Dispensary Rules

State of Ohio Board of Pharmacy
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

• Recall that a general definitions rule and a rule establishing the 500 foot prohibitions apply to all medical marijuana entities and were presented with the cultivator rules package
3796:6-1-01 Definitions

• The proposed dispensary rules include a dispensary-specific definitions section

• These definitions are intended to supplement the common definitions presented with the cultivator rules package
3796:6-2-01 Request for application to operate dispensaries

• Establishes expectations for dispensary RFAs including:
  
  • Timeframe for response
  • Items that will be included in the request
  • Provides that a scoring rubric and geographic dispensary districts will be included with the intent of ensuring patient access
3796:6-2-02 Applications to operate dispensaries

- Establishes baseline expectations for dispensary applications
- Application will need to cover several topics, most notably, an inventory control plan, security plan, employee training plan, and intended plan to meet the needs of Ohio’s patient population
- Establishes financial requirements that will allow for effective implementation of submitted application
- Dispensaries will be asked to include any compassionate care programs intended to benefit veterans and the indigent
3796:6-2-03 Dispensary ownership and ownership requirements

• Defines which natural persons are responsible for signing documents

• Requires owners to be 21 years or older

• Limits relevant ownership provisions of rules to 10% or more, unless requiring the owner or person exercising substantial control would serve the public interest
3796:6-2-04 Dispensary license application evaluation

• Application evaluation will be on a competitive basis

• If no applications are selected the Board may republish an RFA in the applicable dispensary district
3796:6-2-05 Provisional Licenses

• The Board may issue up to 40 dispensary licenses prior to September 8, 2018

• Board has discretion to issue additional provisional licenses after September 9, 2018, based on state’s population and patient population
3796:6-2-06 Final inspections and certificates of operation

• Affords provisional licensees six months from issuance to meet conditions in the application and rules to complete a final inspection and be issued a certificate of operation

• Dispensary cannot dispense until certificate is issued

• Includes a provisions for a dispensary that does not pass inspection

• Limits owners to five dispensary licenses in Ohio
Licensed Dispensary Employees

- **Associated key employees**
  - Owners, corporate officers, board members, partners
  - $500 biennial licensing fee

- **Key employees**
  - Includes the designated representative, clinical director, and managers
  - One key employee must be present during all hours of operation
  - $250 biennial licensing fee

- **Support employees**
  - Dispensary technicians
  - $100 biennial licensing fee
3796:6-2-07–08 Licensing for dispensary employees

• Provides application process for each of the three types of dispensary employees

• Set forth background check procedure

• Biennial licensing procedure
3796:6-2-09 Dispensary employees generally

• Allows a single license in order to work at any dispensary with common ownership

• Requires return of employee cards upon certain conditions

• Establishes reporting requirements for changes in demographic information or arrests/convictions

• Requires all dispensary employees to be 21 or older
3796:6-2-10 Dispensary certificate of operation renewal

• Outlines the process for renewal of a dispensary certificate of operation

• If not renewed before expiration, suspended for 30 days then revoked
3796:6-2-11 License bond

- Requires bond or escrow in the amount of $50,000
- To guarantee compliance with state tax laws and MMCP rules
3796:6-2-12 Changes to ownership

- Defines change of ownership
- Prohibits changes in ownership before 1 year of operation
3796:6-2-13 Request to relocate dispensary

• Authorizes relocation within the same dispensary district

• Requires board to consider population of the state, the patient population, and geographic distribution of dispensary sites
3796:6-2-14 Discontinuing dispensary business

• Requires notice to the Board

• Allows for one-time transfer of medical marijuana to another dispensary

• Dispensary will have to negotiate transfer with a processor and document transfer in seed-to-sale
3796:6-3-01 Dispensary operations generally

• Baseline rules for dispensary operations
  • No out-of-state sales
  • Employee identification requirements
  • Requires an annual review of policies
3796:6-3-02 Dispensary premises generally

- Establishes baseline rules for premises including:
  - Lighting
  - General sanitation
  - Maintenance in compliance with relevant zoning and fire codes

- Requires notice related to edibles in the absence of health inspections and relevant to food allergens
3796:6-3-03 Hours of operation

• Dispensaries must be open a minimum of 35 hours each week

• Hours of operation must be between 7:00 a.m. and 7:00 p.m.
3796:6-3-04 Procedures when dispensary closed

- Certain security measures must be in place when dispensaries are closed

- Sales are prohibited when a dispensary is closed
3796:6-3-05 Designated representative

• Responsible for:

  • Record-keeping

  • Oversight of receipt, storage, dispensing, and handling procedures at a dispensary

  • Notification to the board of changes in employee status and for ensuring the return of employee cards
3796:6-3-06 Clinical director

• Must be a pharmacist, clinical nurse specialist, nurse practitioner, physician, or physician assistant authorized by the provider’s licensing agency

• Must be available for consultation with dispensary employees

• One person may serve as clinical director for up to 5 dispensaries

• Responsible for health-related training of employees
3796:6-3-07 Receipt of medical marijuana

• Requires standard operating procedures related to receipt, storage, dispensing, and disposal of medical marijuana

• Employees must be trained in SOPs

• Requires chain of custody tracking in seed-to-sale system
3796:6-3-08 Security, control, and storage of medical marijuana

• Establishes record-keeping requirements for inventory tracking

• Restricts access to medical marijuana inventory storage only to necessary dispensary employees

• Marijuana eligible for dispensing must be kept separate from that which must be destroyed
3796:6-3-09 Dispensing of medical marijuana

• Sets forth required compatibility with OARRS-related technology and seed-to-sale

• Requires verification of completed, valid recommendation, state-issued ID, and registry identification card

• Limits dispensing to patients 18 years or older; minor patients will require a designated caregiver

• Dispensing must be documented in seed-to-sale and OARRS

• Marijuana must be dispensed in whole day supplies
3796:6-3-10 Labeling requirements and accompanying dispensing materials

• Labeling requirements for plant material and for forms other than plant material

• Labeling requirements can be established through a combination of package labeling and dispensary-created labeling

• Toll-free line intended to respond to inquiries regarding adverse reactions and to provide information about available services and assistance is required to be provided
3796:6-3-11 Reporting to prescription monitoring program

- Requires near-real-time reporting from dispensary system into OARRS

- Near-real-time reporting allows for patient flexibility when choosing a dispensary

- Reporting format is consistent with established national platform for reporting prescription drugs
3796:6-3-12 Duty to report

• Requires dispensaries to monitor for theft and loss of medical marijuana

• Loss or theft must be immediately reported to law enforcement and to the Board

• Suspected fraudulent recommendations must be reported to the Board
3796:6-3-13 Dispensing error reporting

• Dispensaries must establish procedures to identify dispensing errors and to notify patients, caregivers, and physicians

• Requires dispensaries to provide information notifying patients and caregivers about how to report suspected errors in dispensing to the Board
3796:6-3-14 Review of dispensing errors

• Clinical director must:
  • Review dispensing errors
  • Notify employees
  • Keep a record of any resulting changes
3796:6-3-15 Destruction of medical marijuana

• Sets standards for the disposal of medical marijuana waste and what information must be recorded for all disposals

• Requires advanced notice to the state board of pharmacy of medical marijuana disposal

• Two employees must be present for destruction
3796:6-3-16 Educational materials

• Requires dispensary to establish policies for the education of patients and caregivers

• Establishes minimum educational materials

• Requires that pricing be publicly available
3796:6-3-17 Monitoring, surveillance, and security

• Requires dispensary to establish a security policy

• Establishes

  • Physical barrier requirements

  • Surveillance requirements

  • Monitoring and notification requirements
3796:6-3-18 Record-keeping requirements

- Requires dispensary to establish a record-keeping policy

- Policy must include a 3-year retention period
3796:6-3-19 Confidentiality of patient records

• Expressly states that patient records are confidential

• Details the conditions and timing under which patient records must be made available to the Board
3796:6-3-20 Training requirements

• Establishes baseline training requirements for dispensary employees

• Must include:
  • OARRS training
  • Seed-to-sale training
  • Training on forms and methods of administration

• 8 hours of training are required for dispensary employees each year
3796:6-3-21 Dispensary internal inventory control system

• Requires dispensaries to maintain their own inventory control system

• Details required compatibility of that system with state systems and necessary functionality

• Internal inventory system will operate as the official dispensing record

• Reconciling with internal system and state system is required on a weekly basis
3796:6-3-22 Recall procedures

• Requires dispensaries to establish policies related to the mandatory and voluntary recall of medical marijuana, including notification

• Dispensaries must put procedures into action upon notice from the Board or the Department of Commerce
3796:6-3-23 Prohibitions

• General prohibitions related to dispensaries are provided

• Among prohibited items are drive through windows and home delivery
3796:6-3-24 Dispensary access

• Details who may have access to the following areas:
  • Dispensary department – patients, caregivers, employees
  • Restricted access areas – necessary dispensary employees as determined by the dispensary

• All others generally must be authorized by the Board and be under supervision while on premises
3796:6-3-25 Advertising, marketing, and signage

• Requires Board approval of an advertisement before it is disseminated to the public

• Prohibits specific content, as well as distribution media
  • Cannot include cartoon characters
  • Cannot target minors

• Establishes restrictions on the placement and appearance of advertisements

• Places restrictions on a dispensary’s use of social media and web activity
3796:6-4-01–02 Enforcement, compliance, and inspection

• Provides scope of Board’s enforcement authority

• Establishes scope of inspections

• Provides for both announced and unannounced inspections
3796:6-4-03–04 Grounds for discipline and discipline of an issued license

• Establishes grounds under which both dispensary entity and dispensary employee licenses may be subject to discipline

• Provides for when due process rights will be implemented in response for action due to the commission of a prohibited activity
3796:6-4-05 Suspension of a dispensary employee license without a hearing

- Establishes the following as grounds for suspension without a hearing:
  - Substance abuse or addiction
  - Continuing to operate as a dispensary employee presents an immediate and serious harm to oneself or others
  - Upon notification of a felony drug conviction
  - Upon notification of an arrest or conviction of a disqualifying offense
3796:6-4-06 Suspension of a dispensary license without a hearing

• Limits as grounds for suspension without a hearing to when continual operation as a dispensary presents an immediate and serious harm to others
3796:6-4-07 Failure to properly store medical marijuana

- Provides notice that failure to properly store marijuana may subject products to being placed under seal

- Upon reasonable suspicion that improper products are being dispensed, products may be confiscated and submitted to a testing lab
3796:6-4-08 Restoration of license from discipline

• Licenses generally may be restored once all conditions precedent have been met
3796:6-4-09 Interagency cooperation

- Notice will be provided to the Department of Commerce, Medical Board, and law enforcement when dispensary licenses are suspended or revoked
3796:6-4-10 Variances

• Authorizes the granting of variances at the Board’s discretion if listed criteria are met

• Allows for flexibility when encountering unpredictable fact patterns
3796:6-5-01 Fee schedules

• Establishes fees for applications, certificates of operations, renewals, lost/destroyed/stolen certificates and employee identification cards

• Renewal for dispensaries is every two years
  • $100 for support employees
  • $250 for key employees
  • $500 for associated key employees

• Renewal for dispensaries and employees is every two years
  • Application fee is $5,000
  • Biennial license fee is $80,000