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# 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[τ]; product manufacturers[τ];  
15 wholesalers[τ]; retailers[τ]; 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.





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



**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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