CHAPTER 11-850,

Hawaii Administrative Rules

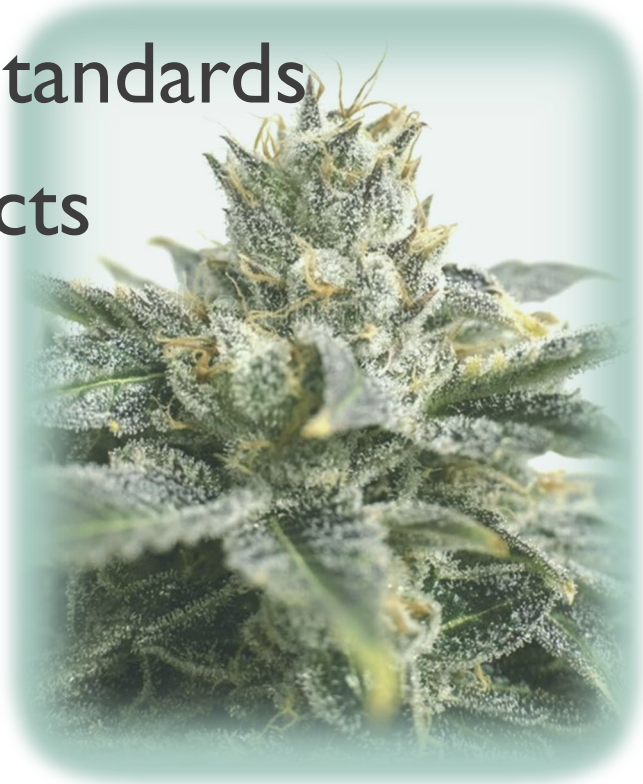
Medical Cannabis Dispensaries

NOTE:

This summary is not exhaustive and is not a substitute for reading the regulations.

SUMMARY OF CHANGES

1) Legislative/statutory changes since 2015
2) Edible cannabis product types and product standards
3) Additional safety requirements for all products
4) Packaging & labeling
5) Sampling
6) Testing
7) Relating to hemp



STATUTORY CHANGES

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1) Change "marijuana" to "cannabis"
2) Allow qualifying out-of-state patients and their caregivers
3) Updated definitions: enclosed indoor facility, subcontractor
4) Added flexibilities for department on allowable number of:
    a) Licenses per county
    b) Production centers per license
    c) Plants per production center
    d) Retail dispensing locations per license

STATUTORY CHANGES

5) New procedure for change of individual licensee [§329D-5.5, HRS]
6) Removal of public housing complexes from siting restriction
7) Clarifying who is subject to background checks
    a) Language changes for members and shareholders of different types of business entities [§329D-12(a)(1) and (4), HRS]
    b) Patients, caregivers, and government officials entering retail dispensary not subject to background checks

STATUTORY CHANGES

8) Conditions for denying employment - shall v. may deny employment to prospective employees convicted of different types of felonies [§329D-6(d), HRS]
9) Office of Medical Cannabis Control and Regulation
10) Clarifying who is allowed to handle cannabis – includes 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 [§329D-6(g)]
11) Retail dispensing hours - allowed opening Sundays, holidays

STATUTORY CHANGES

12) Added product types
    a) "Safe pulmonary administration"
    b) Transdermal patches
    c) Edible cannabis products
13) Interisland transport for testing
14) Unannounced license renewal inspections
15) Reduced retention time for security footage (50 days)

STATUTORY CHANGES

16) Procedures in event of tracking system malfunction
17) Reprocessing allowance
18) Packaging
    a) Increased total THC per package allowed to 1000 mg
    b) "All manufactured cannabis products shall be packaged in their final packaging at the original point of manufacture."
19) Labeling
    a) "Keep out of reach of children."
    b) "This product is a medication that contains cannabis and is not a food."

EDIBLE CANNABIS PRODUCTS

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- Statutory definition applies to existing product types:
  - Capsules
  - Lozenges
  - Pills
  - Oils
  - Tinctures
- New product types:
  - Gummies
  - Hard molded confections made primarily from sugar or syrup
  - Chocolates
  - Cookies
  - Brownies
  - Honey
  - Beverages
  - Powdered beverage mixes or beverage additives
  - Syrup beverage mixes or beverage additives

EDIBLE CP – SAFETY MEASURES

- Product cannot require time/temperature control for safety (determined by water activity [a_w], a_w & pH, or product assessment)
- Must be homogenous in cannabinoid content
- New language restricting "appeal to minors":
  - Not designed to resemble candy or other products marketed to children
  - Not in the shape of or contain a depiction of a human, animal, or fruit
  - "Candy"/"candies" not used on packaging, labeling, menu, etc.
- No infused oils and butters containing garlic/peppers (botulism risk)
- Tinctures: 2 oz max, labeled for use in drops or dropperfuls

EDIBLE CP – PACKAGING & LABELING

- Packaging with portioning guide
  - Single-serving packaging
  - Scoring that guides/assists with breaking into single-serving portions
  - Including a measuring device designed, sized, or clearly marked to measure a single serving
- Labeling
  - Serving size
  - Per serving mg of total THC, D9-THC, CBD, and "any other cannabinoid specifically listed or described in the label or packaging"
  - Allergen statement

PRODUCT SAFETY

for all cannabis and manufactured cannabis products

PRODUCT SAFETY

- No added ingredients in cannabis
- Banned components/ingredients in manufactured cannabis products
  - FDA food/cosmetics banned components/ingredients
  - Psychoactive ingredients not derived from cannabis
  - Ingredients that "increase the potency, toxicity, or addictive potential of the product or create a potentially unsafe combination with cannabinoids"
  - Cannabinoids created through isomerization
  - Synthetic cannabinoids

PRODUCT SAFETY

- Solvents and processing
  - Require food-grade solvents
  - Ban US Pharmacopeia class I solvents ("unacceptable toxicities or deleterious environmental effects")
  - Ban open butane processing and "any other method of processing the department determines poses a risk to health and safety"
- Explicit ban on sale to minor qualifying patients/qualifying out-of-state patients
- Reserve samples

PRODUCT SAFETY

- Good Manufacturing Practices (GMPs)
- Quality Control & QC recordkeeping

- Limited sections effective immediately for products currently produced and dispensed, mostly replaces §75 with similar requirements
- Effective immediately for new products
- Effective January 1, 2023 for existing products

GOOD MANUFACTURING PRACTICE

- Personnel*
- Facility and grounds*
- Sanitary operations*
- Sanitary facilities and controls*
- Equipment and utensils
- Processes and control
- Warehousing and distribution

QUALITY CONTROL

- Standard operating procedures
- Batch production and distribution records
- Quality control review and disposition decisions
- Returned cannabis or manufactured cannabis products
- Product complaints
- Adverse events*
- Recalls
- Recordkeeping for quality control

PACKAGING & LABELING

PACKAGING

- Dosage limits
  - Changed from D9-THC to total THC (10 mg/serving and 1000 mg/package)
  - "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;
    (2) Delta-9-tetrahydrocannabinol (D9-THC);
    (3) Delta-8-tetrahydrocannabinol (D8-THC); and
    (4) Delta-10-tetrahydrocannabinol (D10-THC).

LABELING

- Labeling
  - Label concentration for total THC, D9-THC, CBD, and "any other cannabinoid specifically listed or described in the label or packaging"
  - Ingredient statement
  - For products intended for topical use: "For external use only"

LABELING - READABILITY

- Letters or numbers must be at least 1/16 inch in height
- All words, statements, and other *required* information must be prominently placed with such conspicuousness *(as compared with other words, statements, designs, or devices, in the labeling)* and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use

SAMPLING

SAMPLING

- Definitions relating to sampling
  - Batch
  - Final form
  - Representative sample
  - Reserve sample
- Clarifications
  - Samples must be representative
  - Samples must be taken after the batch has completed all production steps as outlined in standard operating procedures, except packaging and labeling, and is in its final form
  - Sample size must be sufficient to complete all required laboratory analyses and laboratory quality control analyses
  - Statistically valid sampling plan and sampling plan recordkeeping

RESERVE SAMPLES

- Maintain two reserve samples from each batch:
  - In the same packaging in which the product is dispensed
  - Under conditions consistent with the label or, if no storage conditions are recommended on the label, under ordinary storage conditions
  - For one year past the use by date
- Make reserve samples available for analysis or request laboratory analysis of reserve samples as directed

TESTING

CANNABINOID CONTENT

- Total THC
- Delta-9 THC
- CBD
- Any other cannabinoid listed, described, or advertised in the label or packaging

CONTAMINANTS

- Heavy metals – no change
- Pesticides – codifying current guidance
- Solvents
  - More comprehensive list, similar to California requirements
  - Banned USP class 1 solvents added
  - Changing concentration limits for butane, heptane, hexane, toluene, xylenes

CONTAMINANTS

- Microbial contaminants: focusing on those of public health concern
  - Removed: Total viable aerobic bacteria, total yeast and mold, total coliforms, bile tolerant gram negative bacteria
  - Added: Aspergillus terreus
  - Limit changed from <1 CFU/g to "not detected in 1 gram," allowing non-plating methods

- Mycotoxins separated into 2 types
  - Aflatoxins (total of B1, B2, G1, G2) limit 20 ppb
  - Ochratoxin A limit 20 ppb

WATER ACTIVITY

- Replaces moisture content
- Cannabis only <.65 a_w

RELATING TO HEMP

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- No hemp production or processing is allowed in medical cannabis production centers
  - Dispensary licensees can also be hemp processors, but hemp processing facility must be separate
- Chapter 11-37 compliant hemp products may be used as an ingredient in a manufactured cannabis product
- Chapter 11-37 compliant hemp products may be sold in dispensary retail locations

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