STATE OF OKLAHOMA

1st Session of the 59th Legislature (2023)

COMMITTEE SUBSTITUTE
FOR ENGROSSED
SENATE BILL NO. 813 By: Garvin of the Senate

and

Marti of the House

COMMITTEE SUBSTITUTE

An Act relating to medical marijuana; amending 63 O.S. 2021, Section 427.17, as last amended by Section 1, Chapter 353, O.S.L. 2022 (63 O.S. Supp. 2022, Section 427.17), which relates to the medical marijuana testing laboratory license; providing contract condition; allowing testing by Oklahoma Medical Marijuana Authority assurance laboratory; authorizing the Authority to operate a quality assurance laboratory; allowing the Authority to use quality assurance laboratory for certain purposes; permitting the Authority to enter into certain agreements and contracts; allowing the transfer and transport of certain products; requiring the Authority to submit certain report; providing for promulgation of rules; providing for codification; and declaring an emergency.

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 353, 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. ~~1.~~ The Authority is hereby authorized to operate a quality assurance laboratory or 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~~ If the Authority contracts with ~~for compliance testing~~ a private laboratory to implement the requirements of this section:

1. The laboratory shall not employ, or be owned by, the following:

a. any individual that has a direct or indirect interest in a licensed medical marijuana business, or

b. 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~~.~~; and

2. The ~~private~~ laboratory ~~under contract with the Authority for compliance testing~~ and a board or committee comprised of licensed Oklahoma medical marijuana laboratories currently accredited by the International Organization for Standardization (ISO) shall provide to the Authority its recommendations for all equipment and standards to be utilized by licensed medical marijuana testing laboratories when testing samples of medical marijuana, medical marijuana concentrate, and medical marijuana products as well as standard operating procedures when extracting and testing medical marijuana, medical marijuana concentrate, and medical marijuana products. The recommendations shall be submitted to the Authority no later than June 1, 2023. The Authority shall have ninety (90) days from the date it receives the recommendations to promulgate new rules or modify its current rules for laboratory standards and testing. Beginning June 1, 2024, medical marijuana testing laboratories renewing their medical marijuana business license shall be subject to and comply with any new or modified rules relating to the testing of medical marijuana, medical marijuana concentrate, and medical marijuana products. The refusal or failure of a medical marijuana testing laboratory licensee to comply with new or modified rules relating to laboratory standards and testing procedures promulgated

under the provisions of this paragraph shall result in the permanent revocation of the medical marijuana testing laboratory license.

C. The Authority shall develop acceptable testing practices including, but not limited to, testing, standards, quality control analysis, equipment certification and calibration, 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 laboratory or the Authority's 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, and remediation procedures;

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, 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~~ any time 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 or the Authority's quality assurance laboratory 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 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. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 427.17a of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The Oklahoma Medical Marijuana Authority may operate a quality assurance laboratory for the purpose of conducting compliance testing of medical marijuana businesses licensed in this state.

B. The Authority shall utilize the quality assurance laboratory to:

1. Provide recommendations for all equipment and standards to be utilized by licensed medical marijuana testing laboratories when testing samples of medical marijuana, medical marijuana concentrate, and medical marijuana products;

2. Provide standardized operating procedures when procuring, collecting, extracting, and testing medical marijuana, medical marijuana concentrate, and medical marijuana products;

3. Procure, handle, transfer, transport, and test samples taken from medical marijuana licensed businesses;

4. Implement the secret shopper program pursuant to Section 427.25 of Title 63 of the Oklahoma Statutes; and

5. Detect and analyze any compounds that are not among the targeted analytes and are unknown, unidentified, tentatively identified, or known and injurious to human health if consumed.

C. In order to fulfill the provisions of subsection A of this section, the Authority may:

1. Enter into interlocal agreements with any other government agency pursuant to Section 1001 et seq. of Title 74 of the Oklahoma Statutes;

2. Select a laboratory information system through a competitive bidding process pursuant to Section 85.7 of Title 74 of the Oklahoma Statutes; or

3. Collect samples from harvest batches that failed testing.

D. The quality assurance laboratory may transport and transfer medical marijuana, medical marijuana concentrate, and medical marijuana product for testing between the originating medical marijuana business, the quality assurance laboratory, and other licensed medical marijuana testing laboratories pursuant to this section.

E. The quality assurance laboratory shall comply with the provisions of the Oklahoma Medical Marijuana and Patient Protection Act when transporting samples of medical marijuana, medical marijuana concentrate, and medical marijuana product for testing between the originating medical marijuana business, the quality assurance laboratory, and other licensed medical marijuana testing

laboratories pursuant to this section. Nothing in this section shall require the quality assurance laboratory to apply for and receive a license.

F. The Authority shall submit an annual report to the Legislature on quality assurance activities and results.

G. The Authority may promulgate rules necessary for the implementation of a quality assurance laboratory pursuant to this section.

SECTION 3. It being immediately necessary for the preservation of the public peace, health or safety, an emergency is hereby declared to exist, by reason whereof this act shall take effect and be in full force from and after its passage and approval.

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