19)

§11-850-122 Batch production and distribution records. (a) Production records shall document, for each batch of cannabis or manufactured cannabis product:

(1) Review of ingredient records to determine if ingredients are adequately controlled;
(2) Ingredients (name, code, batch number, quantity, etc.) added to the batch;
(3) Production steps (for example, processing, handling, transferring, holding, and filling);
(4) In-process sampling, controlling, and adjusting steps;
(5) Compliance with or deviations from standard operating procedures;
(6) Detailed description of any deviations from standard procedures, justifications for the deviations, and corrective measures taken;
(7) Any quality control review and disposition decision and follow-up required by section 11-850-123; and
(8) Batch number.

(b) Distribution records shall identify, for each batch of cannabis or manufactured cannabis product:

(1) The product;
(2) The batch number;
(3) The retail dispensing location; and
(4) The date of distribution.

(c) Batch production and distribution records shall be adequate to conduct an effective recall.

(d) Batch production and distribution records shall be established and maintained subject to the requirements of section 11-850-41. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §§329D-9, 329D-19)

§11-850-123 Quality control review and disposition decisions. (a) A dispensary shall establish and follow written standard operating

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procedures and assign specific staff persons as quality control personnel to fulfill the requirements of this section.

(b) Quality control personnel shall conduct a review and make a disposition decision if:

(1) A contaminant limit or water activity or moisture content limit established in section 11-850-135 is exceeded;

(2) Production of a batch deviates from established standard operating procedures, including when any step is not completed;

(3) There is any unanticipated occurrence during production operations that contaminates or may lead to contamination of cannabis, a manufactured cannabis product, component, or packaging, or could lead to the use of an incorrect label;

(4) Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch of cannabis or manufactured cannabis product; or

(5) Cannabis or a manufactured cannabis product is returned.

(c) The quality control review shall include examination of the following, as applicable:

(1) Batch production records;

(2) Certificates of analysis or other testing records for ingredients;

(3) Laboratory analysis records for finished product;

(4) Label and packaging integrity;

(5) Use by date; and

(6) Any other examinations necessary to determine whether quality standards are met.

(d) When there is a deviation or unanticipated occurrence during the production and in-process control system that results in or could lead to contamination of cannabis, a manufactured cannabis product, a component, or packaging, or could lead to the use of an incorrect label, quality control personnel shall reject the cannabis, manufactured

cannabis product, component, packaging, or label unless quality control personnel approve a treatment, an in-process adjustment, or reprocessing to correct the applicable deviation or occurrence.

(e) The person who conducts the review and makes the disposition decision shall, at the time of performance, document that review and disposition decision in accordance with section 11-850-128. [Eff and comp 2/24/22; am and comp APR 29 2022] (Auth: HRS §§321-9, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-8, 329D-9, 329D-19)

§11-850-124 Returned cannabis or manufactured cannabis products. (a) Standard operating procedures. A dispensary shall establish and follow written standard operating procedures to fulfill the requirements of this section.

(b) Quarantine and investigation of production processes. Returned cannabis or manufactured cannabis products shall be identified and quarantined until quality control personnel conduct a review as required by section 11-850-123(c).

(c) Investigation of other batches. If the reason for cannabis or a manufactured cannabis product being returned implicates other batches, the dispensary shall conduct an investigation of each of those other batches in accordance with section 11-850-123(c) to determine compliance with subchapter 7 and the contamination limits in section 11-850-135.

(d) Destruction. A dispensary shall destroy any returned cannabis or manufactured cannabis product. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9, 329D-18)

§11-850-125 Product complaints. (a) A dispensary shall establish and follow written

procedures to fulfill the requirements of this section.

(b) Review and investigation of product complaints. A qualified person shall:

(1) Review all product complaints to determine whether the product complaint involves a possible failure of cannabis or a manufactured cannabis product to meet any of the contaminant limits in section 11-850-135 or any other requirements of this chapter, including those requirements that, if not met, may result in a risk of illness or injury; and

(2) Investigate any product complaint that involves a possible failure of cannabis or a manufactured cannabis product to meet any of the contaminant limits in section 11-850-135 or any other requirements of this chapter, including those requirements that, if not met, may result in a risk of illness or injury.

(c) Quality control personnel shall review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of any investigation performed.

(d) The review and investigation of the product complaint by a qualified person, and the review by quality control personnel about whether to investigate a product complaint, and the findings and follow-up action of any investigation performed, shall extend to all relevant batches and records. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-126 Adverse events. (a) A dispensary shall establish and follow written procedures to fulfill the requirements of this section.

(b) A dispensary licensee shall notify the department within forty-eight hours after learning of an adverse event associated with cannabis or a

manufactured cannabis product sold at a retail dispensing location operated by the dispensary licensee. For the purposes of this section, "adverse event" means any untoward medical occurrence associated with the use of cannabis or a manufactured cannabis product, which may include any unfavorable or unintended sign, symptom, or disease. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-9, 329D-27) (Imp: HRS §329D-9)

§11-850-127 Recalls. (a) A dispensary shall establish a written recall plan for cannabis and for each manufactured cannabis product.

(b) The written recall plan shall include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the dispensary:

(1) Notify the retail dispensing locations of the product being recalled, including how to return or dispose of the affected product;

(2) Notify qualifying patients, qualifying out-of-state patients, and the public about any hazard presented by the product when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled product (e.g., through reprocessing or destroying the product).

(c) A dispensary shall notify the department in writing within twenty-four hours of initiating a recall. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9, 329D-18)

§11-850-128 Recordkeeping for quality control. (a) A medical cannabis dispensary shall establish and

maintain the following records documenting compliance with this subchapter:

(1) Written procedures for quality control operations, including:
  (A) Conducting a review and making a disposition decision;
  (B) Approving or rejecting any reprocessing;
  (C) Identifying and investigating additional potentially implicated batches;
  (D) Handling of returned cannabis or manufactured cannabis products, including procedures for quarantine, destruction, and salvaging and reprocessing; and
  (E) Reviewing and investigating product complaints;

(2) Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following:
  (A) Date that the review, approval, or rejection was performed; and
  (B) Signature of the person performing the review, approval, or rejection;

(3) Documentation of any quality control review and disposition decision and follow-up shall be included in the appropriate batch production record and shall include:
  (A) Identification of the specific deviation or unanticipated occurrence;
  (B) Description of the investigation into the cause of the deviation or unanticipated occurrence;
  (C) Evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the cannabis or manufactured cannabis product;

(D) Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or unanticipated occurrence;

(E) Explanation of what was done with the cannabis, manufactured cannabis product, packaging, or label;

(F) A scientifically valid reason for any reprocessing of a manufactured cannabis product that is rejected; and

(G) The signature of the individual(s) designated to perform the quality control operation, who conducted the review and made the disposition decision, and of each qualified individual who provides information relevant to the review and disposition decision;

(4) The results of any laboratory analyses conducted as part of a quality control review or product complaint investigation;

(5) Documentation of the re-evaluation by quality control personnel of any manufactured cannabis product that is reprocessed and the determination by quality control personnel of whether the reprocessed manufactured cannabis product meets contaminant limits established in section 11-850-135;

(6) A written record of every product complaint that is related to production practices or production center standards:

(A) The person who performs the requirements of section 11-850-125 shall document, at the time of performance, that the requirement was performed; and

(B) The written record of the product complaint shall include the following:

(i) The name and description of the cannabis or manufactured cannabis product;

(ii) The batch number of the cannabis or manufactured cannabis product, if available;

(iii) The date the complaint was received and the name, address, or telephone number of the complainant, if available;

(iv) The nature of the complaint including, if known, how the cannabis or manufactured cannabis product was used;

(v) The reply to the complainant, if any; and

(vi) Findings of the investigation and follow-up action taken when an investigation is performed;

(7) A written record of every adverse event and report of an adverse event to the department as required by section 11-850-126; and

(8) A written recall plan as required by section 11-850-127.

(b) The records required by subsection (a) are subject to the requirements of section 11-850-41. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-8, 329D-9, 329D-19)

§§11-850-129 to 11-850-130 (Reserved).

SUBCHAPTER 9

LABORATORY CERTIFICATION, ANALYSIS, AND STANDARDS

§11-850-131 Laboratory analysis required; representative samples; reserve samples. (a) A dispensary licensee shall not dispense cannabis or

manufactured cannabis products unless a laboratory certified by the department pursuant to this chapter has analyzed a representative sample of the cannabis or manufactured cannabis products and they meet the requirements set out in this subchapter.

(b) All samples submitted for laboratory analysis or held as reserve samples shall be representative samples of the batch of cannabis or manufactured cannabis product being sampled.

(c) The sample size shall be sufficient to complete all laboratory analyses required in section 11-850-135 and all laboratory quality control analyses. The required sample size may vary due to sample matrix, analytical method, and laboratory-specific procedures.

(d) Collection of samples used to complete the analyses required by section 11-850-135 must take place after the batch of cannabis or manufactured cannabis product has completed all required production steps as outlined in the dispensary's standard operating procedures, except packaging and labeling, and is in its final form.

(e) A dispensary licensee shall maintain two reserve samples from each batch:

(1) In the same packaging in which the cannabis or manufactured cannabis product is dispensed;

(2) Under conditions consistent with the label or, if no storage conditions are recommended on the label, under ordinary storage conditions; and

(3) For one year past the use by date.

(f) A dispensary shall make reserve samples available for analysis or request laboratory analysis of reserve samples as directed by the department.

[Eff 12/14/15; §11-850-81; am, ren §11-850-131, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9; SLH 2017, Act 170, §3)

§11-850-132 Laboratory certification required. (a) No laboratory is authorized to handle or analyze cannabis or manufactured cannabis products unless that laboratory:

(1) Is certified or provisionally certified by the department;

(2) Is independent from all medical cannabis dispensary licensees and employees and all other persons and entities with a financial interest in a dispensary licensee;

(3) Is accredited in Hawaii by an accreditation body whose standards are equivalent to the International Standards for Organization (ISO) 17025;

(4) Has established standard operating procedures that include chain of custody for samples transferred to the laboratory or between laboratories for analysis; and

(5) Has obtained a certification of registration from the department of public safety in accordance with section 329-32, HRS, and chapter 23-200.

(b) The department may grant a provisional certification to a laboratory to analyze cannabis and manufactured cannabis products if that laboratory:

(1) Is owned or operated by a laboratory that is accredited in another jurisdiction by an accreditation body whose standards are equivalent to the ISO 17025;

(2) Has applied to be ISO 17025 accredited in Hawaii by an accreditation body whose standards are equivalent to the International Standards for Organization (ISO) or the department; and

(3) Meets all other criteria for laboratory certification in accordance with this subchapter.

(c) Notwithstanding subsection (a), a laboratory applying for certification under this part may handle and analyze samples of cannabis or manufactured cannabis products for the purpose of becoming certified pursuant to this part provided the

laboratory has obtained a certification of registration from the department of public safety in accordance with section 329-32, HRS, and chapter 23-200 prior to handling or analyzing samples. [Eff 12/14/15; §11-850-82; am, ren §11-850-132, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9; SLH 2017, Act 170, §3)

§11-850-133 Requirements for laboratory certification and provisional certification. (a) To apply for a laboratory certification to analyze cannabis and manufactured cannabis products, a laboratory shall submit an application to the department on forms and in a manner prescribed by the department. The laboratory applicant shall provide:

(1) All information and documents required by the department, including but not limited to, laboratory employee qualifications, standard operating procedures, quality assurance plan, and validation studies;

(2) An annual certification fee in the amount of $3,000;

(3) A copy of the laboratory's most recent assessment by the laboratory's accreditation body, the laboratory's responses to any findings of non-compliance with standards or recommendations, and the corrective actions taken by the laboratory to address the findings or recommendations; and

(4) A copy of the laboratory's accreditation in Hawaii or another jurisdiction, accompanied by the scope of accreditation.

(b) To be approved by the department for a laboratory certification to analyze cannabis and manufactured cannabis products, a laboratory shall:

(1) Submit the application materials specified in subsection (a);

(2) Undergo an on-site evaluation of the laboratory by the department; and

(3) Demonstrate capacity and proficiency to test cannabis and manufactured cannabis products in accordance with this chapter.

(c) The department may issue a certification to a laboratory that meets the requirements set forth in this chapter.

(d) The department may issue a provisional certification to a laboratory in Hawaii if the laboratory meets the requirements in subsection (b) and section 11-850-132(b).

(e) The department shall deny certification to any laboratory that does not meet the requirements set forth in this subchapter.

(f) A laboratory certification pursuant to this subchapter shall expire one year after the date it is issued by the department.

(g) To apply for renewal of a laboratory certification, a laboratory shall:

(1) Request renewal no later than two months prior to expiration of its certification, on a form and in a manner prescribed by the department;

(2) Provide documentation that it continues to be compliant with the requirements for certification of laboratories in accordance with this subchapter;

(3) Pay a renewal fee in the amount of $3,000; and

(4) Undergo an on-site evaluation of the laboratory by the department.

(h) The department may renew a laboratory certification for an additional one-year period if the department finds that the laboratory has complied with the requirements of this subchapter. [Eff 12/14/15; §11-850-83; am, ren §11-850-133, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9; SLH 2017, Act 170, §3)

§11-850-134 Minimum operating standards for laboratories certified pursuant to this subchapter. Upon being certified by the department, a laboratory shall:

(1) Display a copy of the certification in a prominent location on the laboratory premises;

(2) Obtain department approval of the laboratory's employee qualifications, quality assurance plan, and standard operating procedures to analyze cannabis and manufactured cannabis products;

(3) Follow the scope for which it is accredited for analyzing cannabis and manufactured cannabis products and the requirements for laboratory standards and analysis established in this subchapter;

(4) Notify the department within one business day after receiving notice of any kind that its accreditation has been denied, suspended, or revoked;

(5) Notify the department immediately of any change or anticipated change that may affect the operations of the laboratory with regard to its ability to continue to meet the requirements of this subchapter, including, but not limited to, proficiency test results, employee changes, instrumentation, methodology, standard operating procedures, facilities, and accreditation; and

(6) Follow other conditions set forth in the certification as issued by the department.

[Eff 12/14/15; §11-850-84; am, ren §11-850-134, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9; SLH 2017, Act 170, §3)

§11-850-135 Laboratory standards and analysis. (a) A certified laboratory shall develop and follow a statistically valid sampling plan to collect representative samples from each batch of cannabis or manufactured cannabis product in accordance with section 11-850-131. A certified laboratory shall analyze a representative sample from each batch of cannabis or manufactured cannabis products.

(b) A certified laboratory shall analyze samples according to standard operating procedures prepared by the laboratory based on validated methods published in peer reviewed scientific or regulatory literature, subject to approval by the department, and shall document the accuracy, sensitivity, specificity, and reproducibility of the analysis methods.

(c) A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of cannabis and manufactured cannabis products analyzed for that dispensary; provided that a certified laboratory may only analyze and report on those methods and analytes for which it is certified. The certificate of analysis shall include the results with supporting data for the following:

(1) The chemical profile of the batch for the following cannabinoids:
  (A) Total tetrahydrocannabinol;
  (B) Delta-9-tetrahydrocannabinol;
  (C) Cannabidiol (CBD);
  (D) Any other cannabinoid specifically listed or described in the label or packaging of the cannabis or manufactured cannabis product, including but not limited to cannabigerol (CBG) and cannabinol (CBN).

(2) The presence of the following contaminants, which shall not exceed the specified concentration limits:
  (A) Heavy metals listed in Table 1;

Table 1

Heavy metal	Limit (parts per million)
Arsenic	10.0 ppm
Cadmium	4.0 ppm
Lead	6.0 ppm
Mercury	2.0 ppm

(B) Pesticides listed in Table 2, each with a limit of 1.0 parts per million (ppm);

Table 2

Pesticide	Chemical Abstracts Service Registry Number (CAS No.)
Abamectin	71751-41-2
Acephate	30560-19-1
Acequinocyl	57960-19-7
Acetamiprid	135410-20-7
Aldicarb	116-06-3
Azoxystrobin	131860-33-8
Bifenazate	149877-41-8
Bifenthrin	82657-04-3
Boscalid	188425-85-6
Carbaryl	63-25-2
Carbofuran	1563-66-2
Chlorantraniliprole	500008-45-7
Chlorfenapyr	122453-73-0
Chlorpyrifos	2921-88-2
Clofentezine	74115-24-5
Cyfluthrin	68359-37-5
Cypermethrin	52315-07-8
DDVP (Dichlorvos)	62-73-7
Diazinon	333-41-5
Dimethoate	60-51-5
Ethoprophos	13194-48-4
Etofenprox	80844-07-1
Etoxazole	153233-91-1
Fenpyroximate	134098-61-6

Fipronil	120068-37-3
Flonicamid	158062-67-0
Fludioxonil	131341-86-1
Hexythiazox	78587-05-0
Imazalil	35554-44-0
Imidacloprid	138261-41-3
Kresoxim-methyl	143390-89-0
Malathion	121-75-5
Metalaxyl	57837-19-1
Methiocarb	2032-65-7
Methomyl	16752-77-5
Methyl parathion	298-00-0
MGK-264	113-48-4
Myclobutanil	88671-89-0
Naled	300-76-5
Oxamyl	23135-22-0
Paclobutrazol	76738-62-0
Permethrins (total of cis- and trans-permethrin isomers)[1]	52645-53-1
Phosmet	732-11-6
Piperonyl butoxide	51-03-6
Prallethrin	23031-36-9
Propiconazole	60207-90-1
Propoxur	114-26-1
Pyrethrins (total of pyrethrin 1, cinerin 1, and jasmolin 1)[2]	8003-34-7
Pyridaben	96489-71-3
Spinosad	168316-95-8
Spiromesifen	283594-90-1
Spirotetramat	203313-25-1
Tebuconazole	80443-41-0
Thiacloprid	111988-49-9
Thiamethoxam	153719-23-4
Trifloxystrobin	141517-21-7

Notes to Table 2:
1. Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8, respectively).

2. Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2, respectively).

(C) For manufactured cannabis products, solvents listed in Table 3;

Table 3

Solvent	Chemical Abstracts Service Registry Number (CAS No.)	Limit (parts per million)
Benzene	71-43-2	1.0 ppm
Butane	106-97-8	5000 ppm
Ethanol	64-17-5	5000 ppm
Heptane	142-82-5	5000 ppm
Hexane	110-54-3	290 ppm
Pentane	109-66-0	5000 ppm
Toluene	108-88-3	890 ppm
Total xylenes (ortho-, meta-, para-)	1330-20-7	2170 ppm

(D) Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;

(E) The following microbial contaminants, which must not be detected in one gram of cannabis or manufactured cannabis product:

(i) *Escherichia coli*;

(ii) *Salmonella spp.*;

(iii) *Aspergillus fumigatus*;

(iv) *Aspergillus flavus*; and

(v) *Aspergillus niger*; and

(F) Mycotoxins listed in Table 4;

Table 4

Mycotoxin	Limit (parts per billion)
Aflatoxins (total of B1, B2, G1, G2)	20 ppb
Ochratoxin A	20 ppb

(3) For cannabis:
(A) Water activity (a_w), which shall not exceed 0.65; or
(B) Moisture content, which shall not exceed fifteen per cent; and
(4) Additional analyses requested at the discretion of the department.

(d) The certified laboratory may reanalyze the sample or analyze a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the dispensary licensee or upon request by the department at the dispensary licensee's expense, provided that no more than two re-analyses may be performed for the same batch.

(e) The certified laboratory shall return to the dispensary licensee or destroy in a manner approved by the department any samples or portions of samples of cannabis or manufactured cannabis products that remain after analysis is completed.

(f) A certified laboratory shall create records of analyses it conducts on cannabis and manufactured cannabis products, including but not limited to:
(1) The time and date the sample was obtained;
(2) A description of the sample, including the amount;
(3) What analyses were conducted on each sample;
(4) The results of the analyses including the certificate of analysis; and
(5) Evidence of the time, date, and method of destruction of a sample after analysis is completed, and the amount of sample destroyed, or the time and date a sample was

returned to a dispensary with a description including the amount.

(g) A certified laboratory shall maintain records of the sampling plans required in subsection (a) and the records required in subsection (f) for a minimum of five years and shall make all the records available to the department upon request.

(h) A dispensary licensee shall ensure that each sample is analyzed for each of the analytes set out in subsection (c) and may obtain results from different laboratories for different analytes if one laboratory cannot perform all the analyses.

(i) A dispensary licensee shall maintain records of all laboratory results, including the certificate of analysis, in accordance with section 11-850-41.

(j) The level of contaminants and water activity or moisture content in cannabis and manufactured cannabis products shall not exceed the limits specified in subsection (c), and if any of the limits are exceeded, the dispensary licensee shall not dispense any portion of the batch of cannabis or manufactured cannabis product that does not conform to the standards; provided that:

(1) Cannabis that exceeds the limits for microbial contaminants under clause (c)(2)(E) and manufactured cannabis products that exceed the dosage limit in section 11-850-142(a)(5) may be reprocessed subject to prior department approval, reanalysis, and conformity of the reprocessed product to the standards;

(2) The limit for ethanol does not apply to tinctures; and

(3) The limit for ethanol does not apply to ointments intended for topical application, skin lotions, and transdermal patches.

(k) A dispensary licensee shall dispose of or destroy any batch that does not conform to the standards set out in subsection (c) under video camera surveillance; provided that a dispensary licensee shall quarantine a non-conforming batch until any reanalysis pursuant to subsection (d) or (j) is

completed. The quarantine shall be lifted only by the department, and only upon receipt by the department of a certificate of analysis indicating that the batch conforms to the standards set out in subsection (c). [Eff 12/14/15; §11-850-85; am, ren §11-850-135, and comp 2/24/22; am and comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9, 329D-19; SLH 2017, Act 170, §3)

§11-850-136 Enforcement; suspension and revocation of laboratory certification. (a) A certified laboratory shall provide the department access to inspect the laboratory facility, interview laboratory personnel, or review, inspect, evaluate, and audit records and documents related to the analyses of dispensary licensee samples at any time to verify compliance with this subchapter.

(b) If the department finds that a certified laboratory is not in compliance with the requirements of this chapter, the department shall notify the certified laboratory in writing of the specific areas of non-compliance and the department may do one or more of the following:

(1) Establish a specific timeframe for the correction of areas of non-compliance;

(2) Require the certified laboratory to submit, within fifteen days of receipt of the department's notification, a written corrective action plan that addresses the areas of non-compliance and that shall be subject to approval by the department; or

(3) Suspend a laboratory certification and prohibit the laboratory from handling and analyzing cannabis and manufactured cannabis products.

(c) If a satisfactory corrective action plan is not submitted to the department within the required timeframe or the identified areas of non-compliance are not corrected to the satisfaction of the

department within the required timeframe, the department may suspend or revoke a laboratory certification in accordance with subsection (f).

(d) The department may summarily suspend a laboratory certification if the department finds that a certified laboratory has engaged in a deliberate and willful violation of this subchapter or that a violation presents a substantial probability that physical harm will result.

(e) The department may suspend or revoke a laboratory certification for any of the following reasons:

(1) Violation of any provision of this chapter;
(2) Failure to maintain a current accreditation with an accreditation body whose standards are equivalent to the ISO/IEC 17025;
(3) Submission of misleading, incorrect, false, or fraudulent information;
(4) Failure to allow inspections by the department;
(5) Failure to pass inspections by the department;
(6) Knowingly permitting unauthorized persons to perform technical procedures or issue or sign reports;
(7) Consistent errors in performance of laboratory procedures, based on faulty technique or controls;
(8) Where immediate action is required to comply with the law or protect the health and safety of the general public; or
(9) Any other reason consistent with applicable laws, or other factors that may affect the health, safety, or welfare of the public or a qualifying patient or qualifying out-of-state patient.

(f) The department shall send, by certified mail return receipt requested, written notification of suspension or revocation to the laboratory and include the specific reasons for the department's action and the process to request a reconsideration of the department's action pursuant to section 11-850-137.

(g) Upon suspension of its certification, the laboratory shall:

(1) Cease performing one or more of the analyses allowed by the certification as directed by the department;

(2) Follow all conditions imposed on the certification by the department; and

(3) Take corrective action as required under subsection (b).

(h) Upon revocation of its certification, the laboratory shall:

(1) Surrender its certification to the department;

(2) No longer accept or analyze cannabis or manufactured cannabis products;

(3) Return to the dispensary or destroy in a manner approved by the department any samples of cannabis or manufactured cannabis products in its possession at the time of revocation.

(i) Notwithstanding a laboratory's failure to surrender a revoked certification to the department, the laboratory shall no longer be qualified to analyze cannabis or manufactured cannabis products.

(j) A laboratory aggrieved by a decision made pursuant to this section may request a reconsideration of the action in accordance with section 11-850-137. [Eff 12/14/15; §11-850-86; am, ren §11-850-136, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-8, 329D-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9, 329D-18; SLH 2017, Act 170, §3)

§11-850-137 Request for reconsideration. (a) A laboratory aggrieved by a suspension or revocation made pursuant to section 11-850-136 may request a reconsideration of the action.

(b) A request for reconsideration shall be submitted to the department within five business days after the date of notification; provided that for the

purposes of this section, "date of notification" means three days after the department mailed notice to the laboratory.

(c) A request for reconsideration shall include an explanation of why the laboratory believes the suspension or revocation was improper and shall include all arguments, authorities, factors, affidavits, exhibits, and any other matter which the laboratory may deem relevant.

(d) The director shall issue a written final decision to the laboratory within fifteen business days after the receipt of a request for reconsideration, unless the director determines that an extension is necessary and provides written notice of the extended deadline to the laboratory.

(e) The director's final decision shall, at a minimum, determine whether the director is upholding the suspension or revocation and shall contain a statement of the reasons for the final decision, including factual findings.

(f) A request for reconsideration shall not operate as a stay of the suspension or revocation made pursuant to section 11-850-136.

(g) A final decision by the director on a request for reconsideration is a final agency action. [Eff 12/14/15; §11-850-87; am, ren §11-850-137, and comp 2/24/22; comp APR 29 2022] (Auth: §§321-9, 329D-7, 329D-8, 329D-27) (Imp: §§329D-7, 329D-8)

§§11-850-138 to 11-850-140 (Reserved).

SUBCHAPTER 10

SIGNAGE, PACKAGING, AND LABELING

§11-850-141 Signage. A dispensary licensee shall not post any signage visible from the exterior other than a single sign no greater than one thousand six hundred square inches that bears only the business or trade name in text without any pictures or illustrations; provided that if any applicable law or ordinance restricting outdoor signage is more restrictive, that law or ordinance shall govern. [Eff 12/14/15; §11-850-91; ren §11-850-91 and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-6, 329D-7, 329D-27) (Imp: HRS §§329D-6, 329D-7)

§11-850-142 Packaging for retail sale. (a) A dispensary licensee shall use packaging for cannabis and manufactured cannabis products that:

(1) Meets the requirements for special packaging in Title 16 C.F.R. Part 1700, as published by the U.S. Government Publishing Office as of January 1, 2021;

(2) Is opaque so that the product cannot be seen from outside the packaging;

(3) Protects the product from contamination and does not impart any toxic or harmful substance to the cannabis or manufactured cannabis product;

(4) Is not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the cannabis or manufactured cannabis products as labeled; and

(5) Contains no more than ten milligrams total tetrahydrocannabinol for one dose, serving, or single wrapped item; provided that no manufactured cannabis product that is sold in a pack of multiple doses, servings, or single wrapped items, or any container, shall contain more than one thousand milligrams of total tetrahydrocannabinol per pack or container.

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(b) All manufactured cannabis products shall be packaged in their final packaging at the original point of manufacture. [Eff 12/14/15; §11-850-92; am, ren §11-850-142, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-9, 329D-10, 329D-11, 329D-27) (Imp: HRS §§329D-7, 329D-9, 329D-10, 329D-11, 329D-18; SLH 2017, Act 170, §3)

§11-850-143 Labeling for retail sale. (a) Each package of cannabis or manufactured cannabis product shall be labeled using only black lettering on a white background with no pictures or graphics.

(b) Except as provided in subsection (f), every package of cannabis or manufactured cannabis product shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height:

(1) Product name;

(2) Information about the contents and potency of the cannabis and manufactured cannabis product, including but not limited to:

(A) Net weight in ounces and grams for solids or volume for liquids;

(B) The concentration in milligrams per gram for solids and milligrams per milliliter for liquids of:

(i) Total tetrahydrocannabinol;

(ii) Delta-9-tetrahydrocannabinol;

(iii) Cannabidiol; and

(iv) Any other cannabinoid specifically listed or described in the label or packaging of the cannabis or manufactured cannabis product, including but not limited to cannabigerol (CBG) and cannabinol (CBN).

(3) An ingredient statement that meets the requirements of section 11-850-144;

(4) The dispensary licensee's license number and the name of the production center where cannabis in the product was produced;
(5) The batch number and date of packaging;
(6) A computer tracking inventory identification number barcode generated by tracking software;
(7) Date of harvest for cannabis or date of manufacture for manufactured cannabis products;
(8) Instructions for use and "use by date";
(9) The phrases "For medical use only" and "Not for resale or transfer to another person";
(10) The following warnings:
(A) "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law";
(B) "This product has intoxicating effects and may be habit forming";
(C) "Smoking is hazardous to your health";
(D) "There may be health risks associated with consumption of this product";
(E) "This product is not recommended for use by women who are pregnant or breast feeding";
(F) "Cannabis can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of cannabis;
(G) "When eaten or swallowed, the effects of cannabis may be delayed by two or more hours"; and
(H) "Keep out of the reach of children.".
(11) The name of the laboratory that performed the analysis.

(c) Except as provided in subsection (f), every package of manufactured cannabis product shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height:

(1) The equivalent physical weight of the cannabis used to manufacture the amount of the product that is within the packaging, pursuant to section 329D-9(c), HRS;

(2) A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured cannabis product; and

(3) The warning "This product is a medication that contains cannabis and is not a food".

(d) Except as provided in subsection (f), every edible cannabis product shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height:

(1) The net quantity (in terms of weight, measure, or numerical count) of each serving;

(2) The content (in milligrams) per serving of:

(A) Total tetrahydrocannabinol;

(B) Delta-9-tetrahydrocannabinol;

(C) Cannabidiol (CBD); and

(D) Any other cannabinoid specifically listed or described in the label or packaging of the cannabis or manufactured cannabis product, including but not limited to cannabigerol (CBG) and cannabinol (CBN); and

(3) A statement of the major food allergens the product contains or has protein derived from, to include:

(A) Milk;

(B) Egg;

(C) Fish;

(D) Crustacean shellfish;

(E) Tree nuts;

(F) Wheat;

(G) Peanuts; and

(H) Soybeans.

Highly refined oils derived from any of the eight major food allergens and any

ingredient derived from such highly refined oils are exempt from this requirement.

(e) Except as provided in subsection (f), ointments, skin lotions, and transdermal patches shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height: the statement "For external use only.".

(f) Allowed exceptions.

(1) In lieu of being included on the product label, the information in paragraphs (b)(10)(A) to (G), (b)(11), (c)(2), and (c)(3) may be included on labeling attached to or inserted into the package using a type size no smaller than one-sixteenth inch in height.

(2) Upon request by a dispensary licensee, the department may authorize certain additional information in subsections (b) to (e) to appear on the package insert based on a finding by the department that the size of the package does not reasonably accommodate all of the information in subsections (b) to (e).

(g) A dispensary licensee shall not label as organic any cannabis or manufactured cannabis product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act.

(h) A dispensary shall not use the words "candy" and "candies" on product packaging or labeling. [Eff 12/14/15; §11-850-92 (pt); am, ren §11-850-143, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-9, 329D-11, 329D-27) (Imp: HRS §§329D-7, 329D-9, 329D-11, 329D-17, 329D-18; SLH 2017, Act 170, §3)

§11-850-144 Ingredient statement. (a) All ingredients shall be listed on the label in order of

prominence by weight and shall be preceded by the word "Ingredients".

(b) The common or usual name of ingredients shall be consistent with the names standardized in:

(1) For ingredients that are botanicals (including fungi and algae): *Herbs of Commerce,* second edition, published by the American Herbal Products Association. The listing of these names on the label shall be followed by statements of:

(A) The part of the plant (e.g., root, leaves) from which the ingredient is derived (e.g., "Cannabis flower" or "Cannabis (flower)"), except that this designation is not required for algae; and

(B) The Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in *Herbs of Commerce*, second edition, for the common or usual name listed on the label, and, when required, the Latin binomial name may be listed before the part of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature* (Shenzhen Code), 2018 edition, published by the International Association for Plant Taxonomy, and shall include the designation of the author or authors who published the Latin name, when a positive identification cannot be made in its absence.

(2) For cosmetic ingredients in topical manufactured cannabis products: 21 C.F.R. section 701.3(c), published by the U.S. Government Publishing Office, as amended as of April 1, 2021. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9,

329D-7, 329D-9, 329D-11, 329D-27) (Imp: HRS §§329D-7, 329D-9, 329D-11)

§11-850-145 Advertising and displays. (a) A dispensary licensee shall not engage in advertising in any media including but not limited to:

(1) Broadcast or electronic media:
  (A) Radio;
  (B) Television;
  (C) Internet; and
  (D) Social media;

(2) Print media:
  (A) Newspaper;
  (B) Magazine;
  (C) Billboards; and
  (D) Placards on public transit vehicles or public transit shelters;

provided that a dispensary licensee may provide only general information on the dispensary licensee's contact information, its retail dispensing location, and a list of products available for dispensing with a description limited to the information specified in section 11-850-143 by means of a website or a private messaging system in which an individual requests such information from the dispensary.

(b) A dispensary licensee shall not display cannabis or manufactured cannabis products in windows or in public view.

(c) A dispensary shall not use the words "candy" and "candies" on advertising, product lists, or product menus. [Eff 12/14/15; §11-850-93; am, ren §11-850-145, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-11, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-11; SLH 2017, Act 170, §3)

§§11-850-146 to 11-850-150 (Reserved).

SUBCHAPTER 11

ENFORCEMENT

§11-850-151 Remedies. (a) If the director determines that any person is violating any provision of this chapter, chapter 329D, HRS, or the person's license, the director may have that person served with a notice of violation and an order. The notice shall specify the alleged violation. The order may:

(1) Require that the alleged violator do any or all of the following:
   (A) Cease and desist from the violation;
   (B) Pay an administrative penalty of not less than $100 nor more than $1,000 for each violation; and
   (C) Submit a corrective action plan within ten days and correct the violation at the alleged violator's expense; and
(2) Suspend or revoke a dispensary license pursuant to section 11-850-152 and section 329D-21, HRS.

(b) Subject to subsection (d), the order shall become final twenty days after service unless within those twenty days the alleged violator requests in writing a hearing before the director. When the director issues an order for immediate suspension or revocation of a dispensary license, the department shall provide an opportunity for a hearing to occur within two days after service of the order; provided that if the second day falls on a Saturday, Sunday, or State holiday, the hearing shall be held on the next day that is not a Saturday, Sunday, or State holiday. No order for suspension or revocation shall be stayed pending a hearing. After a hearing pursuant to this subsection, the director may affirm, modify, or rescind the order as appropriate.

(c) The department may consider multiple factors in assessing a penalty or ordering a remedial action

against a dispensary licensee. The factors, any of which may be the basis for assessing a penalty or ordering a remedial action, include but are not limited to:

(1) Whether the violation violates criminal law or imminently jeopardizes the health or safety of the general public, qualifying patients, or qualifying out-of-state patients;

(2) Whether the violation creates a risk to the health or safety of the general public, qualifying patients, or qualifying out-of-state patients;

(3) Whether the violation is a violation of an administrative licensing requirement;

(4) Any prior violations;

(5) Actions taken to prevent or correct the violation;

(6) Whether the violation was deliberate;

(7) Whether the violation is likely to recur;

(8) The nature, circumstances, extent, gravity, and history of the violation and any prior violations; and

(9) Any other factors that may affect the health, safety, or welfare of the public, a qualifying patient, or a qualifying out-of-state patient.

(d) Upon a request for a hearing the director shall specify a time and place for the alleged violator to appear. After a hearing pursuant to this section, the director may affirm, modify, or rescind the order as appropriate. Any penalty imposed under this chapter shall become due and payable twenty days after the notice of penalty is served unless the person or persons named therein request in writing a hearing before the director. Whenever a hearing is requested on a penalty, the penalty shall become due and payable only upon completion of all review proceedings and the issuance of a final order confirming the penalty in whole or in part. Orders for suspension of a dispensary license shall become effective immediately upon service, whether or not a

hearing is requested. No order for suspension or revocation shall be stayed pending a final decision. Whenever a hearing is requested on an order for revocation of a dispensary license, the order shall become effective upon completion of all review proceedings and the issuance of a final order confirming the revocation.

(e) When an applicant who has not received a license requests a hearing pursuant to section 329D-21, HRS, the department shall timely post that applicant's request on its website. A successful applicant may intervene as of right in any hearing by an unsuccessful applicant for the same license.

(f) Any hearing conducted under this section shall be conducted as a contested case under chapter 91, HRS, and chapter 11-1. If after a hearing held pursuant to this section the director finds that a violation or violations have occurred, the director shall affirm or modify any penalties imposed, or shall affirm or modify the order for remedial action, or both, or may order any other corrective action that may be appropriate. If, after a hearing on an order for remedial action or penalty contained in a notice, the director finds that no violation has occurred or is occurring, the director shall rescind the order or penalty.

(g) Notices under this section shall be served either by mail, return receipt requested, or in person. Notice shall be served upon the individual applicant or any employee who is present in the facility, and is effective upon receipt. [Eff 12/14/15; §11-850-101; am, ren §11-850-151, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-7, 329D-21)

§11-850-152 Suspension and revocation of dispensary license. (a) Upon suspension of a dispensary license pursuant to section 329D-21 and this subchapter, the licensee shall immediately do any or all of the following as ordered by the director:

(1) Cease dispensing or manufacturing cannabis and manufactured cannabis products, or both;
(2) Cease transporting cannabis and manufactured cannabis products; or
(3) Cease operations in all applicable dispensary facilities except those operations necessary to maintain the growth of cannabis plants and to maintain security.

(b) Upon revocation of a dispensary license pursuant to section 329D-21 and this subchapter, the licensee shall immediately:
(1) Cease dispensing and manufacturing cannabis and manufactured cannabis products;
(2) Cease transporting all cannabis and manufactured cannabis products;
(3) Cease all operations in dispensary facilities;
(4) Destroy or dispose of all cannabis and manufactured cannabis products owned, controlled by, or in the possession of the licensee, in accordance with this chapter, and enter that information in its tracking system; and
(5) Surrender the dispensary license to the department.

(c) Following a suspension, the department may allow a dispensary licensee to resume operations by written notice to the licensee after the licensee has corrected the violations. [Eff 12/14/15; §11-850-102; am, ren §11-850-152, and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§321-9, 329D-7, 329D-27) (Imp: HRS §§329D-2, 329D-6, 329D-7, 329D-21; SLH 2017, Act 170, §3)

DEPARTMENT OF HEALTH

Chapter 11-850 (Interim Rules), Hawaii Administrative Rules, on the Summary Page dated April 1, 2022 was amended and compiled on April 1, 2022.

The foregoing rulemaking action shall take effect immediately upon filing with the Office of the Lieutenant Governor.

ELIZABETH A. CHAR, M.D.
Director of Health

DAVID Y. IGE
Governor of Hawaii

Dated: 4/19/2022

APPROVED AS TO FORM:

Andrew D. Goff
Deputy Attorney General

Filed

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LIEUTENANT GOVERNOR'S OFFICE

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