

1 STATE OF OKLAHOMA

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

3 COMMITTEE SUBSTITUTE

4 FOR

5 HOUSE BILL NO. 3929

6 By: Pfeiffer

7 COMMITTEE SUBSTITUTE

8 An Act relating to medical marijuana; amending 63  
9 O.S. 2021, Section 427.17, which relates to Oklahoma  
10 Medical Marijuana and Patient Protection Act;  
11 allowing process validation as an acceptable testing  
12 practice; making process validation non-mandatory;  
13 providing list of required standards, policies, and  
14 procedures for process validation; providing for  
15 samples consistent with process validation rules; and  
16 declaring an emergency.

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

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

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

1 B. The Authority is hereby authorized to contract with a  
2 private laboratory for the purpose of conducting compliance testing  
3 of medical marijuana testing laboratories licensed in this state.  
4 Any such laboratory under contract for compliance testing shall be  
5 prohibited from conducting any other commercial medical marijuana  
6 testing in this state. The laboratory the Authority contracts with  
7 for compliance testing shall not employ, or be owned by, the  
8 following:

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

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

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

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

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

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

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

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

22 I. A medical marijuana testing laboratory may accept samples of  
23 medical marijuana, medical marijuana concentrate or medical  
24 marijuana product from a medical marijuana business, medical

1 marijuana research facility or medical marijuana education facility  
2 for testing purposes only, which purposes may include the provision  
3 of testing services for samples submitted by a medical marijuana  
4 business for product development. The Department may require a  
5 medical marijuana business to submit a sample of medical marijuana,  
6 medical marijuana concentrate or medical marijuana product to a  
7 medical marijuana testing or quality assurance laboratory upon  
8 demand.

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

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

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

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

1 L. A medical marijuana testing laboratory may utilize a  
2 licensed medical marijuana transporter to transport samples of  
3 medical marijuana, medical marijuana concentrate and medical  
4 marijuana product for testing, in accordance with the Oklahoma  
5 Medical Marijuana and Patient Protection Act and the rules adopted  
6 pursuant thereto, between the originating medical marijuana business  
7 requesting testing services and the destination laboratory  
8 performing testing services.

9 M. The medical marijuana testing laboratory shall establish  
10 policies to prevent the existence of or appearance of undue  
11 commercial, financial or other influences that may diminish the  
12 competency, impartiality and integrity of the testing processes or  
13 results of the laboratory, or that may diminish public confidence in  
14 the competency, impartiality and integrity of the testing processes  
15 or results of the laboratory. At a minimum, employees, owners or  
16 agents of a medical marijuana testing laboratory who participate in  
17 any aspect of the analysis and results of a sample are prohibited  
18 from improperly influencing the testing process, improperly  
19 manipulating data or improperly benefiting from any ongoing  
20 financial, employment, personal or business relationship with the  
21 medical marijuana business that provided the sample. A medical  
22 marijuana testing laboratory shall not test samples for any medical  
23 marijuana business in which an owner, employee or agent of the  
24

1 medical marijuana testing laboratory has any form of ownership or  
2 financial interest in the medical marijuana business.

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

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

10 2. Testing procedures, testing standards for cannabinoid and  
11 terpenoid potency and safe levels of contaminants, process  
12 validation, and remediation procedures. Process validation shall be  
13 voluntary, and no licensee shall be required to validate their  
14 process. The Department shall develop standards and requirements  
15 for a licensee to achieve process validation. The standards,  
16 policies, and procedures for process validation shall include, but  
17 not be limited to:

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

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

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

5 c. requiring licensees to record and document retention  
6 policies, which at a minimum shall require licensees  
7 to retain all documents and records related to process  
8 validation. Such records shall be maintained by the  
9 licensee for as long as the licensee is continuing to  
10 operate under that validated process. Licensees shall  
11 retain all such documents and records for at least  
12 four (4) years after the licensee has stopped using  
13 the validated process or after the licensee has made a  
14 significant process change to a validated process.  
15 Any significant process change to the validated  
16 processes of a licensee is subject to the same  
17 document retention requirements and shall be retained  
18 for as long as the significant process change is part  
19 of an ongoing validated process, and for at least four  
20 (4) years after the licensee has stopped using the  
21 validated process or after the licensee has made a  
22 subsequent significant process change to the validated  
23 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 fine and fees by  
15       the Authority as allowed by law,
- 16       h. an annual registration fee not to exceed Two Thousand  
17       Five Hundred Dollars (\$2,500.00) per licensee to be  
18       deposited in the Oklahoma Medical Marijuana Revolving  
19       Fund for the enforcement of the laws and regulations  
20       of the Authority, and
- 21       i. a policy which clearly states that no law, rule, or  
22       regulation shall prohibit medical marijuana testing  
23       laboratories from offering services to licensees  
24



1                   seeking to achieve and manage process validation for  
2                   consideration;

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

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

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

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

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

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

23          9.   Standards of performance;

24          10.  The employment of laboratory personnel;

- 1        11. A written standard operating procedure manual to be  
2 maintained and updated by the laboratory;
- 3        12. The successful participation in a Department-approved  
4 proficiency testing program for each testing category listed in this  
5 section, in order to obtain and maintain certification;
- 6        13. The establishment of and adherence to a quality assurance  
7 and quality control program to ensure sufficient monitoring of  
8 laboratory processes and quality of results reported;
- 9        14. The immediate recall of medical marijuana or medical  
10 marijuana products that test above allowable thresholds or are  
11 otherwise determined to be unsafe;
- 12        15. The establishment by the laboratory of a system to document  
13 the complete chain of custody for samples from receipt through  
14 disposal;
- 15        16. The establishment by the laboratory of a system to retain  
16 and maintain all required records, including business records, and  
17 processes to ensure results are reported in a timely and accurate  
18 manner; and
- 19        17. Any other aspect of laboratory testing of medical marijuana  
20 or medical marijuana product deemed necessary by the Department.
- 21        O. A medical marijuana testing laboratory shall promptly  
22 provide the Department or designee of the Department access to a  
23 report of a test and any underlying data that is conducted on a  
24 sample at the request of a medical marijuana business or qualified

1 patient. A medical marijuana testing laboratory shall also provide  
2 access to the Department or designee of the Department to laboratory  
3 premises and to any material or information requested by the  
4 Department to determine compliance with the requirements of this  
5 section.

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

10 Q. A medical marijuana testing laboratory shall test samples  
11 from each harvest batch ~~or~~, product batch, or samples consistent  
12 with the rules promulgated for process validation, as appropriate,  
13 of medical marijuana, medical marijuana concentrate and medical  
14 marijuana product for each of the following categories of testing,  
15 consistent with standards developed by the Commissioner:

- 16 1. Microbials;
- 17 2. Mycotoxins;
- 18 3. Residual solvents;
- 19 4. Pesticides;
- 20 5. Tetrahydrocannabinol (THC) and other cannabinoid potency;
- 21 6. Terpenoid type and concentration; and
- 22 7. Heavy metals.

23 R. A licensed medical marijuana testing laboratory shall test  
24 each individual harvest batch. A grower shall separate each harvest

1 lot of usable marijuana into harvest batches containing no more than  
2 fifteen (15) pounds, with the exception of any plant material to be  
3 sold to a licensed processor for the purposes of turning the plant  
4 material into concentrate which may be separated into harvest  
5 batches of no more than fifty (50) pounds. A processor shall  
6 separate each medical marijuana production lot into production  
7 batches containing no more than four (4) liters of concentrate or  
8 nine (9) pounds for nonliquid products, and for final products, the  
9 Oklahoma Medical Marijuana Authority shall be authorized to  
10 promulgate rules on final products as necessary. Provided, however,  
11 the Authority shall not require testing of final products less often  
12 than every one thousand (1,000) grams of THC. As used in this  
13 subsection, "final products" shall include, but not be limited to,  
14 cookies, brownies, candies, gummies, beverages and chocolates.

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

19 T. A medical marijuana testing laboratory shall be inspected  
20 prior to initial licensure and up to two (2) times per year  
21 thereafter by an inspector approved by the Authority. The Authority  
22 may enter the licensed premises of a testing laboratory to conduct  
23 investigations and additional inspections when the Authority

24

1 believes an investigation or additional inspection is necessary due  
2 to a possible violation of applicable laws, rules or regulations.

3 U. Medical marijuana testing laboratories shall obtain  
4 accreditation by an accrediting body approved by the Commissioner  
5 within one (1) year of the date the initial license is issued.

6 Renewal of any medical marijuana testing laboratory license shall be  
7 contingent upon accreditation in accordance with this subsection.

8 All medical marijuana testing laboratories shall obtain  
9 accreditation prior to applying for and receiving a medical  
10 marijuana testing laboratory license.

11 V. Unless authorized by the provisions of this section, a  
12 commercial grower shall not transfer or sell medical marijuana and a  
13 processor shall not transfer, sell or process into a concentrate or  
14 product any medical marijuana, medical marijuana concentrate or  
15 medical marijuana product unless samples from each harvest batch ~~or,~~  
16 production batch, or samples consistent with the rules promulgated  
17 for process validation from which that medical marijuana, medical  
18 marijuana concentrate or medical marijuana product was derived has  
19 been tested by a medical marijuana testing laboratory and passed all  
20 contaminant tests required by the Oklahoma Medical Marijuana and  
21 Patient Protection Act and applicable laws, rules and regulations.  
22 A licensed commercial grower may transfer medical marijuana that has  
23 failed testing to a licensed processor only for the purposes of  
24 decontamination or remediation and only in accordance with the

1 provisions of the Oklahoma Medical Marijuana and Patient Protection  
2 Act and the rules and regulations of the Department. Remediated and  
3 decontaminated medical marijuana may be returned only to the  
4 originating licensed commercial grower.

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

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

11

12 58-2-11023 LRB 03/03/22

13

14

15

16

17

18

19

20

21

22

23

24