STATE OF OKLAHOMA

1st Session of the 59th Legislature (2023)

SENATE BILL 264 By: Garvin

AS INTRODUCED

An Act relating to medical marijuana; amending 63 O.S. 2021, Section 427.17, as last amended by Section 1, Chapter 351, O.S.L. 2022 (63 O.S. Supp. 2022, Section 427.17), which relates to medical marijuana testing laboratory license; requiring licensee to use process validation; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 63 O.S. 2021, Section 427.17, as last amended by Section 1, Chapter 351, O.S.L. 2022 (63 O.S. Supp. 2022, Section 427.17), is amended to read as follows:

Section 427.17. A. There is hereby created a medical marijuana testing laboratory license as a category of the medical marijuana business license. The Oklahoma Medical Marijuana Authority is hereby enabled to monitor, inspect and audit a licensed testing laboratory under the Oklahoma Medical Marijuana and Patient Protection Act.

B. The Authority is hereby authorized to contract with a private laboratory for the purpose of conducting compliance testing of medical marijuana testing laboratories licensed in this state.

Any such laboratory under contract for compliance testing shall be prohibited from conducting any other commercial medical marijuana testing in this state. The laboratory the Authority contracts with for compliance testing shall not employ, or be owned by, the following:

1. Any individual that has a direct or indirect interest in a licensed medical marijuana business; or

2. Any individual or his or her spouse, parent, child, spouse of a child, sibling or spouse of a sibling that has an application for a medical marijuana business license pending before the Authority or is a member of the board of directors of a medical marijuana business, or is an individual financially interested in any licensee or medical marijuana business located within this state.

C. The Authority shall develop acceptable testing practices including, but not limited to, testing, standards, quality control analysis, equipment certification and calibration, process validation, and chemical identification and substances used.

D. A person who is a direct beneficial owner of a medical marijuana dispensary, medical marijuana commercial grower or medical marijuana processor shall not be an owner of a laboratory.

E. A laboratory and a laboratory applicant shall comply with all applicable local ordinances including, but not limited to, zoning, occupancy, licensing and building codes.

F. A separate license shall be required for each specific laboratory.

G. A medical marijuana testing laboratory license may be issued to a person who performs testing on medical marijuana and medical marijuana products for medical marijuana businesses, medical marijuana research facilities, medical marijuana education facilities, and testing on marijuana and marijuana products grown or produced by a patient or caregiver on behalf of a patient, upon verification of registration. A medical marijuana testing laboratory may also conduct research related to the development and improvement of its testing practices and procedures. No state-approved medical marijuana testing facility shall operate unless a medical laboratory director is on site during operational hours.

H. Laboratory applicants and licensees shall comply with the application requirements of this section and shall submit such other information as required for a medical marijuana business applicant, in addition to any information the Authority may request for initial approval and periodic evaluations during the approval period.

I. A medical marijuana testing laboratory may accept samples of medical marijuana, medical marijuana concentrate or medical marijuana product from a medical marijuana business, medical marijuana research facility or medical marijuana education facility for testing purposes only, which purposes may include the provision of testing services for samples submitted by a medical marijuana

business for product development. The Authority may require a medical marijuana business to submit a sample of medical marijuana, medical marijuana concentrate or medical marijuana product to a medical marijuana testing or quality assurance laboratory upon demand.

J. A medical marijuana testing laboratory may accept samples of medical marijuana, medical marijuana concentrate or medical marijuana product from an individual person for testing only under the following conditions:

1. The individual person is a patient or caregiver pursuant to the Oklahoma Medical Marijuana and Patient Protection Act or is a participant in an approved clinical or observational study conducted by a research facility; and

2. The medical marijuana testing laboratory shall require the patient or caregiver to produce a valid patient license and current and valid photo identification.

K. A medical marijuana testing laboratory may transfer samples to another medical marijuana testing laboratory for testing. All laboratory reports provided to or by a medical marijuana business or to a patient or caregiver shall identify the medical marijuana testing laboratory that actually conducted the test.

L. A medical marijuana testing laboratory may utilize a licensed medical marijuana transporter to transport samples of medical marijuana, medical marijuana concentrate and medical

marijuana product for testing, in accordance with the Oklahoma Medical Marijuana and Patient Protection Act and the rules adopted pursuant thereto, between the originating medical marijuana business requesting testing services and the destination laboratory performing testing services.

M. The medical marijuana testing laboratory shall establish policies to prevent the existence of or appearance of undue commercial, financial or other influences that may diminish the competency, impartiality and integrity of the testing processes or results of the laboratory, or that may diminish public confidence in the competency, impartiality and integrity of the testing processes or results of the laboratory. At a minimum, employees, owners or agents of a medical marijuana testing laboratory who participate in any aspect of the analysis and results of a sample are prohibited from improperly influencing the testing process, improperly manipulating data or improperly benefiting from any ongoing financial, employment, personal or business relationship with the medical marijuana business that provided the sample. A medical marijuana testing laboratory shall not test samples for any medical marijuana business in which an owner, employee or agent of the medical marijuana testing laboratory has any form of ownership or financial interest in the medical marijuana business.

N. The Authority, pursuant to rules promulgated by the Executive Director of the Authority, shall develop standards, policies and procedures as necessary for:

1. The cleanliness and orderliness of a laboratory premises and the location of the laboratory in a secure location, and inspection, cleaning and maintenance of any equipment or utensils used for the analysis of test samples;

2. Testing procedures, testing standards for cannabinoid and terpenoid potency and safe levels of contaminants, process validation, and remediation procedures. Process validation shall be ~~voluntary~~ mandatory, and ~~no~~ a licensee shall be required to validate their process. The Authority shall develop standards and requirements for a licensee to achieve process validation by January 1, 2024. The standards, policies, and procedures for process validation shall include, but not be limited to:

a. initial requirements to achieve process validation and ongoing minimum testing requirements once a licensee has achieved process validation,

b. requiring licensees to track their marijuana and marijuana product inventory with the Authority's designated seed-to-sale system provided the Authority has selected a seed-to-sale system. This requirement for compliance with the seed-to-sale system shall be mandatory for licensees seeking to achieve process

validation whether or not compliance with a seed-to-sale system is mandatory for all licensees,

c. requiring licensees that are utilizing process validation to use a laboratory that is certified as a certified process validation testing laboratory,

d. requiring licensees to record and document retention policies, which at a minimum shall require licensees to retain all documents and records related to process validation. Such records shall be maintained by the licensee for as long as the licensee is continuing to operate under that validated process. Licensees shall retain all such documents and records for at least four (4) years after the licensee has stopped using the validated process or after the licensee has made a significant process change to a validated process. Any significant process change to the validated processes of a licensee is subject to the same document retention requirements and shall be retained for as long as the significant process change is part of an ongoing validated process, and for at least four (4) years after the licensee has stopped using the validated process or after the licensee has made a subsequent significant process change to the validated

process. The Authority shall promulgate rules for any modifications to the validated processes,

e. requiring licensees to keep all records and documents related to their process validation ready and accessible at the address listed on their marijuana business license for inspection or audit by the Authority without any notice from the Authority,

f. a process for biannual inspections by the Authority that, at a minimum, includes random testing of products being produced under process validation. The Authority shall be the entity that obtains the random sample during the biannual inspections and shall have access to all products being produced or grown under process validation. The Authority shall take samples to the quality assurance laboratory,

g. a process to revoke the authority of licensees to operate under process validation,

h. punishment for violations of process validation that, at a minimum, would prohibit a licensee from operating under process validation for five (5) years and the assessment of a fine not to exceed Fifty Thousand Dollars ($50,000.00). Any such fine levied against a licensee found to have violated the laws or rules of

process validation shall be remitted to the Department of Mental Health and Substance Abuse Services,

i. punishment for violations if an adulterated product that was produced under process validation fails testing and the batch or lot has been sold to a dispensary, the first violation shall be the assessment of a fine not to exceed Ten Thousand Dollars ($10,000.00) and a public recall of the product. The licensee shall further be required to revalidate the process. A second violation within two (2) years of a previous violation shall be the assessment of a fine not to exceed Seventy-five Thousand Dollars ($75,000.00) and a public recall of the product. The licensee shall further be prohibited from utilizing process validation for a minimum of five (5) years. A third violation within two (2) years of a previous violation shall be the assessment of a fine of Two Hundred Fifty Thousand Dollars ($250,000.00) and a public recall of the product. The licensee shall further be prohibited from utilizing process validation,

j. any willful violation of process validation shall result in the assessment of a fine of Two Hundred Fifty Thousand Dollars ($250,000.00) and a license

revocation hearing. A second willful violation of process validation shall result in the assessment of a fine of One Million Dollars ($1,000,000.00) and a hearing to permanently revoke the license,

k. an annual registration fee of Five Thousand Dollars ($5,000.00) per licensee, in addition to any other fees due by the licensee, to be deposited in the Oklahoma Medical Marijuana Authority Revolving Fund for the enforcement of the laws and regulations of the Authority,

l. establishing criteria for eligibility of testing laboratories to be certified as a Certified Process Validation Testing Laboratory and to conduct testing for licensees pursuing or operating under process validation. The criteria shall, at a minimum, pass five (5) consecutive blind proficiency tests without a failure over the course of six (6) months. The proficiency tests shall be administered by the quality assurance laboratory,

m. punishment for violations by a Certified Process Validation Testing Laboratory that has been found to have been falsifying data, providing misinformation, or any unethical practices related to process validation at a minimum shall prohibit a licensee from

operating under process validation for up to twenty-five (25) years and the assessment of a fine not to exceed One Million Dollars ($1,000,000.00). Any such fine levied against a licensee shall be remitted to the Authority for deposit into the Oklahoma Medical Marijuana Authority Revolving Fund. In addition to this fine, in response to a finding of a willful violation of process validation by the Authority, the Authority shall also be authorized to collect, levy, or impose any other fee, fine, penalty, or action as allowed by law, and

n. a process to revoke the certification of a testing laboratory that is seeking to be a Certified Process Validation Testing Laboratory;

3. Controlled access areas for storage of medical marijuana and medical marijuana product test samples, waste and reference standards;

4. Records to be retained and computer systems to be utilized by the laboratory;

5. The possession, storage and use by the laboratory of reagents, solutions and reference standards;

6. A certificate of analysis (COA) for each lot of reference standard;

7. The transport and disposal of unused marijuana, marijuana products and waste;

8. The mandatory use by a laboratory of an inventory tracking system to ensure all harvest and production batches or samples containing medical marijuana, medical marijuana concentrate or medical marijuana products are identified and tracked from the point they are transferred from a medical marijuana business, a patient or a caregiver through the point of transfer, destruction or disposal. The inventory tracking system reporting shall include the results of any tests that are conducted on medical marijuana, medical marijuana concentrate or medical marijuana product;

9. Standards of performance;

10. The employment of laboratory personnel;

11. A written standard operating procedure manual to be maintained and updated by the laboratory;

12. The successful participation in a proficiency testing program approved by the Executive Director for each testing category listed in this section, in order to obtain and maintain certification;

13. The establishment of and adherence to a quality assurance and quality control program to ensure sufficient monitoring of laboratory processes and quality of results reported;

14. The immediate recall of medical marijuana or medical marijuana products that test above allowable thresholds or are otherwise determined to be unsafe;

15. The establishment by the laboratory of a system to document the complete chain of custody for samples from receipt through disposal;

16. The establishment by the laboratory of a system to retain and maintain all required records, including business records, and processes to ensure results are reported in a timely and accurate manner; and

17. Any other aspect of laboratory testing of medical marijuana or medical marijuana product deemed necessary by the Executive Director.

O. A medical marijuana testing laboratory shall promptly provide the Authority or designee of the Authority access to a report of a test and any underlying data that is conducted on a sample at the request of a medical marijuana business or qualified patient. A medical marijuana testing laboratory shall also provide access to the Authority or designee of the Authority to laboratory premises and to any material or information requested by the Authority to determine compliance with the requirements of this section.

P. A medical marijuana testing laboratory shall retain all results of laboratory tests conducted on marijuana or products for a

period of at least seven (7) years and shall make them available to the Authority upon request.

Q. A medical marijuana testing laboratory shall test samples from each harvest batch or, product batch, or samples consistent with the rules promulgated for process validation, as appropriate, of medical marijuana, medical marijuana concentrate and medical marijuana product for each of the following categories of testing, consistent with standards developed by the Executive Director:

1. Microbials;

2. Mycotoxins;

3. Residual solvents;

4. Pesticides;

5. Tetrahydrocannabinol (THC) and other cannabinoid potency;

6. Terpenoid type and concentration; and

7. Heavy metals.

R. A licensed medical marijuana testing laboratory shall test each individual harvest batch. A grower shall separate each harvest lot of usable marijuana into harvest batches containing no more than fifteen (15) pounds, with the exception of any plant material to be sold to a licensed processor for the purposes of turning the plant material into concentrate which may be separated into harvest batches of no more than fifty (50) pounds. A processor shall separate each medical marijuana production lot into production batches containing no more than four (4) liters of concentrate or

nine (9) pounds for nonliquid products, and for final products, the Oklahoma Medical Marijuana Authority shall be authorized to promulgate rules on final products as necessary. Provided, however, the Authority shall not require testing of final products less often than every one thousand (1,000) grams of THC. As used in this subsection, "final products" shall include, but not be limited to, cookies, brownies, candies, gummies, beverages and chocolates.

S. Medical marijuana testing laboratory licensure shall be contingent upon successful on-site inspection, successful participation in proficiency testing and ongoing compliance with the applicable requirements in this section.

T. A medical marijuana testing laboratory shall be inspected prior to initial licensure and up to two (2) times per year thereafter by an inspector approved by the Authority. The Authority may enter the licensed premises of a testing laboratory to conduct investigations and additional inspections when the Authority believes an investigation or additional inspection is necessary due to a possible violation of applicable laws, rules or regulations.

U. Medical marijuana testing laboratories shall obtain accreditation by an accrediting body approved by the Executive Director within one (1) year of the date the initial license is issued. Renewal of any medical marijuana testing laboratory license shall be contingent upon accreditation in accordance with this subsection. All medical marijuana testing laboratories shall obtain

accreditation prior to applying for and receiving a medical marijuana testing laboratory license.

V. Unless authorized by the provisions of this section, a commercial grower shall not transfer or sell medical marijuana and a processor shall not transfer, sell or process into a concentrate or product any medical marijuana, medical marijuana concentrate or medical marijuana product unless samples from each harvest batch or, production batch, or samples consistent with the rules promulgated for process validation, from which that medical marijuana, medical marijuana concentrate or medical marijuana product was derived has been tested by a medical marijuana testing laboratory and passed all contaminant tests required by the Oklahoma Medical Marijuana and Patient Protection Act and applicable laws, rules and regulations. A licensed commercial grower may transfer medical marijuana that has failed testing to a licensed processor only for the purposes of decontamination or remediation and only in accordance with the provisions of the Oklahoma Medical Marijuana and Patient Protection Act and the rules and regulations promulgated by the Executive Director. Remediated and decontaminated medical marijuana may be returned only to the originating licensed commercial grower.

W. Kief shall not be transferred or sold except as authorized in the rules and regulations promulgated by the Executive Director.

SECTION 2. This act shall become effective November 1, 2023.

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