



# Oklahoma Medical Marijuana Authority: Testing Overview

September 5, 2018

# Overview

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# Oklahoma Medical Marijuana Authority

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- After the passage of the State Question, OSDH established the Oklahoma Medical Marijuana Authority (OMMA).
- This program area will be responsible for managing the medical marijuana program, including application processing, licensing, and compliance monitoring.
- The OMMA program resides within the Oklahoma State Department of Health and falls under the authority of the agency and the Commissioner of Health.
- Online applications received 8/25-9/4:

Total: 3,524

Grower: 589

Patient: 2,341

Processor: 166

Caregiver: 17

Dispensary: 411



# State Question 788

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- Specifies rapid deadlines for the Oklahoma State Department of Health (OSDH) to make applications available (30 days after passage), to start accepting and processing applications (60 days after passage), and to provide a response to applicants (14 days from application)
- Does not require any qualifying conditions for a medical marijuana license; and **does not require testing of medical marijuana**
- Specifies 8 license categories: medical marijuana (patient), caregiver, dispensary, commercial grower, processing, transportation, research, temporary (out-of-state)
- **Requires the development of a 12-member board to establish food safety standards for medical marijuana processing and handling**
- Allows inspections of processing sites and requires auditing of monthly reports from dispensaries, growers, processors, and researchers



# SQ 788 – Missing Public Health Provisions

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State Question 788 is largely silent to three major aspects of public policy that have the potential to protect the public’s health. These include, but are not limited to:

➤ Laboratory Testing

- Subchapter 8 of prior July 10, 2018 version of the rule included language that could be used as a starting point for future discussions.
- OSDH recommends the establishment of an advisory group to develop laboratory testing guidelines for the medical marijuana program.
- The Food Safety Standards Board, in the immediate future, could begin work to recommend testing guidelines as pertain to food products.

➤ Recall Requirements for Commercial Entities

- In the event medical marijuana products are found to be unsafe or below standards, a recall requirement would ensure such product either did not come into market; or was identified and appropriate consumer notices made.

➤ Packaging and Labeling

- Restrictions on packaging intended for minors, and for standardized labeling requirements (such as a universal symbol indicating the product contains medical marijuana, and consumer cautions)



# Emergency Rules Approved by the Board of Health

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- The Board of Health approved the emergency rules for the implementation of a medical marijuana program on July 10, 2018.
  - A permanent rule-making process will be pursued prior to the 2019 legislative session.
- The Governor approved these emergency rules on July 11, 2018.
- The emergency rulemaking process included the review of over 1,000 public comments and consultation with various stakeholder groups and state agencies.
- The Oklahoma Attorney General issued a letter to OSDH Commissioner on July 18, 2018 indicating that the Board of Health promulgated several rules in excess of its statutory authority.
- The revised emergency rules were posted publicly on July 27, 2018.
  - After reviewing the version of draft rules posted on July 27th, the OSDH received additional advice and counsel from the Attorney General's Office. A special meeting of the Board of Health occurred on August 1, 2018 to consider latest rule draft.
  - The Board of Health approved the rule. The Governor signed the rule on August 6, 2018. The amended sections will replace the rules previously enacted on July 11, 2018.



# Testing Provisions in 7/10/18 Emergency Rules

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The emergency rules considered by the Board of Health on July 10, 2018 contained language in Subchapter 8 Laboratory Testing.

- The majority of the proposed testing language came from Oregon.  
<https://www.oregon.gov/oha/PH/DISEASES/CONDITIONS/CHRONICDISEASE/MEDICALMARIJUANA/PROGRAM/Pages/testing.aspx>
- In collaboration with other partners, Oregon produced a technical report “Oregon Health Authority’s Process to Determine Which Types of Contaminants to Test for in Cannabis Products, and Levels for Action”  
<https://www.oregon.gov/oha/ph/PreventionWellness/marijuana/Documents/oha-8964-technical-report-marijuana-contaminant-testing.pdf>
- A smaller portion of the proposed testing language came from California.
- The following major categories of proposed rule were included:
  - Certain definitions
  - Certain requirements for state approval of and laboratory accreditation by:
    - The NELAC Institute (TNI);
    - ANSI/ASQ National Accreditation Board; or
    - Other similar accrediting entity using the ISO/IEC Standard 17025.



# Testing Provisions in 7/10/18 Emergency Rules

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- The following major categories of proposed rule were included:
  - Certain testing requirements for growers; and processors and dispensaries prohibited from accepting untested products.
  - Certain requirements for testing categories and standards for testing and reporting on:
    - Cannabinoids;
    - Residual pesticides;
    - Heavy metals;
    - Microbiological impurities;
    - Residual solvents and processing chemicals;
    - Water activity and moisture content;
    - Foreign materials;
    - Sterility; and
    - Such other testing categories as the Department may identify.
  - Appendix A of the July 10, 2018 version contained supporting tables for specific categories and action levels.





# Testing Provisions in 7/10/18 Emergency Rules

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- The following major categories of proposed rule were included:
  - Requirements for testing of certain types of medical marijuana:
    - Usable marijuana;
    - Concentrates and extracts;
    - Cannabinoid products; and
    - Random testing.
  - Certain requirements sampling requirements and procedures.
    - Batch samples
    - Standard Operating Procedures for sampling policies and procedures
    - Sample collection, transport, size of sample, labeling & recordkeeping, chain of custody
  - Certain requirements for standard operating procedures for laboratory analyses
  - Certain requirements for retesting
  - Requirements for laboratory quality assurance and quality control



# Public Comments on Testing

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The OSDH received over 1,000 comments from the public at large in June-July.

- OMMA received about 10-15 comments specific to laboratory testing.
- <5 individual laboratory organizations expressed interest in testing medical marijuana.

Major areas of input pertaining to testing were as follows :

- Laboratory Selection and Approval

- No current state process of selecting medical marijuana testing labs.
- Comments from the public sought clarification on state requirements.

- Accreditation/Certification Bodies

- Best practices for labs are monitored by various accrediting bodies.
- Standards for lab operations created by the International Standards Organization (ISO) are common among states with medical marijuana.
- ISO 17025 is often used as a baseline, with more specific standards possible.

# Public Comments on Testing

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## ➤ Cannabis Product Testing

- Numerous cannabis derived products: flower, edibles, concentrates, etc.
- Relevance of testing requirements depends on the product
  - Edibles often involve **food and human handling**: microbial tests.
  - Concentrate testing may involve **solvents and chemicals involved in processing**
- Frequency and comprehensiveness of testing based on regulation is a key consideration. Sampling methods may include testing a percentage of each batch produced on a periodic basis.

## ➤ Detectable Amounts

- Detect (D) and Non-Detect (ND): terms for minimum amount of a chemical to be measured in testing.
- Standard threshold levels can clarify the minimum level of dangerous substances.
- Laboratory equipment sensitivity can vary; accurate calibration needed.

# Public Comments on Testing

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## ➤ Costs for Commercial Entities

➤ Variation depending on type of tests, microbial (low) → solvents (high)

➤ Additional input from industry advocates in late July provided recommendations for Oklahoma to explore testing standards used in Illinois.

➤ Suggested testing rule language provided to the OSDH, but without statutory authority to pursue was not considered in subsequent revisions to emergency rules.

# Testing Provisions in 8/1/18 Emergency Rules

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The revised emergency rules reflect the provisions set forth in State Question 788 and provide for implementation of a regulatory program, including but not limited to clarification and changes to:

- Removes altogether:
  - Subchapter 8 pertaining to requirements for laboratory testing; and
  - Recall procedures for commercial entities issuing voluntary and mandatory recalls for medical marijuana.
- Clarification of certain definitions:
  - “Approved Laboratory” has been removed altogether
- Retains certain product labeling requirements advising of potential risks to children and pregnant women.

# FSSB Provisions in 8/1/18 Emergency Rules

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State Question 788 established the Food Safety Standards Board (FSSB) requiring the development of a 12-member board to establish food safety standards for medical marijuana processing and handling.

The revised emergency rules included certain clarifications and changes to:

- Composition of medical marijuana industry expert board/food safety standards board
- Clarifies standards for handling and processing medical marijuana in accordance with existing rule and statute.
- Clarifies the qualifications of the food safety standards board.
  - Adds that the selection of qualified candidates is not limited to the specified organizations.
  - Adds designee of any Oklahoma public health agency to the list of organizations.
- Changes the deadline for the promulgation of the food safety standards to August 27, 2018, as required by SQ 788.

# Testing Provisions in 8/24/18 FSSB Rule Recommendations

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The FSSB met on August 14, 15 and 24, 2018 to develop and approve recommendations in accordance with the statutory purpose of the board. <http://omma.ok.gov/food-safety-standards-board>

The FSSB received information from the Foundation of Cannabis Unified Standards (FOCUS) standards [www.focusstandards.org](http://www.focusstandards.org); and requested and reviewed the testing standards for the states of IL, CO, OR, WA, MT, and MI.

- The FSSB recommendations were drafted into the form of emergency rules which must be subsequently adopted by the Board of Health. The FSSB recommended rules include but are not limited to clarifications and changes to:
  - Clarification of certain definitions:
    - “Food,” “Information Panel,” “Label,” and “Principal Display Panel” have the same meaning as set forth in existing rule and/or statute.
    - New definitions established for “Lot” and “Oklahoma Uniform Symbol.”
  - Introduces a new rule section (310:681-5-8.1) establishing certain requirements for “Food Safety Standards for Processors”
  - Establishes food safety standards that **processors** must comply with in the preparation, production, manufacturing, processing, handling, packaging, and labeling of edible marijuana products.
  - Does not relieve licensed processors of any obligations under existing laws, rules, and regulations to the extent they are applicable and do not conflict with SQ 788.

# Testing Provisions in 8/24/18 FSSB Rule Recommendations

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- The FSSB approved their recommendations, drafted into the form of emergency rules, which include but are not limited to clarifications and changes to:
  - Requires additional packaging information to include cannabis ingredients; batch; lot code; and THC dosage in mg per unit.
  - Certain requirements for private homes, living or sleeping quarters, to be separate from and not be used for conducting processing operations.
  - Requirements for processors to conduct testing procedures on food products containing medical marijuana.



# Testing Provisions in 8/24/18 FSSB Rule Recommendations

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- The FSSB approved their recommendations, drafted into the form of emergency rules, which include but are not limited to clarifications and changes to:
  - Establishes testing standards and thresholds to be determined on a quarterly basis for one lot of each type of edible medical marijuana product.
  - Certain requirements for processor testing categories and standards for testing and reporting on:
    - Microbiological testing;
    - Solvent and chemical residue;
    - Metals;
    - Pesticide residue;
    - Potency; and
    - Contaminants and filth.

# Potential Impacts – Known and Unknown

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OSDH recommends the establishment of an advisory group to develop laboratory testing guidelines for the medical marijuana program.

Considerations for laboratory testing should include:

- Other state occurrences of adverse events and negative experiences resulting from adulterated products.
- Other state approaches to testing, required vs voluntary.
- In-state laboratory availability, as products should not move across state lines.
- Current state/private laboratory capacity and timeframes for laboratories to conduct medical marijuana testing. May require rule promulgation of other agencies (DEQ, OBN, etc.)
- State role in laboratory accreditation and/or approval, use of national or state standard, or state-run.
- Cost implications for businesses, per required testing category, sample sizes, and frequency of tests.

# Contact Information

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## Oklahoma Medical Marijuana Authority

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