
A BILL FOR AN ACT

RELATING TO HEALTH.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. The legislature finds that the use and sales of
2 cannabidiol and cannabidiol products in the State has increased
3 significantly in the last few years. While there may be some
4 potential health benefits by using cannabidiol and cannabidiol
5 products, research is still being conducted and, as a result,
6 there is widespread confusion and misunderstanding about the
7 potential benefits and negative health risks of cannabidiol.

8 The legislature further finds that since 2015, the federal
9 Food and Drug Administration has issued nearly fifty warning
10 letters to firms marketing products that allegedly contain
11 cannabidiol and found that many of the products did not contain
12 the levels of cannabidiol they claimed to contain. Furthermore,
13 the Food and Drug Administration warns consumers that
14 cannabidiol products are not approved for the diagnosis, cure,
15 mitigation, treatment, or prevention of any disease.

16 The legislature also finds that despite efforts to educate
17 the public about the risks of cannabidiol and prohibit and



1 regulate cannabidiol as a food product, food additive, and
2 cosmetic, it is being marketed as a "dietary supplement" in an
3 effort to circumvent regulation.

4 The federal Agriculture Improvement Act of 2018 (P.L.
5 115-334) removed hemp from the Controlled Substances Act so that
6 cannabis plants and derivatives that contain no more than 0.3
7 per cent of delta-9 tetrahydrocannabinol are no longer
8 controlled substances under federal law. However, the law
9 explicitly preserved the Food and Drug Administration's
10 authority to regulate products containing cannabis or cannabis-
11 derived compounds under the federal Food, Drug, and Cosmetic Act
12 and section 351 of the Public Health Service Act. Additionally,
13 the department of health regulates all cannabis-derived
14 products, regardless of whether they are derived from hemp,
15 which is consistent with the Food and Drug Administration's
16 approach.

17 The legislature further finds that the State's industrial
18 hemp pilot program was enacted, in part, to allow the
19 cultivation of industrial hemp for purposes of agricultural or
20 academic research. However, licensees under the pilot program
21 are currently unable to participate in the cannabidiol



1 marketplace due to provisions that were adopted prior to the
 2 growth of cannabidiol in the consumer marketplace. In order to
 3 properly assess the viability of an industrial hemp industry in
 4 the State, licensees should be allowed to produce cannabidiol
 5 derived from their industrial hemp and legally have an avenue
 6 for the cannabidiol to make it to the consumer market.

7 The purpose of this Act is to:

- 8 (1) Expressly regulate cannabidiol under the department of
 9 health to be consistent with the Hawaii Food, Drug,
 10 and Cosmetic Act under chapter 328, Hawaii Revised
 11 Statutes, including mirroring certain provisions of
 12 the medical cannabis dispensary system under chapter
 13 329D, Hawaii Revised Statutes; and
- 14 (2) Allow licensees under the industrial hemp pilot
 15 program to market their products to the consumer
 16 market in a manner that is regulated and tested for
 17 safety, purity, and potency.

18 SECTION 2. Chapter 328, Hawaii Revised Statutes, is
 19 amended by adding a new part to be appropriately designated and
 20 to read as follows:

21 "PART . CANNABIDIOL PRODUCTS



1 **§328- Objective.** The purpose of this part is to
2 establish the minimum laboratory testing and labeling
3 requirements for cannabidiol products consistent with the
4 Agriculture Improvement Act of 2018, Public Law 115-334, which
5 explicitly preserves the authority to regulate products
6 containing cannabis or cannabis-derived compounds under the
7 Federal Food, Drug, and Cosmetic Act and section 351 of the
8 Public Health Service Act.

9 **§328- Definitions.** As used in this part,
10 "cannabidiol", or "cannabidiol product" means any product
11 derived from cannabis sativa that contains cannabidiol,
12 including cannabidiol derived from hemp as defined in the
13 Agriculture Improvement Act of 2018, Public Law 115-334, with a
14 delta-9 tetrahydrocannabinol, or "THC", concentration of not
15 more than 0.3 per cent on a dry weight basis.

16 **§328- Prohibitions.** Unless approved by the department
17 or sold with and through a physician or advanced practice
18 registered nurse recommendation, cannabidiol shall not be:

- 19 (1) Manufactured, distributed, or sold as a food product
20 or cosmetic;
21 (2) Added to food, beverages, or cosmetics;



- 1 (3) Marketed or sold as a dietary supplement; or
- 2 (4) Distributed or sold to any minor under the age of
- 3 eighteen years old.

4 **§328- Laboratory standards and testing.** (a) Any
 5 cannabidiol product to be manufactured, distributed, or sold in
 6 the State shall be required to undergo laboratory testing by a
 7 laboratory that is certified by the department.

8 (b) The department shall establish and enforce standards
 9 for laboratory-based testing of cannabidiol and cannabidiol
 10 products for content, contamination, and consistency, including
 11 pesticides regulated by the United States Environmental
 12 Protection Agency, microbiological impurities, and heavy metals.

13 (c) Prior to the department adopting rules specifically
 14 for cannabidiol and cannabidiol products, all cannabidiol and
 15 cannabidiol products shall be tested in the same manner and
 16 under the same standards as required for medical cannabis under
 17 section 329D-8 and its regulatory counterparts under title 11,
 18 chapter 850, subchapter 7 of the Hawaii administrative rules, as
 19 amended.

20 **§328- Marketing and labeling.** (a) The department
 21 shall establish standards regarding the advertising and



1 packaging of cannabidiol and cannabidiol products; provided that
2 the standards, at a minimum, shall require the use of packaging
3 that:

- 4 (1) Is child-resistant and opaque so that the product
5 cannot be seen from outside the packaging;
- 6 (2) Uses only black lettering on a white background with
7 no pictures or graphics;
- 8 (3) Is clearly labeled with the phrase "Not for resale or
9 transfer to another person";
- 10 (4) Includes instructions for use and expiration date;
- 11 (5) Contains information about the contents and potency of
12 the product;
- 13 (6) Includes the name and location by country, state, and
14 city of the manufacturer where the cannabidiol or
15 cannabidiol product was manufactured, including the
16 date of packaging;
- 17 (7) Includes a listing of the equivalent physical weight
18 of the cannabidiol used to manufacture the amount of
19 the product that is within the packaging; and
- 20 (8) Includes a clear warning stating that the product:



1 (A) Is a medication that contains cannabidiol and is
2 not a food, dietary supplement, or cosmetic; and

3 (B) Should be kept away from children.

4 §328- Rulemaking. (a) The department shall adopt
5 rules pursuant to chapter 91 that include but are not limited
6 to:

- 7 (1) Inspection and sampling requirements of any
8 cannabidiol or cannabidiol products;
- 9 (2) Testing protocols, including certification by
10 independent third-party laboratories, to determine
11 delta-9-tetrahydrocannabinol concentration of
12 cannabidiol or cannabidiol products and screen for
13 contaminants;
- 14 (3) Reporting and record-keeping requirements;
- 15 (4) Assessment of fees for application, inspecting,
16 sampling, and testing cannabidiol processing;
- 17 (5) A procedure for the disposal of cannabidiol or
18 cannabidiol products found to be in violation of this
19 part;
- 20 (6) Penalties for any violation; and



1 (7) Any other rules and procedures necessary to carry out
2 this part.

3 (b) The department may adopt and amend interim rules,
4 which shall be exempt from chapter 91 and chapter 201M, to
5 effectuate the purposes of this part; provided that any interim
6 rules shall remain in effect until July 1, 2025, or until rules
7 are adopted pursuant to subsection (a), whichever occurs
8 sooner."

9 SECTION 3. Section 141-36, Hawaii Revised Statutes, is
10 amended to read as follows:

11 "§141-36 Growing of industrial hemp; licensee
12 responsibilities. The licensee shall:

13 (1) Assume a limited agency relationship with the board
14 for the sole purpose of research of industrial hemp
15 and its growth, cultivation, and marketability. The
16 licensee shall conduct all agricultural operations in
17 a lawful manner consistent with the standards
18 befitting of an official of the State; provided that
19 such standards are subject to the sole discretion and
20 direction of the board;



- 1 (2) Abide by applicable laws and regulations incident to
2 the growth, cultivation, or marketing of industrial
3 hemp;
- 4 (3) Acknowledge that any action, intended or incidental,
5 that is contrary to such laws and regulations, known
6 or unknown, falls outside the agency relationship of
7 the licensee with the board and the licensee's
8 participation in the industrial hemp pilot program;
9 provided that this paragraph applies to all actions
10 incident to the licensed production of industrial
11 hemp, including but not limited to any sale or
12 disposition of the resulting plants, plant materials,
13 or seeds for which the licensee may otherwise receive
14 some benefit or consideration;
- 15 (4) Indemnify, hold harmless, and release forever the
16 State and its departments, agencies, officers,
17 employees, and agents of any kind from all liability
18 claims arising out of the licensee's actions involving
19 the growth, cultivation, or marketing of industrial
20 hemp;



- 1 (5) Warrant that the licensee is not an employee of the
2 State and shall assume total and sole responsibility
3 for any of the licensee's acts or omissions involving
4 the growth or production of industrial hemp or arising
5 out of the licensee's participation in the industrial
6 hemp pilot program;
- 7 (6) Allow any institution of higher education in the State
8 to access those sites registered by the licensee with
9 the board for production of industrial hemp; provided
10 that such access shall be allowed upon notice from the
11 board to the licensee and shall extend for all
12 purposes determined at the discretion of the board
13 related to research of industrial hemp and its growth,
14 cultivation, and marketing;
- 15 (7) Upon request, allow federal, state, or local
16 authorities to inspect and sample the industrial hemp
17 growing area, plants, plant materials, seeds,
18 equipment, or facilities incident to the growth or
19 production of industrial hemp;
- 20 (8) Remit to the board all license fees and other expenses
21 of the pilot program, including but not limited to all



- 1 fees related to sampling and analysis of hemp plants
2 and plant materials and destruction of resulting hemp
3 crops found by the board to be noncompliant with
4 applicable laws and regulations;
- 5 (9) Agree that with respect to the licensee's production
6 of industrial hemp, the board's role is to fulfill
7 regulatory oversight of the production and, where
8 possible, to facilitate receipt of viable seed;
9 provided that the licensee understands and agrees that
10 the licensee shall not receive compensation or wages
11 from the board and the board shall not offer financial
12 resources, tangible products, or commercial labor in
13 support of the licensee's industrial hemp crop;
- 14 (10) Adhere narrowly to the research focus for which the
15 licensee is participating in the industrial hemp pilot
16 program, if applicable, to include one or more of the
17 following:
- 18 (A) Planting and growing--tracking vital statistics
19 and yield rates with respect to industrial hemp
20 varieties and growing variables, including seed



1 planting rate, soil composition, water usage, and
2 planting and growing season;

3 (B) Pest--tracking the occurrence of pests and
4 effectiveness of various preventative measures in
5 correlation with industrial hemp varieties;

6 (C) Cost centers and financing--tracking average cost
7 estimates of producing industrial hemp varieties,
8 taking into account costs of participation in the
9 industrial hemp pilot program, product
10 acquisition, water usage, equipment, labor, and
11 security measures and reporting financial
12 resources available for production of industrial
13 hemp; or

14 (D) Marketing and industry development--reporting
15 market demand for industrial hemp varieties' raw
16 materials and end products, including
17 identification of actual or potential hemp
18 products, including but not limited to
19 cannabidiol and cannabidiol products as defined
20 and authorized by the Agriculture Improvement Act
21 of 2018, Public Law 115-334; processors[7];



- 1 product manufacturers [7] i wholesalers [7] i
2 retailers [7] i and targeted consumers;
- 3 (11) Complete and submit all reports and statements
4 requested by the board relative to the licensee's
5 production of industrial hemp; provided that a failure
6 to submit any required or requested report may result
7 in revocation of the licensee's industrial hemp
8 license;
- 9 (12) Understand and agree that any industrial hemp grown in
10 Hawaii without an active industrial hemp license
11 issued by the board falls outside the licensee's
12 limited agency with the board, is considered to be
13 marijuana under state law, and constitutes
14 impermissible growth of industrial hemp under federal
15 law; provided that the licensee shall understand that
16 such action will be prosecuted in accordance with all
17 applicable laws;
- 18 (13) At the discretion of the board, destroy or dispose of
19 any industrial hemp crop, plant, plant material, or
20 seed determined by the board or law enforcement to be
21 noncompliant with applicable laws or regulations;



- 1 (14) Use best management practices for growth and
2 production of industrial hemp, as available, and take
3 reasonable precaution to prevent unauthorized growth
4 or distribution of industrial hemp, including but not
5 limited to:
- 6 (A) Keeping records of all persons with access to the
7 growing area or hemp plants, plant materials, or
8 seeds;
- 9 (B) Installing reasonable security measures to
10 prevent theft and posting signs indicating that
11 cameras are used to record activity on the
12 growing area property;
- 13 (C) Inspecting and recording regularly the condition
14 of the growing area, facilities, and equipment
15 used in the production of industrial hemp;
- 16 (D) Conducting regular inventory counts of hemp
17 plants, plant materials, and seeds in order to
18 recognize more quickly if a theft has occurred;
- 19 (E) Contacting local law enforcement to help identify
20 additional security measures and encourage
21 patrols near the growing area;



- 1 (F) Reporting to local law enforcement any suspicious
2 activity and the presence of strangers near the
3 growing area or facility;
- 4 (G) Reporting stolen, lost, or missing hemp plants,
5 plant materials, or seeds to the board and law
6 enforcement authorities as soon as the items are
7 noticed to be missing; and
- 8 (H) Reducing the likelihood of cross pollination
9 between varieties of industrial hemp and among
10 other plants by:
- 11 (i) Separating any growing area from other self-
12 pollinating plants by more than ten feet;
13 and
- 14 (ii) Separating any growing area from other wind
15 and insect pollinating plants by more than
16 three hundred feet; and
- 17 (15) Comply with any direction of the chairperson with
18 respect to the growth, cultivation, or marketing of
19 industrial hemp not otherwise contemplated in this
20 section."



1 SECTION 4. Section 141-38, Hawaii Revised Statutes, is
2 amended to read as follows:

3 "[+]§141-38[+] Violations. In addition to any other
4 violations of this part, the following acts and omissions by any
5 licensee or authorized representative thereof constitute
6 violations for which civil penalties up to \$500 and disciplinary
7 sanctions, including revocation of a license, may be imposed by
8 the chairperson:

- 9 (1) Refusal or failure by a licensee or authorized
10 representative to fully cooperate and assist the board
11 with the inspection process;
- 12 (2) Failure to provide any information required or
13 requested by the board for purposes pursuant to this
14 part;
- 15 (3) Providing false, misleading, or incorrect information
16 pertaining to the licensee's cultivation of industrial
17 hemp to the chairperson by any means, including but
18 not limited to information provided in any application
19 form, report, record, or inspection required or
20 maintained pursuant to this part;



- 1 (4) Growing industrial hemp that when tested is shown to
2 have a delta-9 tetrahydrocannabinol concentration
3 greater than 0.3 per cent on a dry weight basis or a
4 tetrahydrocannabinol concentration allowed by federal
5 law, whichever is greater;
- 6 (5) Failure to pay fees assessed by the chairperson for
7 inspection or laboratory analysis costs; or
- 8 (6) Possessing, outside of a field of lawful cultivation,
9 resin, flowering tops, or leaves that have been
10 removed from the hemp plant; provided that ~~the~~ :
- 11 (A) The presence of a de minimis amount, or
12 insignificant number, of hemp leaves or flowering
13 tops in hemp bales that result from the normal
14 and appropriate processing of industrial hemp;
15 and
- 16 (B) Possession and transport of resin and flowering
17 tops to a licensed medical cannabis dispensary
18 production center's approved manufacturing
19 facility,
- 20 shall not apply to this paragraph."



1 SECTION 5. Section 329D-9, Hawaii Revised Statutes, is
2 amended to read as follows:

3 " ~~[+]~~ §329D-9 ~~[+]~~ **Manufacturing of medical cannabis products.**

4 (a) Any medical cannabis dispensary licensed by the department
5 pursuant to this chapter shall be permitted to manufacture
6 cannabis products; provided that the dispensary shall also
7 obtain any other state or county permits or licenses that may be
8 necessary for a particular manufacturing activity.

9 (b) The department shall establish health, safety, and
10 sanitation standards regarding the manufacture of manufactured
11 cannabis products.

12 (c) A manufacturer of a manufactured cannabis product
13 shall calculate the equivalent physical weight of the cannabis
14 that is used to manufacture the product and shall make the
15 equivalency calculations available to the department and to a
16 consumer of the manufactured cannabis product.

17 (d) A facility that has been approved by the department
18 under this section shall apply to the department to use
19 cannabidiol and cannabidiol products in their manufactured
20 cannabis products when the cannabidiol or cannabidiol product is



1 derived from a licensed industrial hemp producer under chapter
2 141."

3 SECTION 6. Statutory material to be repealed is bracketed
4 and stricken. New statutory material is underscored.

5 SECTION 7. This Act shall take effect on July 1, 2050.



Report Title:

DOH; Cannabidiol; Laboratory Standards and Testing; Marketing and Labeling

Description:

Regulates cannabidiol under the department of health to be consistent with the Hawaii Food, Drug, and Cosmetic Act. Allows licensees under the industrial hemp pilot program to market their products to the consumer market in a manner that is regulated and tested for safety, purity, and potency. Effective 7/1/2050. (HD1)

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