THE SENATE
THIRTIETH LEGISLATURE, 2019
STATE OF HAWAII

S.B. NO. 527

JAN 18 2019

A BILL FOR AN ACT

RELATING TO CANNABIS FOR MEDICAL USE.

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

SECTION 1. The legislature finds that studies have shown the benefits of using cannabis to alleviate certain serious illnesses. The legislature further finds that several states permit the sales of edible cannabis products, either for recreational use or for medical use. These states generally place restrictions on edible cannabis products, such as limiting the amount of psychoactive ingredients per serving, banning manufacturers from making candy-like edibles that might attract children, and requiring proper labeling. Proper labeling and portioning of edible products are especially important, as edible cannabis products are responsible for the majority of cannabis intoxications. In addition, requiring an education protocol for patients prior to the use of edible cannabis products will help reduce the risk of inadvertent overconsumption and accidental intoxication.

The legislature also finds that some states have imposed additional regulations on cannabis and manufactured cannabis

products, including a product recall system and the use of a universal symbol to clearly identify products containing cannabis.

Accordingly, the purpose of this Act is to:

(1) Legalize the manufacturing of edible cannabis products for medical purposes;

(2) Establish standards, including regulations and education protocols, for edible cannabis products;

(3) Require packaging to include a universal symbol, to be developed by the department of health, that identifies any product containing cannabis; and

(4) Require the department of health to implement a cannabis product recall system.

SECTION 2. Section 328-1, Hawaii Revised Statutes, is amended by amending the definition of "food" to read as follows:

""Food" means:

(1) Articles used for food or drink by humans, dogs, or cats;

(2) Chewing gum; or

(3) Articles used for components of any such article.

"Food" does not include edible cannabis products, as defined in section 329D-10."

SECTION 3. Section 329D-1, Hawaii Revised Statutes, is amended by amending the definition of "manufactured cannabis product" to read as follows:

""Manufactured cannabis product" means any [~~capsule, lozenge, oil or oil extract, tincture, ointment or skin lotion, pill, transdermal patch, or pre-filled and sealed container used to aerosolize and deliver cannabis orally, such as an inhaler or nebulizer,~~] product that has been manufactured using cannabis[~~, or any other products as specified by the department~~] pursuant to section 329D-10[~~(a)(9)~~]."

SECTION 4. Section 329D-9, Hawaii Revised Statutes, is amended by amending subsection (b) to read as follows:

"(b) The department shall establish health, safety, and sanitation standards regarding the manufacture of manufactured cannabis products[~~.~~]; provided that the standards for the manufacture of edible cannabis products:

(1) Shall only be manufactured in a facility that meets the minimum sanitary requirements adopted by the department of health that are at least equivalent to

the standards for food establishments provided for in chapter 11-50, Hawaii Administrative Rules;

(2) Shall not be manufactured in any facility permitted by the department of health as a food establishment; and

(3) Shall not be manufactured in any home kitchen."

SECTION 5. Section 329D-10, Hawaii Revised Statutes, is amended to read as follows:

"**§329D-10 Types of manufactured cannabis products.** (a) The types of medical cannabis products that may be manufactured and distributed pursuant to this chapter shall be limited to:

(1) Capsules;

(2) Lozenges;

(3) Pills;

(4) Oils and oil extracts;

(5) Tinctures;

(6) Ointments and skin lotions;

(7) Transdermal patches;

(8) Pre-filled and sealed containers used to aerosolize and deliver cannabis orally, such as with an inhaler or nebulizer; provided that containers need not be manufactured by the licensed dispensary but shall be

filled with cannabis, cannabis oils, or cannabis extracts manufactured by the licensed dispensary; shall not contain nicotine, tobacco-related products, or any other non-cannabis derived products; and shall be designed to be used with devices used to provide safe pulmonary administration of manufactured cannabis products;

(9) Devices that provide safe pulmonary administration; provided that:

(A) The heating element of the device, if any, is made of inert materials such as glass, ceramic, or stainless steel, and not of plastic or rubber;

(B) The device is distributed solely for use with single-use, pre-filled, tamper-resistant, sealed containers that do not contain nicotine or other tobacco products;

(C) The device is used to aerosolize and deliver cannabis by inhalation, such as an inhaler, medical-grade nebulizer, or other similar medical grade volitization device;

(D) There is a temperature control on the device that is regulated to prevent the combustion of cannabis oil; [~~and~~]

(E) The device need not be manufactured by the licensed dispensary; [~~and~~]

(10) Edible cannabis products; and

[~~(10)~~] (11) Other products as specified by the department.

(b) As used in this section[~~, "lozenge"~~]:

"Edible cannabis products" means manufactured cannabis products that are intended to be used, in whole or in part, for gastrointestinal administration of medical cannabis, including but not limited to chewing gum, drinks, baked products, and candy; provided that edible cannabis products:

(1) Shall be tested and specifically labeled for each product's dosage and strength;

(2) Shall not include products such as gummies, brightly colored candies, or other products that the department determines may attract children or bear resemblance to other commercially available products;

(3) May include liquid products that contain no more than ten milligrams of activated tetrahydrocannabinol per serving; and

(4) Shall not include non-shelf stable, potentially hazardous food items, or products containing non-cannabinoid ingredients that would increase the potency, toxicity, or addictive potential of cannabis, or create an unsafe combination with other psychoactive substances.

"Lozenge" means a small tablet manufactured in a manner to allow for the dissolving of its medicinal or therapeutic component slowly in the mouth."

SECTION 6. Section 329D-11, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) The department shall establish standards regarding the advertising and packaging of cannabis and manufactured cannabis products[~~.~~], including the establishment and adoption of a universal symbol to allow consumers to readily identify products containing cannabis or cannabinoid extracts; provided that the standards, at a minimum, shall require the use of packaging that:

(1) Is child-resistant and opaque so that the product cannot be seen from outside the packaging;

(2) Uses only black lettering on a white background with no pictures or graphics; provided that this paragraph shall not apply to the use of a universal symbol;

(3) Is clearly labeled with the phrase "For medical use only";

(4) Is clearly labeled with the phrase "Not for resale or transfer to another person";

(5) Includes instructions for use and "use by date";

(6) Contains information about the contents and potency of the product;

(7) Includes the name of the production center where cannabis in the product was produced, including the batch number and date of packaging;

(8) Includes a barcode generated by tracking software; [~~and~~];

(9) Includes a universal symbol; and

[~~(9)~~] (10) In the case of a manufactured cannabis product, includes a:

(A) Listing of the equivalent physical weight of the cannabis used to manufacture the amount of the product that is within the packaging, pursuant to section 329D-9(c);

(B) Clearly labeled warning stating that the product:

(i) Is a medication that contains cannabis, and is not a food; and

(ii) Should be kept away from children; and

(C) Date of manufacture"

SECTION 7. Section 329D-7, Hawaii Revised Statutes, is amended to read as follows:

"**§329D-7 Medical cannabis dispensary rules.** The department shall establish standards with respect to:

(1) The number of medical cannabis dispensaries that shall be permitted to operate in the State;

(2) A fee structure for the submission of applications and renewals of licenses to dispensaries; provided that the department shall consider the market conditions in each county in determining the license renewal fee amounts;

(3) Criteria and procedures for the consideration and selection, based on merit, of applications for licensure of dispensaries; provided that the criteria shall include but not be limited to an applicant's:

(A) Ability to operate a business;

(B) Financial stability and access to financial resources; provided that applicants for medical cannabis dispensary licenses shall provide documentation that demonstrates control of not less than $1,000,000 in the form of escrow accounts, letters of credit, surety bonds, bank statements, lines of credit or the equivalent to begin operating the dispensary;

(C) Ability to comply with the security requirements developed pursuant to paragraph (6);

(D) Capacity to meet the needs of qualifying patients and qualifying out-of-state patients;

(E) Ability to comply with criminal background check requirements developed pursuant to paragraph (8); and

(F) Ability to comply with inventory controls developed pursuant to paragraph (13);

(4) Specific requirements regarding annual audits and reports required from each production center and dispensary licensed pursuant to this chapter;

(5) Procedures for announced and unannounced inspections by the department or its agents of production centers and dispensaries licensed pursuant to this chapter; provided that inspections for license renewals shall be unannounced;

(6) Security requirements for the operation of production centers and retail dispensing locations; provided that, at a minimum, the following shall be required:

(A) For production centers:

(i) Video monitoring and recording of the premises; provided that recordings shall be retained for fifty days;

(ii) Fencing that surrounds the premises and that is sufficient to reasonably deter intruders and prevent anyone outside the premises from viewing any cannabis in any form;

(iii) An alarm system; and

(iv) Other reasonable security measures to deter or prevent intruders, as deemed necessary by the department;

(B) For retail dispensing locations:

(i) Presentation of a valid government-issued photo identification and a valid identification as issued by the department pursuant to section 329-123 by a qualifying patient or caregiver, or section 329-123.5 by a qualifying out-of-state patient or caregiver of a qualifying out-of-state patient, upon entering the premises;

(ii) Video monitoring and recording of the premises; provided that recordings shall be retained for fifty days;

(iii) An alarm system;

(iv) Exterior lighting; and

(v) Other reasonable security measures as deemed necessary by the department;

(7) Security requirements for the transportation of cannabis and manufactured cannabis products between production centers and retail dispensing locations and between a production center, retail dispensing location, qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient and a certified laboratory, pursuant to section 329-122(f);

(8) Standards and criminal background checks to ensure the reputable and responsible character and fitness of all license applicants, licensees, employees, subcontractors and their employees, and prospective employees of medical cannabis dispensaries to operate a dispensary; provided that the standards, at a minimum, shall exclude from licensure or employment any person convicted of any felony;

(9) The training and certification of operators and employees of production centers and dispensaries;

(10) The types of manufactured cannabis products that dispensaries shall be authorized to manufacture and sell pursuant to sections 329D-9 and 329D-10;

(11) Laboratory standards related to testing cannabis and manufactured cannabis products for content, contamination, and consistency;

(12) The quantities of cannabis and manufactured cannabis products that a dispensary may sell or provide to a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient; provided that no dispensary shall sell or provide to a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient any combination of cannabis and manufactured products that:

(A) During a period of fifteen consecutive days, exceeds the equivalent of four ounces of cannabis; or

(B) During a period of thirty consecutive days, exceeds the equivalent of eight ounces of cannabis;

(13) Dispensary and production center inventory controls to prevent the unauthorized diversion of cannabis or manufactured cannabis products or the distribution of

cannabis or manufactured cannabis products to a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient in quantities that exceed limits established by this chapter; provided that the controls, at a minimum, shall include:

(A) A computer software tracking system as specified in section 329D-6(j) and (k); and

(B) Product packaging standards sufficient to allow law enforcement personnel to reasonably determine the contents of an unopened package;

(14) Limitation to the size or format of signs placed outside a retail dispensing location or production center; provided that the signage limitations, at a minimum, shall comply with section 329D-6(o)(2) and shall not include the image of a cartoon character or other design intended to appeal to children;

(15) The disposal or destruction of unwanted or unused cannabis and manufactured cannabis products;

(16) The implementation of a product recall system to ensure that any cannabis or manufactured cannabis

product determined or suspected to be tainted or detrimental to the public health care be rapidly identified and returned, destroyed, or removed from retail;

[~~(16)~~] (17) The enforcement of the following prohibitions against:

(A) The sale or provision of cannabis or manufactured cannabis products to unauthorized persons;

(B) The sale or provision of cannabis or manufactured cannabis products to a qualifying patient, primary caregiver, qualifying out-of-state patient, or caregiver of a qualifying out-of-state patient in quantities that exceed limits established by this chapter;

(C) Any use or consumption of cannabis or manufactured cannabis products on the premises of a retail dispensing location or production center; and

(D) The distribution of cannabis or manufactured cannabis products, for free, on the premises of a retail dispensing location or production center;

[~~(17)~~] (18) The establishment of a range of penalties for violations of this chapter or rule adopted thereto; and

[~~(18)~~] (19) A process to recognize and register patients who are authorized to purchase, possess, and use medical cannabis in another state, a United States territory, or the District of Columbia as qualifying out-of-state patients; provided that this registration process may commence no sooner than January 1, 2018."

SECTION 8. Section 329D-26, Hawaii Revised Statutes, is amended to read as follows:

"**[~~†~~] §329D-26 [~~†~~] Public education.** (a) The department shall conduct a continuing education and training program to explain and clarify the purposes and requirements of this chapter or to provide substance abuse prevention and education. The program shall target community partner agencies, physicians and other health care providers, patients and caregivers, law enforcement agencies, law and policy makers, and the general public.

(b) The department shall establish a mandatory standard pre-purchasing education protocol to take place at the point of

sale to all qualifying patients or qualifying out-of-state patients who have not previously consumed edible cannabis products, or their caregivers, to reduce the risk of inadvertent overconsumption and accidental intoxication.

[~~(b)~~] (c) The department shall employ at least one full-time staff member whose qualifications and duties include the provision of medical cannabis health education."

SECTION 9. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 10. This Act shall take effect upon its approval.

INTRODUCED BY:

S.B. NO. 527

Report Title:
Medical Cannabis; Edibles; Manufactured Cannabis Products; Warning Labels; Recall System; Universal Symbol; Education Program; Department of Health

Description:
Authorizes and regulates the manufacturing of edible cannabis products as manufactured cannabis products by licensed medical cannabis dispensaries. Establishes standards, including regulations and education protocols, for edible cannabis products. Requires cannabis and manufactured cannabis products to include a universal symbol, developed by the department of health, to identify any product containing cannabis. Requires the department of health to implement a cannabis product recall system.

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