

**7/13/20**

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

**New:**

- 3796:6-3-11 – Outlines the duty to report requirements for all dispensary employees. Requires dispensaries to monitor for theft and loss of medical marijuana and to immediately report any incident to the Board. The rule was amended from the original version to clarify the duty to report requirements for dispensary employees. (Rescinds current version of the rule – amended version is included with this BIA to highlight changes to the rule).
- 3796:6-3-18 – Outlines the requirements for patient records. Establishes that dispensaries shall ensure the confidentiality of all patient transaction records and who may have access to the records. (Rescinds current version of the rule – amended version is included with this BIA to highlight changes to the rule).

**Amend:**

- 3796:6-3-01 – Establishes the requirements for dispensary operations including packaging and labeling requirements and employee identification. The rule is amended to outline when a container package can be modified and amends the requirements for an employee identification card.
- 3796:6-3-02 – Establishes the requirements for dispensary premises. Amends the rule to include an opioid treatment program as a location that dispensaries are prohibited from being situated within 500 feet, adds that a dispensary shall display a placard if a dispensary sells edible products, and adds that a dispensary shall establish, maintain, and comply with written policies and procedures.
- 3796:6-3-03 – Establishes a dispensary's hours of operation. Amended to require that a dispensary posts its hours of operation on its website and that changes in dispensary hours of operation should be submitted and approved by the Board.
- 3796:6-3-05 – Outlines the requirements for a dispensary's designated representative. Removes the requirement of advance notification of a change of a designated representative and removes the requirement that a designated representative's key employee card be returned to the Board upon separation of the key employee from the dispensary. The rule is amended to require that the card be destroyed.

- 3796:6-3-06 – Outlines the requirements of a medical marijuana purchase receipt. Amended to correct spelling.
- 3796:6-3-08 – Establishes the requirements for the dispensing of medical marijuana in a dispensary. The rule is amended to clarify the dispensing requirements.
- 3796:6-3-12 – Requires dispensaries to establish a quality assurance program to prevent dispensing errors. Added the patient to be included as part of a dispensary's quality assurance program communication plan.
- 3796:6-3-13 – Requires a designated representative to review dispensing errors and conduct a quality assurance review. Amended to add that a dispensary designated representative shall report any error in dispensing to the Board within twenty-four hours.
- 3796:6-3-14 – Establishes the methods for destruction and disposal of medical marijuana. Amends the rule to include rendering in accordance with methods of federal controlled substance destruction under 21 CFR 1317.90 as an option for destruction and outlines how products and recalled products may be returned to a dispensary.
- 3796:6-3-15 – Outlines the requirements for dispensary patient and caregiver educational materials. Removes the requirement that patient and caregiver education and support policy include updated information about the purported effectiveness of various forms and strains of medical marijuana.
- 3796:6-3-16 – Establishes the monitoring, surveillance, and security requirements for a dispensary. Amended for grammatical fixes.
- 3796:6-3-17 – Outlines the record-keeping requirements for a dispensary. Amended to include that records need to be made readily retrievable, and clarify what records are required to be maintained.
- 3796:6-3-19 – Outlines the requirements for dispensary employee training. Amended to include duty to report information as part of employee training and adds that training material approval is valid for two years.
- 3796:6-3-20 - Requires dispensaries to maintain their own internal dispensary inventory system and details necessary contents. This internal system will function as the official dispensing record. The rule is amended to modify the requirements for the quarterly financial statements.
- 3796:6-3-21 - Requires dispensaries to establish policies related to the mandatory and voluntary recall of medical marijuana, including notification to relevant parties. Dispensaries must put their recall procedure into action upon notice from the Board or the Department of Commerce. The rule was amended to include recalled products and that recalled products must be returned to the licensed cultivator or processor.
- 3796:6-3-22 – This rule outlines the prohibitions for dispensaries. The rule is amended to include that no food or beverages shall be offered or furnished on premises. The rule also prohibits delivery systems and liquor on premises and allows dispensary employees to utilize discounts if the employee is a registered patient.

- 3796:6-3-23 - Details who may have access to the dispensary department and restricted access areas. Provides that all others must be authorized by the Board (third parties and agents of the Board) except in the case of an emergency. The rule is amended to clarify the process of allowing visitors to visit a dispensary.

Comments on the proposed rules will be accepted until close of business on August 3, 2020. Please send all comments to the following email address: [RuleComments@pharmacy.ohio.gov](mailto:RuleComments@pharmacy.ohio.gov)

In addition, please copy your comments to: [CSIPublicComments@governor.ohio.gov](mailto:CSIPublicComments@governor.ohio.gov)



## Common Sense Initiative

**Mike DeWine**, Governor  
**Jon Husted**, Lt. Governor

**Carrie Kuruc**, Director

### Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Cameron McNamee  
Cameron.mcnamee@pharmacy.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Dispensary Operations

Rule Number(s): 3796:6-3-01, 3796:6-3-02, 3796:6-3-03, 3796:6-3-05, 3796:6-3-06,  
3796:6-3-08, 3796:6-3-11, 3796:6-3-12, 3796:6-3-13, 3796:6-3-14, 3796:6-3-15, 3796:6-3-  
16, 3796:6-3-17, 3796:6-3-18, 3796:6-3-19, 3796:6-3-20, 3796:6-3-21, 3796:6-3-22, 3796:6-  
3-23;

Date of Submission for CSI Review: 7/13/20

Public Comment Period End Date: 8/3/20

**Rule Type/Number of Rules:**

New/ 2 rules

No Change/      rules (FYR?     )

Amended/ 17 rules (FYR? Y)

Rescinded/ 2 rules (FYR?     )

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies

**must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.**

### **Reason for Submission**

- 1. R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

**Which adverse impact(s) to businesses has the agency determined the rule(s) create?**

**The rule(s):**

- a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
  - 3796:6-3-01, 3796:6-3-02, 3796:6-3-04, 3796:6-3-06, 3796:6-3-08, 3796:3-6-11, 3796:6-3-12, 3796:6-3-13, 3796:6-3-14, 3796:6-3-15, 3796:6-3-16, 3796:6-3-17, 3796:6-3-18, 3796:6-3-19, 3796:6-3-20, 3796:6-3-21, 3796:6-3-22 – A certificate of operation is required to operate a dispensary.
  - 3796:6-3-03 – A certificate of operation is required to engage in dispensary operations.
  - 3796:6-3-05 – A designated representative of a dispensary must be licensed as a dispensary key employee.
  - 3796:6-3-11, 3796:6-3-13, 3796:6-3-19 – All employees at a dispensary are required to be licensed by the Board.
- b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
  - 3796:6-3-08 – A person who knowingly dispenses a questionable or suspicious order, as well as the person issuing it, are subject to the penalties provided for violations of the provisions of law relating to controlled substances.
  - 3796:6-3-11 – Failure to report to the Board may result in disciplinary action or fines against the licensee.

- 3796:6-3-22 – Failure to comply with the rule may result in disciplinary action or fines.

**c. ☒ Requires specific expenditures or the report of information as a condition of compliance.**

- 3796:6-3-01 – To comply with this rule, dispensaries are required to report organization policies and procedures and maintain a list of third-party vendors.
- 3796:6-3-02 - This rule requires dispensaries to report building renovations. There is a \$5,000 fee for major renovations. Dispensaries that sell edible products will be required to post specific signs.
- 3796:6-3-03 – A dispensary is required to report if the dispensary is closed for longer than two days. This rule also establishes minimum operating hours and staffing requirements for dispensaries.
- 3796:6-3-04 – Dispensary personnel must report unauthorized access to dispensary.
- 3796:6-3-05 – Key dispensary employees are required to notify the Board within 24 hours of learning of a dispensary employee’s arrest for disqualifying offense and a known or suspected theft, diversion or loss of medical marijuana. A dispensary is required to notify the Board of a change of designated representative.
- 3796:6-3-06 - Requires dispensary employees to use the state inventory tracking system to identify and track all information as it relates to the dispensary’s stock of medical marijuana from the time it is received to the time it is dispensed to a patient or caregiver. This is unchanged from the current rule, so there should not be any additional costs associated with compliance.
- 3796:6-3-08 – Requires a dispensary to utilize an internal inventory control system and card scanner. This is unchanged from the current rule, so there should not be any additional costs associated with compliance.
- 3796:6-3-11 – Requires that any theft or loss of medical marijuana product or device, fraudulent or unlawful recommendation of medical marijuana, and serious or adverse events related to security or administration of medical marijuana be reported to the Board.
- 3796:6-3-12 – Dispensaries are required to provide to the Board a written copy of the quality assurance program that describes policies and procedures to detect, identify, and prevent dispensing errors.
- 3796:6-3-13 – Requires the dispensary employees to report discovery or reporting of a dispensary error and create a record of every quality assurance review.
- 3796:6-3-14 - This rule requires a dispensary to notify the Board of rendering of medical marijuana as unusable, date and time medical marijuana will be rendered unusable and disposed, and to enter all medical marijuana returned by patient for purposes of destruction into tracking system.

- 376:6-3-15 - This rule requires a dispensary to submit a patient and caregiver education plan to the board for review. Expenditures may include the cost to establish the education plan, and the amount and level of detail used to create educational materials
  - 3796:6-3-16 - A dispensary must submit security policies and procedures to the Board for review.
  - 3796:6-3-17, 3796:6-3-18, 3796:6-3-20 – All patient records and product inventory must be made available to the Board on request. There may be administrative costs associated with the cost of maintaining a record keeping system.
  - 3796:6-3-19 – Dispensaries are required to maintain a record of employee training and submit training materials to the Board for approval.
  - 3796:6-3-21 – Dispensaries are required to report product recalls to patients.
  - 3796:6-3-22 – A dispensary must report to the Board immediately if surveillance equipment becomes inoperable.
  - 3796:6-3-23 – A dispensary must submit in writing a request to the Board to allow visitors dispensary access.
- d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**
- Many of the rules require a dispensary licensee to implement security methods as well as training and notification procedures that will result in increased expenses to maintain compliance.

### **Regulatory Intent**

#### **2. Please briefly describe the draft regulation in plain language.**

*Please include the key provisions of the regulation as well as any proposed amendments.*

#### **New:**

- 3796:6-3-11 – Outlines the duty to report requirements for all dispensary employees. Requires dispensaries to monitor for theft and loss of medical marijuana and to immediately report any incident to the Board. The rule was amended from the original version to clarify the duty to report requirements for dispensary employees. (Rescinds current version of the rule – amended version is included with this BIA to highlight changes to the rule).
- 3796:6-3-18 – Outlines the requirements for patient records. Establishes that dispensaries shall ensure the confidentiality of all patient transaction records and who may have access to the records. (Rescinds current version of the rule – amended version is included with this BIA to highlight changes to the rule).

**Amend:**

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- 3796:6-3-02 – Establishes the requirements for dispensary premises. Amends the rule to include an opioid treatment program as a location that dispensaries are prohibited from being situated within 500 feet, add that a dispensary shall display a placard if a dispensary sells edible products, add that a dispensary shall establish, maintain, and comply with written policies and procedures.
- 3796:6-3-03 – Establishes a dispensary's hours of operation. Amended to require that a dispensary posts its hours of operation on its website and that changes in dispensary hours of operation should be submitted and approved by the Board.
- 3796:6-3-05 – Outlines the requirements for a dispensary's designated representative. Removes the requirement of advance notification of a change of a designated representative and it removes the requirement that a designated representative's key employee card be returned to the Board upon separation of the key employee from the dispensary. The rule is amended to require that the card be destroyed.
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- 3796:6-3-13 – Requires a designated representative to review dispensing errors and conduct a quality assurance review. Amended to add that a dispensary designated representative shall report any error in dispensing to the Board within twenty-four hours.
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- 3796:6-3-17 – Outlines the record-keeping requirements for a dispensary. Amended to include that records need to be made readily retrievable, and clarify what records are required to be maintained.
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- 3796:6-3-22 – This rule outlines the prohibitions for dispensaries. The rule is amended to include that no food or beverages shall be offered or furnished on premises. The rule also prohibits delivery systems and liquor on premises and allows dispensary employees to utilize discounts if the employee is a registered patient.
- 3796:6-3-23 - Details who may have access to the dispensary department and restricted access areas. Provides that all others must be authorized by the Board (third parties and agents of the Board) except in the case of an emergency. The rule is amended to clarify the process of allowing visitors to visit a dispensary.

**3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The proposed rules are authorized by section 3796.04 of the Ohio Revised Code. The statutes the rules amplify or implement are sections 3796.04, 3796.06, 3796.07, 3796.08, 3796.13, 3796.16, 3796.17, 3796.20, 3796.30, 4729.771, 4729.80, and 4729.84 of the Revised Code.

**4. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

*If yes, please briefly explain the source and substance of the federal requirement.*

These rules do not implement a federal requirement.

**5. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

This rule package exceeds federal requirements because the regulation of the medical marijuana is done at the state level. The drafting of the rules did take into consideration the United States Department of Justice drug enforcement priorities.

**6. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Ohio House Bill 523 of the 131st General Assembly established the Ohio Medical Marijuana Control Program (“MMCP”). Outlined in Chapter 3796 of the Revised Code, the responsibilities for the MMCP are divided between three state agencies. The Board of Pharmacy is responsible for the administration, implementation, and enforcement related to dispensaries under the MMCP.

Because marijuana is a schedule I controlled substance under federal law, state rules regulating the cultivation, processing, sale, possession, and administration of medical marijuana are necessary to protect against the risk of criminal charges.

**7. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of these regulations will be measured by the availability of safe medical marijuana products and dispensary environments for patients and caregivers. The MMCP rules are designed to accommodate the needs of patients, caregivers, and the industry.

**8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No.

**Development of the Regulation**

**9. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

*If applicable, please include the date and medium by which the stakeholders were initially contacted.*

The rule in this package were reviewed by the public and the Medical Marijuana Advisory Committee (MMAC).

Prior to filing with CSI, the rules were also reviewed and approved by the Board.

**10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

- The Board received comments from the public and stakeholders on these rules during the initial public comment process. These comments were reviewed and discussed by Board staff.

**11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

The rules were originally developed after benchmarking with regulators in other states, talking with industry experts, and hearing from patients and caregivers registered under other state programs. The rules are being amended after the program was implemented, based on feedback from the industry, patients, and caregivers.

**12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

There are no alternative regulations or specific provisions within the regulation to be considered.

**13. Did the Agency specifically consider a performance-based regulation? Please explain.**

*Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

To the extent that these rules relate to the necessary policies and procedures that dispensaries must develop, they do include a performance-based component, which largely sets the floor for compliance but does not completely dictate how dispensaries may achieve compliance. Those internal policies and procedures provide dispensaries the opportunity to adopt and implement procedures most appropriate for each location, in order to achieve compliance with Ohio law. Given the nature of other provisions, though, and the Board's responsibility to ensure a uniform practice across Ohio, performance-based regulations were not considered. At this juncture, it was the determination of the Board that the rule package did not lend itself to a performance-based regulation.

**14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

Although it is the Board's responsibility to regulate dispensaries, to the extent that its regulations could duplicate others, the Board works closely with the Department of Commerce and State Medical Board to ensure consistency and to eliminate redundancy within the MMCP. Board staff reviewed the proposed rule to ensure that the regulation does not duplicate other state regulations.

**15. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

The rules will be posted on the MMCP web site, information concerning the rules will be included in materials e-mailed to licensees, patients, and caregivers. MMCP staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's MMCP agents are trained to educate licensees on current and/or new regulations during on-site inspections.

### **Adverse Impact to Business**

**16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

**a. Identify the scope of the impacted business community; and**

The rule package impacts the following:

- Dispensaries
- Dispensary Employees

**b. Identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance,); and**

Violation of these rules may result in administrative discipline for a licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license.

**c. Quantify the expected adverse impact from the regulation.**

*The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.*

### **New:**

- 3796:6-3-11 – Outlines the duty to report requirements for all dispensary employees. Requires dispensaries to monitor for theft and loss of medical marijuana and to immediately report any incident to the Board. The rule was amended from the original version to clarify the duty to report requirements for dispensary employees. (Rescinds current version of the rule). There may be administrative costs associated with compliance, but the relevant provisions are already required under the current rule.
- 3796:6-3-18 – Outlines the requirements for patient records. Establishes that dispensaries shall ensure the confidentiality of all patient transaction records and who may have access to the records. (Rescinds current version of the rule). There may be administrative costs associated with compliance, but the relevant provisions are already required under the current rule.

### **Amend:**

- 3796:6-3-01 – Establishes the requirements for dispensary operations including packaging and labeling requirements and employee identification. The rule is amended to outline when a container package can be modified and amends the requirements for an employee identification card. There may be administrative costs with providing modified containers.
- 3796:6-3-02 – Establishes the requirements for dispensary premises. Amends the rule to include an opioid treatment program as a location that dispensaries are prohibited from being situated within 500 feet, add that a dispensary shall display a placard if a dispensary sells edible products, add that a dispensary shall establish, maintain, and comply with written policies and procedures. There may be administrative costs associated with compliance, but the relevant provisions are already required under the current rule.
- 3796:6-3-03 – Establishes a dispensary's hours of operation. Amended to require that a dispensary posts its hours of operation on its website and that changes in dispensary hours of operation should be submitted and approved by the Board. There may be administrative costs associated with compliance, but the relevant provisions are already required under the current rule.
- 3796:6-3-05 – Outlines the requirements for a dispensary's designated representative. Removes the requirement of advance notification of a change of a designated representative and it removes the requirement that a designated representative's key employee card be returned to the Board upon separation of key employee from the dispensary. The rule is amended to require that the card be destroyed. There may be a decrease in administrative costs due to not having to return the employee card back to the Board office.
- 3796:6-3-06 – Outlines the requirements of a medical marijuana purchase receipt. Amended to correct spelling. No change in business impact.
- 3796:6-3-08 – Establishes the requirements for the dispensing of medical marijuana in a dispensary. The rule is amended to clarify the dispensing requirements. There may be administrative costs associated with compliance but most requirements in the amended rule exist under the current rule.
- 3796:6-3-12 – Requires dispensaries to establish a quality assurance program to prevent dispensing errors. Added the patient to be included as part of a dispensary's quality assurance program communication plan. There may be administrative costs associated with compliance, but the relevant provisions are already required under the current rule.
- 3796:6-3-13 – Requires a designated representative to review dispensing errors and conduct a quality assurance review. Amended to add that a dispensary designated representative shall report an error in dispensing to the Board within twenty-four hours. There may be administrative costs associated with compliance, but the relevant provisions are already required under the current rule.
- 3796:6-3-14 – Establishes the methods for destruction and disposal of medical marijuana. Amends the rule to include rendering in accordance with methods of destruction under 21 CFR 1317.90 as

an option for destruction and outlines how products and recalled products may be returned to a dispensary. There should be no adverse impacts as a result of this change, as a new disposal method is being added but existing methods have not changed.

- 3796:6-3-15 – Outlines the requirements for dispensary patient and caregiver educational materials. Removes the requirement that patient and caregiver education and support policy included updated information about the purported effectiveness of various forms and strains of medical marijuana. There is no expected adverse business impact because of this change.
- 3796:6-3-16 – Establishes the monitoring, surveillance, and security requirements for a dispensary. Amended for grammatical fixes. There is no expected adverse business impact because of this change.
- 3796:6-3-17 – Outlines the record-keeping requirements for a dispensary. Amended to include that records need to be made readily retrievable, and clarify what records are required to be maintained. There may be administrative costs associated with compliance, but the relevant provisions are already required under the current rule.
- 3796:6-3-19 – Outlines the requirements for dispensary employee training. Amended to include duty to report information as part of employee training and adds that training is valid for two years. There may be additional costs in including duty to report information at part of employee training.
- 3796:6-3-20 - Requires dispensaries to maintain their own internal dispensary inventory system and details necessary contents. This internal system will function as the official dispensing record. The rule is amended to modify the requirements for the quarterly financial statements. There may be administrative costs associated with compliance but are already required under the current rule.
- 3796:6-3-21 - Requires dispensaries to establish policies related to the mandatory and voluntary recall of medical marijuana, including notification to relevant parties. Dispensaries must put their recall procedure into action upon notice from the Board or the Department of Commerce. The rule was amended to include recalled products and that recalled products must be returned to the licensed cultivator or processor. There may be increased monetary costs associated with compliance, as dispensaries are required to accept products that were subject to product recall.
- 3796:6-3-22 – This rule outlines the prohibitions for dispensaries. The rule is amended to include that no food or beverages shall be offered or furnished on premises. The rule also prohibits delivery systems, liquor/beer on premises, and allows dispensary employees to utilize discounts if the employee is a registered patient. Finally, the rule prohibits dispensary employees from receiving rebates or other discounts directly from cultivators and processors. The rule prohibits items that are generally not found in dispensaries so its impact should be negligible on the impacted businesses.
- 3796:6-3-23 - Details who may have access to the dispensary department and restricted access areas. Provides that all others must be authorized by the Board (third parties and agents of the

Board) except in the case of an emergency. The rule is to clarify the process of allowing visitors to visit a dispensary. There is no expected change in business impact, as many of the notification requirements of the rule have not significantly changed.

**17. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

The Board believes that the regulatory intent of the proposed rules is necessary in order to protect the health and safety of all that are participating in the medical marijuana program. The regulatory intent of the rules justifies the adverse impact because the manufacturing, possession, sale, and administration of medical marijuana constitute violations of federal drug laws, necessitating strict compliance with the MMCP.

**Regulatory Flexibility**

**18. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

**19. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

To the extent R.C. 119.14 would apply to a violation of the proposed amendments, the Board will provide verbal and written notification to the small business in an attempt to correct the paperwork violation. Thereafter, the Board would allow the small business a reasonable time to correct the violation. The Board and its staff would also offer any additional assistance necessary to aid in remediation of the violation. No further action would be taken unless the small business fails to remedy the violation within the reasonable time allotted by the Board.

**20. What resources are available to assist small businesses with compliance of the regulation?**

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board's rules and regulations.

3796:6-3-01

**Dispensary operations generally.**

- (A) A dispensary awarded a certificate of operation under this division shall:
- (1) Operate in accordance with the representations made in its application; and
  - (2) Comply with Chapter 3796. of the Revised Code and this division.
- (B) Only a dispensary with an active certificate of operation from the state board of pharmacy may authorize and engage in medical marijuana dispensary operations.
- (C) A dispensary shall not dispense marijuana from, obtain marijuana from, or transfer marijuana to, a location outside of the state of Ohio.
- (D) A dispensary shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:
- (1) It may acquire marijuana from a processor or cultivator holding a plant-only processor designation;
  - (2) It may sell expired plant material to a processor licensed by the department of commerce, if all original tamper-resistant seals from the original cultivator's container remain intact;
  - (3) Dispensary employees may dispense and sell marijuana only to a patient or caregiver, in a dispensary department, in accordance with Chapter 3796. of the Revised Code and this division; and
  - (4) It may initiate a transfer of inventory over the course of discontinuing business pursuant to rule 3796:6-2-14 of the Administrative Code.
- (E) No person at a dispensary shall provide free medical marijuana samples or engage in compounding as defined under ~~rule 4729-16-01 of the Administrative~~[section 4729.01 of the Revised](#) Code.
- (F) A dispensary shall sell medical marijuana only in the original, sealed containers or packaging as delivered by the processor or cultivator holding a plant-only processor designation.
- (G) Upon a patient or caregiver's request, a dispensary may provide the patient or caregiver to whom medical marijuana has been dispensed by the dispensary, with a container that is intended to be used for the transport of medical marijuana aliquots.



Such a container shall:

(1) Meet the requirements in paragraph (A) of rule 3796:8-1-01 of the Administrative Code except;

(a) Upon written request from a patient or caregiver a container that is not child-resistant may be furnished in accordance with requirements of this paragraph;

(b) All written requests must be maintained by the dispensary as part of the patient's official record; and

(c) Accompanying documentation must include the form and method of administration for which the container was furnished, the date it was furnished, and the name and signature of the dispensary employee furnishing the container.

(2) Have an affixed label containing:

(a) The product name, form, dose, product identifier, product identification number, and quantity for which the container was provided;

(b) The date and quantity dispensed, including the net weight measured in ounces and grams or by volume, as appropriate;

(c) The name and registry number of the patient and, if applicable, the name of his or her designated caregiver;

(d) The name, address and license number of the dispensary;

(e) A warning that states: "This product may cause impairment and may be habit-forming;"

(f) The statement: "This product may be unlawful outside of the State of Ohio;"

(g) If the product is in a form other than plant material, the following must be included:

(i) The date on which the product was manufactured and the name and license number of the processor that manufactured the product;

- (ii) A list of all ingredients and all major food allergens as identified in 21 USC 343; and
  - (iii) A warning that states: “Caution: When eaten or swallowed, the effects and impairment caused by this drug may be delayed.”
- (3) All labels printed for the purposes of this paragraph shall be printed as a duplicate, auditable label in the dispensary’s internal inventory control system.
- (4) A record of all containers provided to a patient or caregiver pursuant to this paragraph shall be kept for at least three years. This record shall include at least the following:
  - (a) The product name, form, dose, product identifier, and quantity for which the container was provided;
  - (b) Positive identification of the employee responsible for providing the container; and
  - (c) Signature of the patient or caregiver who received the container and the date on which the container was received.
- (H) A dispensary shall place all products sold to the qualifying patient or caregiver in an opaque package that shall not indicate the contents of the package, the originating facility or in any other way cause another person to believe that the package may contain marijuana.
- (I) A dispensary shall not permit any person to enter the dispensary department unless:
  - (1) Such person is a licensed dispensary employee whose responsibilities necessitate access to the dispensary department;
  - (2) Such person is a registered patient or caregiver whose active registration is verified before entry into the dispensary department. Patients and caregivers shall not be permitted behind the service counter or in other restricted access areas; or
  - (3) Such person’s responsibilities otherwise necessitate access to the dispensary department and then only for as long as necessity requires. Persons

necessitating access may include authorized agents from the state board of pharmacy and local, state, or federal law enforcement authorities. All others who necessitate access shall be under direct personal supervision while on licensed dispensary premises.

(J) All dispensary employees shall at all times while on dispensary premises, wear above the waist, ~~the an~~ employee identification card ~~issued by the state board of pharmacy~~ printed by the dispensary at which they are employed. ~~The card shall clearly identify the employee to the public and contain, at a minimum:~~

(1) ~~An image of the~~ Each employee identification card shall clearly identify the employee to the public and contain, at a minimum, the following features and information;

(a) A clear photo of the image of the employee's face measuring two inches by two inches, taken not more than ninety days prior to the issuance to the employee;

(b) The date on which the identification card was issued to the employee;

(c) The employee's current name;

(d) The medical marijuana employee license number;

(e) Security features to prevent unauthorized duplication of the employee's identification card; and

(f) The name of the dispensary.

~~(2) The date on which the license expires;~~

~~(3) The employee's current name; and~~

~~(4) The name of the dispensary.~~

(2) Identification cards shall expire four years from the date of issuance. The dispensary's designated representative shall be responsible for collecting and destroying all expired cards and cards from employees who are no longer employed by the dispensary.

(3) A dispensary employee shall be issued a separate identification card for each dispensary employing that individual.

(4) Dispensaries may only print an employee identification card for an employee that holds an active license issued pursuant to Chapter 3796. of the Revised

Code and the rules adopted thereunder.

(K) A dispensary shall maintain a list of all third-party vendors. The third-party vendor list shall be provided to the state board of pharmacy upon request.

~~(L) A dispensary shall establish, maintain and comply with written policies and procedures as submitted in an operations and management practices plan, approved by the state board of pharmacy, for the safe handling, security, inventory and distribution of medical marijuana. Such policies and procedures shall include methods for identifying, recording and reporting diversion, theft or loss, for correcting errors and inaccuracies in inventories and any other required policy set forth in Chapter 3796. of the Revised Code and this division.~~

~~(M)~~(L) A dispensary designated representative shall review dispensary organization policies and procedures at least once every twelve months from the issue date of the certificate of operation and update as needed or as requested by the state board of pharmacy. The time and date of such reviews shall be documented at the completion of each review.

~~(N)~~(M) No medical marijuana requiring refrigeration or hot-holding or considered potentially hazardous food shall be possessed or sold by a dispensary.

3796:6-3-02

**Dispensary premises generally.**

- (A) The premises of a dispensary shall be located within Ohio.
- (B) Pursuant to section 3796.30 of the Revised Code, no boundary of a parcel of real estate having situated on it a proposed dispensary shall be located within five hundred feet of the boundaries of a parcel of real estate having situated on it a school, church, public library, public playground, ~~or~~ public park, or an opioid treatment program as defined in rule 3796:6-1-01 of the Administrative Code.
- ~~(C) In addition to the limitations on a dispensary location pursuant to paragraph (B) of this rule, a dispensary shall not be located within five hundred feet of a community addiction services provider as defined under section 5119.01 of the Revised Code.~~
- ~~(D)~~(C) The dispensary shall be equipped as to land, buildings, and equipment to properly carry on the business of a medical marijuana dispensary.
- ~~(E)~~(D) The dispensary certificate of operation shall be prominently displayed at the location where the licensee is authorized to operate.
- ~~(F)~~(E) The premises and operations of a licensee shall conform to all relevant fire codes, local zoning and planning requirements.
- ~~(G)~~(F) It is the responsibility of a dispensary's associated key employees to promptly notify the state board of pharmacy of any change of the principal place of business.
- ~~(H)~~(G) No major renovation or modification shall be undertaken without notification to and inspection and approval from the state board of pharmacy and submittal of the required fee. Such renovations include, but are not limited to:
- (1) New facilities to be constructed or used for medical marijuana; and
  - (2) Work or storage areas to be constructed or used for medical marijuana.
- ~~(I)~~(H) All lighting outside and inside of a dispensary location must be maintained in good working order and wattage sufficient for clear security and surveillance.
- ~~(J)~~(I) A dispensary shall ensure that any building or equipment used by a dispensary for the storage or sale of medical marijuana is maintained in a clean and sanitary condition.
- ~~(K)~~(J) Each dispensary that sells edible medical marijuana products shall display a

placard that states the following: “Edible medical marijuana products were produced in a kitchen, not subject to public health inspections, that may also process common food allergens.”

- (1) The placard shall be no smaller than twenty-four inches tall by thirty-six inches wide, with typed letters no smaller than two inches.
- (2) The placard shall be clearly visible and readable by customers and shall be written in English.
- (3) The signage shall be placed in the area where edible medical marijuana products are sold, and may be translated into additional languages as needed.

(K) A dispensary shall display a placard, meeting the specifications of the placard described in paragraph (J) of this rule, providing a warning specified by the state board of pharmacy if the board determines that the warning is necessary to avoid imminent harm to public health.

(L) A dispensary shall establish, maintain and comply with written policies and procedures for the safe handling, security, inventory and distribution of medical marijuana. Such policies and procedures shall include methods for identifying, recording and reporting diversion, theft or loss, for correcting errors and inaccuracies in inventories and any other required policy set forth in Chapter 3796. of the Revised Code and this division.

3796:6-3-03

**Hours of operation.**

- (A) A dispensary shall: conspicuously post the hours of operation of the dispensary at all public entrances to the dispensary and on the dispensary's website homepage if one is maintained by the dispensary.
- ~~(1) Conspicuously post the hours of operation of the dispensary at all public entrances to the dispensary; and~~
- ~~(2) Clearly state the hours of operation of the dispensary in all advertising for the dispensary.~~
- (B) A dispensary shall not sell, serve, or dispense medical marijuana at any time other than between the hours of seven am ~~ESTET~~ and nine pm ~~ESTET~~.
- (1) Changes in the dispensary hours of operation shall be submitted to and approved by the board prior to hours of operation being modified.
- (2) Requests for modification of hours of operation shall be submitted on a form determined by the board no less than seven days prior to the requested modification of hours of operation go into effect.
- (3) The dispensary must maintain approved hours for no less than forty-five days before submitting a request to change hours, unless approved due to unusual circumstances as determined by the board.
- (C) A dispensary shall be open for qualifying patients and caregivers to purchase medical marijuana for a minimum of thirty-five hours a week, except as otherwise authorized by the state board of pharmacy.
- (D) A dispensary that closes during its normal hours of operation shall implement procedures to notify qualifying patients and caregivers of when the dispensary will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs. If the dispensary is, or will be, closed during its normal business hours for longer than two days, the dispensary shall immediately notify the state board of pharmacy.
- (E) A dispensary location must have at least two employees physically present at the dispensary location during all hours that the dispensary is open. At least one of those employees shall be a dispensary key employee.

3796:6-3-05

**Medical marijuana dispensary designated representative.**

- (A) Each dispensary shall have a designated representative at all times. The designated representative must hold a dispensary associated key or key employee license. Maintaining a designated representative is a continuing requirement for a certificate of operation.
- (B) The designated representative shall be physically present at licensed dispensary premises at least twenty hours each week and must be able to be contacted by dispensary employees during a dispensary's hours of operation.
- (C) A dispensary key employee shall be the designated representative for no more than one dispensary location.
- (D) A designated representative for a licensed dispensary shall be responsible for:
  - (1) Oversight of the delivery and receipt of medical marijuana and medical marijuana products to a dispensary;
  - (2) The supervision and control of medical marijuana and medical marijuana products under the custody of a dispensary;
  - (3) Adequate safeguards of medical marijuana and medical marijuana products to assure that the sale or other distribution of medical marijuana and medical marijuana products will occur only by dispensary employees licensed by the state board of pharmacy;
  - (4) Notifying the state board of pharmacy within twenty-four hours of learning of a dispensary employee's arrest for disqualifying offense;
  - (5) Ensuring that prompt, written notice is provided to the state board of pharmacy, including the date of the event, when a dispensary employee will no longer serves as an associated key employee or key employee or is no longer employed by the dispensary;
  - (6) Maintaining all required dispensary records;
  - (7) Ensuring that the state board of pharmacy is immediately notified of a known or suspected theft, diversion or loss of medical marijuana; and
  - (8) Maintaining a current and active medical marijuana key employee or associated key employee license.



3796:6-3-05

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- (E) The designated representative and all licensed medical marijuana associated key [employees](#), key [employees](#), and support employees are responsible for compliance with all state laws, regulations and rules regulating the dispensing of medical marijuana.
- (F) When there is a change of designated representative, the state board of pharmacy shall be notified within ten [businesscalendar](#) days of the effective date of the appointment of a new designated representative in a manner prescribed by the state board of pharmacy.
- (1) A complete inventory shall be taken of the medical marijuana and medical marijuana products on hand with the new designated representative on the effective date of the change of designated representative.
  - (2) The new designated representative shall be responsible for completing and maintaining this inventory record at the site of the dispensary.
  - (3) Upon separation of a designated representative's employment, the dispensary shall reclaim the designated representative's key employee card and promptly ~~return it to the state board of pharmacy~~[destroy the card](#).
- ~~(G) If advanced notification of a change of designated representative to the state board of pharmacy is impracticable due to such events as death, incapacity, or termination, the dispensary shall immediately notify the state board of pharmacy and request a temporary certificate of authority allowing the continuing operation:~~
- ~~(1) The request shall include the name of an interim designated representative until a replacement is identified, or shall include the name of the replacement. If an interim designated representative is named, the interim designated representative shall be a licensed dispensary employee.~~
  - ~~(2) The state board of pharmacy shall issue the temporary certificate of authority promptly after it receives the request.~~
  - ~~(3) If a dispensary fails to immediately notify the state board of pharmacy and request a temporary certificate of authority after the separation of the designated representative, its certificate of operation shall become ineffective until the state board of pharmacy approves the temporary certificate of authority or registers a new designated representative.~~
  - ~~(4) No temporary certificate of authority shall be valid for more than ninety days.~~
  - ~~(5) The succeeding designated representative shall register with the state board of pharmacy as a dispensary key employee under this division. Once the~~

~~permanent designated representative replacement is licensed as a dispensary key employee, the temporary certificate of authority is void.~~

~~(H)~~(G) No designated representative for a licensed medical marijuana dispensary shall:

- (1) Have ever been denied a license to prescribe, dispense, administer, supply, or sell a controlled substance by the appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the person's inappropriate ~~prescribing~~ dispensing, administering, supplying or selling a controlled substance or other dangerous drug other than medical marijuana dispensed.
- (2) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted or surrendered, based, in whole or in part, on the ~~prescriber's~~person's inappropriate prescribing, dispensing, personally furnishing, diverting, administering, supplying, or selling a controlled substance or other dangerous drug.
- (3) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the ~~prescribers~~person's inappropriate prescribing, dispensing, diverting, administering, personally furnishing, diverting, supplying or selling a controlled substance or other dangerous drug.

3796:6-3-06

**Receipt of medical marijuana by a dispensary.**

(A) Each dispensary shall:

- (1) Establish a standard operating procedure for all aspects of the receipt, storage, packaging, labeling, handling, tracking and dispensing of products containing medical marijuana and medical marijuana waste~~;~~.
- (2) Use the state inventory tracking system, established pursuant to section 3796.07 of the Revised Code, to identify and track all information deemed necessary by the state board of pharmacy as it relates to the dispensary's stock of medical marijuana from the time it is received to the time it is dispensed to a patient or caregiver. All information related to the receipt, dispensing, and destruction of all medical marijuana, that the state board of pharmacy deems necessary, shall be transmitted electronically to the department of commerce through the inventory tracking system.
- (3) Transmit electronically to the state board of pharmacy the information related to the dispensing of all medical marijuana as set forth in rules 3796:6-3-08 and 3796:6-3-10 of the Administrative Code~~;~~ and.
- (4) Train each dispensary employee in the standard operating procedures related to the receipt, storage, dispensing, and disposal of medical marijuana and retain employee training attendance records.

(B) Before accepting a delivery of medical marijuana, a dispensary key employee must inspect and acknowledge that the delivery meets relevant packaging and labeling requirements. The delivery of any medical marijuana failing to adhere to relevant packaging and labeling requirements shall not be accepted by a dispensary and shall be immediately returned to the processor or cultivator holding a plant-only processor designation.

(C) A dispensary shall not accept expired, damaged, deteriorated, misbranded, or adulterated medical marijuana.

(D) All areas where medical marijuana is delivered shall be secured and monitored with video surveillance. Access shall be limited to necessary licensed processor, cultivator, and dispensary employees.

(E) All areas where medical marijuana and devices are stored must be dry, ~~well-lighted~~ well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and under lighting conditions which will ensure the integrity of medical marijuana prior to its use.

(F) Only individuals authorized pursuant to Chapter 3796. of the Revised Code and this division may have unsupervised access to medical marijuana.

3796:6-3-08

**Dispensing of medical marijuana.**

(A) A dispensary is authorized to sell medical marijuana only to:

- (1) Qualified patients, ~~aged~~ eighteen years of age and older, and designated caregivers. No one other than employees of a dispensary shall sell medical marijuana to a patient or caregiver; and
- (2) Laboratories licensed under Chapter 4729-13 of the Administrative Code to possess dangerous drugs and controlled substances for scientific and clinical purposes.

(B) A dispensary employee may exercise ~~his or her~~their judgment to determine whether to dispense medical marijuana to a patient or caregiver if the dispensary employee suspects that dispensing medical marijuana to the patient or caregiver may have negative health or safety consequences for the patient or for the public, or when the patient is exhibiting signs of potential abuse or diversion. Such a determination shall be reported to the state board of pharmacy within twenty-four hours.

(C) A dispensary employee shall require the presentation of a registry identification card together with another form of approved state-issued photographic identification belonging to a qualifying patient or caregiver, prior to selling medical marijuana to such qualifying patient or caregiver.

(D) ~~A dispensary employee may dispense any portion of a patient's ninety-day supply of medical marijuana. The~~Except as provided in paragraph (B) of this rule, a dispensary employee ~~may~~shall dispense ~~the remaining portion of the ninety-day supply of~~ medical marijuana ~~at any time except that no patient shall receive more than a ninety-day supply of medical marijuana in a ninety-day period~~in accordance with the fill periods specified in rule 3796:7-2-04 of the Administrative Code. No caregiver shall receive more than the aggregate amount of medical marijuana authorized for each of the caregiver's patients.

(E) Each dispensary internal inventory system shall be compatible with and capable of integrating with the state inventory tracking system.

(F) Each dispensary shall use a scanner approved by the state board of pharmacy to retrieve patient registry data by scanning patient or caregiver registry identification cards and government issued photographic identification.

(G) A dispensary shall not dispense expired, damaged, deteriorated, misbranded, adulterated, or opened medical marijuana.

(H) When dispensing or selling medical marijuana all dispensaries shall comply with division (B) of section 3796.20 of the Revised Code including:

(1) Dispense or sell only upon a showing of a current, valid patient or caregiver registry identification card; and current and valid state photo identification or other identification approved by the board. Medical marijuana may not be dispensed to a patient or caregiver who does not possess a registry identification card issued by the state board of pharmacy, unless the dispensation is in accordance with a reciprocal agreement established pursuant to section 3796.16 of the Revised Code.

(2) A dispensary employee shall verify:

(a) The validity of the patient or caregiver's registration by scanning the patient or caregiver's state-issued identification, such as a driver's license, ~~or United States passport~~ other identification approved by the board. The identification number on the item presented by the patient or caregiver must be identical to the identification number included in the patient's or caregiver's registry record;

(b) Possession of a patient or caregiver registry card with the holder's name and ~~state-issued~~ identification card number ~~that are~~ identical to the ~~name and state-issued~~ identification ~~card number on the state-issued~~ identification card provided pursuant to subdivision (2)(a) of paragraph (H) of this rule;

(c) ~~That the individual is a patient the patient has not purchased more than a ninety-day supply of medical marijuana in the last ninety days. If the individual is a caregiver, that the caregiver has not purchased more than a ninety-day supply of medical marijuana for a single patient in the last ninety days~~ The patient or caregiver has not exceeded the purchase limits established in rule 3796:7-2-04 of the Administrative Code or that the amount of medical marijuana that the patient or caregiver is requesting would not cause the patient to exceed the purchase limits established in rule 3796:7-2-04 of the Administrative Code.;

(d) ~~That the amount of medical marijuana that the patient or caregiver is requesting would not cause the patient to exceed a ninety-day supply of medical marijuana during any ninety-day calendar period, unless approved by the state board of pharmacy.~~

(3) A dispensary employee shall confirm that each recommendation is complete. A

complete recommendation contains the following:

- (a) Patient full name;
- (b) Patient residential address;
- (c) Patient telephone number;
- (d) Patient date of birth;
- (e) Patient qualifying condition;
- (f) State-issued identification number (such as driver's license number), or ~~United States passport number~~ other identification approved by the board;
- (g) Patient registration number issued by the state board of pharmacy;
- (h) Recommending physician's full name (first name and last name);
- (i) ~~Physician's~~ Recommending physician's drug enforcement administration identification number;
- (j) Recommending physician's medical license number issued by the state medical board;
- (k) Recommending physician's certificate to recommend identification issued by the state medical board;
- (l) Date recommendation was issued by the recommending physician;
- (m) Recommending physician's business address, telephone number, and email address;
- (n) Indication whether the recommendation is new or a refill;
- (o) Number of the refill being dispensed; and
- (p) Date order written, which shall be the date the written recommendation

was issued.

- (4) Update the patient record in the dispensary's internal inventory system with the following information:
  - (a) Dispensary certificate of operation number, which shall be populated by a number provided by the board;
  - (b) Dispensary name;
  - (c) Dispensary address;
  - (d) Dispensary telephone number;
  - (e) Date order filled, which shall be the date medical marijuana is dispensed;
  - (f) Order number, which shall be the serial number assigned to each medical marijuana product dispensed to a patient;
  - (g) Quantity;
  - (h) Days' supply;
  - (i) Product identifier, which shall be assigned by the state board of pharmacy;
  - (j) Payment code for either cash or third-party provider; and
  - (k) Drug name, which shall be the brand name of the medical marijuana.
- (I) A dispensary may sell medical marijuana to patients and caregivers only in a direct, face-to-face exchange without the assistance of any electronic or mechanical device (such as a vending machine or other automated dispensing unit). A dispensary must sell medical marijuana in whole day increments.
- (J) A dispensary shall dispense medical marijuana in a manner consistent with any instructions for use as determined by the recommending physician.
- (K) A dispensary must include the name of the dispensary on the packaging of any medical marijuana or medical marijuana product it sells. Each package sold must be



placed in an unmarked, opaque bag before leaving the dispensary.

(L) All recommendations must be serially numbered when dispensed.

(1) There must be a complete accounting of all numbers used in the serial numbering system.

(2) All recommendations which are not refillable, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon an authorization for additional dispensing by a recommending physician.

(M) A dispensary shall maintain a record of each sale, purchase and return of medical marijuana in the inventory tracking system established pursuant to section 3796.07 of the Revised Code.

(N) An order purporting to be a recommendation issued not in the usual course of professional treatment or in legitimate and authorized research is not a recommendation within the meaning and scope of Chapter 3796. of the Revised Code and the person who knowingly dispenses such a purported recommendation, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. A dispensary employee is not required to dispense a recommendation of doubtful, questionable, or suspicious origin.

(O) No medical marijuana shall be sold, dispensed, or distributed to a patient or caregiver via a delivery service or any other manner outside of a dispensary, except that a caregiver may deliver medical marijuana to the caregiver's registered patient.

3796:6-3-11

**Duty to report.**

- (A) Each dispensary employee is responsible to monitor for suspicious recommendations, unusual usage, or questionable disposition of medical marijuana.
- (B) Each dispensary employee shall notify the following upon discovery of the theft or loss of any medical marijuana or medical marijuana device, including medical marijuana in transit that was either shipped from or to the dispensary:
  - (1) The state board of pharmacy, by telephone immediately upon discovery of the theft or loss;
  - (2) Law enforcement authorities with jurisdiction over the location where the theft or loss occurred pursuant to section 2921.22 of the Revised Code.
- (C) Medical marijuana thefts or unexplained losses must be reported to the state board of pharmacy in writing irrespective of whether the medical marijuana is recovered and/or the responsible parties are identified and action taken against them. Written reports must be provided to the state board of pharmacy within forty-eight hours following the discovery of such theft or loss.
  - (1) The written report must include:
    - (a) The name, address, and license number of the dispensary;
    - (b) The amount and type of medical marijuana lost or stolen;
    - (c) The circumstances surrounding the loss or theft;
    - (d) The date the loss or theft was discovered;
    - (e) The person who discovered the loss or theft;
    - (f) The person responsible for the loss or theft if known; and
    - (g) Any other information that the reporter believes might be helpful in establishing the cause of the loss or theft.
  - (2) An exemption may be obtained upon sufficient cause if written notification cannot be completed within five ~~business~~calendar days.

- (3) A request for waiver of the five ~~business~~calendar day limit must be requested in writing.
- (D) Each dispensary employee, immediately upon discovery of any fraudulent or otherwise unlawful recommendation, shall notify the state board of pharmacy and law enforcement authorities. Upon receiving such notice, the state board of pharmacy shall notify the state medical board of all suspected fraudulent recommendations.
- (E) Each designated representative who knows or should know that a prohibited facility or ~~a community addiction services provider as defined under section 5119.01 of the Revised Code~~an opioid treatment program as defined in rule 3796:6-1-01 of the Administrative Code, has been established within five hundred feet of the dispensary shall notify the state board of pharmacy, for purposes of assessing the adequacy of existing security measures.
- ~~(F) All dispensary employees must report all known violations of state drug laws, including all rules adopted pursuant to Chapter 3796. of the Revised Code, to the state board of pharmacy immediately.~~
- ~~(G) Serious adverse events related to security and administration of medical marijuana, that a dispensary employee knows or should know, shall be reported to the state board of pharmacy within twenty-four hours.~~
- ~~(H) Any adverse action taken against the employee by any licensing authority in any state or any territory of the United States or any foreign jurisdiction, any governmental agency, any law enforcement agency or any court, shall be reported to the state board of pharmacy within five business days.~~
- (F) A dispensary employee who has knowledge, from direct observation or objective evidence, of violations described in paragraph (G) of this rule shall report such conduct to the state board of pharmacy, in a manner specified by the board, within ten days of learning or witnessing the alleged violations.
- (G) The following shall be reported to the board:
- (1) Except as provided in paragraph (G)(1)(a) of this rule, conduct indicating a dispensary employee is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.
- (a) A dispensary employee shall not be required to report in accordance with this rule if the dispensary employee becomes aware of any condition described in paragraph (G)(1) of this rule as a result of either:

(i) The employee's treatment of the individual for the condition; or

(ii) The employee having access to the individual's protected health information.

(2) Violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Chapters 4729., 3796., 2925., and 2913. of the Revised Code, or any rule adopted by the board under those provisions, by an individual or entity licensed or registered under chapter 3796:6 and chapter 3796:7 of the Revised Code.

(3) Conduct by a dispensary employee that constitutes unprofessional conduct or dishonesty as defined in rule 3796:6-1-01 of the Administrative Code.

(H)

(1) Pursuant to section 4729.23 of the Revised Code, the identity of the pharmacist making a report in accordance with this rule shall remain confidential.

(2) Notwithstanding the confidentiality provided in accordance with paragraph (H)(1) of this rule, a dispensary employee may be required to testify in a disciplinary proceeding as to the conduct or violations listed in paragraph (G) of this rule without disclosing the pharmacist was the reporting individual.

(I) A dispensary employee shall notify the board of any of the following:

(1) Any criminal conviction within ten days after the date of conviction, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.

(2) The employee is convicted of, pled guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section 2951.041 of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.

(3) The employee is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.

(4) Any arrest for a felony within ten days after the arrest.

(J) A dispensary employee shall notify the board of any disciplinary licensing or registration action taken by another state against the licensee within ten days of the notice action. This includes, but is not limited to, a disciplinary action that is stayed pending appeal.

(K) Reporting required in accordance with this rule shall be made in writing, either by mail or using the board's online complaint form (available on the board's web site: [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)).

3796:6-3-12

~~Dispensing error reporting~~Quality assurance to prevent dispensing errors.

- (A) A dispensary shall display a sign concerning the reporting of dispensing errors in a conspicuous location visible to qualifying patients and caregivers. The sign shall:
- (1) Measure a minimum of eight inches in height and ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty;
  - (2) Read: “If you have a concern that an error may have occurred in the dispensing of your medical marijuana, you may contact the state of Ohio board of pharmacy, using the contact information found at [medicalmarijuana.ohio.gov](http://medicalmarijuana.ohio.gov).”
- (B) A dispensary designated representative shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify and prevent dispensing errors. A dispensary shall:
- (1) Provide to the state board of pharmacy a written copy of such quality assurance program;
  - (2) Distribute it to all dispensary employees; and
  - (3) Make it readily available on the premises of the dispensary.
- (C) A dispensary’s quality assurance program shall include:
- (1) Directions for communicating the details of a dispensing error to the physician who recommended a qualifying patient, [the patient](#), the patient’s caregiver [where appropriate](#), or appropriate family member if the patient is deceased or is unable to fully comprehend communication. Such communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and
  - (2) A process to document and assess dispensing errors to determine the cause of the error and the appropriate response.
- (D) A dispensary shall use the findings of its quality assurance program to develop dispensary systems and workflow processes designed to prevent dispensing errors.
- (E) A dispensary designated representative shall inform dispensary employees of changes

to dispensary policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

3796:6-3-13

**Review of dispensing errors.**

(A) A dispensary designated representative shall notify all dispensary employees that the discovery or reporting of a dispensing error shall be relayed immediately to a dispensary designated representative.

(B) The dispensary designated representative shall report an error in dispensing to the state board of pharmacy, in a manner determined by the board, within twenty-four hours of learning of such error.

~~(B)~~(C) A dispensary designated representative shall ensure that a quality assurance review for each dispensing error is completed and that such review is commenced as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered.

~~(C)~~(D) A dispensary shall create a record of every quality assurance review. This record must contain, but is not limited to, the following:

- (1) The date or dates of the quality assurance review;
- (2) The pertinent data and other information relating to the dispensing error reviewed;
- (3) Documentation of contact with the qualifying patient, caregiver where applicable, and the recommending physician;
- (4) The findings and determinations generated by the quality assurance review; and
- (5) Recommended changes to dispensary policy, procedure, systems or processes if any.



3796:6-3-14

**Destruction and disposal of medical marijuana.**

- (A) Medical marijuana products must be destroyed by ~~rendering it unusable following the methods set forth in this rule.;~~

(1) Rendering it unusable following the methods set forth in this rule; or

(2) Rendering it non-retrievable in accordance with methods of destruction under 21 CFR 1317.90 (as of 4/1/2019).

- (B) At least seven days prior to rendering medical marijuana unusable and disposing of it, the dispensary shall notify the state board of pharmacy. Notification shall include the date and time the marijuana will be rendered unusable or non-retrievable and disposed. If the dispensary designates the destruction of medical marijuana on the same day and time weekly, communication of that day and time shall be sufficient to comply with this paragraph. Any change in the date and time must be communicated to the state board of pharmacy.

- (C) Unless otherwise required by local, state, or federal waste management authorities, the allowable method for rendering marijuana waste unusable is by grinding and incorporating the marijuana waste with other ground material so the resulting mixture is at least fifty percent non-marijuana waste. Other methods to render marijuana waste unusable must be approved by the state board of pharmacy before implementation. Material used to grind with the marijuana falls into two categories, compostable waste and non-compostable waste.

- (1) Compostable mixed waste: Marijuana waste to be disposed as compost feedstock or in another organic waste method (for example, anaerobic digester) may be mixed with the following type of waste materials:

(a) Food waste;

(b) Yard waste;

(c) Vegetable based grease or oils; or

(d) Other wastes as approved by the state board of pharmacy (e.g., agricultural material, biodegradable products and paper, clean wood, fruits and vegetables, plant material).

- (2) Non-compostable mixed waste: Marijuana waste to be disposed in a landfill or by another disposal method may be mixed with the following types of waste materials:

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- (a) Paper waste;
  - (b) Cardboard waste;
  - (c) Plastic waste;
  - (d) Soil; or
  - (e) Other wastes as approved by the state board of pharmacy (e.g., non-recyclable plastic, broken glass, leather).
- (3) Marijuana waste rendered unusable following the methods described in this rule can be disposed. Disposal of the marijuana waste rendered unusable may be delivered to a permitted solid waste facility for final disposition. Examples of acceptable permitted solid waste facilities include:
- (a) Compostable mixed waste: compost, anaerobic digester, or other facility.
  - (b) Non-compostable mixed waste: landfill, incinerator, or other facility.
- (4) All ~~waste and unusable product shall be weighed, recorded and entered into the inventory tracking system prior to rendering it unusable. The destruction of medical marijuana by a dispensary employee shall be witnessed by a key employee and the event shall be conducted in a designated area with fully functioning video surveillance~~ external refuse containers shall be maintained in a locked condition and secured to prevent unauthorized access.
- ~~(5) Electronic documentation of destruction and disposal shall be maintained for a period of at least three years.~~
- ~~(6) All external refuse containers shall be maintained in a locked condition.~~
- (D) All medical marijuana to be rendered non-retrievable or unusable following the methods described in this rule shall be weighed, recorded, and entered into the inventory tracking system prior to rendering it non-retrievable or unusable. The destruction of medical marijuana shall require at least two employees and include at least one key employee serving as a witness to the destruction to the medical marijuana. The destruction of medical marijuana shall be conducted in a designated area with fully functioning video surveillance. Electronic documentation of destruction and disposal shall be maintained for a period of at least three years.

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~~(D)~~(E) A dispensary may offer as a service to its patients and caregivers, the ability to return unused medical marijuana for purposes of destroying the medical marijuana. Any dispensary that chooses to offer such services to its patients and caregivers shall develop a policy, which ~~describing its buyback policies and that policy~~ must be approved by the state board of pharmacy before any medical marijuana may be accepted by a dispensary pursuant to this paragraph.

(1) All medical marijuana returned pursuant to this paragraph shall be entered into the state inventory tracking system; and

(2) Prices for such services, if any, shall be publicly available.

(F) The following products may be returned to a dispensary by a registered patient or registered caregiver for the exclusive purpose of being destroyed. A dispensary may provide the patient or caregiver to whom the product was dispensed a refund of the purchase price of the product:

(1) Defective product;

(2) Product that does not match the item stated on the purchase receipt; and

(3) Medical marijuana that is mislabeled by the cultivator or processor of the product. All medical marijuana returned to a dispensary due to mislabeling by a cultivator or processor must be reported in writing to state board of pharmacy in a format and medium approved by the board.

(G) Recalled products must be returned to the dispensary where they were purchased by a registered patient or registered caregiver for the exclusive purpose of being destroyed. The dispensary shall provide the patient or caregiver to whom the product was dispensed a refund if the product is returned within thirty days of the product recall notice.

3796:6-3-15

**Dispensary patient and caregiver educational materials.**

(A) Each dispensary shall develop and maintain a policy regarding patient and caregiver education and support.

(B) A patient and caregiver education and support policy shall include:

~~(1) Updated information about the purported effectiveness of various forms and methods of medical marijuana administration;~~

~~(2) Updated information about the purported effectiveness of strains of medical marijuana for specific conditions;~~

~~(3)~~(1) Information regarding the signs and symptoms of substance abuse, including tolerance, dependency, and withdrawal;

~~(4)~~(2) Whether possession of medical marijuana is illegal under federal law;

~~(5)~~(3) Information about possible side effects and contraindications for medical marijuana including possible impairment with use and operation of a motor vehicle or heavy machinery, when caring for children, or of job performance;

~~(6)~~(4) Guidelines for contacting the recommending physician if side effects or contraindications occur;

~~(7)~~(5) A warning that smoking of medical marijuana is not permitted per Ohio law;

~~(8)~~(6) Information on drug-to-drug interactions, including interactions with alcohol, prescription drugs, non-prescription drugs, and supplements; and

~~(9)~~(7) Offer any other appropriate patient education or support materials.

(C) A dispensary shall make available information to patients and caregivers regarding the possession and use of marijuana. All such information shall be submitted to the state board of pharmacy for approval prior to being provided to qualifying patients and caregivers and shall include:

(1) Limitations on the right to possess and use marijuana pursuant to Chapter 3796. of the Revised Code;

(2) Safe techniques for the proper use of medical marijuana and medical marijuana paraphernalia;

- (3) Prohibition against and dangers associated with medical marijuana extractions;
  - (4) Alternative methods and forms of consumption or inhalation by which one can use medical marijuana;
  - (5) Instruction for patients and caregivers with medical marijuana-related inquiries or reports of adverse reactions to the toll-free telephone line established by the state board of pharmacy in accordance with section 3796.17 of the Revised Code;
  - (6) Signs and symptoms of substance abuse; and
  - (7) Opportunities to participate in substance abuse programs.
- (D) No dispensary shall include in its education policy, instruction for patients or caregivers to cut or otherwise partition medical marijuana patches as appropriate preparation for transdermal administration.
- (E) A dispensary shall make publicly available the price of all medical marijuana products offered by the dispensary to prospective qualifying patients and caregivers. Such disclosure may include posting information on the dispensary internet website.
- (F) A dispensary shall post a sign directing patients and caregivers with medical marijuana-related inquiries or reports of adverse reactions to the toll-free telephone line established by the state board of pharmacy in accordance with section 3796.17 of the Revised Code. Such sign shall be clearly visible and unobstructed.

3796:6-3-16

**Monitoring, surveillance, and security requirements.**

- (A) All licensed dispensaries shall maintain security policies and procedures that include, but are not limited to:
- (1) A security plan with protocols for patient, caregiver, and employee safety and management and security of medical marijuana and currency;
  - (2) Restricted access to the areas in the dispensary that contain medical marijuana to authorized employees;
  - (3) Identification of authorized employees through means including current employee identification card in the employee's immediate possession whenever the employee is present at the dispensary;
  - (4) Controlled access and prevention of loitering both inside and outside of the facility;
  - (5) Conducting electronic monitoring;
  - (6) Use of a panic button; and
  - (7) Prepares for, protects against, and addresses how to handle any crisis that affects the security or operation of a dispensary in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency.
- (B) All licensed dispensaries shall implement security measures to protect the premises, patients, caregivers and employees, including the following measures:
- (1) The dispensary department shall be accessible to patients and caregivers, dispensary employees, service professionals conducting business with the dispensary and who are escorted and supervised by a dispensary employee, and other persons authorized by Chapter 3796. of the Revised Code and this division. To prevent unauthorized access to the dispensary department, establish a locked door or barrier between the facility's entrance and the dispensary department.
  - (2) Post a sign at all entry ways into any area of the dispensary containing medical marijuana, including a room with an approved vault, which sign shall be a minimum of twelve inches in height and twelve inches in width and shall state: "Do Not Enter – Restricted Access Area – Access Restricted to Authorized Employees Only." In lettering no smaller than one-half inch in

height.

- (3) Maintenance of a supply of medical marijuana that is not more than the quantity required for normal, efficient operation;
- (4) Prevent individuals from remaining on the premises if they are not engaging in authorized activities under Chapter 3796. of the Revised Code or this division;
- (5) Develop a policy that addresses the maximum capacity and patient flow in the waiting rooms, dispensary department, and patient care areas;
- (6) Dispose of medical marijuana in accordance with this division;
- (7) During hours of operation, store all medical marijuana in established restricted access areas accessible only to authorized employees. The minimum number of dispensary employees necessary for efficient operations shall be in the restricted access area;
- (8) Keep all safes, vaults and any other equipment or medical marijuana storage areas securely locked and protected from unauthorized entry;
- (9) Keep a daily log of dispensary employees with access to the safe or vault and knowledge of the access code or combination;
- (10) Keep all locks and security equipment in good working order. All security equipment must be inspected and tested at regular intervals, not to exceed thirty calendar days from the previous inspection and test to ensure the systems remain functional. A dispensary must maintain a log documenting such inspections and tests;
- (11) Prohibit keys, if applicable, from being left in locks or stored or placed in a location accessible to persons other than specifically authorized personnel;
- (12) Prohibit accessibility of security measures, including combination numbers, passwords or electronic or biometric security systems to persons other than persons specifically authorized in accordance with this division;
- (13) Ensure that trees, bushes and other foliage outside of the dispensary do not allow for a person to conceal themselves from sight;

- (14) Develop emergency policies and procedures for securing all product and currency following any instance of diversion, theft or loss of medical marijuana, and conduct an assessment to determine whether additional safeguards are necessary; and
  - (15) Develop sufficient additional safeguards in response to any special security concerns, or as required by the state board of pharmacy.
- (C) The state board of pharmacy may request or approve alternate security provisions that it determines are an adequate substitute for a security measure specified in this rule. Any additional protections may be considered by the state board of pharmacy in evaluating overall security measures.
- (D) When physical security controls become inadequate because of such items as a significant increase in the quantity of medical marijuana, the physical controls shall be expanded and extended accordingly.
- (E) All licensed dispensaries shall have a security system that is operational at all times and that uses commercial grade equipment to prevent and detect diversion, theft, or loss of medical marijuana, including:
- (1) A perimeter alarm;
  - (2) Motion detectors;
  - (3) Video cameras in all areas, unless prohibited by law, including all points of entry and exit from the dispensary, the dispensary department, and restricted access areas which shall be appropriate for the normal lighting conditions of the area under surveillance, so as to allow for the capture of clear and certain identification of any person located in the surveillance area. Such surveillance shall be sufficient to distinctly view the entire area under surveillance;
  - (4) A video camera or cameras recording at each point of sale location allowing for the identification of the dispensary employee dispensing the medical marijuana and any patient or caregiver purchasing the medical marijuana. The camera or cameras shall capture the sale, the individuals and the computer monitors used for the sale;
  - (5) In accordance with rule 3796:6-3-04 of the Administrative Code, a minimum of constant streaming from all video cameras during hours when a dispensary is closed;



- (6) Recording from all video cameras during hours of operation, which the dispensary shall make available for immediate viewing by the state board of pharmacy or the board's authorized representative upon request and shall be retained for at least six months.
  - (a) Unaltered copies of such recordings shall be made available upon request;
  - (b) If a dispensary knows or should know of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the registered organization shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the dispensary that it is not necessary to retain the recording.
- (7) A duress alarm, which for purposes of this rule means a silent security alarm system signal generated by the entry of a designated code into an arming station to signal that the alarm user is being forced to turn off the system;
- (8) A panic alarm, which for purposes of this section, means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening [event](#) or emergency requiring a law enforcement response;
- (9) A holdup alarm, which for purposes of this section, means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;
- (10) An automatic voice dialer, which for purposes of this section means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;
- (11) A failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the dispensary within five minutes of the failure, either by telephone, email, or text message;
- (12) The ability to immediately produce a clear color still photo that is a minimum of ninety-six hundred dpi from any camera image, either live or recorded. All cameras shall be capable of capturing at least thirty frames per second;

- (13) A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture;
  - (14) The ability to remain operational during a power outage and ensure that all access doors are not solely controlled by an electronic access panel to ensure that locks are not released during a power outage; and
  - (15) All video surveillance equipment shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be in an industry standard file format that can be played on a standard computer operating system. All recordings shall be erased or destroyed prior to disposal.
- (F) A surveillance system at a dispensary shall have electronic monitoring capacity including:
- (1) Monitors that are each at least nineteen inches or greater;
  - (2) A video printer capable of immediately producing a clear still photo from any video image; and
  - (3) A failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system.
- (G) All surveillance systems at a dispensary shall comply with the requirements herein and shall provide secure access and secure override access for the system to the state board of pharmacy in a manner suitable to the board. At any time and without notice, the dispensary surveillance system, and its component parts, shall be subject to testing by the state board of pharmacy. Each surveillance camera must be programed with a defined home position that remains consistent when a surveillance system is restarted. The defined home position feature must remain enabled at all times and allow for automatic return to the home position.
- (H) If dispensary premises present special security issues, such as an extremely large stock of medical marijuana, exposed handling or unusual vulnerability to diversion, theft or loss, the state board of pharmacy may require additional safeguards, including, but not limited to, a supervised watchman service.

- (I) If diversion, theft or loss of medical marijuana has occurred from a dispensary, the state board of pharmacy shall review and approve the improvements in the appropriate storage and security requirements for all medical marijuana in such dispensary and may require additional safeguards to ensure security of the medical marijuana.
- (J) ~~Preventative~~ Preventive-maintenance must be performed on a dispensary's surveillance system at least annually by a vendor approved by the state board of pharmacy.

3796:6-3-17

**Record keeping requirements.**

- (A) Dispensary records may be maintained either manually and/or electronically and shall be available for inspection by the state board of pharmacy in a readily retrievable manner upon request. The dispensary shall develop recordkeeping policies and procedures consistent with this division.
- (B) Any dispensary that uses an electronic system for the storage and retrieval of patient information or other medical marijuana records; shall use a system that:
- (1) Guarantees the confidentiality of the information contained within;
  - (2) Can be accessed by the state board of pharmacy in accordance with this division;
  - (3) Can provide safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the dispensary;
  - (4) Contains a true audit trail that indicates and dates any edits or deletions to a patient record; and
  - (5) Is capable of being reconstructed or retrieved within three business days, in the event of a computer malfunction or accident resulting in the destruction of the database.
- (C) Each dispensary shall keep a record of all medical marijuana received, dispensed, sold, destroyed, or used. The acts of dispensing and destroying of a controlled substance must be documented with the positive identification of the responsible individual. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.
- (D) Any dispensary intending to maintain records at a location other than the licensed dispensary premises must first send a written request to the state board of pharmacy. The request shall contain the dispensary name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the dispensary documenting the approval or denial of the request. A copy of the ~~board's~~state board of pharmacy's approval shall be maintained with the medical marijuana records located on the licensed dispensary premises. Any alternate location shall be secured and accessible only to authorized dispensary employees.
- (E) Documentation maintained and organized by a dispensary in the normal course of business must be available for inspection by the state board of pharmacy and

include, but is not limited to:

- (1) Background checks for employees conducted by the dispensary, if applicable;
- (2) Operating procedures;
- (3) Inventory records;
- (4) Audit records;
- (5) Staffing plan;
- (6) Business records that include:
  - (a) Assets and liabilities;
  - (b) Third party vendor list;
  - (c) Monetary transactions;
  - (d) Written or electronic accounts that shall include bank statements, journals, ledgers, and supporting documents, agreements, checks, invoices ~~and~~, vouchers; and
  - (e) Any other financial accounts reasonably related to dispensary operations.
- (7) Surveillance records;
- (8) Attendance logs;
- (9) Employee training records;
- (10) Quality assurance review logs;
- (11) Records relating to the purchase or return, dispensing, distribution, destruction, and sale of medical marijuana; and
- ~~(11)~~(12) All other records required under Chapter 3796. of the Revised Code and this division.

- (F) ~~All records relating to the purchase or return, dispensing, distribution, destruction, and sale of medical marijuana shall be maintained under appropriate supervision and control to restrict unauthorized access~~All records listed in paragraph (E) of this rule shall be maintained for at least three years under appropriate supervision to ensure confidentiality and be made readily available for release in accordance with rule 3796:6-3-18 of the Administrative Code.

3796:6-3-18

**Confidentiality Release of patient records related to patient transactions maintained by dispensaries.**

Dispensaries shall ensure the confidentiality of all records related to patient transactions, the contents of which may only be released to the following:

(A) The patient or that patient's designated caregiver;

(B) The certified physician who issued the recommendation to the patient;

(C) Certified or licensed health care personnel who are responsible for the care of the patient;

(D) The state board of pharmacy;

(E) Any person that the dispensary is legally required to release the information to, including upon issuance of a valid subpoena, court order, or other similar document only in a criminal matter or an equivalent juvenile matter;

(F) If applicable, an agent of a medical insurance company who provides insurance coverage for medical marijuana upon authorization and proof of insurance by the patient or proof by the insurance company for those medications requested;

(G) An agent who contracts with the dispensary as a "business associate" in accordance with the regulations promulgated by the secretary of the United States department of health and human services pursuant to the federal standards for the privacy of individually identifiable health information;

(H) Any person, other than those listed in paragraphs (A) through (G) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient is unable to deliver written consent, in which case, written consent must be provided by the patient's caregiver or legal guardian.

(1) Any consent must be signed by the patient or caregiver and dated.

(2) Any consent for disclosure is valid until rescinded by the patient or caregiver.

(3) In an emergency, a dispensary may disclose the recommendation information when it is deemed to be in the best interest of the patient. A dispensary employee making an oral disclosure in an emergency must prepare a written statement showing the patient's name, the date and time the disclosure was made, and the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.

~~(A) Pursuant to division (B) of section 3796.08 of the Revised Code and division (C) of section 4729.80 of the Revised Code, patient-specific dispensary transactions are confidential and not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone~~

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~~except:~~

- ~~(1) The patient for whom the recommendation or medical marijuana order was issued or that patient's designated caregiver;~~
- ~~(2) The certified physician who issued the recommendation;~~
- ~~(3) Certified and or licensed health care personnel who are responsible for the care of the patient;~~
- ~~(4) A member, inspector, agent, or other investigator of the state board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug;~~
- ~~(5) A government agent charged with the responsibility of providing medical care for the patient upon a written request by an authorized representative of the agency requesting such information;~~
- ~~(6) If applicable, an agent of a medical insurance company who provides insurance coverage for medical marijuana upon authorization and proof of insurance by the patient or proof by the insurance company for those medications requested;~~
- ~~(7) An agent who contracts with the dispensary as a "business associate" in accordance with the regulations promulgated by the secretary of the United States department of health and human services pursuant to the federal standards for the privacy of individually identifiable health information;~~
- ~~(8) Any person, other than those listed in paragraphs (A)(1) to (A)(7) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient is unable to deliver written consent, in which case, written consent must be provided by the patient's caregiver.~~
  - ~~(a) Any consent must be signed by the patient or caregiver and dated;~~
  - ~~(b) Any consent for disclosure is valid until rescinded by the patient or caregiver.~~
  - ~~(c) In an emergency, a dispensary may disclose the recommendation information when it is deemed to be in the best interest of the patient. A dispensary employee making an oral disclosure in an emergency must prepare a written statement showing the patient's name, the date and time the disclosure was made, and the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.~~



~~(B) Patient-specific information related to the dispensing of medical marijuana which may be required as evidence of a violation of Chapter 3796. of the Revised Code or of this division shall be released to a member, inspector, agent, or investigator of the state board of pharmacy, state medical board or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug upon his request. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a recommendation, the receipt shall list the following information:~~

~~(1) Recommendation identification number;~~

~~(2) The name of the patient;~~

~~(3) The quantity of the medical marijuana or medical marijuana product dispensed;~~

~~(4) Name of the recommending physician; and~~

~~(5) Date, name and address of the agency, and signature of the person removing the records.~~

~~(C) All patient-specific information related to the dispensing of medical marijuana, including consents, written statements of emergency disclosures, and written requests pursuant to paragraph (A)(8) of this rule, shall be kept on file at the dispensary for a period of three years in a readily retrievable manner.~~

3796:6-3-19

**Employee training requirements.**

- (A) A dispensary designated representative shall establish and oversee a dispensary employee training program.
- (B) Each dispensary shall maintain evidence of all training provided for every dispensary employee in its files. Such records are subject to inspection and audit by the state board of pharmacy. Acceptable forms of evidence are:
  - (1) Transcripts;
  - (2) Certificates of completion; or
  - (3) Other form of documentation which includes:
    - (a) The participant's name;
    - (b) Course title;
    - (c) Course content;
    - (d) Date(s) of training;
    - (e) Provider's name(s); and
    - (f) Signature of the course instructor.
- (C) All dispensary employees shall receive foundational training regarding the dispensing of medical marijuana before dispensing any medical marijuana. Training received in accordance with this paragraph does not qualify as continuing education described in paragraphs (D) and (E) of this rule. Mandatory training for dispensary employees before the employee may begin dispensing medical marijuana includes:
  - (1) Relevant training on the drug database established pursuant to section 4729.75 of the Revised Code;
  - (2) Relevant training on the inventory tracking system established pursuant to section 3796.07 of the Revised Code;
  - (3) Responsible use training, which shall include specific instruction on:

- (a) Use of the toll-free telephone line established pursuant to section 3796.17 of the Revised Code; and
    - (b) Learning to recognize signs of medicine abuse or adverse events in the medical use of marijuana by a patient.
  - (4) The proper use of security measures and controls that have been adopted by the dispensary for the prevention of diversion, theft or loss of medical marijuana;
  - (5) Confidentiality requirements of a dispensary;
  - (6) Instruction on the different forms, methods of administration, and strains of medical marijuana;
  - (7) Instruction on qualifying conditions for medical marijuana patients;
  - (8) Authorized uses of medical marijuana in the treatment of qualifying conditions;
  - (9) Instruction regarding regulatory inspection preparedness and law enforcement interaction;
  - (10) Awareness of the legal requirements for maintaining status as a licensed dispensary employee, including but not limited to the duty to report information to the board; and
  - (11) Other topics as specified by the state board of pharmacy.
- (D) Dispensary employees shall receive a minimum of sixteen hours of continuing education, on topics described in paragraph (E) of this rule, for each two-year licensing period. Continuing education hours shall not be carried over from one licensing period to another. A dispensary employee who is licensed within six months of a dispensary employee biennial renewal cycle shall be exempt from continuing education requirements.
- (E) The designated representative shall be responsible for ensuring that each dispensary key and support employee receives continuing education on the following subjects during each biennial licensing period:
- (1) Guidelines for providing information to patients and caregivers related to the risks associated with medical marijuana, including possible drug interactions;

- (2) Guidelines for providing support to patients related to the patients' symptoms;
  - (3) Recognizing signs and symptoms of substance abuse;
  - (4) Guidelines for refusing to provide medical marijuana to an individual who appears to be impaired or abusing medical marijuana;
  - (5) The safe handling of medical marijuana, including an overview of common industry hazards, current health and safety standards, and dispensary best practices;
  - (6) Legal updates training pertaining to the Ohio medical marijuana control program; and
  - (7) Other topics as specified by the state board of pharmacy.
- (F) Before any training in paragraphs (C) and (E) of this rule may be provided to dispensary employees for credit, a designated representative shall submit, in a manner determined by the board, all of the following items to the state board of pharmacy and obtain approval:
- (1) Names and qualifications of the persons responsible for training content;
  - ~~(2) The primary objective of the training and how it is intended to improve the participants' competency as dispensary employees;~~
  - ~~(3) The number of intended trainings for the next twelve month period and the number of participants for each training;~~
  - ~~(4) Any brochures describing the activity;~~
  - ~~(5) The method or manner of presenting materials;~~
  - ~~(6)~~(2) The agenda with a detailed time schedule;
  - ~~(7)~~(3) A set of training materials, ~~if requested~~; and
  - ~~(8)~~(4) Any other items requested by the state board of pharmacy.
- (G) Before training may be provided to dispensary employees for credit under paragraphs (C)(3)(b), (C)(7), and (E)(1) to (E)(4) of this rule, a designated representative shall

submit, in a manner determined by the board, all of the following to the state board of pharmacy:

- (1) A signed attestation by the person responsible for training content that the person or persons responsible for the content of the educational materials is a pharmacist licensed under Chapter 4729. of the Revised Code, or any of the following professionals authorized to prescribe under division (I) of section 4729.01 of the Revised Code:
    - (a) A clinical nurse specialist or certified nurse practitioner;
    - (b) A physician; or
    - (c) A physician assistant;
  - (2) The professional license number of the person or persons identified in paragraph (G)(1) of this rule; and
  - (3) That the person or persons approve of the content.
- (H) All training materials submitted for approval ~~pursuant to~~ under paragraph (F) of this rule shall be submitted a minimum of sixty days prior to the date of presentation of the intended training. Any representation that the training has been approved for dispensary employee credit is prohibited until such approval is received by the designated representative who submitted the application for approval.
- (I) Training approved for credit by the state board of pharmacy pursuant to paragraphs (F) and (G) of this rule, shall be valid for dispensary employee continuing education credit for remainder of the two-year licensing period in which the continuing education credit will be offered. Training material is valid for two years from the date of approval. Approved training shall be available to any licensed dispensary employee.
- (J) Before or at the time of training, each participant shall be provided with course materials in the form of written, electronic, or other format that are of such quality and quantity to indicate that adequate time has been devoted to their preparation and that they will be of value to participants. Any presentation materials, electronic or otherwise, shall be subject to the same criteria as other materials.
- (K) Training credit shall not be awarded for breaks or opening or closing remarks. Only time of actual instruction shall count toward a credit hour. Partial hours shall be

rounded to the nearest one-quarter of an hour and should be expressed in decimals.

- (L) The state board of pharmacy, upon receipt of evidence that any approved training program or training provider is not conforming to the requirements developed pursuant to this rule, may revoke or otherwise limit the scope of the board's prior approval.
- (M) An attendee at an out-of-state training may seek post-program approval if such approval is sought within sixty days after the program is presented. An application for out-of-state training shall be made on a completed form, developed in accordance with section 3796.04 of the Revised Code.
- (N) A designated representative shall, in cooperation with the individual or individuals described in paragraph (O) of this rule, provide oversight for the development and dissemination of:
  - (1) Educational materials for patients and caregivers in accordance with paragraphs (C)(6) and (C)(7) of rule 3796:6-3-15 of the Administrative Code;
  - (2) A system for a patient or caregiver to document the patient's symptoms related to a qualifying condition that includes:
    - (a) A ~~log-book~~logbook, maintained by the patient and/or caregiver, in which the patient or the caregiver may track the use and effects of medical marijuana;
    - (b) A rating scale for symptoms associated with a qualifying condition;
    - (c) Guidelines for the patient's self-assessment, or if applicable, assessment of the patient by the caregiver; and
    - (d) Guidelines for reporting usage and symptoms to the recommending physician and any other treating physicians.
  - (3) Policies and procedures for refusing to provide medical marijuana to an individual who appears to be impaired or abusing medical marijuana.
- (O) A designated representative shall maintain all of the following records regarding the educational materials outlined in paragraph (N) of this rule:

- (1) A signed attestation by the person or persons responsible for content described in paragraph (N) of this rule is a pharmacist licensed under Chapter 4729. of the Revised Code, or any of the following professionals authorized to prescribe under division (I) of section 4729.01 of the Revised Code:
  - (a) A clinical nurse specialist or certified nurse practitioner;
  - (b) A physician; or
  - (c) A physician assistant;
- (2) The professional license number of the person or persons identified in paragraph (O)(1) of this rule; and
- (3) That the person or persons approve of the content.

3796:6-3-20

**Medical marijuana dispensary internal inventory control system.**

- (A) A dispensary designated representative shall have primary oversight of the dispensary's medical marijuana inventory control system. The inventory control system shall be real-time, web-based, backed-up at least daily and accessible by the state board of pharmacy immediately upon request.
- (B) A dispensary's inventory control system shall allow for tracking so that the oldest stock of medical marijuana is distributed first. A dispensary may deviate from this requirement, if such deviation is temporary and appropriate.
- (C) A dispensary shall establish and implement an inventory control system for its medical marijuana that documents an exact accounting of:
  - (1) Each transaction and each day's beginning inventory, acquisitions, sales, disposal and ending inventory.
  - (2) Acquisitions of medical marijuana from a licensed processor or cultivator holding a plant-only processor designation, including:
    - (a) A description of the products including the quantity, strain, variety and batch number of each product received;
    - (b) For each product, the finished form, number of units or volume of each finished form in each container, the number of commercial containers of each finished form;
    - (c) The name and license number of each of the processors and cultivators providing the medical marijuana;
    - (d) The name and license number of the licensed processor and cultivator agents delivering the medical marijuana;
    - (e) The name and license number of the licensed dispensary employee receiving the medical marijuana;
    - (f) The date of acquisition; and
    - (g) Any other information deemed appropriate by the state board of pharmacy.



- (3) Records of the sale or dispensing of medical marijuana and denials of such sales, which shall contain:
  - (a) A description of the products including the quantity, strain, variety and batch number of each product dispensed;
  - (b) The name and license number of the licensed dispensary employee selling, dispensing, or denying the sale or dispensing of the medical marijuana;
  - (c) The date of dispensing; and
  - (d) The name and registration number of the patient and, if applicable, the caregiver.
- (4) The disposal of medical marijuana, including:
  - (a) A description of the products, including quantity, strain, variety, batch number and cause for the medical marijuana being destroyed;
  - (b) The name and license number of the dispensary employee destroying the medical marijuana or medical marijuana product;
  - (c) The name and license number of the dispensary key employee verifying the destruction of the medical marijuana or medical marijuana product;
  - (d) The method of disposal and the name, address and telephone number of the disposal company; and
  - (e) The date of disposal.
- (D) The designated representative shall conduct and document an audit of the dispensary's daily inventory according to generally accepted accounting principles at least once weekly.
  - (1) If the audit identifies a reduction in the amount of medical marijuana in the dispensary's inventory not due to documented causes, the dispensary shall determine where the loss occurred and immediately take and document corrective action. The dispensary shall immediately inform the state board of pharmacy of the loss by telephone and provide written notice of the loss and

the corrective action taken within two business days after first discovery.

- (2) If the reduction in the amount of medical marijuana in the inventory is due to criminal activity or suspected criminal activity, the dispensary shall immediately make a report identifying the circumstances surrounding reduction to the state board of pharmacy and law enforcement with jurisdiction where the suspected criminal acts occurred.
- (3) If the audit identifies an increase in the amount of medical marijuana in the dispensary's inventory not due to documented causes, the dispensary shall determine where the increase occurred and take and document corrective action.
- (4) ~~The~~ Every medical marijuana dispensary shall ~~submit~~ complete or cause to be completed quarterly financial ~~audit~~ statements ~~in a format and medium approved by the state board of pharmacy. Quarterly audits may include, but are not limited to, an income statement, balance sheet and weekly medical marijuana inventory, including marijuana acquisition, wholesale cost and sales, prepared in accordance with~~ prepared by a certified public accountant under generally accepted accounting principles (GAAP) that includes, at a minimum, an income statement, balance sheet, and cash flow statement. ~~Annually, the~~ Following the end of every fiscal year, a medical marijuana dispensary shall ~~submit~~ cause an audit ~~including the same information, compiled and to be prepared and~~ certified by ~~an~~ a licensed independent auditor or certified public accountant. Both such quarterly and annual submissions shall be in a format and medium approved by the state board of pharmacy under generally accepted auditing standards (GAAS).

(E) A dispensary shall:

- (1) Maintain the documentation required of this rule in a secure, locked location for three years from the date on the document. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day;
- (2) Provide any documentation required to be maintained in this rule to the state board of pharmacy for review upon request; and
- (3) If maintaining a bank account, retain for a period of three years a record of each deposit or withdrawal from the account.

(F) A dispensary shall not accept returns of medical marijuana, unless the return is

pursuant to a program offered under paragraph (D) of rule 3796:6-3-14 of the Administrative Code, a recall, or the consequence of an error in dispensing. If medical marijuana is abandoned at the dispensary, it shall be accounted for and destroyed. All returned or abandoned medical marijuana shall be destroyed in compliance with rule 3796:6-3-14 of the Administrative Code. A dispensary shall notify the state board of pharmacy in writing of any returned or abandoned medical marijuana.

- (G) All records of each day's beginning inventory, acquisitions, sales, disposal and ending inventory shall be kept for a period of three years at the place where the medical marijuana and medical marijuana products are located. Any dispensary intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the dispensary name and license number and the name and address of the alternate location. The state board of pharmacy will send written notification to the dispensary documenting the approval or denial of the request. A copy of the state board of pharmacy's approval shall be maintained with the other records of medical marijuana. Any such alternate location shall be secured and accessible only to authorized dispensary employees.

3796:6-3-21

**Recall procedures.**

(A) A dispensary shall establish policies and procedures to conduct mandatory and voluntary recalls of medical marijuana. The procedure shall be adequate to deal with recalls due to any action initiated at the request of the department of commerce or the state board of pharmacy and any voluntary action by the dispensary to remove defective or potentially defective medical marijuana from the market or any action undertaken to promote public health and safety by replacing existing medical marijuana with improved products or packaging.

(B) A dispensary's policy must establish a plan for communicating a recall of medical marijuana. The communication plan ~~should~~shall include:

- (1) A mechanism to contact all customers who have, or likely have, obtained the product from the dispensary. The communication must include information on the process for return of the recalled product;
- (2) A mechanism to contact the processor or cultivator that manufactured the recalled product;
- (3) Communication with the state board of pharmacy, the department of commerce, and the state medical board within twenty-four hours; and
- (4) Outreach via media, as necessary and appropriate.

(C) In the event of a product recall, a patient and/or caregiver may return the recalled product to the dispensary where the product was purchased. The dispensary must accept the return of unused recalled product from the patient and/or caregiver.

~~(D)~~ Any recalled medical marijuana or medical marijuana product returned to the dispensary because of the recall must be destroyed by ~~the dispensary, in a manner consistent with rule 3796:6-3-14 of the Administrative Code.~~

(1) The dispensary in a manner consistent with rule 3796:6-3-14 of the Administrative Code; or

(2) Returning the recalled medical marijuana to the licensed cultivator or processor that manufactured the recalled medical marijuana to be destroyed in a manner approved by the department of commerce.

3796:6-3-22

**Prohibitions.**

- (A) No dispensary employee may share office space with, compensate, receive compensation from, or refer patients to a physician holding a certificate to recommend issued by the state medical board under section 4731.30 of the Revised Code.
- (B) A dispensary shall not allow a physician holding a certificate to recommend issued by the state medical board under section 4731.30 of the Revised Code to conduct a physical examination of a patient or any follow up care for purposes of diagnosing or treating a qualifying medical condition at the dispensary.
- (C) No dispensary shall be open or in operation, and no person shall be in the dispensary department, unless a designated representative is actively employed by the dispensary and available for consultation by any dispensary employee. At all other times, the dispensary shall be closed and properly secured, in accordance with standard operating security procedures and in compliance with this division.
- (D) No dispensary shall be left unattended by dispensary employees during hours of operation.
- (E) No dispensary shall sell anything other than authorized medical marijuana, medical marijuana products, medical marijuana devices, and advertising materials authorized pursuant to rule 3796:6-3-24 of the Administrative Code.
- (F) No dispensary shall offer coupons except in the case of coupons intended to benefit patients registered as indigent or as a veteran.
- (G) No medical marijuana or medical marijuana products shall be consumed on the premises of a dispensary.
- (H) No food or beverages shall be offered, furnished, or consumed on the premises of a dispensary, except that complimentary non-alcoholic beverages may be available for patients and caregivers who are at the dispensary. Licensed dispensary employees shall be authorized to consume food and non-alcoholic beverages in designated employee break areas. No medical marijuana shall be accessed, stored, possessed, or administered in designated employee break areas.
- (I) A dispensary shall not produce or manufacture medical marijuana or medical marijuana products without being licensed pursuant to this division by the department of commerce.
- (J) No dispensary shall operate a drive through window (pickup unit).

- (K) ~~No dispensary shall transport medical marijuana or medical marijuana products to residences of patients or caregivers.~~ No medical marijuana shall be sold, dispensed, or distributed to a patient or caregiver via a delivery service or any other manner outside of a dispensary, except that a caregiver may deliver medical marijuana to the caregiver's registered patient.
- (L) A dispensary shall not operate if its surveillance equipment is inoperable. If the surveillance equipment is partially inoperable, that matter should be immediately reported to the state board of pharmacy to determine whether the dispensary may continue to operate in any fashion.
- (M) A dispensary shall not allow intoxicating liquor or beer as defined in section 4301.01 of the Revised Code onto its licensed premises.
- (N) Dispensaries may offer employees, who have an active patient or caregiver registration, discounts only if the discount applies to all products offered at the dispensary and the same discounts are offered to all patients and caregivers.
- (O) Dispensary employees who have an active patient or caregiver registration shall not receive rebates or discounts on medical marijuana products offered by a cultivator, processor, or third-party entity.

3796:6-3-23

**Dispensary access.**

(A) Except as provided under this division, no person, except a dispensary employee, or a cultivator or processor employee who is delivering medical marijuana, shall be allowed in the dispensary department without an active qualifying patient or caregiver registration issued by the state board of pharmacy.

(B) In addition to authorized dispensary employees, cultivator employees, and processor employees, the following may be granted access to a dispensary so long as presence is maintained in the dispensary visitor log and ~~obtain~~ a visitor identification badge ~~from the~~ is provided by a dispensary employee, prior to entering the dispensary:

~~(1) One individual accompanying each patient or caregiver who shall remain in the waiting area. Such visitors shall remain under supervision of a dispensary employee while on dispensary premises;~~

~~(2)~~(1) Third party service personnel, such as technicians, utility workers, and employee representatives, may access portions of the premises that do not contain medical marijuana without prior written notice, provided that such visitors are entered in the visitor log, are identified on the third party vendor list maintained in compliance with rule 3796: 6-3-17 E(6)(b) of the Administrative Code, and are accompanied at all times by a dispensary employee. Such visitors may only enter non-restricted areas, such as employee break rooms or restrooms, and may not have access to areas containing medical marijuana without ~~prior approval or in the event of an emergency in accordance with paragraph (C) of this rule~~ continuous supervision by a dispensary employee; and

~~(3)~~(2) Local, state or federal law enforcement, emergency service personnel, or government officials ~~if necessary to perform~~ in the performance of their civil or administrative governmental duties.

(C) Upon prior written request, on a form approved and provided by the board, the state board of pharmacy may authorize persons who are otherwise prohibited from being on dispensary premises, temporary access to a dispensary.

(1) Such access shall only be permitted as follows:

(a) Credentialed members of the media may access dispensaries only during non-operating hours. A credentialed member of the media is an individual who operates or is employed by a media organization and whose primary professional employment is through the media organization that has issued the individual's credentials. The media organization must have a record of substantial and original news coverage. The request shall be made a minimum of seven days prior to

the requested date of access.

(b) Physicians with a Certificate to Recommend (CTR) and government officials and their staff may access dispensaries for educational and policy making purposes. The request shall be made a minimum of seventy-two hours prior to the requested date of access.

~~(1)~~(2) All persons not expressly permitted to be on the premises of a dispensary under this rule, but who have been authorized, in writing, to enter the dispensary by the state board of pharmacy, shall obtain a visitor identification badge from the dispensary, prior to entering the dispensary.

~~(2)~~(3) A dispensary employee shall escort and supervise such visitors at all times that the visitor is on the dispensary premises. ~~Visitors shall visibly display the visitor identification badge at all times that the visitor is on dispensary premises and shall return the visitor identification badge to a dispensary employee upon exiting the dispensary.~~

(4) Visitors shall visibly display the visitor identification badge at all times that the visitor is on dispensary premises and shall return the visitor identification badge to a dispensary employee upon exiting the dispensary.

~~(3)~~(5) All visitors shall log in and out. The dispensary shall maintain the visitor log, which shall include the date, time, and purpose of the visit ~~and~~ which shall be available to the state board of pharmacy upon request.

(6) No photographs or recordings in any form shall be made of restricted dispensary areas.

(7) No photographs or recordings that identify patients or caregivers shall be made absent a consent form signed by the identified patient or caregiver.

~~(4)~~(8) If an emergency requires the presence of a visitor and makes it impracticable for the dispensary to obtain a waiver pursuant to this section, the dispensary shall provide written notice to the state board of pharmacy as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. The dispensary shall monitor and maintain a log of such ~~visit~~visits.

~~(D) No medical marijuana shall be sold, dispensed, or distributed to a patient or caregiver via a delivery service or any other manner outside of a dispensary, except that a caregiver may deliver medical marijuana to the caregiver's qualified patient.~~