

05/18/2022 02:31:20 PM

HOUSE OF REPRESENTATIVES
CONFERENCE COMMITTEE REPORT

Mr. President:
Mr. Speaker:

The Conference Committee, to which was referred

HB3929

By: Pfeiffer of the House and Rogers of the Senate

Title: Medical marijuana; process validation; acceptable testing practice; non-mandatory;
emergency.



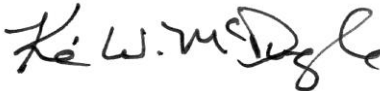



Together with Engrossed Senate Amendments thereto, beg leave to report that we have had the same under consideration and herewith return the same with the following recommendations:

1. That the Senate recede from its amendment; and
2. That the attached Conference Committee Substitute be adopted.

Respectfully submitted,

House Action _____ Date _____ Senate Action _____ Date _____

HB3929 CCR (B)
HOUSE CONFEREES

Echols, Jon		Hill, Brian	
Kannady, Chris	<hr/>	McDugle, Kevin	
Osburn, Mike		Pfeiffer, John	
Phillips, Logan		Turner, Mauree	<hr/>
Virgin, Emily	<hr/>	West, Tammy	<hr/>

HB3929 CCR B

SENATE CONFEREES

Rogers C. H. Rogers
Paxton _____
Leewright [Signature]
Taylor Tack Taylor
Rosino _____
Dossett (J.J.) J.J. Dossett

House Action _____ Date _____ Senate Action _____ Date _____

House Action _____ Date _____ Senate Action _____ Date _____

1 STATE OF OKLAHOMA

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

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

By: Pfeiffer and McDugle of the
House

7 and

Rogers, Coleman, and
Leewright of the Senate

8
9
10 CONFERENCE COMMITTEE SUBSTITUTE

11 An Act relating to medical marijuana; amending 63
12 O.S. 2021, Section 427.17, as amended by Section 17
13 of Enrolled Senate Bill No. 1543 of the 2nd Session
14 of the 58th Oklahoma Legislature, which relates to
15 the Oklahoma Medical Marijuana and Patient Protection
16 Act; allowing process validation as an acceptable
17 testing practice; making process validation non-
18 mandatory; providing list of required standards,
19 policies, and procedures for process validation;
20 providing for samples consistent with process
21 validation rules; and declaring an emergency.

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

23 SECTION 1. AMENDATORY 63 O.S. 2021, Section 427.17, as
24 amended by Section 17 of Enrolled Senate Bill No. 1543 of the 2nd
Session of the 58th Oklahoma Legislature, is amended to read as
follows:

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

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

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

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

24

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

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

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

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

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

24

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

6 I. A medical marijuana testing laboratory may accept samples of
7 medical marijuana, medical marijuana concentrate or medical
8 marijuana product from a medical marijuana business, medical
9 marijuana research facility or medical marijuana education facility
10 for testing purposes only, which purposes may include the provision
11 of testing services for samples submitted by a medical marijuana
12 business for product development. The Authority may require a
13 medical marijuana business to submit a sample of medical marijuana,
14 medical marijuana concentrate or medical marijuana product to a
15 medical marijuana testing or quality assurance laboratory upon
16 demand.

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

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

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

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

9 L. A medical marijuana testing laboratory may utilize a
10 licensed medical marijuana transporter to transport samples of
11 medical marijuana, medical marijuana concentrate and medical
12 marijuana product for testing, in accordance with the Oklahoma
13 Medical Marijuana and Patient Protection Act and the rules adopted
14 pursuant thereto, between the originating medical marijuana business
15 requesting testing services and the destination laboratory
16 performing testing services.

17 M. The medical marijuana testing laboratory shall establish
18 policies to prevent the existence of or appearance of undue
19 commercial, financial or other influences that may diminish the
20 competency, impartiality and integrity of the testing processes or
21 results of the laboratory, or that may diminish public confidence in
22 the competency, impartiality and integrity of the testing processes
23 or results of the laboratory. At a minimum, employees, owners or
24 agents of a medical marijuana testing laboratory who participate in

1 any aspect of the analysis and results of a sample are prohibited
2 from improperly influencing the testing process, improperly
3 manipulating data or improperly benefiting from any ongoing
4 financial, employment, personal or business relationship with the
5 medical marijuana business that provided the sample. A medical
6 marijuana testing laboratory shall not test samples for any medical
7 marijuana business in which an owner, employee or agent of the
8 medical marijuana testing laboratory has any form of ownership or
9 financial interest in the medical marijuana business.

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

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

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

- 1 a. initial requirements to achieve process validation and
2 ongoing minimum testing requirements once a licensee
3 has achieved process validation,
- 4 b. requiring licensees to track their marijuana and
5 marijuana product inventory with the Authority's
6 designated seed-to-sale system provided the Authority
7 has selected a seed-to-sale system. This requirement
8 for compliance with the seed-to-sale system shall be
9 mandatory for licensees seeking to achieve process
10 validation whether or not compliance with a seed-to-
11 sale system is mandatory for all licensees,
- 12 c. requiring licensees that are utilizing process
13 validation to use a laboratory that is certified as a
14 certified process validation testing laboratory,
- 15 d. requiring licensees to record and document retention
16 policies, which at a minimum shall require licensees
17 to retain all documents and records related to process
18 validation. Such records shall be maintained by the
19 licensee for as long as the licensee is continuing to
20 operate under that validated process. Licensees shall
21 retain all such documents and records for at least
22 four (4) years after the licensee has stopped using
23 the validated process or after the licensee has made a
24 significant process change to a validated process.

1 Any significant process change to the validated
2 processes of a licensee is subject to the same
3 document retention requirements and shall be retained
4 for as long as the significant process change is part
5 of an ongoing validated process, and for at least four
6 (4) years after the licensee has stopped using the
7 validated process or after the licensee has made a
8 subsequent significant process change to the validated
9 process. The Authority shall promulgate rules for any
10 modifications to the validated processes,

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

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

- 1 g. a process to revoke the authority of licensees to
2 operate under process validation,
- 3 h. punishment for violations of process validation that,
4 at a minimum, would prohibit a licensee from operating
5 under process validation for five (5) years and the
6 assessment of a fine not to exceed Fifty Thousand
7 Dollars (\$50,000.00). Any such fine levied against a
8 licensee found to have violated the laws or rules of
9 process validation shall be remitted to the Department
10 of Mental Health and Substance Abuse Services,
- 11 i. punishment for violations if an adulterated product
12 that was produced under process validation fails
13 testing and the batch or lot has been sold to a
14 dispensary, the first violation shall be the
15 assessment of a fine not to exceed Ten Thousand
16 Dollars (\$10,000.00) and a public recall of the
17 product. The licensee shall further be required to
18 revalidate the process. A second violation within two
19 (2) years of a previous violation shall be the
20 assessment of fine not to exceed Seventy-five Thousand
21 Dollars (\$75,000.00) and a public recall of the
22 product. The licensee shall further be prohibited
23 from utilizing process validation for a minimum of
24 five (5) years. A third violation within two (2)

1 years of a previous violation shall be the assessment
2 of a fine of Two Hundred and Fifty Thousand Dollars
3 (\$250,000.00) and a public recall of the product. The
4 licensee shall further be prohibited from utilizing
5 process validation,

6 j. any willful violation of process validation shall
7 result in the assessment of a fine of Two Hundred and
8 Fifty Thousand Dollars (\$250,000.00) and a license
9 revocation hearing. A second willful violation of
10 process validation shall result in the assessment of a
11 fine of One Million Dollars (\$1,000,000.00) and a
12 hearing to permanently revoke the license,

13 k. an annual registration fee of Five Thousand Dollars
14 (\$5,000.00) per licensee, in addition to any other
15 fees due by the licensee, to be deposited in the
16 Oklahoma Medical Marijuana Authority Revolving Fund
17 for the enforcement of the laws and regulations of the
18 Authority,

19 l. establishing criteria for eligibility of testing
20 laboratories to be certified as a Certified Process
21 Validation Testing Laboratory and to conduct testing
22 for licensees pursuing or operating under process
23 validation. The criteria shall, at a minimum, pass
24 five (5) consecutive blind proficiency tests without a

1 failure over the course of six (6) months. The
2 proficiency tests shall be administered by the quality
3 assurance laboratory,

4 m. punishment for violations by a Certified Process
5 Validation Testing Laboratory that has been found to
6 have been falsifying data, providing misinformation,
7 or any unethical practices related to process
8 validation at a minimum shall prohibit a licensee from
9 operating under process validation for up to twenty-
10 five (25) years and the assessment of a fine not to
11 exceed One Million Dollars (\$1,000,000.00). Any such
12 fine levied against a licensee shall be remitted to
13 the Authority for deposit into the Oklahoma Medical
14 Marijuana Authority Revolving Fund. In addition to
15 this fine, in response to a finding of a willful
16 violation of process validation by the Authority, the
17 Authority shall also be authorized to collect, levy,
18 or impose any other fee, fine, penalty, or action as
19 allowed by law, and

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

- 1 3. Controlled access areas for storage of medical marijuana and
2 medical marijuana product test samples, waste and reference
3 standards;
- 4 4. Records to be retained and computer systems to be utilized
5 by the laboratory;
- 6 5. The possession, storage and use by the laboratory of
7 reagents, solutions and reference standards;
- 8 6. A certificate of analysis (COA) for each lot of reference
9 standard;
- 10 7. The transport and disposal of unused marijuana, marijuana
11 products and waste;
- 12 8. The mandatory use by a laboratory of an inventory tracking
13 system to ensure all harvest and production batches or samples
14 containing medical marijuana, medical marijuana concentrate or
15 medical marijuana products are identified and tracked from the point
16 they are transferred from a medical marijuana business, a patient or
17 a caregiver through the point of transfer, destruction or disposal.
18 The inventory tracking system reporting shall include the results of
19 any tests that are conducted on medical marijuana, medical marijuana
20 concentrate or medical marijuana product;
- 21 9. Standards of performance;
- 22 10. The employment of laboratory personnel;
- 23 11. A written standard operating procedure manual to be
24 maintained and updated by the laboratory;

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

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

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

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

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

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

21 O. A medical marijuana testing laboratory shall promptly
22 provide the Authority or designee of the Authority 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 Authority or designee of the Authority to laboratory
3 premises and to any material or information requested by the
4 Authority 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 Authority 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 Executive Director:

- 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 Executive
5 Director within one (1) year of the date the initial license is
6 issued. Renewal of any medical marijuana testing laboratory license
7 shall be contingent upon accreditation in accordance with this
8 subsection. 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 promulgated by the Executive
3 Director. Remediated and decontaminated medical marijuana may be
4 returned only to the originating licensed commercial grower.

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

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.

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12 58-2-11600 GRS 05/18/22

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