MMCP Rules Update for JCARR Filing
Background

- The primary focus of the rules is to develop a program that ensures
  - Public safety
  - Access to a safe medical product
  - Scalability to allow the program to respond to changes in demand

- The draft rules presented to the Medical Marijuana Advisory Committee were developed after
  - Benchmarking with other states and talking with industry experts
  - Engaging with registered patients and caregivers outside of Ohio
  - Listening to concerns from prospective patients and caregivers in Ohio
Processor and Testing Laboratory Rules Updates

Medical Marijuana Control Program
Ohio Department of Commerce
Processor Rules Revisions

• The Department received two comments during the CSI public comment period for the Processor rules.

• No substantive changes were made to the rules as a result of these comments.

• Minor revisions to the product labelling requirements were made as a result of collaboration with the Board of Pharmacy.
Testing Laboratories Rules Revisions

• The Department received four comments during the CSI public comment period for the Testing Laboratory rules.

• Comments largely pertained to statutory matters.

• Few substantive changes were made to the rules as a result of these comments.
Testing Laboratories Rules Revisions

• Prior to the CSI comment period, the following revisions were made:

  • Added language to rules 3796:4-1-02(B)(3) and 3796:4-2-02(A) to provide clarity with respect to ISO/IEC 17025 accreditation compliance and the validation of alternative methods as part of ISO/IEC 17025 accreditation.

  • Language modified in rules 3796:4-2-01(A)(6), 3796:4-2-01(C)(2), and 3796:4-2-02(G) to clarify accreditation standards for external entities performing assessments of testing laboratories, including ISO/IEC 17011, 17034, and 17043.

  • Rule 3796:4-2-10 was added to regulate the transportation of medical marijuana samples by a licensed testing laboratory.
Dispensary Rules
Medical Marijuana Control Program
State of Ohio Board of Pharmacy
Public comment – Dispensaries

• Public comment accepted from March 9, 2017 through March 23, 2017

• Comments submitted by 9 entities

• Reminder that general rules were filed with cultivator rules and have been adopted, including general definitions and a 500 foot rule applying to all medical marijuana entities
• Definition of “abandoned application”

• Concern raised over delays in dispensary application review process should applicants submitting incomplete applications be given 30 days to submit missing information

• Applicant now has 5 calendar days to complete missing information when notified by the Board
Definitions 3796:6-1-01

• Definition of “positive identification”
  
  • CSI request to better define “reasonable time” for manually signing a printout of transactions
  
  • A print out of transactions at a dispensary must be completed in no more than 48 hours
Clarified that the definitions applying to economically disadvantaged groups is the same as those used for MBE purposes.
Application Evaluation
3796:6-2-07

- Applications for an associated key employee license—owners, board members, etc.—run parallel to dispensary applications

- Associated key employee licensing is dependent upon the award of a dispensary license

- Clarified that the associated key employee fee is not required until 30 days after the award of a provisional license
License Bond
3796:6-2-11

- Harmonized with other MMCP rule language
- Bond or surety account required if available
General Dispensary Operations 3796:6-3-01

- Authorized dispensaries to provide an alternate container to patients and caregivers who may need to travel with aliquots

- Concern over proper storage of edibles at a dispensary raised
  - Products requiring hot and cold-holding prohibited at a dispensary
  - Requirement for use-by date removed from labeling requirements (3796:6-3-09)
Sale of Medical Marijuana 3796:6-3-08

• Compatibility requirements at point of sale modified to better align with information developed through progress with the patient registry

• Expressly prohibits dispensaries from selling expired, damaged, deteriorated, misbranded, adulterated, or opened medical marijuana
Patient and Caregiver Rules

Medical Marijuana Control Program
State of Ohio Board of Pharmacy
Public comment – Patients and caregivers

• Public comment accepted from April 21, 2017 through May 5, 2017

• Comments submitted by 5 entities
  
  • Exception taken with the use of the term “caregiver”
  
  • Suggested certain exemptions to registration
  
  • Concern over email requirements
Notification requirements
3796:7-2-08

- Request for a clarification that patient or caregiver is only responsible for notifying the Board of information within their control
- Clarifying language added
Fee Structure
3796:7-3-01

• Previous drafts required a $25 fee for each patient associated with a caregiver

• Rule amended to require a flat $25 for caregivers each year
Form and Method of Administration Rules
Medical Marijuana Control Program
State of Ohio Board of Pharmacy
Public comment – Form and method

• Public comment accepted from May 5, 2017 through May 19, 2017

• Comments submitted by 1 entity
  • Suggested reliance on physician instruction
  • Characterizing flavors
Authorized Forms and Methods of Administration 3796:8-2-01

- Lotions, creams, or ointments for topical administration included
- 90-day supply is consistent with patches
Medical Board Updates for Ohio Medical Marijuana Control Program

June 2017
Medical Board Rules Update

The board has developed these draft rules:

• 4731-32-01 Definitions
• 4731-32-02 Licensure Eligibility, Process and Renewal
• 4731-32-03 Standard of Care
• 4731-32-04 Suspension and Revocation of Certificate to Recommend
• 4731-32-05 Requirements for Petition to Add Qualifying Condition

Timeline:

• March 23- Filed with CSI March 23
• June 9- Plan to file with JCARR
• July 10- Public hearing at 1 p.m.
• September 8- Deadline set forth by HB 523
Physicians wishing to recommend must have competed at least 2 hours (per year) of continuing medical education in a course or courses certified by the Ohio State Medical Association (OSMA) or the Ohio Osteopathic Association (OOA) that assist physicians in both of the following:

- Diagnosing qualifying medical conditions as defined in Ohio Revised Code Section 3796.01.
- Treating qualifying medical conditions with medical marijuana, including the characteristics of medical marijuana and possible drug interactions.

**Ohio State Medical Association**
- osma.org/marijuana

**Ohio Osteopathic Association**
- ooanet.org