

JAN 17 2020

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, the research is still being conducted and, as a
6 result, there is widespread confusion and misunderstanding about
7 the 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 to 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 2018 Farm Bill removed hemp from the Controlled
5 Substances Act so that cannabis plants and derivatives that
6 contain no more than 0.3 per cent of delta-9
7 tetrahydrocannabinol are no longer controlled substances under
8 federal law. However, the law explicitly preserved the Food and
9 Drug Administration's authority to regulate products containing
10 cannabis or cannabis-derived compounds under the federal Food,
11 Drug, and Cosmetic Act and section 351 of the Public Health
12 Service Act. Additionally, the state department of health
13 regulates all cannabis-derived products, regardless of whether
14 they are derived from hemp, which is consistent with the Food
15 and Drug Administration's approach.

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



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

6 The purpose of this Act is to:

7 (1) Expressly regulate cannabidiol under the department of
8 health to be consistent with the Hawaii Food, Drug,
9 and Cosmetic Act under chapter 328, Hawaii Revised
10 Statutes, including mirroring certain provisions of
11 the medical cannabis dispensary system under chapter
12 329D, Hawaii Revised Statutes; and

13 (2) Allow licensees under the industrial hemp pilot
14 program to market their products to the consumer
15 market in a manner that is regulated and tested for
16 safety, purity, and potency.

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

20 "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 2018
4 Farm Bill, Public Law 115-334, which explicitly preserves the
5 authority to regulate products containing cannabis or cannabis-
6 derived compounds under the Federal Food, Drug, and Cosmetic Act
7 and section 351 of the Public Health Service Act.

8 **§328- Definitions.** As used in this part, "cannabidiol",
9 or "cannabidiol product" means any product derived from cannabis
10 sativa that contains cannabidiol, including cannabidiol derived
11 from hemp as defined in the 2018 Farm Bill, Public Law 115-334,
12 with a delta-9 tetrahydrocannabinol, or "THC", concentration of
13 not more than 0.3 per cent on a dry weight basis.

14 **§328- Prohibitions.** Unless approved by the department
15 or sold with and through a physician or advanced practice
16 registered nurse recommendation, cannabidiol shall not be:

- 17 (1) Manufactured, distributed, or sold as a food product
18 or cosmetic;
- 19 (2) Added to food, beverages, or cosmetics;
- 20 (3) Marketed or sold as a dietary supplement; or



1 (4) Distributed or sold to any minor under the age of
2 eighteen years old.

3 §328- Laboratory standards and testing. (a) Any
4 cannabidiol product to be manufactured, distributed, or sold in
5 the State shall be required to undergo laboratory testing by a
6 laboratory that is certified by the department.

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

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

19 §328- Marketing and labeling. (a) The department shall
20 establish standards regarding the advertising and packaging of
21 cannabidiol and cannabidiol products; provided that the



1 standards, at a minimum, shall require the use of packaging
2 that:

- 3 (1) Is child-resistant and opaque so that the product
4 cannot be seen from outside the packaging;
- 5 (2) Uses only black lettering on a white background with
6 no pictures or graphics;
- 7 (3) Is clearly labeled with the phrase "For medical use
8 only";
- 9 (4) Is clearly labeled with the phrase "Not for resale or
10 transfer to another person";
- 11 (5) Includes instructions for use and expiration date;
- 12 (6) Contains information about the contents and potency of
13 the product;
- 14 (7) Includes the name and location by country, state, and
15 city of the manufacturer where the cannabidiol or
16 cannabidiol product was manufactured, including the
17 date of packaging;
- 18 (8) Includes a listing of the equivalent physical weight
19 of the cannabidiol used to manufacture the amount of
20 the product that is within the packaging; and
- 21 (9) 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 SECTION 3. Section 141-36, Hawaii Revised Statutes, is
5 amended to read as follows:

6 "**§141-36 Growing of industrial hemp; licensee**
7 **responsibilities.** The licensee shall:

- 8 (1) Assume a limited agency relationship with the board
- 9 for the sole purpose of research of industrial hemp
- 10 and its growth, cultivation, and marketability. The
- 11 licensee shall conduct all agricultural operations in
- 12 a lawful manner consistent with the standards
- 13 befitting of an official of the State; provided that
- 14 such standards are subject to the sole discretion and
- 15 direction of the board;
- 16 (2) Abide by applicable laws and regulations incident to
- 17 the growth, cultivation, or marketing of industrial
- 18 hemp;
- 19 (3) Acknowledge that any action, intended or incidental,
- 20 that is contrary to such laws and regulations, known
- 21 or unknown, falls outside the agency relationship of



1 the licensee with the board and the licensee's
2 participation in the industrial hemp pilot program;
3 provided that this paragraph applies to all actions
4 incident to the licensed production of industrial
5 hemp, including but not limited to any sale or
6 disposition of the resulting plants, plant materials,
7 or seeds for which the licensee may otherwise receive
8 some benefit or consideration;

9 (4) Indemnify, hold harmless, and release forever the
10 State and its departments, agencies, officers,
11 employees, and agents of any kind from all liability
12 claims arising out of the licensee's actions involving
13 the growth, cultivation, or marketing of industrial
14 hemp;

15 (5) Warrant that the licensee is not an employee of the
16 State and shall assume total and sole responsibility
17 for any of the licensee's acts or omissions involving
18 the growth or production of industrial hemp or arising
19 out of the licensee's participation in the industrial
20 hemp pilot program;



- 1 (6) Allow any institution of higher education in the State
2 to access those sites registered by the licensee with
3 the board for production of industrial hemp; provided
4 that such access shall be allowed upon notice from the
5 board to the licensee and shall extend for all
6 purposes determined at the discretion of the board
7 related to research of industrial hemp and its growth,
8 cultivation, and marketing;
- 9 (7) Upon request, allow federal, state, or local
10 authorities to inspect and sample the industrial hemp
11 growing area, plants, plant materials, seeds,
12 equipment, or facilities incident to the growth or
13 production of industrial hemp;
- 14 (8) Remit to the board all license fees and other expenses
15 of the pilot program, including but not limited to all
16 fees related to sampling and analysis of hemp plants
17 and plant materials and destruction of resulting hemp
18 crops found by the board to be noncompliant with
19 applicable laws and regulations;
- 20 (9) Agree that with respect to the licensee's production
21 of industrial hemp, the board's role is to fulfill



1 regulatory oversight of the production and, where
2 possible, to facilitate receipt of viable seed;
3 provided that the licensee understands and agrees that
4 the licensee shall not receive compensation or wages
5 from the board and the board shall not offer financial
6 resources, tangible products, or commercial labor in
7 support of the licensee's industrial hemp crop;

8 (10) Adhere narrowly to the research focus for which the
9 licensee is participating in the industrial hemp pilot
10 program, if applicable, to include one or more of the
11 following:

12 (A) Planting and growing--tracking vital statistics
13 and yield rates with respect to industrial hemp
14 varieties and growing variables, including seed
15 planting rate, soil composition, water usage, and
16 planting and growing season;

17 (B) Pest--tracking the occurrence of pests and
18 effectiveness of various preventative measures in
19 correlation with industrial hemp varieties;

20 (C) Cost centers and financing--tracking average cost
21 estimates of producing industrial hemp varieties,



1 taking into account costs of participation in the
2 industrial hemp pilot program, product
3 acquisition, water usage, equipment, labor, and
4 security measures and reporting financial
5 resources available for production of industrial
6 hemp; or

7 (D) Marketing and industry development--reporting
8 market demand for industrial hemp varieties' raw
9 materials and end products, including
10 identification of actual or potential hemp
11 products, including, but not limited to
12 cannabidiol and cannabidiol products as defined
13 and authorized by the 2018 Farm Bill, Public Law
14 115-334; processors [] ; product manufacturers [] ;
15 wholesalers [] ; retailers [] ; and targeted
16 consumers;

17 (11) Complete and submit all reports and statements
18 requested by the board relative to the licensee's
19 production of industrial hemp; provided that a failure
20 to submit any required or requested report may result



- 1 in revocation of the licensee's industrial hemp
2 license;
- 3 (12) Understand and agree that any industrial hemp grown in
4 Hawaii without an active industrial hemp license
5 issued by the board falls outside the licensee's
6 limited agency with the board, is considered to be
7 marijuana under state law, and constitutes
8 impermissible growth of industrial hemp under federal
9 law; provided that the licensee shall understand that
10 such action will be prosecuted in accordance with all
11 applicable laws;
- 12 (13) At the discretion of the board, destroy or dispose of
13 any industrial hemp crop, plant, plant material, or
14 seed determined by the board or law enforcement to be
15 noncompliant with applicable laws or regulations;
- 16 (14) Use best management practices for growth and
17 production of industrial hemp, as available, and take
18 reasonable precaution to prevent unauthorized growth
19 or distribution of industrial hemp, including but not
20 limited to:



- 1 (A) Keeping records of all persons with access to the
- 2 growing area or hemp plants, plant materials, or
- 3 seeds;
- 4 (B) Installing reasonable security measures to
- 5 prevent theft and posting signs indicating that
- 6 cameras are used to record activity on the
- 7 growing area property;
- 8 (C) Inspecting and recording regularly the condition
- 9 of the growing area, facilities, and equipment
- 10 used in the production of industrial hemp;
- 11 (D) Conducting regular inventory counts of hemp
- 12 plants, plant materials, and seeds in order to
- 13 recognize more quickly if a theft has occurred;
- 14 (E) Contacting local law enforcement to help identify
- 15 additional security measures and encourage
- 16 patrols near the growing area;
- 17 (F) Reporting to local law enforcement any suspicious
- 18 activity and the presence of strangers near the
- 19 growing area or facility;
- 20 (G) Reporting stolen, lost, or missing hemp plants,
- 21 plant materials, or seeds to the board and law



1 enforcement authorities as soon as the items are
2 noticed to be missing; and

3 (H) Reducing the likelihood of cross pollination
4 between varieties of industrial hemp and among
5 other plants by:

6 (i) Separating any growing area from other self-
7 pollinating plants by more than ten feet;
8 and

9 (ii) Separating any growing area from other wind
10 and insect pollinating plants by more than
11 three hundred feet; and

12 (15) Comply with any direction of the chairperson with
13 respect to the growth, cultivation, or marketing of
14 industrial hemp not otherwise contemplated in this
15 section."

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

18 "[+]§141-38[+] Violations. In addition to any other
19 violations of this part, the following acts and omissions by any
20 licensee or authorized representative thereof constitute
21 violations for which civil penalties up to \$500 and disciplinary



1 sanctions, including revocation of a license, may be imposed by
2 the chairperson:

3 (1) Refusal or failure by a licensee or authorized
4 representative to fully cooperate and assist the board
5 with the inspection process;

6 (2) Failure to provide any information required or
7 requested by the board for purposes pursuant to this
8 part;

9 (3) Providing false, misleading, or incorrect information
10 pertaining to the licensee's cultivation of industrial
11 hemp to the chairperson by any means, including but
12 not limited to information provided in any application
13 form, report, record, or inspection required or
14 maintained pursuant to this part;

15 (4) Growing industrial hemp that when tested is shown to
16 have a delta-9 tetrahydrocannabinol concentration
17 greater than 0.3 per cent on a dry weight basis or a
18 tetrahydrocannabinol concentration allowed by federal
19 law, whichever is greater;

20 (5) Failure to pay fees assessed by the chairperson for
21 inspection or laboratory analysis costs; or



1 (6) Possessing, outside of a field of lawful cultivation,
2 resin, flowering tops, or leaves that have been
3 removed from the hemp plant; provided that ~~the~~:

4 (A) The presence of a de minimis amount, or
5 insignificant number, of hemp leaves or flowering
6 tops in hemp bales that result from the normal
7 and appropriate processing of industrial hemp;
8 and

9 (B) Possession and transport of resin and flowering
10 tops to a licensed medical cannabis dispensary
11 production center's approved manufacturing
12 facility,

13 shall not apply to this paragraph."

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

16 "[+]§329D-9[+] **Manufacturing of medical cannabis products.**

17 (a) Any medical cannabis dispensary licensed by the department
18 pursuant to this chapter shall be permitted to manufacture
19 cannabis products; provided that the dispensary shall also
20 obtain any other state or county permits or licenses that may be
21 necessary for a particular manufacturing activity.



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1 (b) The department shall establish health, safety, and
 2 sanitation standards regarding the manufacture of manufactured
 3 cannabis products.

4 (c) A manufacturer of a manufactured cannabis product
 5 shall calculate the equivalent physical weight of the cannabis
 6 that is used to manufacture the product and shall make the
 7 equivalency calculations available to the department and to a
 8 consumer of the manufactured cannabis product.

9 (d) A facility that has been approved by the department
 10 under this section shall be authorized to use cannabidiol and
 11 cannabidiol products in their manufactured cannabis products
 12 when the cannabidiol or cannabidiol product is derived from a
 13 licensed industrial hemp producer under chapter 141."

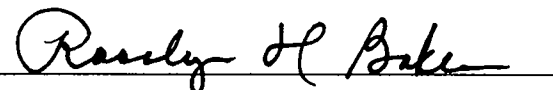
14 SECTION 6. Statutory material to be repealed is bracketed
 15 and stricken. New statutory material is underscored.

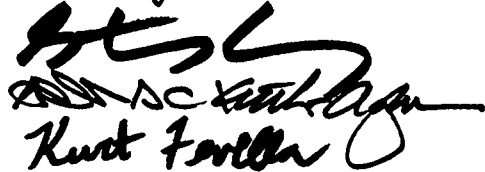
16 SECTION 7. This Act shall take effect on July 1, 2020.

17

INTRODUCED BY:









S.B. NO. 2274



Anna Morales

Clara Morales



S.B. NO. 2274

Report Title:

Cannabidiol; Department of Health; 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.

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