HOUSE OF REPRESENTATIVES
TWENTY-NINTH LEGISLATURE, 2018
STATE OF HAWAII

H.B. NO. 2534

A BILL FOR AN ACT

RELATING TO MEDICAL CANNABIS.

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

SECTION 1. The legislature finds that Act 241, Session Laws of Hawaii 2015, codified as Hawaii Revised Statutes chapter 329D, established a license scheme for a statewide system of medical cannabis dispensaries to ensure access to medical cannabis for qualifying patients. Further amendments to the dispensary program were made by Act 230, Session Laws of Hawaii 2016, and by Act 41, Session Laws of Hawaii 2017.

The legislature further finds that the medical cannabis dispensary program still lacks clear administrative guidelines for independent laboratory certification. To date, two laboratories in the State are certified to test a limited range of the statutorily-permitted medical cannabis product forms. There is no laboratory currently certified to test all of the permitted cannabis product forms. This has not only resulted in delays for dispensary licensees to dispense explicitly permitted products, it also prevents qualified patients from accessing the

range of products that they may need to treat their specific conditions.

The legislature further finds that some of the testing requirements and standards established in the administrative rules governing the medical cannabis dispensary program are based on requirements and standards previously implemented in other jurisdictions but Hawaii's administrative rules do not include the corresponding action limits or thresholds of compliance. Therefore, Hawaii's administrative rules lack clear medical cannabis sampling guidelines. This has resulted in widely varying sampling protocols and sample weights, which in turn results in widely varying testing costs that are passed onto and borne by qualifying patients.

The legislature further finds that the current administrative rules lack a process for dispensary licensees to appeal test results or challenge the validity of testing methodologies employed by licensed laboratories. This potentially has a negative impact on patient access to certain types of medical cannabis products since certain testing methodologies commonly produce inaccurate results when applied to genetic variants of cannabis that are rich in cannabidiol.

The purpose of this Act is to establish standards for independent laboratory testing for medical cannabis including:

(1) Evidence-based action limits for Environmental Protection Agency registered pesticides and microbial contaminants that have been successfully employed in other jurisdictions in the United States;

(2) Fixed sample size and sampling protocol for batches of medical cannabis and manufactured cannabis products; and

(3) A clear appeal process for laboratory test results.

SECTION 2. Section 329D-8, Hawaii Revised Statutes, is amended to read as follows:

"**§329D-8 Laboratory standards and testing; laboratory certification.** (a) The department shall establish and enforce standards for laboratory-based testing of cannabis and manufactured cannabis products for content, contamination, and consistency[~~.~~] by requiring that a certified laboratory issue a certificate of analysis for each batch of cannabis and manufactured cannabis products as required under this section to include results and supporting data for the following:

(1) The chemical profile of the batch for the following compounds:

(A) Delta 9 Tetrahydrocannabinol (THC);

(B) Tetrahydrocannabinolic Acid (THCA);

(C) Cannabidiol (CBD);

(D) Cannabidiolic Acid (CBDA);

(E) Cannabigerol (CBG); and

(F) Cannabinol (CBD);

(2) The presence of the following heavy metal contaminants, which shall not exceed the following parts per million (ppm) levels:

(A) Arsenic: 10 ppm;

(B) Lead: 6 ppm;

(C) Cadmium: 4 ppm; and

(D) Mercury: 2 ppm;

(3) The presence of Environmental Protection Agency-regulated pesticides which shall not exceed the following levels:

(A) Abamectin: 1 ppm;

(B) Acephate: 1 ppm;

(C) Acequinocyl: 2 ppm;

(D) Acetamiprid: 1 ppm;

(E) Aldicarb: 1 ppm;

(F) Azoxystrobin: 1 ppm;

(G) Bifenazate: 1 ppm;

(H) Bifenthrin: 1 ppm;

(I) Boscalid: 1 ppm;

(J) Carbaryl: 1 ppm;

(K) Carbofuran: 1 ppm;

(L) Chlorantraniliprole: 1 ppm;

(M) Chlorfenapyr: 1 ppm;

(N) Chlorpyrifos: 1 ppm;

(O) Clofentezine: 1 ppm;

(P) Cyfluthrin: 1 ppm;

(Q) Cypermethrin: 1 ppm;

(R) Dichlorvos (DDVP): 1 ppm;

(S) Diazinon: 1 ppm;

(T) Dimethoate: 1 ppm;

(U) Ethoprophos: 1 ppm;

(V) Etofenprox: 1 ppm;

(W) Etoxazole: 1 ppm;

(X) Fenpyroximate: 1 ppm;

(Y) Fipronil: 1 ppm;

(Z) Flonicamid: 1 ppm;

(AA) Fludioxonil: 1 ppm;

(AB) Hexythianox: 1 ppm;

(AC) Imazalil: 0.1 ppm;

(AD) Imidacloprid: 1 ppm;

(AE) Kresoxim-methyl: 1 ppm;

(AF) Malathion: 1 ppm;

(AG) Metalaxil: 1 ppm;

(AH) Methiocarb: 1 ppm;

(AI) Methomyl: 1 ppm;

(AJ) Methyl parathion: 1 ppm;

(AK) MGK-264: 1 ppm;

(AL) Myclobutanil: 1 ppm;

(AM) Naled: 1 ppm;

(AN) Oxamyl: 1 ppm;

(AO) Paclobutrazol: 1 ppm;

(AP) Permethrins: 1 ppm;

(AQ) Phosmet: 1 ppm;

(AR) Piperonyl butoxide: 1 ppm;

(AS) Prallethrin: 1 ppm;

(AT) Propiconazole: 1 ppm;

(AU) Propoxur: 1 ppm;

(AV) Pyrethrins: 1 ppm;

(AW) Pyridaben: 1 ppm;

(AX) Spinosad: 1 ppm;

(AY) Spiromesifen: 1 ppm;

(AZ) Spirotetramat: 1 ppm;

(AAA) Tebuconazole: 1 ppm;

(AAB) Thiacloprid: 1 ppm;

(AAC) Thiamethoxam: 1 ppm; and

(AAD) Trifloxystrobin: 1 ppm;

(4) The presence of solvents, which shall not exceed the following levels:

(A) Butanes: 800 ppm;

(B) Heptanes: 500 ppm;

(C) Benzene: 1 ppm;

(D) Toluene: 1 ppm;

(E) Hexane: 10 ppm; and

(F) Total xylenes (m,o,p-xylene): 1 ppm;

(5) Any visible foreign or extraneous material that is not intended to be part of the product being produced,

including but not limited to mold, hair, insects, metal, or plastic;

(6) Moisture content of plant material which shall be less than fifteen per cent;

(7) Microbiological impurities, including but not limited to:

(A) Total viable aerobic bacteria, which shall not exceed:

(i) Unprocessed and processed materials: 100,000 colony forming units per gram; and

(ii) Carbon dioxide and solvent based extracts: 10,000 colony forming units per gram;

(B) Total yeast and mold, which shall not exceed:

(i) Unprocessed and processed materials: 20,000 colony forming units per gram; and

(ii) Carbon dioxide and solvent based extracts: 100 colony forming units per gram.

(C) Total coliforms, which shall not exceed:

(i) Unprocessed and processed materials: 1,000 colony forming units per gram; and

(ii) Carbon dioxide and solvent based extracts: 100 colony forming units per gram.

(D) Bile-tolerant gram-negative bacteria, which shall not exceed:

(i) Unprocessed and processed materials: 1,000 colony forming units per gram; and

(ii) Carbon dioxide and solvent based extracts: 100 colony forming units per gram.

(E) E. coli (pathogenic strains) and salmonella spp., which shall not be detected in 1 gram;

(F) Aspergillus fumigatus, Aspergillus flavus, and Aspergillus niger, which shall not exceed 1 colony forming units per gram; and

(G) Mycotoxins, which shall not exceed 20 micrograms per kilogram of material.

(b) The department may adopt additional standards; provided that in establishing these standards, the department shall:

(1) Review and take guidance from the testing programs and standards utilized in other jurisdictions;

(2) Consider the impact of the standards on the retail cost of the product to the qualifying patient;

(3) Review and take guidance from the testing programs and standards for pesticides under the regulations of the United States Environmental Protection Agency;

(4) For the testing for microbiological impurities, consider the benefits of organically grown cannabis that features the use of bacteria in lieu of pesticides; and

(5) Include permission for qualifying patients and primary caregivers to obtain testing services directly from certified laboratories on the island where the qualifying patient and primary caregiver reside.

(c) In conducting testing for cannabis and manufactured cannabis products pursuant to this section, a certified laboratory shall randomly select the minimal sample required for statistical representativeness from each batch of medical cannabis or manufactured cannabis products provided by the licensed dispensary; provided that:

(1) The maximum batch size for cannabis flower shall be _____; and

(2) The maximum batch size for manufactured cannabis products shall be the equivalent of one gallon, or its equivalent weight, of cannabis extract.

(d) The department shall provide a dispensary licensee the opportunity for resampling and retesting of a failed batch of medical cannabis or manufactured cannabis products by a certified laboratory; provided that:

(1) If the retesting results in a second failing result, the batch shall be considered to have definitively failed; and

(2) If the retesting results in a passing result, the department shall:

(A) Review the two results and make a determination as to whether the batch has passed or failed, or whether additional testing is required; and

(B) Notify the dispensary licensee and the relevant certified laboratories of its decision within five business days.

(e) The department shall establish a process that conforms with the requirements of chapter 91 to permit a dispensary

licensee to challenge the validity of a testing methodology employed by a certified laboratory as follows:

(1) The dispensary licensee shall submit to the department, in writing, its basis and justification for the challenge along with relevant evidence, background information, and any supporting data;

(2) The department shall notify the certified laboratory whose testing methodology is the subject of the challenge and shall provide the laboratory with an opportunity to respond in writing and to submit evidence, background information, and data to rebut the challenge; and

(3) The department shall evaluate the written submissions and make a final determination as to the validity of the testing methodology being challenged within thirty days, and notify all dispensary licensees and certified laboratories of the final determination.

[~~(b)~~] (f) The department may certify laboratories that can test cannabis and manufactured cannabis products prior to the sale of cannabis and manufactured cannabis products."

SECTION 3. This Act does not affect rights and duties that matured, penalties that were incurred, and proceedings that were begun before its effective date.

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

SECTION 5. This Act shall take effect upon its approval.

INTRODUCED BY: John M. Mizuno

JAN 2 3 2018

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Report Title:
Medical Cannabis Laboratory Testing

Description:
Establishes standards for medical cannabis testing and certification.

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