3/9/2017

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 Rules – Dispensary Rules

3796:6-1-01, 3796:6-2-01, 3796:6-2-02, 3796:6-2-03, 3796:6-2-04, 3796:6-2-05, 3796:6-2-06, 3796:6-2-07, 3796:6-2-08, 3796:6-2-09, 3796:6-2-10, 3796:6-2-11, 3796:6-2-12, 3796:6-2-13, 3796:6-2-14, 3796:6-3-01, 3796:6-3-02, 3796:6-3-03, 3796:6-3-04, 3796:6-3-05, 3796:6-3-06, 3796:6-3-07, 3796:6-3-08, 3796:6-3-09, 3796:6-3-10, 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, 3796:6-3-24, 3796:6-4-01, 3796:6-4-02, 3796:6-4-03, 3796:6-4-04, 3796:6-4-05, 3796:6-4-06, 3796:6-4-07, 3796:6-4-08, 3796:6-4-09, 3796:6-4-10, 3796:6-5-01

Comments on the proposed rules will be accepted until close of business on **March 24, 2017**. Please send all comments to the following email addresses: MMCPRules@Pharmacy.Ohio.gov; CSIPublicComments@Governor.Ohio.gov.

To view the business impact analysis (BIA) and a complete set of the Ohio Medical Marijuana Control Program draft rules please visit: www.MedicalMarijuana.Ohio.gov/rules.

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CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Board of Pharmacy

Regulation/Package Title: Medical Marijuana Control Program Dispensary Rules

Rule Number(s): 3796:6-1-01, 3796:6-2-01, 3796:6-2-02, 3796:6-2-03, 3796:6-2-04, 3796:6-2-05, 3796:6-2-06, 3796:6-2-07, 3796:6-2-08, 3796:6-2-09, 3796:6-2-10, 3796:6-2-11, 3796:6-2-12, 3796:6-2-13, 3796:6-2-14, 3796:6-3-01, 3796:6-3-02, 3796:6-3-03, 3796:6-3-04, 3796:6-3-05, 3796:6-3-06, 3796:6-3-07, 3796:6-3-08, 3796:6-3-09, 3796:6-3-10, 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, 3796:6-3-24, 3796:6-4-01, 3796:6-4-02, 3796:6-4-03, 3796:6-4-04, 3796:6-4-05, 3796:6-4-06, 3796:6-4-07, 3796:6-4-08, 3796:6-4-09, 3796:6-4-10, 3796:6-5-01

Date: March 9, 2017

Rule Type: New

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   Ohio House Bill 523 of the 131st General Assembly established the Ohio Medical Marijuana Control Program ("the Program"). Outlined in Chapter 3796 of the Revised Code, the responsibilities for the Program are outlined are divided between three state agencies. These agencies are the Ohio Department of Commerce ("Department"), State of Ohio Board of Pharmacy, and the State Medical Board of Ohio. The Board of Pharmacy is responsible for the administration, implementation and enforcement of dispensaries under the Program. This Business Impact Analysis addresses rules that apply to medical marijuana dispensaries.

   - 3796:6-1-01: Defines terms specific to dispensary licensing, operations, and enforcement.
   - 3796:6-2-01: Establishes procedure for issuance of a request for dispensary applications and provides overview of the timeframe for responding as well as items that the board will include with the request.
   - 3796:6-2-02: Provides requirements to be included in a dispensary license application.
   - 3796:6-2-03: Defines which natural persons are responsible for signing documents required as part of the application.
   - 3796:6-2-04: Establishes that applications will be evaluated on a competitive basis with the burden of proving qualifications rests with applicants.
   - 3796:6-2-05: Establishes the maximum number of dispensary provisional licenses that are permitted at any one time. Sets a ceiling of 60 provisional licenses prior to September 8, 2018. Board has discretion to issue additional provisional licenses after September 9, 2018, if state's population, patient population support it, and geographic location support it.
   - 3796:6-2-06: Requires provisional licensee to notify the board and request an inspection when capable of operating in compliance with application. A final inspection must be completed to the board's satisfaction before a certificate of operation is issued.
   - 3796:6-2-07: Provides background check procedures as well as initial and biennial renewal licensing for dispensary owners and operational decision-makers.
   - 3796:6-2-08: Provides background check procedures as well as initial and biennial renewal licensing for general dispensary staff.

- 3796:6-2-09: Applies to all dispensary employees. Includes provisions requiring: (1) That all employees be twenty-one years of age; (2) The return of employee identification cards; (3) Consent to be enrolled in Rapback; (4) The reporting of an arrest or conviction for a disqualifying offense or any change in a information provided within the employee's application.
- 3796:6-2-10: Mandates the renewal of a dispensary certificate of operation at least once every two years. Affords ninety days' notice of expiration of certificate. Requires a roster of dispensary employees and applicable fees. Sets forth the conditions that may result in a denied renewal application.
- 3796:6-2-11: Requires a surety bond or escrow in the amount of $50,000 in order to guarantee compliance with state tax laws and that dispensary operations continue in compliance with ORC 3796 and OAC 3796:6.
- 3796:6-2-12: Defines a change in ownership and requires a minimum fee of $5,000. Any change that requires a new EIN, DBA, change in business form, cessation of one business and replacement by another, or 100% stock purchase by another entity requires a new $35,000 certificate of operation fee.
- 3796:6-2-13: Authorizes the relocation of a dispensary within the same dispensing district for a $5,000 fee. Requires the board to consider the population of the state, the patient population and the geographic distribution of dispensary sites.
- 3796:6-2-14: Establishes required notice to the board when a dispensary discontinues business. Allows for a one-time transfer of medical marijuana to another dispensary. Requires negotiation with a licensed processor for the transfer.
- 3796:6-3-01: Sets forth the baseline rules for the operation of a dispensary including: (1) A prohibition on out-of-state sales; (2) A requirement that all employees wear their employee identification card; and (3) Requiring at least an annual review of policies and procedures for updates.
- 3796:6-3-02: Requires premises to be well-lit, maintained in a clean and sanitary conditions, and meet all relevant zoning and fire codes, among other items.
- 3796:6-3-03: Requires dispensaries to be open at least 35 hours/week from 7:00 a.m. to 9:00 p.m. and to conspicuously post hours of operation.
- 3796:6-3-04: Requires specific security measures to be in place when a dispensary is closed and prohibits medical marijuana from being sold when a dispensary is closed.
- 3796:6-3-05: Modeled after the "responsible person" position required for all other entities licensed by the board. The responsible person is responsible for record-keeping, oversight of the receipt, storage, dispensing and handling procedures related to a

dispensary's marijuana inventory, notification to the board of changes in an employee's status and the return of employee cards, notification of loss or theft of marijuana. The responsible person must hold a dispensary key employee license.

- 3796:6-3-06: Requires that a dispensary: (1) Establish standard operating procedures related to the receipt, storage, dispensing and disposal of medical marijuana; (2) Track such information in the seed-to-sale system; and (3) Train employees in the standard operating procedures. All products must be inspected for compliance with packaging and labeling requirements. Requires areas containing marijuana to be well-lighted, clean, and dry.
- 3796:6-3-07: Sets forth: (1) Specific record-keeping and record-storage requirements related to tracking of a dispensary's marijuana inventory; (2) That a dispensary must maintain adequate physical conditions; (3) Restricted access areas as the only authorized space for the storage of marijuana; and (4) A requirement to maintain marijuana eligible for dispensing separate from that which must be destroyed.
- 3796:6-3-08: Requires: (1) Point-of-Sale compatibility with OARRS-related technology and seed-to-sale system; (2) Verification of completed recommendation; (3) Verification that patient has not exceeded 90-day or recommended supply; (4) Documentation in seed-to-sale and dispensary's inventory system.
- 3796:6-3-09: Requires specific labeling for plant material and additional notification for forms other than plant material. Requirements can be met through a combination of packaging labels and dispensary-created labels. Accompanying materials that must be provided are also set forth.
- 3796:6-3-10: Consistent with requirements placed on pharmacies, mandates batch reporting in specified format to OARRS.
- 3796:6-3-11: Requires dispensaries to monitor for theft and loss of marijuana and to immediately report the incident to the board. Also, obligates dispensary employees to report suspected fraudulent recommendations.
- 3796:6-3-12: Requires dispensaries to provide information notifying patients on how to report errors in dispensing to the board. Dispensaries must establish a procedure to identify errors in dispensing and to notify recommending physicians, patients, and caregivers.
- 3796:6-3-13: Requires the designated representative to review dispensing errors, notify employees, and keep a record of any resulting policy changes.
- Rule 3796:6-3-14: Establishes acceptable disposal methods for medical marijuana.

- 3796:6-3-15: Requires dispensaries to have a policy in place for the education of patients and caregivers and establishes minimum medical marijuana-related educational materials that must be made available for patients and caregivers. Requires that pricing be made publicly available.
- 3796:6-3-16: Requires a dispensary to establish a security policy. Creates physical barrier requirements, electronic surveillance requirements, and monitoring/notification requirements.
- 3796:6-3-17: Requires a dispensary to establish record-keeping policies.
- 3796:6-3-18: Expressly provides that medical marijuana patient records are confidential and identifies who may have access. Details the condition and timing when patient records must be made available to the board.
- 3796:6-3-19: Provides training requirements for dispensary employees. This includes technology training, medical marijuana use training, and training on Ohio-specific rules and regulations. 8 hours of continuing education are required each year for dispensary employees.
- 3796:6-3-20: Requires dispensaries to maintain their own internal dispensary inventory system and details required compatibility with state systems as well as necessary contents. This internal system will function as the official dispensing record.
- 3796:6-3-21: Requires dispensaries to establish policies related to the mandatory and voluntary recall of marijuana, including notification to relevant parties. Dispensaries must put their recall procedure into action upon notice from the board or the department.
- 3796:6-3-22: General dispensary prohibitions set forth including: (1) Certain relationships with or authorizations for physicians; (2) Requirement that dispensary not be left unattended when open; (3) Sale of items unrelated to the medical marijuana operation; (4) Use of marijuana on licensed premises; (5) Drive-thru windows and delivery; and (6) sales when surveillance is down.
- 3796:6-3-23: Details who may have access to the dispensary department (patients, caregivers, and dispensary employees) and restricted access areas (employees). Provides that all others must be authorized by the board (third parties and agents of the board) except in the case of an emergency.
- 3796:6-3-24: Creates guidelines for licensees' marketing and advertising abilities, including external signage, social media and traditional media outlets.
- 3796:6-4-01: Provides scope of board's enforcement authority.
- 3796:6-4-02: Establishes scope of inspections and the different inspections by the board including compliance inspections conducted with or without notice.

- 3796:6-4-03: Establishes the grounds under which a dispensary or employee license may be suspended, revoked, placed on probation or renewal denied. Provides chapter 119 due process.
- 3796:6-4-04: Details when general chapter 119 process will be implemented, tethering the initiation of the process to the commission of one of the grounds for discipline listed in rule 3796:6-4-03.
- 3796:6-4-05: Establishes summary suspension grounds for a dispensary employee, including: (1) Substance abuse or addiction; (2) Continuing to operate as a dispensary employee presents an immediate and serious harm to oneself or others; and (3) Upon notification of a felony drug conviction.
- 3796:6-4-06: Establishes summary suspension grounds for a licensed dispensary when continual operation would result in immediate and serious harm to others. Includes notice that product may be placed under seal.
- 3796:6-4-07: Provides notice that failure to properly store marijuana may subject products to being placed under seal. Upon reasonable suspicion that improper products are being sold to patients or caregivers, products may be confiscated for laboratory testing.
- 3796:6-4-08: Establishes when a license may be restored.
- 3796:6-4-09: Requires the department, pharmacy board and medical board to notify the other agencies as well as local law enforcement when action is taken on a license.
- 3796:6-4-10: Allows for variances at the boards discretion if four listed elements are met.
- 3796:6-5-01: Establishes the fees for applications, certificates of operation, renewals, reissued certificates and employee identification cards. Renewal for IDs is every two years and every two years for entity certificate of operations.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Chapters 119 and 3796 of the Revised Code are the authorizing statutes for these rules.

3. 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?

While the MMCP rules do not implement a federal requirement, care was taken in the drafting of all MMCP rules to consider the United States Department of Justice drug enforcement priorities.

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

   Not applicable.

5. **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)?**

   The dispensary rule set is intended to afford patients and caregivers a safe and secure location from which to purchase medical marijuana products from an informed industry. Moreover, because marijuana is a schedule I controlled substance under federal law, state rules regulating the cultivation, processing, sale, possession, and administration of marijuana are necessary to protect against the risk of criminal charges.

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

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

Development of the Regulation

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

   The Board solicited comments from the public and the Medical Marijuana Advisory Committee (MMAC). Comments were tracked by category—one comment could have more than one category. Tracked in this manner, over 300 comments were received. The Board received feedback from many different groups and stakeholders with an interest in the Program, including Ohio citizens, Ohio businesses, advocacy groups, prospective patients and caregivers, and both in-state and out-of-state industry associations. Further, the Board conducted a survey of persons eligible to serve in the position of a clinical director—a position removed from the instant draft rules.

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

   In general, the feedback received can be categorized into the following areas:

   - Advertising
     - 21 of the public comments received were related to advertising
     - 12 suggested additional restrictions
     - 9 suggested relaxed rules

- Number of dispensary licenses
  - 16 of the public comments received were related to the number of dispensaries
  - 15 sought an increase in the number of dispensaries

- Dispensary fees
  - 31 of the public comments related to dispensary fees
  - 10 suggested fees be left unchanged
  - 21 suggested reducing fees

- The requirement that each dispensary employ a part-time clinical director
  - 13 public comments related to the clinical director were received
  - 8 comments suggested an amendment to the clinical director rule
  - 5 comments suggested removing the clinical director
  - A survey of eligible persons revealed few who were both willing to serve as a clinical director and had an employer who would allow them to serve in the part-time position

- Prohibition on home delivery of medical marijuana
  - 16 public comments received
  - 5 suggested allowing home deliver
  - 10 suggested prohibiting home delivery

- Purchasing options/products at a dispensary
  - 10 public comments received
  - 9 comments suggested prohibiting coupons and discounts except to benefits the indigent and veterans
  - 1 comment sought to exclude coupons and discounts in their entirety

- Hours of operation
  - This was a topic of interest for the Medical Marijuana Advisory Committee

Based on MMAC feedback, public feedback, and discussions between stakeholders and regulators from other states, the following changes were made to the draft rules:

- **Advertising** – Pre-approval requirements on advertising have been lifted and replaced with a requirement that advertisements be submitted before publication—in a manner similar to FDA regulations for traditional pharmaceuticals. Prohibitions were placed on several specific items requested in most of the public comments—the use of slang terms, broadcast ads, clothing, handheld signs, and marijuana leaves.

- **Number of licenses** – The Board increased the number of dispensary provisional licenses that it may issue before September 8, 2018, from 40 to 60. The rule allows the Board to award additional licenses thereafter based on the state population, patient population, and geographic location.

- **Dispensary fees** – The Board decreased the biennial fee for a dispensary certificate of operation from $80,000 every two years to $70,000 every two years. The Board also revised its application fee rules to clarify that the board will return fees to an applicant if an RFA is withdrawn before an award is made or if the board grants permission to withdraw an application due to a change in federal, state, or local rules or regulations.

- **Dispensary location** – Based on feedback from Committee members, dispensaries cannot be located within 500 feet of rehabilitation facilities licensed under 5119.01 of the Revised Code.

- **Clinical director** – Because the clinical director position was intended to be a part-time position and very few eligible persons responded to our survey that they were both willing and had an employer who would allow them to serve as a dispensary clinical director, the clinical director position was removed from the rules. As a compromise, the training rules have been enhanced to require contracting with certain professionals to develop content.

- **Home delivery** – Due to the public feedback and the increased access offered by additional dispensaries, the prohibition on home delivery of medical marijuana remains in the draft rules.

- **Purchasing options/products at a dispensary** – Based on changes to the draft rules, coupons and discounts are prohibited except those intended to benefit the indigent and veterans.

- **Hours of operation –** The Board expanded the hours during which a dispensary is permitted to operate from 7 a.m. – 7 p.m., to 7 a.m. – 9 p.m.

- **Whistleblower protection** – Based on Committee feedback, rules related to employee licensing discipline were amended so that an employee's report of a violation does not constitute independent grounds for discipline against that employee's license.

- **Expired plant material** – Based on Committee feedback the draft rules were amended to allow dispensaries to sell expired plant material to a licensed processor.

- **Unused medical marijuana** – Based on comments received from the patient and caregiver rule set, the current rule set allows dispensaries to accept unused medical marijuana from patients and caregivers for destruction.

- **Security and surveillance** – Based on industry concerns over data storage, security and surveillance rules were amended to allow for live streaming from a motion-activated camera, rather than 24-hour recording, during hours when a dispensary is closed.

The Board reviewed every comment submitted to the Medical Marijuana Control Program (MMCP) rules address. There were a variety of subjects within the remaining categories that made it difficult to generalize those comments. Some of those comments included:

- General comments regarding the approval or disapproval of certain aspects within the rules
- Questions related to information that will be available through another rule set related to forms and methods of administration
- Suggested changes that would require a statutory change to effect
- Comments related to regulations falling under the purview of either the State Medical Board or the Department of Commerce

9. 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?

Rules were developed after benchmarking with regulators in other states, talking with industry experts, and hearing from patients and caregivers registered under other state programs.

10. 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.

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

Performance-based regulation was considered for these rules. For example, the application criteria were developed as a merit-based system, where applicants must demonstrate their knowledge and abilities in this specific field to be considered for a license.

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

Because the MMCP is a new program, there are no existing rules to duplicate. The Board works closely with the Department of Commerce and State Medical Board to ensure consistency and to eliminate redundancy as the MMCP rules are being created. For instance, with the cultivator rules, a single, Program-wide definitions section was filed.

13. 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 Board established standards and procedures that apply to every entity that will be licensed by the Board under the Program. Much like the rules already filed by the Department of Commerce, the Board's proposed rules set forth a consistent process for the issuance of dispensary provisional licenses, dispensary certificates of operation and employee identification cards. The rules require the development of an impartial scoring rubric to evaluate applicants. The application of a consistent set of requirements will result in highly qualified and capable businesses receiving licenses in Ohio. The regulations also establish and communicate the process for the issuance of licenses and employee identification cards, which speaks to the predictability of the MMCP operations.

Adverse Impact to Business

14. 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;

These rules regulate medical marijuana retail dispensaries. "Dispensary," as used in Chapter 3796. of the Revised Code, means an entity licensed pursuant to sections 3796.04 and 3796.10 of the Revised Code and any rules promulgated thereunder to sell medical marijuana to qualifying patients and caregivers. Dispensaries will be the sole entities authorized to sell medical marijuana to patients and caregivers in the state of Ohio.

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

The Board established a licensing fee schedule for medical marijuana dispensaries and their employees under rule 3796:6-5-01 of the Administrative Code. The application fee will be $5,000. Dispensaries operating under a provisional license will have six months to pass a pre-operation inspection and become operational. The biennial license fee will be $70,000.

Individuals seeking a medical marijuana dispensary employee license will be required to submit fingerprints for a background check at a cost of less than $50 each. Three employee licenses—dependent upon responsibility within the dispensary organization—are available. Owners will register as associated key employees for a biennial fee of $500. Operational decision makers will register as key employees for a biennial fee of $250. Staff employees will register as support employees for a biennial fee of $100.

With respect to fines, the Board has the authority under rule 3796:6-4-04 to issue fines for violations of the rules chapter and Chapter 3796 of the Revised Code of up to $50,000 per violation. Applicants that are issued a provisional license have six months to pass a pre-operation inspection and become operational.

Various compliance-related costs will be incurred. These include items such as waste removal and security requirements. Similarly, while the State Board of Pharmacy does not consider continuing education to be an adverse impact on industry, costs associated with continuing education will be incurred to comply with the promulgated dispensary rules. Because this is an emerging industry, no generally accepted industry practices for compliance are available to estimate industry costs. In many cases, compliance-related costs will depend on costs charged by third parties that will serve this new industry.

Costs associated with employee time for compliance will likely be incurred as dispensaries prepare for any announced inspections, produce requested documents, and escort inspectors who are on the premises. Businesses will incur employee time costs associated with preparing applications for licensure, formulation of standard operating procedures and performing record-keeping duties. These requirements are intended to enforce the principles on which the MMCP is built—public safety, safe products, and a scalable program that responds to evolving needs.

c. Quantify the expected adverse impact from the regulation.

Each dispensary will be required to comply with these new regulations to ensure the public health and safety, while mitigating security and diversion risks.

The Board does not have data to provide a quantified potential impact for the reasonable compliance costs associated with compliance with the rules, beyond the fees established in rule.

While the ultimate adverse impact for a violation of the Board's rules could be a fine, suspension, revocation, or rejection of an entity's license, the Board intends to work to assist and educate all dispensaries to avoid such repercussions.

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

The regulation of medical marijuana is new to Ohio. The dispensary rule set is designed to provide a balanced, transparent, and accountable method for individuals and entities to obtain and maintain dispensary licenses. 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. Accordingly, the MMCP establishes a unique industry that requires strict regulation for the health, safety, and protection of the public. The State has a compelling interest in promoting safe and temperate use of medical marijuana while avoiding risks associated with the diversion and theft of medical marijuana.

Regulatory Flexibility

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

There are no exemptions or alternative means of compliance specific to small businesses.

17. 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?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care or the preparation/distribution of controlled substances is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

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

The Board can be contacted via multiple sources:
The Program website: http://medicalmarijuana.gov
The Board's office is located at: 77 S. High St., 17th Floor, Columbus, OH 43215