DEPARTMENT OF HEALTH

Adoption of Chapter 11-850
Hawaii Administrative Rules

December 7, 2015

SUMMARY

Chapter 11-850, Hawaii Administrative Rules, entitled "Medical Marijuana Dispensaries", is adopted.
HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 850

MEDICAL MARIJUANA DISPENSARIES

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SUBCHAPTER 1

GENERAL PROVISIONS

§11-850-1 Purpose. The purpose of this chapter is to regulate a statewide dispensary system to ensure safe and legal access to medical marijuana for qualifying patients. [Eff DEC 14 2015 ] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-1 to 329D-27)

§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).
"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 the amount of marijuana or the amount of each type of manufactured marijuana product that is prepared for sale at one time.
"Business days" means Monday through Friday, excluding State holidays.
"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 test marijuana and manufactured marijuana products for content, contamination, and consistency as provided in this chapter.

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

"Department" means the department of health.

"Director" means the director of the department of health, State of Hawaii, or the director's designee.

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

"Enclosed indoor facility" means a permanent stationary structure with a solid floor, rigid exterior walls that encircle the entire structure on all sides, and a roof which protect the entire interior area from any exterior view and elements of weather. An enclosed indoor facility excludes a greenhouse or shade house.

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

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

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

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

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

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

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

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

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

"Public housing project or complex" has the same meaning as defined in section 329D-22, HRS.

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

"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.

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

"School" has the same meaning as defined in chapter 329D, HRS.

"Scope of accreditation" means a document issued by an accreditation body which describes the methodologies, range, and parameters for testing
products for which the accreditation has been granted. "Subcontractor" and "contractor" mean any person or entity with whom the dispensary licensee has a contract to perform any of its production center or retail dispensing location operations.
(Imp: HRS §§329-121, 329D-1 to 329D-27)

§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.
(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 marijuana pursuant to federal law.

§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, 2017, the department may issue dispensary licenses in addition to those authorized by subsection (a), based on qualifying patient need; provided that no more than one license may be issued per five hundred qualifying patients residing in any single county.
(c) The number of licenses the department issues is subject to the availability of qualified applicants in each county. [Eff DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §329D-2)

§11-850-6 Number of production centers per license. (a) A dispensary shall be allowed to operate up to two production centers.
(b) 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 DEC 14 2015] (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.
(b) No more than one retail dispensing location may be located at the same address. [Eff DEC 14 2015] (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.
(c) A dispensary facility shall not be permitted within seven hundred fifty feet of the real property comprising a playground, public housing project or complex, or school. [Eff DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-1, 329D-2, 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 marijuana or manufactured marijuana products. [Eff DEC 14 2015 ] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-1 to 329D-27)

§11-850-10 (Reserved)

SUBCHAPTER 2
LICENSING

§11-850-11 License required. No person shall operate a medical marijuana dispensary unless the person has a license issued by the department pursuant to this chapter. [Eff DEC 14 2015 ] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-2, 329D-5, 329D-6)

§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 DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-4, 329D-7)

§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 DEC 14 2015] (Auth: HRS §§321-9, 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;
(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;
(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;

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

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

(b) The information and documents shall be submitted electronically, or in a method 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.

(Imp: HRS §§329D-3, 329D-4, 329D-6, 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 this chapter. [Eff DEC 14 2015] (Auth: HRS §§321-9, 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;

(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) 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); and
(I) To establish proof of no felony convictions for each individual listed in section 329D-12, HRS, 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; and
   (ii) Consent to a background check including fingerprinting.
(b) The information and documents shall be submitted electronically, or in a method 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.

§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, shareholders with at least twenty-five percent ownership interest or more, members, and managers of an entity applicant or licensee;
(3) Each employee of a dispensary;
(4) Each subcontractor of a dispensary;
(5) All officers, directors, shareholders with at least twenty-five percent ownership interest or more, members, 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 dispensary facilities pursuant to sections 329D-6, 329D-15, and 329D-16, 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 any responsibility for operating a dispensary if the person:

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

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

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

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

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

(c) 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.

(d) 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 subsection (b). [Eff DEC 14 2015] (Auth: HRS §§321-9, 329D-12, 329D-15, 329D-16, 329D-27, 846-2.7) (Imp: HRS §§329D-3, 329D-6, 329D-7, 329D-12)

§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, Office of Health Care Assurance, 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.
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(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 DEC 14 2015] (Auth: HRS §§321-9, 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.

(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 DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§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 marijuana dispensary business;
(F) Creating and implementing a business plan, including a timeline for opening a business;

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(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 marijuana 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 marijuana 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, including but not limited to:

(A) Educating patients on how marijuana can be used to assist patients with debilitating medical conditions and about the marijuana and manufactured marijuana products that will be
available in the applicant's retail dispensing locations;
(B) Producing and maintaining a supply of marijuana that is sufficient to meet the needs of qualifying 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-7, 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;
(8) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;
(9) Ability to comply with the requirements for certified laboratory testing on marijuana and manufactured marijuana products pursuant to this chapter and sections 329D-7 and 329D-8, HRS;
(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 marijuana and manufactured marijuana products;
(12) Ability to ensure product safety, in accordance with this chapter and sections 329D-8, 329D-10, 329D-11, HRS; 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.
§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 application 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 marijuana or manufactured marijuana 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.


§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 marijuana and manufactured marijuana 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 DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329-33, 329D-6, 329D-7)

§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 DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-2, 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:
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(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, Act 241, SLH 2015, 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 or qualifying 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 DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-3, 329D-4, 329D-5)

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

(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.

(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 marijuana and manufactured marijuana products in the dispensary licensee's possession pursuant to this chapter.

$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 marijuana and manufactured marijuana 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 DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-4, 329D-6, 329D-7)

§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 DEC 14 2015 ] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-4, 392D-6, 329D-7)

§11-850-28 to 30 (Reserved)

SUBCHAPTER 3

OPERATIONS

§11-850-31 Dispensary operations. (a) In all dispensary facilities, only the licensee, if an individual, authorized employees of the dispensary, and authorized employees of the subcontracted dispensary facilities, if any, shall be permitted to touch or handle any marijuana or manufactured marijuana products; provided that a qualifying patient or the primary caregiver of a qualifying patient may receive marijuana or manufactured marijuana 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 marijuana for any person.
(d) A dispensary licensee shall not transfer any marijuana or manufactured marijuana products to any other dispensary.

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


§11-850-32 Production centers. (a) Not less than thirty days prior to producing or manufacturing any marijuana or manufactured marijuana 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 marijuana or begin producing or manufacturing marijuana or manufactured marijuana 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

§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 dispensary shall not possess or dispense marijuana or manufactured marijuana products.

(c) Retail dispensing locations shall:

(1) Remain locked at all times;

(2) Be open for dispensing only between 8:00 a.m. and 8:00 p.m., Hawaii-Aleutian Standard Time, Monday through Saturday;

(3) Be closed on Sundays and official state and federal holidays;

(4) Be in an enclosed indoor facility;

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

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

(7) Require a qualifying patient or primary caregiver to present a valid government-issued photo identification and a valid medical use of marijuana registration card issued by the department pursuant to chapter 329, HRS, and use the sign-in system in accordance with section 11-850-51, before entering the premises;

(7) Display a copy of the dispensary license and any other required permits or licenses at all times, including pursuant to 11-50; and

(8) Store all marijuana or manufactured marijuana products behind a counter or other barrier to ensure that a qualifying patient or primary caregiver does not have direct access to the product prior to sale.

(d) Retail dispensing locations shall not:
(1) Provide free samples of marijuana or manufactured marijuana products;
(2) Dispense marijuana or manufactured marijuana products as premade or manufactured cigarettes or in any form prepared specifically for smoking or inhaling; or
(3) Make available for sale or as gifts or premiums any supplies or paraphernalia that provide for the use of medical marijuana in smokable or inhalable form.


§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.
§11-850-36

(e) The dispensary licensee shall provide the names of all employees to the department.

§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.
(Imp: HRS §§329D-6, 329D-7, 329D-12)

§11-850-36 Transport. (a) A dispensary may transport marijuana and manufactured marijuana products between its facilities, and between its facilities and a laboratory for testing.
(b) Only employees designated by the dispensary licensee, who are trained and knowledgeable on the transportation protocols required by this chapter, shall transport marijuana and manufactured marijuana products. Every transport of marijuana and manufactured marijuana products shall be accompanied by at least two employees.
(c) Each time marijuana and manufactured marijuana 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 marijuana or manufactured marijuana products that are listed on the manifest.
(e) A dispensary licensee shall transport marijuana or manufactured marijuana 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) Marijuana and manufactured marijuana products shall be transported under conditions that maintain their quality and safety.

(h) Upon receipt of marijuana and manufactured marijuana products the dispensary licensee or the laboratory shall immediately report to the department any discrepancies between what is received and what is on the manifest.

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

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

(k) A dispensary licensee shall not transport marijuana or manufactured marijuana products:

(1) Off site to qualifying patients or to primary caregivers;

(2) To another county or another island within the same county; 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 DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-11, 329D-17, 329D-18, 329D-19, 329D-21)
§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.

(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 9. [Eff DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-7, 329D-15, 329D-16, 329D-21, 329D-23)

§11-850-38 Reports. (a) A dispensary licensee shall submit quarterly reports on January 15, April 15, July 15, and October 15. 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 but not be limited to:

(1) Records of entry and exit for all individuals who entered a dispensary facility;
(2) Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale;
(3) Amounts by category of marijuana and manufactured marijuana products sold;
(4) A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed;
(5) A summary financial statement;
(6) Laboratory results of all tests conducted;
(7) Description of any breach or halt in its security system and tracking system; and

§11-850-39 Audits. (a) A dispensary licensee shall obtain an independent financial audit annually, at the dispensary licensee's expense, and shall provide a copy of the audit's findings to the department.

(b) The report 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 DEC 14 2015] (Auth: HRS §§321-9, 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 or the medical condition of a qualifying 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 DEC 14 2015 ] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §329D-7)

§11-850-41 Record retention. (a) A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:

(1) Inventory tracking including transport of marijuana and manufactured marijuana products;
(2) Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
(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.


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

(b) Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of marijuana or manufactured marijuana products purchased
by a qualifying patient or primary caregiver from any other licensed dispensary within the state and shall not sell any amount of marijuana or manufactured marijuana products to that qualifying patient or primary caregiver of a qualifying patient that exceeds the limits identified in this chapter.

(Imp: HRS §§329D-6, 392D-7, 329D-13, 329D-14, 329D-17)

§11-850-43 Disposal or destruction. (a) A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana 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 marijuana or manufactured marijuana 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 marijuana or manufactured marijuana 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 marijuana and manufactured marijuana products.


§11-850-44 to 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 marijuana and manufactured marijuana products are produced, moved, or stored; all points of sale areas; any room used to pack or unpack a secured container used to transport marijuana or manufactured marijuana 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 sections 329D-15 and 329D-16, HRS; and

(B) Other approved individuals with government issued photo identification including:

(i) Qualifying patients;

(ii) Primary caregivers;

(iii) A government employee or official acting in the person's official capacity;

(iv) Dispensary employees; provided that qualifying patients and primary caregivers may only be authorized to enter retail dispensing locations;

(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 sign-in 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.

(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.


§11-850-52 Required security in production centers. In addition to other security features as set forth 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 marijuana in any form;


§11-850-53 Required security in retail dispensing locations. In addition to the other security features as set forth in this chapter and chapter 329D, HRS, all retail dispensing locations shall have the following security features:
(1) A protocol for admitting qualifying patients or primary caregivers with valid government issued photo identification and medical marijuana 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 marijuana and manufactured marijuana products;

(3) A maximum occupancy limit ratio in the secured sales room of two customers to every one retail dispensing location employee;

(4) All marijuana and manufactured marijuana products shall be secured in a locked room, vault, or locked container securely affixed to a wall or floor; and


§11-850-54 to 60 (Reserved)

SUBCHAPTER 5

TRACKING REQUIREMENTS

§11-850-61 Tracking requirements. (a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana 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.
(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 329D-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits 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.

(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. [Eff 11 DEC 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-6, 329D-7, 329D-8, 329D-11, 329D-13, 329D-14, 329D-18, 329D-19)

§11-850-62 to 70 (Reserved)

SUBCHAPTER 5

PRODUCTS AND PRODUCT STANDARDS

§11-850-71 Marijuana. (a) A dispensary licensee may dispense marijuana only in the form of dried matured processed flowers of female cannabis plants.

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(b) A dispensary licensee shall establish and maintain a written policy and procedure 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 of marijuana;

(3) Adequate protocols for laboratory testing of marijuana pursuant to this chapter; and

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

(c) A dispensary licensee shall report to the department prior to producing marijuana the strains of marijuana to be cultivated by the dispensary.

(Imp: HRS §§329D-6, 329D-7, 329D-9, 329D-10)

§11-850-72 Manufactured marijuana products. (a)
A dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions.

(b) A dispensary licensee shall establish and maintain a written policy and procedure 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 marijuana products;

(3) Effective training and monitoring of employees and subcontractors who participate in the production of manufactured marijuana products;

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

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

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

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

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

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


§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, including under chapter 11-50 for any product that is intended to be ingested orally or chewed.

(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 marijuana 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
§11-850-73

§11-850-74 Equivalent weights for manufactured marijuana products. (a) A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.
(b) A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale.

§11-850-75 Quality control, health, safety, and sanitation standards. (a) A dispensary licensee shall ensure that all marijuana and manufactured marijuana products it dispenses are safe for use or consumption by qualifying 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.
(c) Any person who has or appears to have an illness, or open lesion including boils, sores, or infected wounds, or any other source of contamination, shall be excluded from any contact with a dispensary's marijuana or manufactured marijuana products until the condition is corrected.
(d) A dispensary shall have hand washing facilities that are adequate and convenient, furnished with running water, and provide effective hand cleaning and sanitizing preparations.
(e) All persons working in direct contact with marijuana and manufactured marijuana products shall
conform to hygienic practices while on duty, including but not limited to:

(1) Maintaining adequate personal cleanliness; and

(2) Washing hands thoroughly in an adequate hand washing area before starting work and at any other time when the hands may have become soiled or contaminated.

(f) A dispensary licensee shall ensure that all litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where marijuana or manufactured marijuana products are exposed.

(g) The floors, walls, and ceilings of a dispensary facility shall be constructed in such a manner that they may be adequately cleaned and kept clean and in good repair.

(h) The dispensary licensee shall ensure that there is adequate lighting in all areas where marijuana or manufactured marijuana products are stored or sold, and where equipment or utensils are cleaned.

(i) The dispensary licensee shall provide adequate screening or other protection against the entry of pests and shall dispose of rubbish to minimize the development of odor and the potential for waste to become an attractant, harborage, or breeding place for pests.

(j) The dispensary licensee shall not allow animals in dispensary facilities, except for service animals in accordance with section 347-2.5, HRS.

(k) The dispensary licensee shall maintain buildings, fixtures, and other facilities in a sanitary condition.

(l) The dispensary licensee shall use and maintain any toxic cleaning compounds, sanitizing agents, and pest control measures such as bait traps, in a manner that protects against contamination of marijuana or manufactured marijuana products and in a manner that is in accordance with any applicable

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local, state, or federal law, rule, regulation or ordinance.

(m) A dispensary licensee shall not alter marijuana or manufactured marijuana products to change their appearance, flavor, or smell in a way that would appeal to minors. [Eff DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-7, 329D-9, 329D-10)

$11-850-76 to 80 (Reserved)

SUBCHAPTER 7

LABORATORY CERTIFICATION, TESTING, AND STANDARDS

$11-850-81 Laboratory testing required. A dispensary licensee shall not dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter. [Eff DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9, 329D-10)

$11-850-82 Laboratory certification required. (a) No laboratory is authorized to handle, test, or analyze marijuana or manufactured marijuana products unless that laboratory:

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

(2) Is independent from all medical marijuana 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; and
(4) Has established standard operating procedures that include chain of custody for samples transferred to the laboratory for testing.

(b) The department may grant a provisional certification to a laboratory to test marijuana and manufactured marijuana 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


§11-850-83 Requirements for laboratory certification and provisional certification. (a) To apply for a laboratory certification to test marijuana and manufactured marijuana products, a laboratory shall submit an application to the department in a manner prescribed by the department. The laboratory applicant shall provide:

(1) All information and documents required by the department;

(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 and the laboratory's responses to any findings of non-compliance with standards or recommendations; and

(4) A copy of the laboratory's accreditation in Hawaii or another jurisdiction, accompanied by the scope of accreditation.
$11-850-83

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

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

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

(3) Demonstrate capacity and proficiency to test marijuana and manufactured marijuana 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 11-850-82(b).

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

(f) A laboratory certification pursuant to this chapter shall expire one year after the date it is issued, but may be renewed if the laboratory:

(1) Requests renewal in writing within three months prior to expiration in a manner prescribed by the department;

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

(3) Pays a renewal fee in the amount of $3,000.

(g) A laboratory certification may be extended beyond the one year expiration at the discretion of the department if the laboratory timely requests renewal of its certification, and the department approves the extension in writing prior to the expiration date.  [Eff DEC 14 2015] (Auth: HRS §§321-9, 329D-27) (Imp: HRS §§329D-7, 329D-8, 329D-9)

§11-850-84 Minimum operating standards for laboratories certified pursuant to this chapter. (a)
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. Establish standard operating procedures to test marijuana and manufactured marijuana products;
3. Follow the scope for which it is accredited for testing marijuana and manufactured marijuana products and the requirements for laboratory standards and testing established in this chapter;
4. Notify the department within one business day after receiving notice of any kind that its accreditation has been denied, suspended, or revoked; and
5. Follow other conditions set forth in the certification as issued by the department.

(b) If the department finds that a laboratory is not in compliance with the requirements of this chapter, the department may:
1. Provide a list of deficiencies and require a plan for correction;
2. Suspend the license subject to conditions ordered by the department; or
3. Initiate revocation of the certification in accordance with section 11-850-86.

§11-850-85 Laboratory standards and testing.
(a) A certified laboratory shall test a statistically representative sample from each batch of marijuana or manufactured marijuana products. The dispensary licensee shall maintain in a secure tamper-proof manner a similar sample from the same batch, for verification testing as directed by the department.
(b) A certified laboratory shall test and 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.

(c) A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of marijuana and manufactured marijuana products tested for that dispensary; provided that a certified laboratory may only test and report on those things 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 compounds:

(A) Δ⁹ (delta 9) - Tetrahydrocannabinol (THC)
(B) Tetrahydrocannabinol Acid (THCA)
(C) Cannabidiol (CBD)
(D) Cannabidiolic Acid (CBDA)
(E) Cannabigerol (CBG)
(F) Cannabinol (CBN)

(2) The presence of the following contaminants, which shall not exceed the following levels:

(A) Heavy metals:
   (i) Arsenic    10.0 ppm
   (ii) Lead      6.0 ppm
   (iii) Cadmium  4.0 ppm
   (iv) Mercury   2.0 ppm

(B) Pesticides regulated by the U.S. Environmental Protection Agency: 1.0 ppm

(C) Solvents:
   (i) Butanes    800 ppm
   (ii) Heptanes  500 ppm
   (iii) Benzene** 1 ppm
   (iv) Toluene** 1 ppm
   (v) Hexane**  10 ppm
   (vi) Total Xylenes (m,o,p-xylene) 1 ppm

** Contaminants in solvents

(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) Moisture content of plant material <15%

(F) Microbiological impurities, including but not limited to:

(i) Total Viable Aerobic Bacteria:
   (a) Unprocessed and Processed Materials: $10^5$ Colony Forming Unit (CFU)/g
   (b) CO$_2$ and Solvent Based Extracts: $10^4$ CFU/g

(ii) Total Yeast and Mold:
   (a) Unprocessed and Processed Materials: $10^4$ CFU/g
   (b) CO$_2$ and Solvent Based Extracts: $10^3$ CFU/g

(iii) Total Coliforms:
   (a) Unprocessed and Processed Materials: $10^3$ CFU/g
   (b) CO$_2$ and Solvent Based Extracts: $10^2$ CFU/g

(iv) Bile-tolerant Gram Negative Bacteria:
   (a) Unprocessed and Processed Materials: $10^3$ CFU/g
   (b) CO$_2$ and Solvent Based Extracts: $10^2$ CFU/g

(v) E. coli (pathogenic strains) and Salmonella spp.: Not detected in 1 g

(vi) Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger : <1 CFU/g;

(vii) Mycotoxins: <20 µg (micrograms) of any mycotoxin per kg of material; and

(3) Additional testing requested at the discretion of the department.

(d) The certified laboratory may retest or reanalyze the sample or 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.

(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 marijuana or manufactured marijuana products that remain after testing and analysis are completed.

(f) A certified laboratory shall create, and maintain for a period of at least five years, records of testing it conducts on marijuana and manufactured marijuana 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 tests were conducted on each sample;
4. The results of the tests including the certificate of analysis; and
5. Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount;

and shall make all the records available to the department upon request.

(g) A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection (c), and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.

(h) A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.

(i) The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection (c), and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of
marijuana or manufactured marijuana product that does not conform to the standards.

(j) A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. 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 testing standards set out in subsection (c).

(Imp: HRS §§329D-7, 329D-8, 329D-9)

§11-850-86 Suspension and revocation of laboratory certification. (a) 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 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.

(b) 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 11-850-87.

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

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

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

(3) Submit to the department for approval a written plan of correction for each correctable violation.

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

(1) Surrender its certification to the department;

(2) No longer accept or test marijuana or manufactured marijuana products;

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

(e) Notwithstanding a laboratory's failure to surrender a revoked certification to the department, the laboratory shall no longer be qualified to test or analyze marijuana or manufactured marijuana products.
(f) A laboratory aggrieved by a decision made pursuant to this section may request a reconsideration of the action in accordance with section 11-850-87.

§11-850-87 Request for reconsideration. (a) A laboratory aggrieved by a suspension or revocation made pursuant to section 11-850-86 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 11-850-86.

(g) A final decision by the director on a request for reconsideration is a final agency action.
§11-850-91

§11-850-88 to 90 (Reserved)

SUBCHAPTER 8

SIGNAGE, PACKAGING, AND LABELING

§11-850-91 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.

§11-850-92 Packaging and labeling for retail sale. (a) A dispensary licensee shall use packaging for marijuana and manufactured marijuana products that:

(1) Is child resistant in accordance with Title 16 C.F.R. 1700 of the Poison Prevention Packaging Act;

(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 marijuana or manufactured marijuana product; and

(4) Contains no more than ten milligrams tetrahydrocannabinol for one dose, serving, or single wrapped item; provided that no manufactured marijuana product that is sold in a pack of multiple doses, servings, or single wrapped items, or any containers of oils, shall contain a total of more than one hundred milligrams of tetrahydrocannabinol per pack or container.
(b) Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:

(1) Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
   (A) Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;
   (B) The concentration of tetrahydrocannabinol or Δ⁹-tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;

(2) The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;

(3) The batch number and date of packaging;

(4) Includes a computer tracking inventory identification number barcode generated by tracking software;

(5) Date of harvest or manufacture and "Use by date";

(6) Instructions for use;

(7) The phrases "For medical use only" and "Not for resale or transfer to another person";

(8) 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) "Marijuana can impair concentration, coordination, and judgment. Do not
operate a vehicle or machinery under the influence of this drug"; and

(G) "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";

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

(10) The name of the laboratory that performed the testing;

provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.

(c) A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act. [Eff DEC 14 2015 ]


§11-850-93 Advertising and displays prohibited.

(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) Bill boards; and

(D) Placards on public transit vehicles or public transit shelters;

provided that the dispensary licensee may establish a website that provides 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 11-850-92.

(b) A dispensary licensee shall not display marijuana or manufactured marijuana products in windows or in public view. [Eff DEC 14 2015]


§11-850-94 to 100 (Reserved)

SUBCHAPTER 9

ENFORCEMENT

§11-850-101 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 require that the alleged violator do any or all of the following:

(1) Cease and desist from the violation;
(2) Pay an administrative penalty of not less than $100 nor more than $1,000 for each violation; or
(3) Submit a corrective action plan within ten days and correct the violation at the alleged violator's expense.

The order may also suspend or revoke a dispensary license pursuant to section 11-850-102 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 or of qualifying patients;

(2) Whether the violation creates a risk to the health or safety of qualifying patients or to the public;

(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; or

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

§11-850-102  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 marijuana and manufactured marijuana products, or both;

(2) Cease transporting marijuana and manufactured marijuana products; or

(3) Cease operations in all applicable dispensary facilities except those operations necessary to maintain the growth of marijuana 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 marijuana and manufactured marijuana products;

(2) Cease transporting all marijuana and manufactured marijuana products;

(3) Cease all operations in dispensary facilities;

(4) Destroy or dispose of all marijuana and manufactured marijuana 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 DEC 14 2015 ]

DEPARTMENT OF HEALTH

The adoption of chapter 11-850 shall take effect upon filing with the Office of the Lieutenant Governor.

Virginia Pressler
Virginia Pressler, M.D.
Director
Department of Health

APPROVED:

David I. Ige
Governor
State of Hawaii

Dated: 12-13-15

APPROVED AS TO FORM:

James W. Wattles
Deputy Attorney General

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Filed