

# **Summary of Amendments Ch. 11-37 (Interim Rules) Hawaii Administrative Rules – “Hemp Processing and Manufactured Hemp Products”**

**Interim rule effective date January 28, 2026**

Prepared by Department of Health – Office of Medical Cannabis Control and Regulation

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## Disclaimer

**This document is for informational purposes only and does not replace Chapter 11-37, Hawaii Administrative Rules (Interim Rules) effective date January 28, 2026. Readers should refer to the official version of the interim rules for complete and accurate information and consult their own legal counsel for specific legal advice.**

Access to Chapter 11-37 (interim rules), HAR, be found at:

DOH - Office of Planning, Policy and Program Development <https://health.hawaii.gov/opppd/administrative-rules/>

Or DOH - Office of Medical Cannabis Control and Regulation <https://health.hawaii.gov/hempprogram/har-statutes/>

Questions? Email [DOH.hemp@doh.hawaii.gov](mailto:DOH.hemp@doh.hawaii.gov)

# Summary of Key Changes to Interim Rules

(1) Add NEW definitions and requirements for businesses, including online operators, to obtain certificate of registration to sell manufactured hemp products (MHP).

- “Certificate of Registration”
- “Manufactured hemp product distributor”
- “Manufactured hemp product retailer”
- “Registrant”
- “Registry”
- “Sale, “sell”, or “selling”
- “Temporary Event”
- “Tincture”

Please visit our Hemp Program page at [www.health.hawaii.gov/hempprogram](http://www.health.hawaii.gov/hempprogram) for Retailer and Distributor FAQ and instructions on how to register your business to sell and/or distribute MHP.

(2) Amend total THC limits and add age restriction for sale of oil-based tinctures:

Edible MHP	Max total THC p/serving	Max total THC p/container	Max Volume limit p/container	Total THC must remain $\leq 0.3\%$	Restricted Sale to 21 or Older
Oil-based tincture	3 mg	85 mg	1 oz.	Yes	Yes

(3) Clarify that ingredients used to make an edible MHP shall be limited to those allowed in food and be manufactured in compliance with federal regulations.

## Summary of Key Changes to Interim Rules (cont.)

- (4) Inspection authority. Clarify that a business selling or distributing any product containing or derived from hemp, or marketed as containing or being derived from hemp shall:
- Permit entry to DOH for purpose of inspection to verify compliance
  - Give access to all parts of property, books, papers, records
  - Allow DOH to take samples and conduct tests to verify compliance
  - Not refuse to allow inspection at any of its facilities, and its employees and personnel shall not delay or interfere with any inspection.
- (5) Seizure of products, forfeiture, disposition:
- DOH may seize and confiscate any product containing or derived from hemp, or marketed as containing or being derived from hemp, that is possessed, kept, stored, retained, held, owned, received, acquired, distributed, sold, or offered for sale in violation of this chapter. The department shall not be responsible for the care and maintenance of the products seized.
  - Any product seized under this section may be subject to forfeiture and destruction by the department pursuant to a final order finding that a violation of this chapter has been committed.
  - When DOH imposes an administrative order for the forfeiture of seized products, the department shall notify the owner of the seized products in writing of the reason for the forfeiture.
  - The owner of the seized products may appeal the administrative order by submitting a written request for a hearing to the department not later than twenty days from the date of the order.

NOTE: DOH maintains existing authority to embargo and detain any product containing hemp or derived from hemp that is in violation of this chapter or chapter 328G, HRS.

# Overview of Crude Extract and Manufactured Hemp Products

- DOH hemp processor permit required to process, manufacture, package, repackage, label or relabel. Must follow Ch. 11-37 interim rules (facility design, GMP's, testing, labeling, training, recordkeeping, recall procedures, etc.).
- Comply with package labeling and lab testing requirements for cannabinoid content and contaminants
- Non-hemp ingredients must be allowed for use in food, manufactured in compliance with federal regulations and safe for human consumption (*applies to crude extract and edible MHP*).
- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Multi-serving package must be in continuous child resistant container (*applies to edible MHP*).
- Cannot resemble commercially available candy or other products marketed to children or have appearance, flavor or smell designed to appeal to children. Cannot be in shape of human, animal, fruit, cartoon characters or caricatures. "Candy" and "candies" cannot be used on packaging, labeling, advertising (*applies to edible and topical MHPs*)
- In-state sale to consumer: Edible MHP must comply with p/serving and p/container total THC mg limits.
- Out-of-state sale to consumer: Edible MHP that exceeds total THC mg limits for in-state sale, can be sold to consumers in another state or country (*applies to DOH permitted Hemp Processors only*).

# Hemp Crude Extract

“Crude extract” means an extract from hemp biomass that:

- (1) Has not been processed to concentrate or remove botanical constituents after the initial extraction is made;
- (2) Has not undergone the complete manufacturing process into a manufactured hemp product; and
- (3) Is not yet fit for use or consumption by consumers.



Establish unique requirements for testing, labeling and sale of crude extract:

Lab Test for Cannabinoid Content and Contaminants	Label Information (partial list)	Sale Allowed	Sale Prohibited
<ul style="list-style-type: none"> <li>• Total THC (sum of THCA, D9 THC and D8 THC)</li> </ul> <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> <li>• Mycotoxins</li> </ul>	<ul style="list-style-type: none"> <li>• Total THC mg p/container.</li> <li>• Provides access to lab results</li> <li>• Ingredient list</li> <li>• Required statements informing not fit for consumer consumption and sale allowed only to permitted hemp processors.</li> </ul>	<ul style="list-style-type: none"> <li>• Only between DOH permitted hemp processors.</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>• To/from a permitted hemp processor in another state or country (if allowed).</li> </ul>	<ul style="list-style-type: none"> <li>• To consumer</li> <li>• If total THC &gt; 0.3%</li> <li>• Exceeds mycotoxin limit</li> </ul>

- Specific section detailing allowance to filter, press, add ingredients that only dilute and stabilize.
- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.

# GUMMIES - Edible MHP

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

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.



Requirements for the sale, manufacture, testing, packaging and labeling of gummies:

Serving size limit	Max Total THC p/serving	Max Total THC p/container	Total THC must remain $\leq 0.3\%$	Non-hemp Ingredients	Compliant with Required Lab Testing	Child resistant packaging	Label Information (partial list)
1 gummy	1 mg	5 mg	Yes	<ul style="list-style-type: none"> <li>• Approved for use in food</li> <li>• Complies with federal rules</li> </ul>	<ul style="list-style-type: none"> <li>• Cannabinoid content</li> <li>• Contaminants</li> </ul>	Required for container with multi-servings	<ul style="list-style-type: none"> <li>• Total THC mg p/serving, plus amount p/serving of other cannabinoids (i.e., CBD)</li> <li>• Provides access to lab results</li> <li>• Ingredient list</li> <li>• Directions for use</li> <li>• Required statements and warnings, including “Not for sale to persons under the age of 21.”</li> </ul>

# BEVERAGE - Edible MHP

Allowed as edible manufactured hemp product.

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.



Requirements for the sale, manufacture, testing, packaging and labeling of a beverage:

Max Total THC p/container	Total THC must remain ≤0.3%	Volume limit p/container	Non-hemp Ingredients	Compliant with Required Lab Testing	Child resistant packaging	Label Information (partial list)
0.5 mg	Yes	No less than 6 fl. oz and no more than 12 fl. oz.	<ul style="list-style-type: none"> <li>• Approved for use in food</li> <li>• Complies with federal rules</li> </ul>	<ul style="list-style-type: none"> <li>• Cannabinoid content</li> <li>• Contaminants</li> </ul>	Required for container with multi-servings	<ul style="list-style-type: none"> <li>• Total THC mg p/serving, plus amount p/serving of other cannabinoids (i.e., CBD)</li> <li>• Provides access to lab results</li> <li>• Ingredient list</li> <li>• Directions for use</li> <li>• Required statements and warnings, including “Not for sale to persons under the age of 21.”</li> </ul>

# OIL-BASED TINCTURE - Limits on total THC, Ingredients, Volume

- **SALE PROHIBITED TO CONSUMER UNDER 21 YEARS OF AGE.**
- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.
- Must be packaged with dropper or spray top.



Requirements for the sale, manufacture, testing, packaging and labeling of oil-based tinctures:

Max Total THC p/serving	Max Total THC p/container	Total THC must remain ≤0.3%	Volume limit p/container	Non-hemp Ingredients	Compliant with Lab Testing	Child resistant packaging	Label Information (partial list)
3 mg	85 mg	Yes	Max 1 oz.	<ul style="list-style-type: none"> <li>• Cannot be used to sweeten or to add flavor</li> <li>• Approved for use in food</li> <li>• Complies with federal rules</li> </ul>	<ul style="list-style-type: none"> <li>• Cannabinoid content</li> <li>• Contaminants</li> </ul>	Required for container with multi-servings	<ul style="list-style-type: none"> <li>• Total THC mg p/serving, plus amount p/serving of other cannabinoids (i.e., CBD)</li> <li>• Provides access to lab results</li> <li>• Ingredient list</li> <li>• Directions for use</li> <li>• Required statements and warnings, including “Not for sale to persons under the age of 21.”</li> </ul>

# TABLETS, CAPSULES, POWDERS, SOFTGELS, AND GELCAPS

Allowed as manufactured hemp product to be orally consumed.

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.



Requirements for the sale, manufacture, testing, packaging and labeling of tablets, capsules, powders, softgels, and gelcaps:

Serving size limit	Max Total THC p/serving	Max Total THC p/container	Total THC must remain ≤0.3%	Non-hemp Ingredients	Compliant with Required Lab Testing	Child resistant packaging	Label Information (partial list)
<ul style="list-style-type: none"> <li>• 1 tablet</li> <li>• 1 capsule</li> <li>• 1 pk powder</li> <li>• 1 softgel</li> <li>• 1 gelcap</li> </ul>	1 mg	5 mg	Yes	<ul style="list-style-type: none"> <li>• Approved for use in food</li> <li>• Complies with federal rules</li> </ul>	<ul style="list-style-type: none"> <li>• Cannabinoid content</li> <li>• Contaminants</li> </ul>	Required for container with multi-servings	<ul style="list-style-type: none"> <li>• Total THC mg p/serving, plus amount p/serving of other cannabinoids (i.e., CBD)</li> <li>• Provides access to lab results</li> <li>• Ingredient list</li> <li>• Directions for use</li> <li>• Required statements and warnings, including “Not for sale to persons under the age of 21.”</li> </ul>

# TOPICAL MANUFACTURED HEMP PRODUCTS

Allowed as manufactured hemp product to be applied topically

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.



Requirements for the sale, manufacture, testing, packaging and labeling of a topical:

Max Total THC p/container	Total THC must remain ≤0.3%	Volume limit p/container	Non-hemp Ingredients	Compliant with Required Lab Testing	Child resistant packaging	Label Information (partial list)
N/A	Yes	N/A	Safe for human use	<ul style="list-style-type: none"> <li>• Cannabinoid content</li> <li>• Contaminants</li> </ul>	N/A	<ul style="list-style-type: none"> <li>• Total THC mg p/container, plus amounts of other cannabinoids (i.e., CBD) in container.</li> <li>• Provides access to lab results</li> <li>• Ingredient list</li> <li>• Directions for use</li> <li>• Required statements and warnings, including “For external use only” and “Not for sale to persons under the age of 21.”</li> </ul>

# DOH Permitted Processors - MHP Sale Outside the State

§11-37-6: DOH Permitted Hemp Processor requirements for the manufacture, holding and sale of MHPs that are not allowed for sale in Hawaii because it exceeds the total THC mg limits established for edible MHP in §11-37-5(a) & (b):

Total THC must remain ≤0.3%	Required Lab Testing Prior to Sale	Required Label Information Prior to Sale	Sale Allowed	Sale Prohibited	Limitations
Yes	<ul style="list-style-type: none"> <li>• Must meet lab testing requirements in interim rules to determine cannabinoid content and compliance with contaminant limits.</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>• Meet the testing requirements of state or country MHP to be sold in prior to shipment.</li> </ul>	<ul style="list-style-type: none"> <li>• Must meet labeling requirements found in interim rules.</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>• Meet the labeling requirements of the state or country to be sold in prior to shipment.</li> </ul>	To consumers, retailers and distributors in another state or country (if allowed)	To consumers, retailers and distributors in Hawaii.	<p>MHP must comply with all other requirements in interim rules. This means only:</p> <ul style="list-style-type: none"> <li>• Oil-based tinctures,</li> <li>• Gummies,</li> <li>• Beverages,</li> <li>• Tablets,</li> <li>• Capsules,</li> <li>• Powders,</li> <li>• Softgels,</li> <li>• Gelcaps,</li> <li>• Topicals (nonedible MHP, however §11-37-6 applies to all MHP forms) can be made and must adhere to all rules regarding packaging, volume, use of ingredients, etc.</li> </ul>

- DOH permitted hemp processor must store MHP intended for out of state sale in clearly marked quarantine area that is separate from other MHP's intended for sale to consumers in Hawaii.
- Records maintained on quantity of product shipped and name, address, phone number of distributor, retailer or individual.

# Bulk Manufactured Hemp Products

§11-37-7: DOH Permitted Hemp Processor requirements for the sale and purchase of bulk MHPs that are not allowed for sale in Hawaii because it exceeds the total THC mg limits established for edible MHP in §11-37-5(a) & (b):

Total THC must remain ≤0.3%	Required Lab Testing Prior to Sale	Required Label Information Prior to Sale	Sale and Purchase Allowed	Sale Prohibited	Limitations
Yes	<ul style="list-style-type: none"> <li>• Must meet lab testing requirements in interim rules to determine cannabinoid content and compliance with contaminant limits.</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>• Meet the testing requirements of state or country where MHP is to be sold prior to shipment.</li> </ul>	<ul style="list-style-type: none"> <li>• Must meet labeling requirements found in interim rules.</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>• Meet the labeling requirements of the state or country to be sold in prior to shipment.</li> </ul>	<ul style="list-style-type: none"> <li>• To/from DOH permitted processor</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>• To/from permitted hemp processor in another state or country (if allowed)</li> </ul>	To consumers, retailers, distributors and processors not authorized by the state or country they operate in.	<p>Bulk MHP must comply with all other requirements in interim rules. This means only bulk packages of:</p> <ul style="list-style-type: none"> <li>• Oil-based tinctures,</li> <li>• Gummies,</li> <li>• Beverages,</li> <li>• Tablets,</li> <li>• Capsules,</li> <li>• Powders,</li> <li>• Softgels,</li> <li>• Gelcaps,</li> <li>• Topicals (nonedible MHP, however §11-37-7 applies to all MHP forms) can be made and must adhere to all rules regarding use of ingredients, artificial and synthetic cannabinoids, etc.</li> </ul>

# Crude Extract and MHPs for Use by Medical Cannabis Licensees

- §11-850-77 interim rules amended to allow a medical cannabis licensee to use hemp crude extract and MHPs, that are compliant with §11-37 interim rules, for use in a medical cannabis product (except medical cannabis liquid SPA cartridges).
- A medical cannabis licensee must obtain a DOH hemp processor permit to purchase crude extract and bulk MHPs as in-state sale of these products are only allowed between DOH permitted hemp processors (see §11-37-3(i) and §11-37-7 for criteria to sell crude and bulk MHPs).

# PROHIBITIONS ON SALE §11-37-3

Sale, hold for sale, offer or distribute of the following is PROHIBITED:

- Crude extract or MHP that is adulterated or misbranded
- Crude extract or MHP that fails to meet applicable testing requirements
- Any food into which a cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, hemp, hemp biomass, or MHP has been added as ingredient. \*This does not apply to hemp that is GRAS by FDA for use in foods, nor allowable edible MHP forms that are compliant with §11-37-5 (tablets, capsules, powders, softgels, gelcaps, oil-based tinctures, gummies, beverages).
- Crude extract or MHP that has total THC concentration above 0.3%.
- Vape or other product used to aerosolize for respiratory routes of delivery containing hemp-derived cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, or hemp.
- Hemp leaf, hemp floral material, including but not limited to hemp cigars or hemp cigarettes, viable seeds. \*This does not apply to sale of hemp leaf, hemp floral material, or viable seeds to a USDA licensed hemp producer or a DOH permitted hemp processor.

# PROHIBITIONS ON SALE §11-37-3 (continued)

Sale, hold for sale, offer or distribute of the following is PROHIBITED:

- MHP containing any viable seeds, leaf or floral materials.
- Except for external topically applied MHP, any product containing a hemp-derived cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, hemp, hemp biomass, or MHP as an ingredient intended to be introduced via non-oral routes of entry to body (i.e., eyes, ears and nasal cavities, etc.).
- Crude extract directly to a consumer. \*Crude extract shall only be sold to a permitted hemp processor or person with equivalent authority from regulatory agency in another jurisdiction (i.e., another state or country).
- Contents from an open package of MHP to a consumer. \*Sample packs of MHP must comply with all packaging, labeling and testing requirements.
- Advertising, packaging, labeling that contains health or benefit claims that are unsubstantiated, false, or misleading in any way. \*Excludes FDA approved drugs that contain cannabinoids.