Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

Business Impact Analysis

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

Rule Contact Name and Contact Information: Summer Corson
summer.corson@pharmacy.ohio.gov

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

FYR 2024 (Pharmacists, Interns, Drug Database)

Rule Number(s): 4729-4-01, 4729-4-02, 4729-7-01, 4729:1-3-05, 4729:2-3-01, 4729:2-3-02, 4729:8-5-01, 3796:6-3-10

Date of Submission for CSI Review: 2/13/2024

Public Comment Period End Date: 2/29/2024

Rule Type/Number of Rules:

New/ 1 rules
No Change/ 2 rules (FYR? Y)
Amended/ 4 rules (FYR? Y)
Rescinded/ 1 rules (FYR? Y)

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.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

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

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

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/Rescinds:

- 4729:8-5-01 – Lists the required information to be sent to the board after the dispensing of medical marijuana. (Rescinds current OAC 3796:6-3-10)

Amend:

- 4729:2-3-01 – Lists the professional functions that may be performed by a pharmacy intern.
- 4729:2-3-02 – Allows a pharmacy intern to fit, measure, and dispense therapeutic diabetic shoes and shoe inserts.
- 4729-4-01 – Provides definitions related to accessing confidential personal information maintained by the Board of Pharmacy.
- 4729-4-02 – Outlines regulations related to accessing confidential personal information maintained by the Board of Pharmacy.

No Change:

- 4729:1-3-05 – Allows a pharmacist to fit, measure, and dispense therapeutic diabetic shoes and shoe inserts.
- 4729-7-01 – Provides definition for current license renewal and pharmacist continuing education rule chapter.

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 sections 1347.15 and 4729.26 of the Ohio 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 implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   N/a

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)?**

   Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Section 1347.15 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules regulating access to the personal information the agency maintains.

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

   The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

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 rules in this package were distributed for public comment to all licensees and registrants of the Board.

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

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

    Stakeholders did not provide any comments on the proposed rules in this package.

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?**

    Scientific data was not used to develop or review this rule.

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?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    As the regulations are essential to protecting the public's safety by ensuring uniform standards for pharmacist and intern practice and the reporting of data to OARRS, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

    Section 1347.15 of the Ohio Revised Code requires the Board of Pharmacy to adopt rules regulating access to the personal information the agency maintains.

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

    The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation. A corresponding rule in Chapter 3796. is being rescinded to avoid duplicate regulations.

14. **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 Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, quarterly staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

- Pharmacists
- Pharmacy interns
- Medical Marijuana Dispensaries

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).
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/Rescinds:

- 4729:8-5-01 – Lists the required information to be sent to the board after the dispensing of medical marijuana. (Rescinds current OAC 3796:6-3-10). Violation of these rules may result in administrative discipline for a licensed dispensary. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license.

Amend:

4729:2-3-01 – Lists the professional functions that may be performed by a pharmacy intern. Violation of these rules may result in administrative discipline for a Board of Pharmacy licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine and/or revocation of a license.

- 4729:2-3-02 – Allows a pharmacy intern to fit, measure, and dispense therapeutic diabetic shoes and shoe inserts.
- 4729-4-01 – Provides definitions related to accessing confidential personal information maintained by the Board of Pharmacy. This is a rule that governs the Board's operation. Therefore, it will have no adverse impact on business.
- 4729-4-02 – Outlines regulations related to accessing confidential personal information maintained by the Board of Pharmacy. This is a rule that governs the Board's operation. Therefore, it will have no adverse impact on business.

No Change:

- 4729:1-3-05 – Allows a pharmacist to fit, measure, and dispense therapeutic diabetic shoes and shoe inserts. This rule is permissive and therefore should have no adverse impact on business.
- 4729-7-01 – Provides definition for current license renewal and pharmacist continuing education rule chapter. This is a definition section and therefore should have no adverse impact on business.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).*

No, as a majority of the changes in these rules are grammatical in nature.

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

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for pharmacy practice and the distribution of drugs.

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?

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 in the practice of pharmacy by pharmacists and pharmacy interns is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

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

Board of Pharmacy staff are 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 of Pharmacy rules and regulations.

Furthermore, the Board also developed external inspection guides available to all licensees to ensure compliance with our regulations.

Rule 4729-4-01 | Definitions - confidential personal information. (AMEND)

For the purposes of administrative rules promulgated in accordance with section 1347.15 of the Revised Code, the following definitions apply:

(A) "Access," as a noun, means an opportunity to copy, view, or otherwise perceive whereas "access" as a verb means to copy, view, or otherwise perceive.

(B) "Acquisition of a new computer system" means the purchase of a "computer system,"**[INSERT SPACE]**as defined in this rule, that is not a computer system currently in place nor one for which the acquisition process has been initiated as of the effective date of the board rule addressing requirements of section 1347.15 of the Revised Code.

(C) "Board" means the state of Ohio board of pharmacy.

(D) "Computer system" means a "system," as defined by section 1347.01 of the Revised Code, that stores, maintains, or retrieves personal information using electronic data processing equipment.

(E) "Confidential personal information" (CPI) has the **same** meaning as defined by division (A)(1) of section 1347.15 of the Revised Code and identified by rules promulgated by the board in accordance with division (B)(3) of section 1347.15 of the Revised Code that reference the federal or state statutes or administrative rules that make personal information maintained by the board confidential.

(F) "Employee of the board" means each employee of the board regardless of whether the employee holds an elected or appointed office or position within the board. "Employee of the board" is limited to the board of pharmacy.

(G) "Incidental contact" means contact with the information that is secondary or tangential to the primary purpose of the activity that resulted in the contact.

(H) "Individual" means natural person or the natural person's authorized representative, legal counsel, legal custodian, or legal guardian.

(I) "Information owner" means the individual appointed in accordance with division (A) of section 1347.05 of the Revised Code to be directly responsible for a system.

(J) "Person" means natural person.

(K) "Personal information" has the same meaning as defined in division (E) of section 1347.01 of the Revised Code.

(L) "Personal information system" means a "system" that "maintains" "personal information" as those terms are defined in section 1347.01 of the Revised Code.

(M) "Research" means a methodical investigation into a subject.

(N) "Routine" means **commonplace**, regular, habitual, or ordinary.

(O) "Routine information that is maintained for the purpose of internal office administration, the use of which would not adversely affect a person" as that phrase is used in division (F) of section 1347.01 of the Revised Code means personal information relating to the board's employees that is maintained by the board for administrative and human resource purposes.

(P) "System" has the same meaning as defined by division (F) of section 1347.01 of the Revised Code.

(Q) "Upgrade" means a substantial redesign of an existing system for the purpose of providing a substantial amount of new application functionality, or application modifications that would involve substantial administrative or fiscal resources to implement, but would not include maintenance, minor updates and patches, or modifications that entail a limited addition of functionality due to changes in business or legal requirements.

Rule 4729-4-02 | Confidential personal information. (AMEND)

(A) Procedures for accessing confidential personal information.

For personal information systems, whether manual or computer systems, that contain confidential personal information, the board shall do the following:

(1) Criteria for accessing confidential personal information. Personal information systems of the board are managed on a "need-to-know" basis whereby the information owner determines the level of access required for an employee of the board to fulfill the employee's job duties. The determination of access to confidential personal information shall be approved by the employee's supervisor and the information owner prior to providing the employee with access to confidential personal information within a personal information system. The board shall establish procedures for determining a revision to an employee's access to confidential personal information upon a change to that employee's job duties including, but not limited to, transfer or termination. Whenever an employee's job duties no longer require access to confidential personal information in a personal information system, the employee's access to confidential personal information shall be removed.

(2) Individual's request for a list of confidential personal information. Upon the signed written request of any individual for a list of confidential personal information about the individual maintained by the board, the board shall do the following:

(a) Verify the identity of the individual by a method that provides safeguards commensurate with the risk associated with the confidential personal information;

(b) Provide to the individual the list of confidential personal information that does not relate to an investigation about the individual or is otherwise not excluded from the scope of Chapter 1347. of the Revised Code; and

(c) If all information relates to an investigation about that individual, inform the individual that the board has no confidential personal information about the individual that is responsive to the individual's request.

(3) Notice of invalid access:

(a) Upon discovery of or notification that confidential personal information of a person has been accessed by an employee for an invalid reason, the board shall notify the person whose information was invalidly accessed as soon as practical and to the extent known at the time. However, the board shall delay notification for a period of time necessary to ensure that the notification would not delay or impede an investigation or jeopardize homeland or national security. Additionally, the board may delay the notification consistent with any measures

necessary to determine the scope of the invalid access, including which individuals' confidential personal information was invalidly accessed, and to restore the reasonable integrity of the system.

"Investigation" as used in this paragraph means the investigation of the circumstances and involvement of an employee surrounding the invalid access of the confidential personal information. Once the board determines that notification would not delay or impede an investigation, the board shall disclose the access to confidential personal information made for an invalid reason to the person.

(b) Notification provided by the board shall inform the person of the type of confidential personal information accessed and the date(s) of the invalid access.

(c) Notification may be made by any method reasonably designed to accurately inform the person of the invalid access, including written, electronic, or telephone notice.

(4) Appointment of a data privacy point of contact. The ~~**board**~~ **board's** executive director shall designate an employee of the board to serve as the data privacy point of contact. The data privacy point of contact shall work with the chief privacy officer within the office of information technology to assist the board with both the implementation of privacy protections for the confidential personal information that the board maintains **in** compliance~~s~~ with section 1347.15 of the Revised Code and the rules adopted pursuant to the authority provided by that chapter.

(5) Completion of a privacy impact assessment. The board executive director shall designate an employee of the board to serve as the data privacy point of contact who shall**, in a** timely **manner,** complete the privacy impact assessment form developed by the office of information technology.

(B) Valid reasons for accessing confidential personal information.

Pursuant to the requirements of division (B)(2) of section 1347.15 of the Revised Code, this rule contains a list of valid reasons, directly related to the board's exercise of its powers or duties, for which only authorized employees of the board or board members may access confidential personal information (CPI) regardless of whether the personal information system is a manual system or a computer system.

(1) Performing the following functions constitute valid reasons for authorized employees or members of the board to access confidential personal information:

(a) Responding to a public records request;

(b) Responding to a request from an individual for the list of CPI the board maintains on that individual;

(c) Administering a constitutional provision or duty;

(d) Administering a statutory provision or duty;

(e) Administering an administrative provision or duty;

(f) Complying with any state or federal program requirements;

(g) Processing or payment of claims or otherwise administering a program with individual participants or beneficiaries;

(h) Auditing purposes;

(i) Licensure processes;

(j) Investigation or law enforcement purposes;

(k) Administrative hearings;

(l) Litigation, complying with an order of the court, or subpoena;

(m) Human resource matters, including hiring, promotion, demotion, discharge, salary or compensation issues, processing leave requests or issues, **timecard** approvals or issues, and payroll processing;

(n) Complying with an executive order or policy;

(o) Complying with a board policy or a state administrative policy issued by the department of administrative services, the office of budget and management or other similar state agency; or

(p) Complying with a collective bargaining agreement provision.

(2) To the extent that the general processes described in paragraph (A) of this rule do not cover the following circumstances, for the purpose of carrying out specific duties of the board, authorized employees, contractors, and board members would also have valid reasons for accessing CPI in these following circumstances:

(a) Conducting a review of individuals who may be potential witnesses or other sources of information in a criminal or administrative proceeding;

(b) Administering the dangerous drug database also known as the "Ohio Automated Rx Reporting System" or "OARRS";

(c) Inspection purposes;

(d) Administering board orders; or

(e) Research performed for official duties.

(C) Confidentiality statutes, regulations, and rules.

The following federal statutes or regulations or state statutes or administrative rules make personal information maintained by the board confidential and identify the confidential personal information within the scope of rules promulgated by this board in accordance with section 1347.15 of the Revised Code:

(1) Social security numbers: 5 U.S.C. 552a (12/19/2014), unless the individual was told that the number would be disclosed.

(2) "Bureau of Criminal Identification and Investigation" criminal records check results: section 4776.04 of the Revised Code.

(3) Student education records: 20 U.S.C. 1232g (1/14/2013).

(4) Dangerous drug database information: division (C) of section 4729.79 of the Revised Code.

(5) Personal health information: 45 C.F.R. 164.502 (1/25/2013) from the federal "Health Insurance Portability and Accountability Act of 1996 (HIPAA)."

(6) Substance abuse treatment records: section 5119.27 of the Revised Code and 42 U.S.C. 290dd-2 (~~**7/20/2016**~~ **3/27/2020**).

(7) Records of dangerous drugs and controlled substances: section 3719.13 of the Revised Code.

(8) Security or infrastructure records: division (B) of section 149.433 of the Revised Code.

(9) Information or records that are **attorney-client** privileged: division (A)(1) of section 2317.02 of the Revised Code.

(10) Mediation communications or records: section 2710.03 of the Revised Code.

(11) Trial preparation records: division (A)(1)(g) of section 149.43 of the Revised Code.

(12) Court filings: Rule 45(D)(1) of the rules of superintendence for the courts of Ohio.

(13) Section 4729.23 of the Revised Code.

(D) Restricting and logging access to confidential personal information in computerized personal information systems.

For personal information systems that are computer systems and contain confidential personal information, the board shall do the following:

(1) Access restrictions. Access to confidential personal information that is kept electronically shall require a password or other authentication measure.

(2) Acquisition of a new computer system. When the board acquires a new computer system that stores, manages, or contains confidential personal information, the board shall include a mechanism for recording specific access by employees of the board to confidential personal information in the system.

(3) Upgrading existing computer systems. When the board modifies an existing computer system that stores, manages, or contains confidential personal information, the board shall make a determination whether the modification constitutes an upgrade. Any upgrades to a computer system shall include a mechanism for recording specific access by employees of the board to confidential personal information in the system.

(4) Logging requirements regarding confidential personal information in existing computer systems.

(a) The board shall require employees of the board who access confidential personal information within computer systems to maintain a log that records that access.

(b) Access to confidential information is not required to be entered into the log under the following circumstances:

(i) The employee or contractor of the board is accessing confidential personal information for official board purposes, including research, and the access is not specifically directed toward a specifically named individual or a group of specifically named individuals.

(ii) The employee of the board is accessing confidential personal information for routine office procedures and the access is not specifically directed toward a specifically named individual or a group of specifically named individuals.

(iii) The employee of the board comes into incidental contact with confidential personal information and the access of the information is not specifically directed toward a specifically named individual or a group of specifically named individuals.

(c) The employee of the board accesses confidential personal information about an individual based upon a request made under either of the following circumstances:

(i) The individual requests confidential personal information about **the individual** ~~**himself or herself**~~.

(ii) The individual makes a request that the board take some action on that individual's behalf and accessing the confidential personal information is required in order to consider or process the request.

(d) For purposes of this paragraph, the board may choose the form or forms of logging, whether in electronic or paper formats.

(5) Log management. The board shall issue a policy that specifies the following:

(a) Who shall maintain the log;

(b) What information shall be captured in the log;

(c) How the log is to be stored;

(d) How long information kept in this log is to be retained.

(6) Nothing in this rule limits the board from requiring logging in any circumstance that it deems necessary.

Rule 4729-7-01 | Severability. (NO CHANGE)

If any provision of the rules in agency 4729 of the Administrative Code or if the application of any provision of the rules in agency 4729 of the Administrative Code is held or found to be invalid, unconstitutional, void, or ineffective, the invalidity shall not affect any other provision of the rules in this agency, or the application of any other provision of the rules in this agency, that can be given effect without the invalid provision or application, and, to this end, the provisions of the rules in this agency are hereby declared severable.

Rule 4729:1-3-05 | Therapeutic diabetic shoes. (NO CHANGE)

(A) Pursuant to section 4779.02 of the Revised Code, a pharmacist may fit and measure individuals for therapeutic diabetic shoes and shoe inserts and may dispense those shoes and shoe inserts.

(B) A pharmacist shall not provide any other services that are authorized under Chapter 4779. of the Revised Code.

Rule 4729:2-3-01 | Practice as a pharmacy intern. (AMEND)

In addition to assisting a pharmacist with technical functions, a pharmacy intern may perform the following professional functions under the direct supervision of a pharmacist:

(A) The sale of schedule V controlled substances pursuant to agency 4729 of the Administrative Code.

(B) The receipt of oral prescriptions pursuant to rule 4729:5-5-10 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code.

(C) The transfer and receipt of a non-controlled prescription copy pursuant to rule 4729:5-5-11 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code.

(D) The act of patient counseling pursuant to rule 4729:5-5-09 of the Administrative Code and other applicable provisions of agency 4729 of the Administrative Code.

(E) The administration of immunizations pursuant to section 4729.41 of the Revised Code and agency 4729 of the Administrative Code.

(F) The documentation of informed consent to administer an immunization pursuant to section 4729.41 of the Revised Code.

(G) The dispensing of ~~**naloxone**~~ **overdose reversal drug** pursuant to section ~~**4729.44**~~ **3715.502** of the Revised Code and other dangerous drugs as authorized under Chapter 4729. of the Revised Code.

(H) Non-sterile compounding.

(I) Sterile compounding.

(J) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner.

(K) Contacting a prescriber or prescriber's agent to obtain clarification for a prescription order if the clarification does not require the exercise of professional judgment.

(L) Performing diagnostic laboratory testing pursuant to agency 4729 of the Administrative Code.

(M) Requesting refill authorizations for dangerous drugs from a prescriber or the prescriber's agent.

(N) Notwithstanding the definition of direct supervision, a pharmacy intern may stock an automated drug dispensing unit and floor stock at a location licensed as a terminal distributor of dangerous drugs if a pharmacist is not physically present at the licensed location and all of the following apply:

(1) A pharmacist is readily available to answer questions of the intern;

(2) A pharmacist is responsible for conducting routine verifications of the activities of the intern to prevent the diversion of dangerous drugs;

(3) A pharmacist is fully responsible for all activities conducted by the intern at the licensed location.

Rule 4729:2-3-02 | Therapeutic diabetic shoes. (AMEND)

(A) Pursuant to section 4779.02 of the Revised Code, a pharmacy intern, acting under the direct supervision of a pharmacist, may fit and measure individuals for therapeutic diabetic shoes and shoe inserts and may dispense those shoes and shoe inserts.

(B) A pharmacy intern, acting under the direct supervision of a pharmacist, shall not provide any other services that are authorized under Chapter 4779. of the Revised Code.

Rule 4729:8-5-01 | Dispensary reporting into the prescription monitoring program. (NEW) (RESCIND 3796:6-3-10)

(A) **Pursuant to section 4729.771 of the Revised Code, a** dispensary**, licensed in accordance with Chapter 3796. of the Revised Code,** shall transmit electronically to the state board of pharmacy, in a format suitable to the board, the information set forth below within five minutes of the dispensing of any and all medical marijuana:

(1) State license number, which shall be populated by a number provided by the **Department of Commerce**;

(2) Dispensary name;

(3) Dispensary address;

(4) Dispensary telephone number;

(5) Patient full name;

(6) Patient registry identification number;

(7) Patient residential address;

(8) Patient telephone number;

(9) Patient date of birth;

(10) Patient gender;

(11) Recommending physicians full name (first name and last name);

(12) Drug enforcement administration physician identification number;

(13) Date recommendation was issued by the recommending physician;

(14) Indication whether the recommendation is new or a refill;

(15) Number of the refill being dispensed;

(16) Date order filled, which shall be the date medical marijuana is dispensed;

(17) Order number, which shall be the serial number assigned to each medical marijuana product dispensed to a patient;

(18) Quantity;

(19) Days supply;

(20) Product identifier, which shall be assigned by the **Department of Commerce**;

(21) Date order written, which shall be the date the written recommendation was issued;

(22) Payment code for either cash or third-party provider; and

(23) Drug name, which shall be the brand name of the medical marijuana.

(B) If a dispensary has no drug dispensing information required to be submitted to the board of pharmacy over any twenty-four-hour period, it must submit a "zero report."

(C) The dispensing report or the "zero report" shall be consecutive and inclusive from the last date and time that information was submitted and shall be reported no later than thirty-six hours after the last time reported on a previous report.

(D) Any dispensary whose normal business hours are not seven days per week shall electronically indicate its normal business hours to the board and a "zero report" will be automatically submitted on the dispensary's behalf on non-business days.

(E) If a dispensary ceases to possess medical marijuana for dispensing, the designated representative shall notify the board of pharmacy electronically or in writing. The board shall be notified if the dispensary resumes dispensing.

(F) All dispensing information required to be submitted to the board of pharmacy pursuant to paragraph (A) of this rule, must be transmitted in the format specified by the American society for automation in pharmacy ("ASAP"), for prescription monitoring systems.

(G) If a dispensary cannot electronically transmit the required information pursuant to paragraph (A) of this rule, they must immediately contact the board of pharmacy to determine a mutually acceptable method of reporting. The dispensary must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

(H) A dispensary shall transmit the information required pursuant to this section in such a manner as to ensure the confidentiality of the information in compliance with all federal and state laws, including the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

(I) All medical marijuana dispensing information submitted to the drug database pursuant to this rule must be reported in an accurate and timely manner.

(J) If the omission of dispensing information is discovered, the corrected information must be submitted to the board of pharmacy during the next reporting period after the discovery.

(K) If the omission of data or erroneous data is the result of a computer programming error, the dispensary must notify the board of pharmacy immediately by telephone and submit written documentation. The documentation shall fully describe the error and propose a date for submitting the corrected dispensing information. The board will review the written documentation to ensure compliance with paragraph (A) of this rule.

(L) Except as noted in paragraph (E) of this rule, all data must be submitted or corrected electronically unless prior permission for an alternate method is approved by the board of pharmacy.