August 8, 2018

Senator Greg McCortney  
2300 N. Lincoln Blvd., Room 528B  
Oklahoma City, OK  73105

Representative Jon Echols  
Majority Floor Leader  
2300 N. Lincoln Blvd., Room 442  
Oklahoma City, OK  73105

Dear Legislators,

Thank you for the invitation to share developments, research, insights and recommendations with the bipartisan working group on medical marijuana implementation. The Oklahoma Medical Marijuana Authority (OMMA) was established by OSDH to implement the will of the people as enacted though State Question 788, passed on June 26, 2018. Since passage of 788 and the compressed implementation timelines that it contains, many of us are experiencing an accelerated learning curve on issues surrounding medical marijuana. There are many questions being raised and I appreciate your leadership in this area. I look forward to our continued work together as additional statutory authority is discussed and a best path forward for our state is determined.

In your invitation you indicated the areas of most interest to the working group are:

- The latest version of the rules, timeline for implementation, and future hurdles;
- Trends from the public comment period; and
- Things that still need to be done, but the department doesn’t feel it has the authority to do without further legislative action.

While my presentation at the August 8th meeting will include information on the first two items, I want to provide this letter and attachments as additional information specifically responding to the third item requested.

The OSDH appreciates the counsel and guidance provided by the Attorney General. This counsel gives clear direction related to the rulemaking authority of the Board of Health under 788, and the newly approved revised rules permit OSDH to remain squarely within its statutory authority. However, these rules demonstrate the significant gaps within 788 that make adequate regulation of a new medical marijuana industry problematic. There remains much work to be done. For purposes of discussion among the Joint Committee, I am providing to you
three major categories of statutory changes for your consideration. These categories are; (1) public health concerns, (2) operational concerns, and (3) suggestions from the inter-agency committee. The attached document entitled “Potential Statute Change Recommendations” identifies recommendations from the OSDH, and separately those the OSDH has received from inter-agency partners through the course of meetings held before passage of 788.

Lastly, I know that you are aware that the staff of the OSDH has been through an acutely stressful environment these past 9 months. Since my arrival in April of 2018, I have observed OSDH staff not only willing to go above and beyond, but who are exceptionally competent and professional in their work. In April, I asked the Board of Health to consider and give approval for the commencement of work to begin planning for the implementation of SQ788, should it pass. Since that time the OMMA team, comprised of staff who were asked to redirect large portions of their time to this effort, has and continues to deliver results amidst the agency’s numerous challenges. They have risen to the occasion, are delivering a high quality product, and are to be commended for their work and dedication to the state.

Again, thank you for the opportunity to address the working group and I look forward to discussing these matters with you.

Respectfully,

Tom Bates, J.D.
Interim Commissioner of Health
PUBLIC HEALTH CONCERNS

Include requirements for laboratory testing of medical marijuana to ensure product is safe for consumption and use.

Define an "Approved Laboratory".

Include commercial entity recall procedures, and dispensary product storage standards.

Address child safety guidelines (labeling, packaging, safety/warning messages, advertising, product appearance similarities and forms not to resemble child-preferred items (candy, etc).

Amend Title 63 and Title 21 to include marijuana in Smoking In Public Places and Clean Indoor Air statutes, and close loopholes.

Amend OAC Title 310, Chapter 515 to include explicit reporting of cannabis-related poisonings or other injuries/conditions, modify the Health Care Information Act to allow such.

OPERATIONAL CONCERNS

Extend operational timeframes currently outlined by SQ788 (14 days) to allow up to 90 days for OSDH (or other entity) to return commercial entity application decisions on licensure.

Establish explicit authority for OSDH BOH and/or Commissioner (or other entity) to promulgate administrative rules.

Extend implementation timeframes currently outlined by SQ788; to a minimum 150-180 days after passage. A full 12 months after passage would be most ideal.

Allow for notices and all licensure communications to be provided to applicants in electronic mail format.

Establish fees for transportation, research and caregiver licenses.

Establish fund for OSDH (or other entity) to receive generated revenue (sales tax, fees, fines).
SUGGESTIONS FROM THE INTER-AGENCY COMMITTEE

Establish all commercial grows must be indoor only.

Prohibit homegrow.

Prohibit all smokeable forms. Prohibit dispensaries from selling smokeable forms (i.e. flower, dry leaf or plant, etc).

Extend time period from which individuals with felony convictions can hold licenses for dispensary, commercial, grower, processors, etc. to at least 10 years.

Establish criminal penalties for dispensing or giving medical marijuana to non-licensed individuals.

Require medical marijuana to be included as a mandatory reportable field within the PMP. Require physician reporting into the PMP for every medical marijuana recommendation they provide.

Require dispensaries to maintain a pharmacist onsite. Require pharmacist to look up and verify product recommendation in the PMP.

Require dispensaries to be OBN registrants (as is required today for any entity handling schedule 2-4 drugs), as a condition of licensure. Define medical marijuana as a controlled dangerous substance (currently defined in statute as schedule 1-4 drugs).

Permit cities and local municipalities to opt-out or restrict zoning laws and ordinances to limit medical marijuana availability and use.

Require medical marijuana license status as a field within the RealID system (tied to driver’s license).

Require qualifying conditions for patient licenses.

Require a physician registry for those able/willing to recommend medical marijuana products to people.

Require physician standards that mirror those for Opioid prescribing (title 63, section 2, 309 (I)).

Limit the number of patients on a physician’s panel at any given time who will be treated with medical marijuana to not more than 30 in the year 1; 100 in year 2; 275 in year 3.

Prohibit physicians from displaying signage to the public indicating the recommending physician’s ability to recommend medical marijuana.

Include physician training requirements

Include physician ongoing responsibility for care and treatment of patient

Establish a transparent and knowledgeable/qualified group to determine and recommend qualifying conditions for statutory authority.
Establish a patient cultivation license for home growers, separate from the patient license. Eliminate ability for home growers to self-process into concentrated and other forms.

Establish authority and requirement for state seed to sale system.

Increase application fees and establish a separate license fee. For example, in AR growers, processors and dispensaries can be subject to a $15k application fee (1/2 of which is refunded if application isn’t awarded); and an $100k license fee (upon award). A $500k performance bond is also required.

Reduce possession limits. OK possession limits are currently 6.5 times the felony limit in Colorado.

Increase financial penalty for being over-the-possession-limit. Currently at $400.

Establish per patient/per day possession and consumption limits; and/or limit amount dispensaries allowed to dispense per day/week pursuant to the physician recommendation.

Allow for and increase amounts of financial penalties for all infractions, violations, unmet compliance, etc. (Minimum $5000 per infraction).

Increase state tax rate to a minimum of 18%.

Specify that no state/public funds may be used for non-FDA approved medical marijuana products.

Limit maximum THC content of any product to no more than 12%.

Identify one serving size as 10mg.

Include patient validation and authentication steps for commercial entities.

Establish additional requirements for advertising/marketing/signage. Limits on number of signs, true and accurate content, no media venues where at least 20% of population is expected to be <21 years or college student, no signage within 1000 feet of school or church or public playground, no signage on public transit vehicle/shelter/property, no offer of free or donated products such as giveaways or coupons.

Limit the number of dispensaries either per geographic area (4 per county) or per population density (2 per 100k population).

Establish a “first-in-first-process” approach to dispensary applications and licenses.

Establish authority with Dept of Ag to be the inter-mediary for intra state transport of initial seeds, seedlings, cuttings, clones, etc. All initial plants/seeds/cuttings must go through Ag (as provided in current industrial hemp program rules) for tracking and registration.

Require medical licensure boards to promulgate rules establishing guidelines for product recommendation, continuing education curriculum and periodicity of recurring training, and a system for reporting adverse effects/events.
Require physicians to report the conditions and diagnosis code(s) for which they are recommending medical marijuana.

Require the medical examiner’s office to collect and report on presence of medical marijuana in deaths.

Address employer and employee rights while a person is on the job and under the influence of or in possession of medical marijuana.

Address employee safety and protections mandated at grower/processor/distributor commercial businesses.

Remove data restrictions and allow data capture of all fields, data sharing among state entities involved in the program, and de-identified analysis and reporting for research and public health surveillance.

Allow OSDH and other involved agencies to retain records and information on licensure, criteria, reporting, etc.
Overview

➢ State Question 788
➢ Current OSDH Efforts
➢ Oklahoma Medical Marijuana Authority
➢ Emergency Rules Approved and Revised
➢ Important Dates & Future Rule Making Timelines
➢ Impact of Potential Legal/Legislative Action
➢ Contact Information
State Question 788

- 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
- 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

Current OSDH Efforts

In order meet the rapid deadlines within the State Question, OSDH mobilized workgroups in April to leverage existing expertise in the agency. With the passage of the State Question, members of these groups have been responsible for tasks necessary to implement the program until permanent program staff are in place:

1. Licensing
2. Reporting and Data Security
3. Creation of Regulations/Promulgation of Agency Rules
4. Monitoring Health Impacts/Injury Prevention
5. Communications
6. Building Operations and Staffing

The Medical Marijuana Steering Committee includes members from each of the workgroups and meets (at minimum) weekly to present progress to OSDH leadership, subject matter experts (SMEs), and project managers.
Current OSDH Efforts

- **Application Requirements and Forms**: Application requirements, instructions, and supporting documentation forms (e.g., physician recommendation form) are posted on OMMA.ok.gov.

- **Technology Platform**: In partnership with OMES, OSDH has researched potential technology solutions for application processing and license issuance. The agencies anticipate a solution will be ready for testing by mid-August.

- **Building Operations and Staffing**: OSDH is currently working to ensure the necessary staff, equipment, and space are available for the program.

- **Communications**: OSDH staff are maintaining the OMMA.ok.gov website to ensure public information is available and updated regularly.

- **Monitoring Health Impacts**: OSDH staff are researching impacts in other states and potential methods to gather data, as well as coordinating with stakeholders.

Oklahoma Medical Marijuana Authority

- 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.

- The Program Director will be responsible for and oversee all aspects of the program administration. Selection of the Director is currently on hold, pending implementation and stabilization of the program after August 25th.

- Hiring of program management staff is currently under way.

- Public information related to the program will be maintained on the OMMA website, [http://omma.ok.gov](http://omma.ok.gov).

Oklahoma Medical Marijuana Authority
Website Analytics

- On July 26, 2018 the OMMA website received significant traffic. The numbers below were experienced in one day. The first milestone identified in SQ788 for OSDH to make application instructions and forms available online.
  - Unique Visitors: 11,101
  - Page Views: 23,056
- Similar traffic was experienced on 7/27/18 on social media platforms as follows:
  - OMMA Twitter Account
    - 144 followers
    - 5,049 tweet impressions
  - OMMA Facebook Account
    - 637 Page Views on 7/26/18
    - 341 Page Likes as of 7/27/18
    - 4,848 People Reached on 7/26/18
    - 381 Page Followers as of 7/27/18

Emergency Rules Approved by the Board of Health

- 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.
SQ 788 – Missing Public Health Provisions

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 versions 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)

SQ 788 – Provisions for Employers & Zoning

➢ Specifies an employer may not discriminate against a person in hiring, termination or imposing any term or condition of employment or otherwise penalize a person based solely upon:
  • The person’s status as a license holder;
  • The results of a drug test showing positive for marijuana.

➢ Employers may take action against a license holder if the holder uses or possesses marijuana while in the holder’s place of employment or during hours of employment.

➢ Employers may not take action against a license holder based solely on the status as a license holder.

➢ No city or local municipality may unduly change or restrict zoning laws to prevent the opening of retail marijuana establishments.
  • Per emergency rules, dispensaries must provide proof its location is not within 1000 feet of any public or private school entrance.
Revisions to Emergency Rules

➢ 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:
  ➢ Certain definitions
  ➢ Certain requirements for commercial applicants
  ➢ Certain requirements of a recommending physician
  ➢ Certain patient licenseholder requirements
  ➢ Certain medical marijuana product requirements
  ➢ Requirements for dispensing medical marijuana
  ➢ Requirements of inventory tracking, records, reports, and audits of commercial entities
  ➢ Composition of medical marijuana industry expert board/food safety standards board

OKLAHOMA MEDICAL MARIJUANA AUTHORITY

Revisions to Emergency Rules

➢ 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 of certain definitions:
    • “Dispensary Manager,” and the requirements for a licensed pharmacist, have been removed.
    • “Licensee” has been modified to exclude inmates of “any local, county, state, or federal correctional facility or jail.” Prior definition just excluded inmates of the Department of Corrections.
    • Definitions for public and private schools have been added. These definitions have been taken from Black’s Law Dictionary. When terms are not defined in statutes, their plain meaning applies.
    • “Owners” and “Ownership interest”, and the requirements for minimum percent interest, have been removed.
    • “Approved Laboratory” has been removed altogether.

OKLAHOMA MEDICAL MARIJUANA AUTHORITY
Revisions to Emergency Rules

➢ Clarification of certain requirements for commercial applicants:
  • Removes background checks for principal officers. Adds background checks for research applicants and all principal investigators involved in the research project.
  • Makes clear that commercial applicants are required under existing law to register with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control ("OBNDD"), and to pay associated fees.
  • No longer requires applicants to provide hours of operation. Submission of this information is optional.
  • Requires commercial applicants to provide a certificate of good standing from the Oklahoma Secretary of State to prove they are registered to do business in Oklahoma as required in SQ 788.
  • Adjusts the age restriction on employees from 21 to 18.
  • Removes altogether the requirement to post a surety bond or to validate the authenticity of the patient or caregiver’s license.
  • Removes requirement that commercial establishments be enclosed and other additional requirements. Provides instead that the construction of commercial establishments must meet the standards of any applicable state and local electrical, fire, plumbing, waste, and building specification codes.

Revisions to Emergency Rules (continued):

➢ Clarification of certain requirements for commercial applicants (continued):
  • Removes requirements for dispensing medical marijuana and product storage standards at a dispensary.
  • Removes all requirements for transportation of marijuana except for medical marijuana must be transported in a clearly labeled and locked container, shielded from public view.
  • Removes altogether Subchapter 4 pertaining to requirements for medical research licenses; and Subchapter 8 pertaining to requirements for laboratory testing. Retains research license application, reporting and auditing processes.
  • Limits processors as the only commercial establishment subject to annual inspections.
  • Requires commercial entities to address all waste generated by medical marijuana in a manner consistent with existing rule and statute. Removes other requirements for waste.
  • Removes altogether recall procedures for commercial facilities issuing voluntary and mandatory recalls for medical marijuana.
  • No longer prohibits dispensaries from repackaging products; being co-located with other commercial establishments; displaying signage or products; and advertising in certain markets. Retains prohibitions on false advertising; and advertising to induce persons under 21 to purchase or consume products.
Revisions to Emergency Rules

Changes to certain requirements of a recommending physician:
- Makes physician registration optional.
- Requires that a physician use accepted standards a reasonable and prudent physician would follow when recommending any medication to a patient.
- Removes language requiring physician registration with OBDD and for the physician to have completed all required training per their licensure board.
- Removes requirements for a bona fide physician-patient relationship and for a physician to have ongoing responsibility for the care of the individual.
- Removes requirements for any physician determination relating to risk of substance abuse; removes restrictions on physician ownership interest in a commercial establishment and ability for a physician to personally hold a medical marijuana license if actively making recommendations for other patients.
- Removes language that a physician ascertain whether a patient is pregnant or likely to become pregnant during term of license and, in such case, mandates discussion of adverse risks of marijuana use. Removes requirement for pregnancy test.
- Removes requirement that physicians be pediatricians or pediatric subspecialists who state same medical diagnosis and do not work together.

OKLAHOMA MEDICAL MARIJUANA AUTHORITY

Revisions to Emergency Rules

Changes to certain patient license holder requirements:
- Removes requirement for applicant to attest they will not divert marijuana to an individual/entity that is not lawfully entitled to possess marijuana.
- Removes language for patient and caregiver disposal of medical marijuana, grounds for sanctions, and variance.
- Removes requirements for homegrown medical marijuana such as obtaining property owner’s written permission; security and visibility of home grows; and closed loop system processing performed by a patient license holder.
- Clarifies a caregiver’s license pertains to a homebound individual, per SQ788.

Changes to certain medical marijuana product requirements:
- Removes restrictions on smokable medical marijuana and medical marijuana products.
- Removes subsections (c) and (d), which limit the forms of medical marijuana and prohibit the dispensing of marijuana in flower, dry leaf, or plant form.
- Removes limitations on THC content.
- Adds 6 mature plants and 6 seedling plants to the approved transaction amount.
- Retains certain product labeling requirements advising of potential risks to children and pregnant women; and no longer requires labels to contain certain patient, physician or dispensing individual information.
- Clarifies minors are not prohibited from using nebulizers or other aerosolized medical devices, and smokable or vaporized products must have two physicians agree it is medically necessary for the minor.

OKLAHOMA MEDICAL MARIJUANA AUTHORITY
Revisions to Emergency Rules

➢ Changes to requirements for dispensing medical marijuana:
  • Removes all references to a dispensary manager.
  • Places the responsibilities of the dispensary manager upon the dispensary as a whole.
  • Limitations on hours of operation are removed entirely.
  • Removes prohibition on dispensaries co-locating with other business entities or commercial establishments.
  • Removes limitation that commercial establishments may only sell medical marijuana and medical marijuana products.
  • Removes limitation on sale of items bearing a symbol of or referencing marijuana or medical marijuana products.
  • Still prohibits commercial establishments from manufacturing or selling medical marijuana and medical marijuana products that are intentionally attractive to children or minors but revises the language of that prohibition.
  • Allows licensed dispensaries to sell marijuana seedlings and mature plants.

Revisions to Emergency Rules

➢ Changes to certain requirements of inventory tracking, records, reports, and audits of commercial entities:
  • Provides that the Department may conduct audits and inspect the books and records to ensure the accuracy of the monthly reports.
  • Requires commercial licensees to provide the Department access to their books and records in a reasonable amount of time not to exceed 15 days.
  • Requires the Department to disclose criminal activity discovered during an audit to law enforcement.

➢ 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.
Important Dates

The State Question mandates certain timeframes related to applications and food safety standards.

6/26 30 days
Passage of SQ 788
- Application requirements and instructions available on omma.ok.gov for patients, caregivers, growers, processors, and dispensaries
- Food Safety Board members identified

7/26 30 days
- OMMA receives applications through online system
- OMMA reviews and processes applications next business day (8/27)
- Food Safety standards recommended by board and made available

8/25 14 days
- First approval/denial letters and licenses mailed to applicants

9/10

Future Rule Making Timeframes

The Emergency Rule as signed by Governor Fallin on August 6, 2018 must undergo additional promulgation activities through the permanent rule making process.

- The permanent rule making process will include a public comment period.
- Permanent rules must be submitted to the legislature by April 1, of each year.
- The next final action on the rule would occur during the 2019 regular legislative session.

Due to changes to the governance structure of the OSDH Board of Health, the promulgation of agency rules will be initiated by the Commissioner of Health, after the BOH becomes an advisory body effective January 19, 2019.
Impact of Potential Legal/Legislative Action

- Pending lawsuits, and orders that may result, could potentially change certain aspects of the program or delay implementation.
- Any future statutory changes to current law as passed in State Question 788 could also impact the program.
  - Implementation timeframes of potential statutory changes would be dependent upon the scope of such changes, and areas of operational impact.
- However, OSDH is continuing to work to implement the program within the framework and timelines of the State Question and the emergency rules.

Contact Information

Oklahoma Medical Marijuana Authority

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