

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

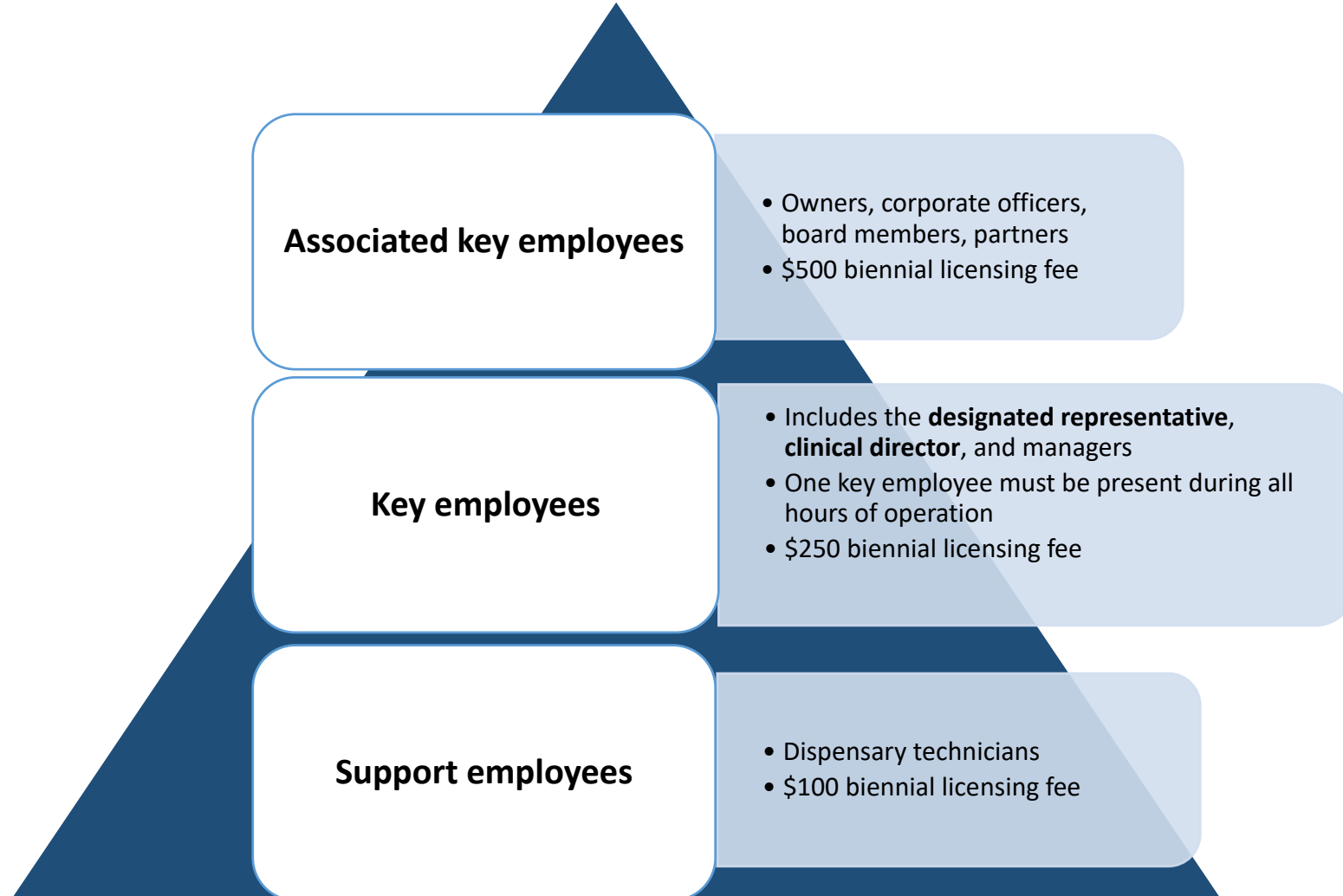


3796:6-2-06 Final inspections and certificates of operation

- 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





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