

1 STATE OF OKLAHOMA

2 2nd Session of the 58th Legislature (2022)

3 COMMITTEE SUBSTITUTE
4 FOR ENGROSSED
5 HOUSE BILL NO. 3929

By: Pfeiffer and McDugle of the
House

6 and

7 Rogers and Leewright of the
8 Senate

9 COMMITTEE SUBSTITUTE

10 [medical marijuana - allowing process validation as
11 an acceptable testing practice - emergency]

12
13 BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

14 SECTION 1. AMENDATORY 63 O.S. 2021, Section 427.17, is
15 amended to read as follows:

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

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

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

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

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

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

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

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

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

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

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

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

1 business for product development. The Department may require a
2 medical marijuana business to submit a sample of medical marijuana,
3 medical marijuana concentrate or medical marijuana product to a
4 medical marijuana testing or quality assurance laboratory upon
5 demand.

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

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

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

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

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

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

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

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1 N. The Department, pursuant to rules promulgated by the State
2 Commissioner of Health, shall develop standards, policies and
3 procedures as necessary for:

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

8 2. Testing procedures, testing standards for cannabinoid and
9 terpenoid potency and safe levels of contaminants, process
10 validation, and remediation procedures. Process validation shall be
11 voluntary, and no licensee shall be required to validate their
12 process. The Department shall develop standards and requirements
13 for a licensee to achieve process validation by October 1, 2023, to
14 allow licensees to operate process validation; provided, that
15 nothing in this act shall prohibit the Authority from establishing
16 an earlier date to allow licensees to operate under process
17 validation. The standards, policies, and procedures for process
18 validation shall include, but not be limited to:

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

22 b. requiring licensees to track their marijuana and
23 marijuana product inventory with the Department's
24 designated seed-to-sale system provided the Department

1 has selected a seed-to-sale system. This requirement
2 for compliance with the seed-to-sale system shall be
3 mandatory for licensees seeking to achieve process
4 validation whether or not compliance with a seed-to-
5 sale system is mandatory for all licensees,

6 c. requiring licensees to record and document retention
7 policies, which at a minimum shall require licensees
8 to retain all documents and records related to process
9 validation. Such records shall be maintained by the
10 licensee for as long as the licensee is continuing to
11 operate under that validated process. Licensees shall
12 retain all such documents and records for at least
13 four (4) years after the licensee has stopped using
14 the validated process or after the licensee has made a
15 significant process change to a validated process.
16 Any significant process change to the validated
17 processes of a licensee is subject to the same
18 document retention requirements and shall be retained
19 for as long as the significant process change is part
20 of an ongoing validated process, and for at least four
21 (4) years after the licensee has stopped using the
22 validated process or after the licensee has made a
23 subsequent significant process change to the validated
24 process,

- 1 d. testing requirements to maintain process validation
2 when a licensee has made a significant process change
3 to a validated process,
- 4 e. requiring licensees to keep all records and documents
5 related to their process validation ready and
6 accessible at the address listed on their marijuana
7 business license for inspection or audit by the
8 Authority without any notice from the Authority,
- 9 f. a process to revoke the authority of licensees to
10 operate under process validation,
- 11 g. punishment for willful violations of process
12 validation that, at a minimum, would prohibit a
13 licensee from operating under process validation for
14 five (5) years and the assessment of a fine up to
15 Seventy-five Thousand Dollars (\$75,000.00). Any such
16 fine levied against a licensee found to have willfully
17 violated the laws or rules of process violation shall
18 be remitted to the Department of Mental Health and
19 Substance Abuse Services. In addition to this fine,
20 in response to a finding of a willful violation of
21 process validation by the Authority, the Authority
22 shall also be authorized to collect, levy, or impose
23 any other fee, fine, penalty, or action as allowed by
24 law,

1 h. an annual registration fee not to exceed Two Thousand
2 Five Hundred Dollars (\$2,500.00) per licensee, in
3 addition to any other fees due by the licensee, to be
4 deposited in the Oklahoma Medical Marijuana Revolving
5 Fund for the enforcement of the laws and regulations
6 of the Authority,

7 i. establishing criteria for eligibility of testing labs
8 to conduct testing for licensees pursuing or operating
9 under process validation, and

10 j. a policy which clearly states that no law, rule, or
11 regulation shall prohibit medical marijuana testing
12 laboratories from offering services to licensees
13 seeking to achieve and manage process validation for
14 consideration;

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

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

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

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

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

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

12 9. Standards of performance;

13 10. The employment of laboratory personnel;

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

16 12. The successful participation in a Department-approved
17 proficiency testing program for each testing category listed in this
18 section, in order to obtain and maintain certification;

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

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

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

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

8 17. Any other aspect of laboratory testing of medical marijuana
9 or medical marijuana product deemed necessary by the Department.

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

19 P. A medical marijuana testing laboratory shall retain all
20 results of laboratory tests conducted on marijuana or products for a
21 period of at least seven (7) years and shall make them available to
22 the Department upon request.

23 Q. A medical marijuana testing laboratory shall test samples
24 from each harvest batch ~~or~~, product batch, or samples consistent

1 with the rules promulgated for process validation, as appropriate,
2 of medical marijuana, medical marijuana concentrate and medical
3 marijuana product for each of the following categories of testing,
4 consistent with standards developed by the Commissioner:

- 5 1. Microbials;
- 6 2. Mycotoxins;
- 7 3. Residual solvents;
- 8 4. Pesticides;
- 9 5. Tetrahydrocannabinol (THC) and other cannabinoid potency;
- 10 6. Terpenoid type and concentration; and
- 11 7. Heavy metals.

12 R. A licensed medical marijuana testing laboratory shall test
13 each individual harvest batch. A grower shall separate each harvest
14 lot of usable marijuana into harvest batches containing no more than
15 fifteen (15) pounds, with the exception of any plant material to be
16 sold to a licensed processor for the purposes of turning the plant
17 material into concentrate which may be separated into harvest
18 batches of no more than fifty (50) pounds. A processor shall
19 separate each medical marijuana production lot into production
20 batches containing no more than four (4) liters of concentrate or
21 nine (9) pounds for nonliquid products, and for final products, the
22 Oklahoma Medical Marijuana Authority shall be authorized to
23 promulgate rules on final products as necessary. Provided, however,
24 the Authority shall not require testing of final products less often

1 than every one thousand (1,000) grams of THC. As used in this
2 subsection, "final products" shall include, but not be limited to,
3 cookies, brownies, candies, gummies, beverages and chocolates.

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

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

15 U. Medical marijuana testing laboratories shall obtain
16 accreditation by an accrediting body approved by the Commissioner
17 within one (1) year of the date the initial license is issued.
18 Renewal of any medical marijuana testing laboratory license shall be
19 contingent upon accreditation in accordance with this subsection.
20 All medical marijuana testing laboratories shall obtain
21 accreditation prior to applying for and receiving a medical
22 marijuana testing laboratory license.

23 V. Unless authorized by the provisions of this section, a
24 commercial grower shall not transfer or sell medical marijuana and a

1 processor shall not transfer, sell or process into a concentrate or
2 product any medical marijuana, medical marijuana concentrate or
3 medical marijuana product unless samples from each harvest batch ~~or,~~
4 production batch, or samples consistent with the rules promulgated
5 for process validation from which that medical marijuana, medical
6 marijuana concentrate or medical marijuana product was derived has
7 been tested by a medical marijuana testing laboratory and passed all
8 contaminant tests required by the Oklahoma Medical Marijuana and
9 Patient Protection Act and applicable laws, rules and regulations.
10 A licensed commercial grower may transfer medical marijuana that has
11 failed testing to a licensed processor only for the purposes of
12 decontamination or remediation and only in accordance with the
13 provisions of the Oklahoma Medical Marijuana and Patient Protection
14 Act and the rules and regulations of the Department. Remediated and
15 decontaminated medical marijuana may be returned only to the
16 originating licensed commercial grower.

17 W. Kief shall not be transferred or sold except as authorized
18 in the rules and regulations of the Department.

19 SECTION 2. It being immediately necessary for the preservation
20 of the public peace, health or safety, an emergency is hereby
21 declared to exist, by reason whereof this act shall take effect and
22 be in full force from and after its passage and approval.

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