1	HOUSE BILL NO. 598	
2	INTRODUCED BY M. HOPKINS	
3		
4	A BILL FOR AN ACT ENTITLED: "AN ACT REQUIRING THE STATE ENVIRONMENTAL LABORATORY TO	
5	LICENSE AND INSPECT TESTING LABORATORIES UNDER THE MONTANA MEDICAL MARIJUANA ACT;	
6	PROVIDING RULEMAKING AUTHORITY; AND AMENDING SECTIONS 50-46-302, 50-46-303, 50-46-311	
7	50-46-312, 50-46-326, 50-46-329, AND 50-46-344, MCA."	
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9	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:	
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11	Section 1. Section 50-46-302, MCA, is amended to read:	
12	"50-46-302. Definitions. As used in this part, the following definitions apply:	
13	(1) "Canopy" means the total amount of square footage dedicated to live plant production at a registered	
14	premises consisting of the area of the floor, platform, or means of support or suspension of the plant.	
15	(2) "Chemical manufacturing" means the production of marijuana concentrate.	
16	(3) "Correctional facility or program" means a facility or program that is described in 53-1-202 and to	
17	which an individual may be ordered by any court of competent jurisdiction.	
18	(4) "Debilitating medical condition" means:	
19	(a) cancer, glaucoma, positive status for human immunodeficiency virus, or acquired immune deficiency	
20	syndrome when the condition or disease results in symptoms that seriously and adversely affect the patient's	
21	health status;	
22	(b) cachexia or wasting syndrome;	
23	(c) severe chronic pain that is persistent pain of severe intensity that significantly interferes with daily	
24	activities as documented by the patient's treating physician;	
25	(d) intractable nausea or vomiting;	
26	(e) epilepsy or an intractable seizure disorder;	
27	(f) multiple sclerosis;	
28	(g) Crohn's disease;	
29	(h) painful peripheral neuropathy;	
30	(i) a central nervous system disorder resulting in chronic, painful spasticity or muscle spasms;	

1 (j) admittance into hospice care in accordance with rules adopted by the department; or

(k) posttraumatic stress disorder.

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- 3 (5) "Department" means the department of public health and human services provided for in 2-15-2201.
- 4 (6) "Dispensary" means a registered premises from which a provider or marijuana-infused products
 5 provider is approved by the department to dispense marijuana or marijuana-infused products to a registered
 6 cardholder.
 - (7) (a) "Employee" means an individual employed to do something for the benefit of an employer or a third person.
 - (b) The term includes a manager, agent, or director of a partnership, association, company, corporation, limited liability company, or organization.
 - (8) "Local government" means a county, a consolidated government, or an incorporated city or town.
- 12 (9) "Marijuana" has the meaning provided in 50-32-101.
 - (10) "Marijuana concentrate" means any type of marijuana product consisting wholly or in part of the resin extracted from any part of the marijuana plant.
 - (11) "Marijuana derivative" means any mixture or preparation of the dried leaves, flowers, resin, and byproducts of the marijuana plant, including but not limited to marijuana concentrates and marijuana-infused products.
 - (12) (a) "Marijuana-infused product" means a product that contains marijuana and is intended for use by a registered cardholder by a means other than smoking.
 - (b) The term includes but is not limited to edible products, ointments, and tinctures.
 - (13) (a) "Marijuana-infused products provider" means a person licensed by the department to manufacture and provide marijuana-infused products for a registered cardholder.
 - (b) The term does not include the cardholder's treating or referral physician.
- 24 (14) "Mature marijuana plant" means a harvestable female marijuana plant that is flowering.
- 25 (15) "Paraphernalia" has the meaning provided in 45-10-101.
- 26 (16) "Person" means an individual, partnership, association, company, corporation, limited liability company, or organization.
- 28 (17) (a) "Provider" means a person licensed by the department to assist a registered cardholder as 29 allowed under this part.
 - (b) The term does not include a cardholder's treating physician or referral physician.



- 1 (18) "Referral physician" means an individual who:
- 2 (a) is licensed under Title 37, chapter 3;

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- 3 (b) has an established office in Montana; and
- 4 (c) is the physician to whom a patient's treating physician has referred the patient for physical 5 examination and medical assessment.
 - (19) "Registered cardholder" or "cardholder" means a Montana resident with a debilitating medical condition who has received and maintains a valid registry identification card.
 - (20) "Registered premises" means the location at which a provider or marijuana-infused products provider:
 - (a) has indicated that marijuana will be cultivated, chemical manufacturing will occur, or marijuana-infused products will be manufactured for a registered cardholder; or
 - (b) has established a dispensary for sale of marijuana or marijuana-infused products to a registered cardholder.
 - (21) "Registry identification card" means a document issued by the department pursuant to 50-46-303 that identifies an individual as a registered cardholder.
 - (22) (a) "Resident" means an individual who meets the requirements of 1-1-215.
 - (b) An individual is not considered a resident for the purposes of this part if the individual:
- 18 (i) claims residence in another state or country for any purpose; or
- (ii) is an absentee property owner paying property tax on property in Montana.
- 20 (23) "Second degree of kinship by blood or marriage" means a mother, father, brother, sister, son, 21 daughter, spouse, grandparent, grandchild, mother-in-law, father-in-law, brother-in-law, sister-in-law, son-in-law, 22 daughter-in-law, grandparent-in-law, grandchild-in-law, stepfather, stepmother, stepsother, stepson, 23 stepdaughter, stepgrandparent, or stepgrandchild.
 - (24) "Seedling" means a marijuana plant that has no flowers and is less than 12 inches in height and 12 inches in diameter.
 - (25) "Standard of care" means, at a minimum, the following activities when undertaken by a patient's treating physician or referral physician if the treating physician or referral physician is providing written certification for a patient with a debilitating medical condition:
 - (a) obtaining the patient's medical history;
 - (b) performing a relevant and necessary physical examination;



1 (c) reviewing prior treatment and treatment response for the debilitating medical condition;

(d) obtaining and reviewing any relevant and necessary diagnostic test results related to the debilitating
 medical condition;

- (e) discussing with the patient and ensuring that the patient understands the advantages, disadvantages, alternatives, potential adverse effects, and expected response to the recommended treatment;
 - (f) monitoring the response to treatment and possible adverse effects; and
- (g) creating and maintaining patient records that remain with the physician.
- (26) "State laboratory" means the laboratory operated by the department of public health and human services to conduct environmental analyses.
- (26)(27) "Testing laboratory" means a qualified person, licensed by the department, who meets the requirements of 50-46-311 and:
 - (a) provides testing of small samples of marijuana and marijuana-infused products; and
- (b) provides information regarding the chemical composition, the potency of a sample, and the presence of molds or pesticides in a sample.
- 15 (27)(28) "Treating physician" means an individual who:
- 16 (a) is licensed under Title 37, chapter 3;

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- 17 (b) has an established office in Montana; and
 - (c) has a bona fide professional relationship with the individual applying to be a registered cardholder.
 - (28)(29) (a) "Usable marijuana" means the dried leaves and flowers of the marijuana plant and any marijuana derivatives that are appropriate for the use of marijuana by an individual with a debilitating medical condition.
 - (b) The term does not include the seeds, stalks, and roots of the plant.
- 23 (29)(30) "Written certification" means a statement signed by a treating physician or referral physician that
 24 meets the requirements of 50-46-310 and is provided in a manner that meets the standard of care."
- Section 2. Section 50-46-303, MCA, is amended to read:
 - "50-46-303. Department responsibilities -- issuance of cards and licenses -- confidentiality -- inspections -- reports. (1) The department shall establish and maintain a program for:
- (a) the issuance of registry identification cards to Montana residents who have debilitating medical
 conditions and who submit applications meeting the requirements of this part;



(b) the issuance of licenses:

- (i) to persons who apply to operate as providers, <u>or</u> marijuana-infused products providers, <u>or testing</u>

 laboratories and who submit applications meeting the requirements of this part; and
 - (ii) for dispensaries established by providers or marijuana-infused products providers; and
- (iii) through the state laboratory, to testing laboratories that submit applications meeting the requirements of this part;
- (c) the issuance of endorsements for chemical manufacturing to a provider or a marijuana-infused products provider who applies for a chemical manufacturing endorsement and meets requirements established by the department by rule; and
- (d) the tracking of marijuana and marijuana-infused products from either the seed or the immature plant stage until the marijuana or marijuana-infused product is sold to a registered cardholder to ensure that the marijuana or marijuana-infused product cultivated, manufactured, possessed, and sold under this part is not sold or otherwise provided to an individual who is not authorized under this part to possess the item. The tracking system must be provided to providers, marijuana-infused products providers, dispensaries, and testing laboratories at no additional cost.
- (2) (a) An individual who obtains a registry identification card and does not name a provider or marijuana-infused products provider is authorized to cultivate, manufacture, possess, and transport marijuana as allowed by this part.
- (b) An individual who obtains a registry identification card and names a provider or marijuana-infused products provider is authorized to possess marijuana as allowed by this part.
- (c) A person who obtains a provider, marijuana-infused products provider, or dispensary license or an employee of a licensee is authorized to cultivate, manufacture, possess, sell, and transport marijuana as allowed by this part.
- (d) A person who obtains a testing laboratory license or an employee of a licensee is authorized to possess, test, and transport marijuana as allowed by this part.
- (3) The department shall conduct criminal history background checks as required by 50-46-307 and 50-46-308 before issuing a license to a person named as a provider or marijuana-infused products provider.
 - (4) (a) Registry identification cards and licenses issued pursuant to this part must:
- (i) be laminated and produced on a material capable of lasting for the duration of the time period forwhich the card or license is valid;



(ii) state the name, address, and date of birth of the registered cardholder and of the cardholder's provider or marijuana-infused products provider, if any;

- (iii) indicate whether a provider or marijuana-infused products provider has an endorsement for chemical
 manufacturing;
 - (iv) state the date of issuance and the expiration date of the registry identification card or license;
- 6 (v) contain a unique identification number; and

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- 7 (vi) contain other information that the department may specify by rule.
- 8 (b) Except as provided in subsection (4)(c), in addition to complying with subsection (4)(a), registry 9 identification cards issued pursuant to this part must:
 - (i) include a picture of the registered cardholder; and
 - (ii) be capable of being used to track registered cardholder purchases.
 - (c) The department may issue temporary identification cards valid for 60 days that do not meet the requirements of subsection (4)(b).
 - (5) (a) The department <u>or state laboratory</u>, <u>as applicable</u>, shall review the information contained in an application or renewal submitted pursuant to this part and shall approve or deny an application or renewal within 30 days of receiving the application or renewal and all related application materials.
 - (b) The department shall issue a registry identification card, license, or endorsement within 5 days of approving an application or renewal.
 - (6) Rejection of an application or renewal is considered a final department action, subject to judicial review.
 - (7) (a) Registry identification cards expire 1 year after the date of issuance unless:
- 22 (i) a physician has provided a written certification stating that a card is valid for a shorter period of time; 23 or
 - (ii) a registered cardholder changes providers or marijuana-infused products providers.
 - (b) Licenses and endorsements issued to providers, marijuana-infused products providers, and testing laboratories must be renewed annually.
 - (8) (a) A registered cardholder shall notify the department of any change in the cardholder's name, address, physician, provider, or marijuana-infused products provider or change in the status of the cardholder's debilitating medical condition within 10 days of the change.
 - (b) A registered cardholder who possesses mature plants or seedlings under 50-46-319(1) shall notify



the department of the location of the plants and seedlings or any change of location of plants or seedlings. The department shall provide the names and locations of cardholders who possess mature plants or seedlings to the local law enforcement agency having jurisdiction in the area in which the plants or seedlings are located. The law enforcement agency and its employees are subject to the confidentiality requirements of 50-46-332.

- (c) If a change occurs and is not reported to the department, the registry identification card is void.
- (9) The department shall maintain a confidential list of individuals to whom the department has issued registry identification cards. Except as provided in subsections (8)(b) and (10), individual names and other identifying information on the list must be confidential and are not subject to disclosure, except to:
- (a) authorized employees of the department as necessary to perform the official duties of the department; and
- (b) authorized employees of state or local government agencies, including law enforcement agencies, only as necessary to verify that an individual is a lawful possessor of a registry identification card.
- (10) The department shall provide the names and phone numbers of providers and marijuana-infused products providers and the city, town, or county where registered premises and testing laboratories are located to the public on the department's website. The department may not disclose the physical location or address of a provider, marijuana-infused products provider, dispensary, or testing laboratory.
- (11) The department may share only information about providers, marijuana-infused products providers, dispensaries, and testing laboratories with the department of revenue for the purpose of investigation and prevention of noncompliance with tax laws, including but not limited to evasion, fraud, and abuse. The department of revenue and its employees are subject to the confidentiality requirements of 15-64-111(1).
- (12) The department shall report biannually to the legislature the number of applications for registry identification cards, the number of registered cardholders approved, the nature of the debilitating medical conditions of the cardholders, the number of providers and marijuana-infused products providers licensed, the number of endorsements approved for chemical manufacturing, the number of testing laboratories licensed, the number of dispensaries licensed, the number of registry identification cards and licenses revoked, the number of physicians providing written certification for registered cardholders, and the number of written certifications each physician has provided. The report may not provide any identifying information of cardholders, physicians, providers, marijuana-infused products providers, dispensaries, or testing laboratories.
- (13) The board of medical examiners shall report annually to the legislature on the number and types of complaints the board has received involving physician practices in providing written certification for the use of



marijuana, pursuant to 37-3-203."

- Section 3. Section 50-46-311, MCA, is amended to read:
- **"50-46-311. Testing laboratories.** (1) (a) The department state laboratory shall license testing laboratories that meet the requirements of this part to measure the tetrahydrocannabinol and cannabidiol content of marijuana and marijuana-infused products and to test marijuana and marijuana-infused products for pesticides, solvents, water levels, mold, and other contaminants. A testing laboratory may transport samples to be tested.
- (b) The analytical laboratory services provided by the department of agriculture pursuant to 80-1-104 may be used for the testing provided for in this section.
- (2) A person with a financial interest in a licensed testing laboratory may not have a financial interest in a provider for whom testing services are performed.
- (3) Each licensed testing laboratory shall employ a scientific director who is responsible for ensuring the achievement and maintenance of quality standards of practice. The scientific director must have the following minimum qualifications:
- (a) a doctorate in chemical or biological sciences from a college or university accredited by a national or regional certifying authority and a minimum of 2 years of postdegree laboratory experience; or
- (b) a master's degree in chemical or biological sciences from a college or university accredited by a national or regional certifying authority and a minimum of 4 years of postdegree laboratory experience.
- (4) All owners and employees of a testing laboratory shall submit fingerprints to the department state laboratory to facilitate a fingerprint and background check by the department of justice and the federal bureau of investigation. A testing laboratory may not be owned, operated, or staffed by a person who has been convicted of a felony offense.
 - (5) To qualify for licensure, a testing laboratory shall demonstrate that:
 - (a) staff members are proficient in operation of the laboratory equipment;
 - (b) the laboratory maintains the equipment and instrumentation required by rule;
- (c) the laboratory meets insurance and bonding requirements established by rule; and
- (d) the laboratory has passed a relevant proficiency program. The department state laboratory shall establish by rule the proficiency programs considered relevant for the purposes of this section.
 - (6) Except as provided in 50-46-326(1)(b), a testing laboratory shall conduct tests of:
 - (a) samples of marijuana, marijuana concentrate, and marijuana-infused products submitted by providers



1 and marijuana-infused products providers pursuant to 50-46-326 and related administrative rules prior to sale of 2 the marijuana or marijuana-infused products;

- (b) samples of marijuana or marijuana-infused products collected by the department during inspections of registered premises; and
 - (c) samples submitted by registered cardholders."

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- **Section 4.** Section 50-46-312, MCA, is amended to read:
- **"50-46-312. License as privilege -- criteria.** (1) A provider, marijuana-infused products provider, dispensary, or testing laboratory license or an endorsement for chemical manufacturing is a privilege that the state may grant to an applicant and is not a right to which an applicant is entitled. In making a licensing decision, the department shall consider:
 - (a) the qualifications of the applicant; and
 - (b) the suitability of the proposed registered premises.
- (2) The department <u>or state laboratory</u>, <u>as applicable</u>, may deny or revoke a license based on proof that the applicant made a false statement in any part of the original application or renewal application.
- (3) The department <u>or state laboratory</u>, <u>as applicable</u>, may deny a license if the applicant's proposed registered premises:
- (a) is situated within a zone of a city, town, or county where an activity related to the medical use of marijuana is prohibited by ordinance or resolution, a certified copy of which has been filed with the department; or
 - (b) will adversely affect the welfare of the people residing in or of retail businesses located in the vicinity.
- (4) (a) The department <u>or state laboratory</u>, <u>as applicable</u>, may deny a license or endorsement if the applicant's proposed registered premises or testing laboratory:
 - (i) is not approved by local building, health, or fire officials; or
- (ii) is within 500 feet of and on the same street as a building used exclusively as a church, synagogue, or other place of worship or as a school or postsecondary school other than a commercially operated school. This distance must be measured in a straight line from the center of the nearest entrance of the place of worship or school to the nearest entrance of the licensee's premises.
- (b) The department may not approve a license for a provider, marijuana-infused products provider, or dispensary if a local government has adopted an ordinance or resolution prohibiting the operation of dispensaries



- 1 or storefront businesses as allowed under 50-46-328.
- 2 (c) For the purposes of this subsection (4), "school" and "postsecondary school" have the meanings provided in 20-5-402."

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- **Section 5.** Section 50-46-326, MCA, is amended to read:
- "50-46-326. Testing of marijuana and marijuana-infused products. (1) (a) Except as provided in subsection (1)(b), a provider or marijuana-infused products provider may not sell marijuana or marijuana-infused products until the marijuana or products have been tested by a testing laboratory or the department of agriculture and met the requirements of this section.
- (b) A provider or marijuana-infused products provider who has been named as a provider by 10 or fewer registered cardholders is exempt from the testing requirements of this section until April 30, 2020.
- (2) A provider or marijuana-infused products provider shall submit material that has been collected in accordance with a sampling protocol established by the department state laboratory by rule. The protocol must address the division of marijuana and marijuana-infused products into lot sizes for testing. Each lot must be tested in the following categories:
- 16 (a) flower;
- 17 (b) concentrate; and
- 18 (c) marijuana-infused product.
- (3) The department state laboratory shall adopt rules regarding the types of tests that must be performed
 to ensure product safety and consumer protection. Rules must include but are not limited to testing for:
 - (a) the potency of the cannabinoid present; and
- 22 (b) the presence of contaminants.
 - (4) The testing laboratory shall conduct a visual inspection of each lot to determine the presence of levels of foreign matter, debris, insects, and visible mold.
- 25 (5) The department state laboratory shall establish by rule the acceptable levels of pesticides, residual solvents, mold, foreign matter, debris, insects, and other contaminants that marijuana-infused products may contain.
- 28 (6) The testing laboratory shall:
- 29 (a) issue a certificate of analysis certifying the test results; and
- 30 (b) report the results to the seed-to-sale tracking system established pursuant to 50-46-303.



(7) A provider or marijuana-infused products provider may request that material that has failed to pass the required tests be retested. The department state laboratory shall adopt rules that provide for retesting parameters and requirements.

(8) Marijuana or a marijuana-infused product must include a label indicating whether the marijuana or marijuana-infused product has been tested."

- **Section 6.** Section 50-46-329, MCA, is amended to read:
- **"50-46-329. Inspection procedures.** (1) The department shall conduct unannounced inspections of registered premises and testing laboratories. The department shall report biennially to the children, families, health, and human services interim committee concerning the results of unannounced inspections.
 - (2) (a) The department shall inspect annually each registered premises and testing laboratory.
- (b) The department shall collect samples during the inspection of registered premises and submit them to a testing laboratory for testing as provided by the department state laboratory by rule.
- (3) (a) Each provider and marijuana-infused products provider shall keep a complete set of records necessary to show all transactions with registered cardholders. The records must be open for inspection by the department or state laboratory, as appropriate, and state or local law enforcement agencies during normal business hours.
- (b) The department may require a provider or marijuana-infused products provider to furnish information that the department considers necessary for the proper administration of this part.
- (4) (a) A registered premises, including any places of storage, where marijuana is cultivated, manufactured, sold, or stored is subject to entry by the department or state or local law enforcement agencies for the purpose of inspection or investigation during normal business hours.
- (b) If any part of the registered premises consists of a locked area, the provider or marijuana-infused products provider shall make the area available for inspection without delay upon request of the department or state or local law enforcement officials.
- (5) A provider or marijuana-infused products provider shall maintain records showing the names and registry identification numbers of registered cardholders to whom mature plants, seedlings, usable marijuana, or marijuana-infused products were sold or transferred and the quantities sold or transferred to each cardholder.
 - (6) The state laboratory shall conduct the inspections of testing laboratories required under this section.

 (6) The department may establish penalties, including financial penalties and license revocation, for



1 the violation of agricultural or public health standards."

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- 3 **Section 7.** Section 50-46-344, MCA, is amended to read:
- "50-46-344. Rulemaking authority -- fees. (1) The department shall adopt rules necessary for the 4 5 implementation and administration of this part. The rules must include but are not limited to:
 - (a) the manner in which the department will consider applications for licenses and endorsements and applications for registry identification cards for individuals with debilitating medical conditions and renewal of licenses, endorsements, and registry identification cards;
 - (b) the acceptable forms of proof of Montana residency;
- 10 (c) the procedures for obtaining fingerprints for the fingerprint and background check required under 11 50-46-307 and 50-46-308;
 - (d) the security and operating requirements for dispensaries;
 - (e) the security and operating requirements for chemical manufacturing, including but not limited to requirements for:
 - (i) safety equipment;
- 16 (ii) extraction methods, including solvent-based and solvent-free extraction; and
- 17 (iii) postprocessing procedures;
- 18 (f) the amount of usable marijuana that a registered cardholder who has not named a provider or marijuana-infused products provider may possess;
 - (g) the canopy for which a provider or marijuana-infused products provider is licensed;
 - (h) implementation of a system to allow the tracking of marijuana and marijuana-infused products as required by 50-46-303;
 - (i) requirements and standards for the testing and retesting of marijuana and marijuana-infused products, including testing of samples collected during the department's inspections of registered premises; and
 - (j) other rules necessary to implement the purposes of this part.
- 26 (2) In establishing the canopy for a provider or marijuana-infused products provider, the department shall 27 take into consideration:
- 28 (a) safety and security issues;
- 29 (b) the provision of adequate access to usable marijuana to accommodate the needs of registered 30 cardholders; and



(c) e	economies of scale and their effect on the ability of licensees to comply with regulatory rec	quirements
and undercut	t illegal market prices.	

- (3) The administrative rules promulgated under this part for testing laboratories must be developed and proposed by the state laboratory.
- (3)(4) (a) Except as provided in subsection (3)(b) (4)(b), license fees for providers and marijuana-infused products providers are \$1,000 for 10 or fewer registered cardholders and \$5,000 for more than 10 registered cardholders.
- (b) The department may revise the fee provided for in subsection (3)(a) (4)(a) as needed to adequately fund the administration of the Montana Medical Marijuana Act and the seed-to-sale tracking system, including operating reserve funds of \$250,000. The department shall establish revised fees by rule.
 - (c) A provider of both marijuana and marijuana-infused products is required to have only one license.
- (4)(5) The department shall establish by rule the fees for dispensaries, endorsements for chemical manufacturing, and testing laboratories.
- (5)(6) All fees and civil penalties collected under this part must be deposited in the medical marijuana state special revenue account established in 50-46-345.
- (6)(7) The department's rules must establish application and renewal fees that generate revenue sufficient to offset all expenses of implementing and administering this part."

18 - END -

