10/2/18

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 Ohio State 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.

Rescinds

- **Chapter 4729-37** – Drug Database – Ohio Automated Rx Reporting System (OARRS)

New

- **4729:8-1-01** – Provides the definition for the division governing the Ohio Automated Rx Reporting System (OARRS).
- **4729:8-2-01** – Provides the list of controlled substance drugs to be reported to OARRS.
- **4729:8-2-02** – Provides additional non-controlled drugs of abuse to be reported to OARRS.
- **4729:8-3-01 –** Lists the entities that are required to submit the sales of dangerous drugs to OARRS.
- **4729:8-3-02 –** Provides the specific information on drug sales that must be reported to OARRS.
- **4729:8-3-03 –** Specifies the electronic format for the transmission of drug sales.
- **4729:8-3-04 –** Provides the frequency of when sales data must be transmitted to OARRS.
- **4729:8-3-05** – Provides the process for correcting data errors in OARRS.
- **4729:8-4-01** – Specifies the OARRS data provided to a hospital peer review committee and how an individual obtains their own OARRS report.
- **4729**:**8-4-02** – Specifies the procedures for retaining information in OARRS for open investigations conducted by law enforcement.

Comments on the proposed rules will be accepted until close of business on October 16, 2016. Please send all comments to the following email address:
Ali.Simon@pharmacy.ohio.gov

In addition, please copy your comments to:
CSIPublicComments@governor.ohio.gov

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Drug Database - OARRS

Rule Number(s): 4729:8-1-01, 4729:8-2-01, 4729:8-2-02, 4729:8-3-01, 4729:8-3-02, 4729:8-3-03, 4729:8-3-04, 4729:8-3-05, 4729:8-4-01, 4729:8-4-02 (Rescind Chapter 4729-37)

Date: 10/2/2018

Rule Type:

New	5-Year Review
Amended	**Rescinded**

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.

Rescinds

- **Chapter 4729-37** – Drug Database – Ohio Automated Rx Reporting System (OARRS)

New

- **4729:8-1-01** – Provides the definition for the division governing the Ohio Automated Rx Reporting System (OARRS).
- **4729:8-2-01** – Provides the list of controlled substance drugs to be reported to OARRS.
- **4729:8-2-02** – Provides additional non-controlled drugs of abuse to be reported to OARRS.
- **4729:8-3-01 –** Lists the entities that are required to submit the sales of dangerous drugs to OARRS.
- **4729:8-3-02 –** Provides the specific information on drug sales that must be reported to OARRS.

- **4729:8-3-03 –** Specifies the electronic format for the transmission of drug sales.
- **4729:8-3-04 –** Provides the frequency of when sales data must be transmitted to OARRS.
- **4729:8-3-05** – Provides the process for correcting data errors in OARRS.
- **4729:8-4-01** – Specifies the OARRS data provided to a hospital peer review committee and how an individual obtains their own OARRS report.
- **4729**:**8-4-02 –** Specifies the procedures for retaining information in OARRS for open investigations conducted by law enforcement.

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

The proposed rules are authorized by sections 4729.26, 3719.28, 4729.80 and 4729.84 of the Ohio Revised Code. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.75, 4729.76, 4729.77, 4729.78, 4729.79, 4729.81, 4729.82 and 4729.83.

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?

The rule does not implement a federal requirement.

4. 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 operation of prescription drug monitoring programs (i.e. OARRS) have traditionally been done at the state level by legislatively created state boards of pharmacy, such as the State of Ohio Board of Pharmacy. The State of Ohio Board of Pharmacy regulates all aspects of pharmacy practice and distribution of drugs in Ohio, including the operation of OARRS.

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)?

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

Section 3719.28 of the Ohio Revised Code authorizes the state board of pharmacy to adopt rules prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

Section 4729.84 of the Ohio Revised Code authorizes the state board of pharmacy, for the purposes of establishing and maintaining a drug database (i.e. OARRS) pursuant to section 4729.75 of the Revised Code, to adopt rules in to carry out and enforce sections 4729.75 to 4729.83 of the Revised Code.

The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in the above referenced chapters of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Set uniform reporting requirements for the Ohio Automated Rx Reporting System; and
- Collect data on a non-controlled drug (gabapentin) that is subject to abuse and diversion.

6. 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 and prescribers regarding the provisions of the rules.

Development of the Regulation

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

The initial draft rules were posted to the Board's website and distributed to the Board's stakeholder list that includes representatives of retail pharmacies, hospital pharmacies, prescribers, wholesalers and manufacturers.

All rules are subject to final approval by the state board of pharmacy prior to filing with the Joint Committee on Agency Rule Review.

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

The Board received the input from the following stakeholders:

- OhioHealth – Allow hospitals to report wholesale sales data to OARRS using an alternative method. The rules already include an option for the reporting of wholesales sales data using an alternative format that is mutually agreed upon.
- Pfizer – Remove the requirement to report the purchaser's terminal distributor number as part of the wholesaler sales data. This requirement was removed from the draft rules.

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?

Scientific data was not used to develop the rule.

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?**

As the regulations are essential to protecting the public's health and safety by ensuring uniform collection of data on controlled substances and other drugs of abuse, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. **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.***

The Board did not consider a performance-based regulation for the rules in this package. It is the Board's responsibility to ensure that regulations are consistent throughout the state. It was the determination of the Board that the rule package did not lend itself to performance-based regulations.

12. **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.

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

Pharmacy Board 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, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director for every citation submitted.

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;**

    The rule package impacts the following:

- Pharmacies licensed as Terminal Distributors of Dangerous Drugs.
- Wholesale Distributors of Dangerous Drugs and Manufacturers of Dangerous Drugs that sell controlled substances and other drugs of abuse in or into Ohio.
- Prescribers who personally furnish (i.e. dispense) controlled substances and other drugs of abuse from their offices.
- Individuals seeking a copy of their own OARRS report.
- Law enforcement.

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

Violation of these rules may result in administrative licensure discipline of a terminal distributor of dangerous drugs or a wholesaler distributor/manufacturer of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

- **4729:8-1-01** – Provides the definition for the division governing the Ohio Automated Rx Reporting System (OARRS). This should have no adverse impact as it is a definition section.

- **4729:8-2-01** – Provides the list of controlled substance drugs to be reported to OARRS. Current rules require to submission of all Schedule II – V controlled substances. The new rule does not change this requirement.

- **4729:8-2-02** – Provides additional non-controlled drugs of abuse to be reported to OARRS. Current rules require the submission of data on the sale of gabapentin. The new rule does not change this reporting requirement.

- **4729:8-3-01 –** Lists the entities that are required to submit the sales of dangerous drugs to OARRS. The overall cost of the rule includes administrative and technological costs incurred by the listed entities to submit the data to OARRS. Except for prescribers, this process has been automated by most pharmacies, manufacturers and wholesalers.

- **4729:8-3-02 –** Provides the specific information on drug sales that must be reported to OARRS. The cost of the rule is administrative and technological costs incurred by the entities to submit the data to OARRS. This only impacts a small proportion of prescribers who personally furnish reportable drugs. Pharmacies and wholesalers/manufacturers have developed an automated process to provide the required data to OARRS.

- **4729:8-3-03 –** Specifies the electronic format for the transmission of drug sales. All entities currently submitting data have adopted the electronic format specified in the rules. The rule also allows for alternative methods of submitting data.

- **4729:8-3-04 –** Provides the frequency of when sales data must be transmitted to OARRS. Requires a reporting prescriber or pharmacy to submit their business hours electronically. It also requires notification if a prescriber or pharmacy no longer submits data to OARRS. The notification requirements listed in the rule will result in administrative costs to pharmacies and prescribers that dispense controlled substances and gabapentin. This burden is lessened in that there is online form that can be submitted from the OARRS interface. Submission of the form takes approximately 5 minutes.

- **4729:8-3-05** – Provides the process for correcting data errors in OARRS. The adverse impact of this rule is the time it takes an entity to correct an error. This will depend on the number and extent of the data errors.

- **4729:8-4-01** – Specifies the OARRS data provided to a hospital peer review committee and how an individual obtains their own OARRS report. The adverse impact to an individual seeking their own report is the cost associated with coming to the Board office to request a copy of their report.

- **4729:8-4-02** – Specifies the procedures for retaining information in OARRS for open investigations conducted by law enforcement. The adverse impact on law enforcement is the submission of a request to maintain data in the system. This form takes approximately 15 minutes to complete and submit.

15. 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 the information required to be reported to the Ohio Automated Rx Reporting System (OARRS).

OARRS is an important tool to track the dispensing and personal furnishing of drugs of abuse to patients. OARRS is designed to monitor this information for suspected abuse or diversion (i.e., channeling drugs into illegal use), and can give a prescriber or pharmacist critical information regarding a patient's controlled substance prescription history. This information can help prescribers and pharmacists identify high-risk patients who would benefit from early interventions.

Regulatory Flexibility

16. 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.

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 in the practice of pharmacy 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?

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. Additionally, field staff (i.e. compliance staff) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Rescind Chapter 4729-37
Drug Database – Ohio Automated Rx Reporting System

PLEASE NOTE: The proposed rules will be placed into a newly created division 4729:8 of the Ohio Administrative Code and will result in the rescission of Chapter 4729-37 of the Ohio Administrative Code. As a result of this move, the Board made every effort to highlight any major changes to the new rules. Stakeholders are still advised to review the rule package in its entirety.

4729:8-1-01 Drug Database – Ohio Automated Rx Reporting System - Definitions.

As used in Division 4729:8 of the Administrative Code:

(A) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(B) "Distributor of Dangerous Drugs" or "Drug Distributor" means the following persons licensed in accordance with section 4729.52 of the Revised Code:

(1) Wholesale distributors of dangerous drugs, including:

(a) Virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Repackagers of dangerous drugs.

(C) "Outpatient" means any person who receives drugs for use outside of the institutional facility as defined in agency 4729 of the Administrative Code.

(D) "Peer review committee" has the same meaning as in section 2305.25 of the Revised Code, except that it includes only a peer review committee of a hospital or a peer review committee of a nonprofit health care corporation that is a member of the hospital or of which the hospital is a member.

(E) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

(F) "Pharmacy" has the same meaning as in section 4729.01 of the Revised Code.

(G) "Prescriber" or "licensed health professional authorized to prescribe drugs" have the same meaning as in section 4729.01 of the Revised Code.

(H) "Terminal distributor of dangerous drugs" has the same meaning as in section 4729.01 of the Revised Code.

(I) "Sale" and "sell" have the same meaning as in section 4729.01 of the Revised Code.

(J) "Wholesale sale" and "sale at wholesale" have the same meaning as in section 4729.01 of the Revised Code. Wholesale sale also includes the following:

(1) An occasional sale conducted in accordance with section 4729.51 of the Revised Code;

(2) The sale of a sample or complimentary supply to a terminal distributor of dangerous drugs;

(3) The sale of non-patient specific dangerous drugs for administration by a prescriber.

(K) “Zero report” means a report documenting that none of the drugs listed in Chapter 4729:8-2 of the Administrative code were dispensed or personally furnished during the required reporting period.

4729:8-2-01 List of drugs to be reported.

Pursuant to section 4729.75 of the Revised Code, the required information for the following list of drugs pursuant to an outpatient prescription, personally furnished by a prescriber, or sold at wholesale to a terminal distributor of dangerous drugs shall be submitted to the board of pharmacy pursuant to sections 4729.77, 4729.78 and 4729.79 of the Revised Code and this division of the Administrative Code:

(A) All schedule II controlled substances;

(B) All schedule III controlled substances;

(C) All schedule IV controlled substances;

(D) All schedule V controlled substances.

4729:8-2-02 Additional drugs to be reported.

Pursuant to section 4729.75 of the Revised Code, the required information for the following list of drugs pursuant to an outpatient prescription, personally furnished by a prescriber, or sold at wholesale to a terminal distributor of dangerous drugs shall be submitted to the state board of pharmacy in accordance with sections 4729.77,4729.78 and 4729.79 of the Revised Code and this division of the Administrative Code:

All dangerous drug products containing gabapentin.

4729:8-3-01 Entities required to submit information.

The following entities are required to submit the specified dispensing, personal furnishing, or wholesale sale information in accordance with this chapter of the Administrative Code to the board of pharmacy for the drug database:

(A) All ~~pharmacies~~ entities located within this state and licensed as a terminal distributor of dangerous drugs shall report all drugs listed in chapter 4729:8-2 of the Administrative Code that are dispensed to outpatients ~~residing in this state~~.

(B) All ~~pharmacies~~ entities located outside this state and licensed as a terminal distributor of dangerous drugs shall report all drugs listed in chapter 4729:8-2 of the Administrative Code that are dispensed to outpatients residing in this state.

(C) All licensed drug distributors and terminal distributors of dangerous drugs located within this state that sell at wholesale drugs listed in chapter 4729:8-2 of the Administrative Code to prescribers or terminal distributors of dangerous drugs shall report those drug transactions in accordance with the wholesale reporting requirements of this chapter.

(D~~C~~) All licensed drug distributors and terminal distributors of dangerous drugs located outside this state that sell at wholesale drugs listed in chapter 4729:8-2 of the Administrative Code to prescribers or terminal distributors of dangerous drugs located within this state ~~in this state listed in chapter 4729:8-2 of the Administrative Code~~ shall report those drug transactions in accordance with the wholesale reporting requirements of this chapter.

(E~~D~~) All prescribers, except veterinarians, located within this state shall report all drugs identified in chapter 4729:8-2 of the Administrative Code that are personally furnished to patients.

4729:8-3-02 Information required for submission.

(A) ~~Pharmacies~~ Terminal distributors pursuant to paragraphs (A) and (B) of rule 4729:8-3-01 of the Administrative Code that dispense drugs listed in chapter 4729:8-2 of the Administrative Code to outpatients ~~residing in this state~~ shall report the following dispensing information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Pharmacy drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Pharmacy name;

(3) Pharmacy address;

(4) Pharmacy telephone number;

(5) Patient full name;

(6) Patient residential address;

(7) Patient telephone number;

(8) Patient date of birth;

(9) Patient gender;

(10) Prescriber's full name (first name and last name)

(11) Prescriber's drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(12) Date prescription was issued by the prescriber;

(13) Date the prescription was dispensed or sold by the pharmacy;

(14) Indication of whether the prescription dispensed is new or a refill;

(15) Number of the refill being dispensed;

(16) National drug code of the actual drug dispensed;

(17) Quantity of the drug prescribed;

(18) Quantity of drug dispensed;

(19) Number of days' supply of drug dispensed as indicated by the prescriber pursuant to agency 4729 of the Administrative Code, except as follows:

(a) If a days' supply is not indicated by the prescriber, the pharmacy shall calculate and report the number of days' supply of drug dispensed;

(b) If the quantity of drug dispensed is different from the quantity indicated on the prescription, the pharmacy shall calculate and report the number of days' supply of drug dispensed.

(20) Serial or prescription number assigned to the prescription order;

(20) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation;

(21) Pharmacy national provider identification (NPI) number;

(22) Prescriber's national provider identification (NPI) number, if prescriber does not have an NPI, then another mutually acceptable identifier;

(23) Any of the following as indicated by the prescriber pursuant to agency 4729. of the Administrative Code:

(a) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance drug is being used to treat. The code shall, at a minimum, include the first four alpha-numeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5);

(b) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the Code on Dental Procedures and Nomenclature (CDT Code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription;

(c) If no such code is indicated on the prescription, the pharmacy shall indicate "NC" in the diagnosis data field.

(B) Prescribers pursuant to paragraph (E) of rule 4729:8-3-01 of the Administrative Code that personally furnish drugs listed in Chapter 4729:8-2 of the Administrative Code shall report the following information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Prescriber drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Prescriber full name (first and last name);

(3) Prescriber address;

(4) Prescriber telephone number;

(5) Patient full name;

(6) Patient residential address;

(7) Patient telephone number;

(8) Patient date of birth;

(9) Patient gender;

(10) Date the drug was personally furnished by the prescriber;

(11) National drug code of the actual drug personally furnished;

(12) Quantity of drug personally furnished;

(13) Number of intended days' supply of drug personally furnished; ~~and~~

(14) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation.

(15) Either of the following:

(a) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance drug is being used to treat. The code shall, at a minimum, include the first four alpha numeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5);

(b) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the Code on Dental Procedures and Nomenclature (CDT Code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription.

(C) Drug distributors and ~~pharmacies~~ terminal distributors pursuant to paragraphs (C) of rule 4729:8-3-01 of the Administrative Code that sell at wholesale drugs listed in chapter 4729:8-2 of the Administrative Code shall report the following information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Distributor or ~~pharmacy~~ terminal distributor drug enforcement administration registration number. If not applicable, then another mutually acceptable identifier;

(2) Purchaser's drug enforcement administration registration number. If not applicable, then another mutually acceptable identifier;

(3) National drug code number of the actual drug sold;

(4) Quantity of the drug sold;

(5) Date of sale; and

(6) Transaction identifier or invoice number.

4729:8-3-03 Electronic format required for the transmission of drug sales.

(A) All ~~pharmacy~~ prescription dispensing information or prescriber personally furnishing information required to be submitted to the board of pharmacy pursuant to rule 4729-8-3-02 of the Administrative Code must be transmitted in the following format specified by the "American Society for Automation in Pharmacy" (ASAP) for prescription monitoring programs:

ASAP Version 4.2 A Standard for Prescription Drug Monitoring Programs (3/15/2017).

(B) In the event that a pharmacy or a prescriber cannot electronically transmit the required information pursuant to paragraph (A) of this rule, the pharmacy or prescriber may request a variance from the board’s executive director or the director’s designee to submit drug sales information in a mutually acceptable format.

(C) All wholesale data required to be submitted to the board of pharmacy pursuant to rule 4729-8-3-02 of the Administrative Code must be transmitted in the report format used when transmitting controlled substance data to the federal drug enforcement administration via the "Automation of Reports and Consolidated Orders System (ARCOS)" or other mutually acceptable format.

(D) In the event that a drug distributor or pharmacy cannot electronically transmit the required information pursuant to paragraph (C) of this rule, the drug distributor or pharmacy may request a variance from the board’s executive director or the director’s designee to submit drug sales information in a mutually acceptable format.

4729:8-3-04 Frequency requirements for submitting drug database information.

(A) A ~~pharmacy~~ terminal distributor or prescriber that has been in possession of a drug listed in Chapter 4729:8-2 of the Administrative Code for dispensing or personally furnishing within the previous ~~two~~ three years shall submit to the board of pharmacy, at least daily, either of the following:

(1) All information required to be submitted to the board of ~~pharmacy~~ terminal distributor pursuant to this division of the Administrative Code.

(2) A zero report, if a ~~pharmacy~~ terminal distributor has no drug dispensing information or a prescriber has no personally furnishing information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code.

(B) The information required to be reported pursuant to paragraph (A) of this rule shall be consecutive and inclusive from the last date and time the information was submitted to the board of pharmacy and shall be reported no later than thirty-six hours after the last time reported.

(C) Any record of a dispensed or personally furnished drug listed in Chapter 4729:8-2 of the Administrative Code shall be reported to the board of pharmacy within twenty-four hours of being dispensed or personally furnished.

(D) Any ~~pharmacy~~ terminal distributor or prescriber whose normal business hours are not seven days per week shall electronically indicate their normal business hours to the board and no zero report will be required for the terminal distributor's non-business days. ~~and a zero report will be automatically submitted on their behalf on non-business days.~~

(E) If a ~~pharmacy~~ terminal distributor or prescriber ceases to dispense or personally furnish ~~possess~~ a drug listed in Chapter 4729:8-2 of the Administrative Code ~~for dispensing or personally furnishing~~ , the responsible person on the terminal distributor of dangerous drugs license or the prescriber shall notify the board of pharmacy ~~electronically or~~ in writing and request an exemption to reporting. ~~a permanent zero report.~~

(1) If at any time a ~~pharmacy~~ terminal distributor or prescriber begins dispensing or personally furnishing drugs listed in Chapter 4729:8-2 of the Administrative Code, the exemption to reporting ~~permanent zero report~~ shall no longer be valid and the ~~pharmacy~~ terminal distributor or prescriber shall start reporting in accordance with this rule.

(F) All wholesale sale information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code must be submitted at least monthly. ~~as follows:~~ The information shall be consecutive and inclusive from the last date and time the information was submitted and shall be reported no later than forty-five days after the date of the wholesale sale.

~~(1) During the first through the fifteenth day of each month; and~~

~~(2) The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than forty-five days after the date of the wholesale sale.~~

(G) If a drug distributor, prescriber, or ~~pharmacy~~ terminal distributor cannot submit the required information at the required intervals specified in this rule, the drug distributor, ~~pharmacy~~ terminal distributor or prescriber may request an extension from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable timeframe.

4729:8-3-05 Corrections to the drug database.

(A) All information required to be submitted in accordance with this division shall be submitted to the drug database in an accurate and timely manner.

(B) If the omission of drug sale information is discovered, the omitted information shall be submitted to the board of pharmacy by the ~~pharmacy~~terminal distributor, prescriber, or drug distributor during the next reporting time period after the discovery.

(C) If erroneous drug sale information is discovered, the terminal distributor or drug distributor or the prescriber shall notify the board of pharmacy within twenty-four hours of the discovery. ~~t~~The corrected information must be submitted to the board of pharmacy by the ~~pharmacy~~terminal distributor, prescriber or drug distributor ~~distributor during the next reporting time period after the discovery.~~within seven days of the discovery.

(D) If the omission of data or erroneous data is the result of a computer programming error, the ~~pharmacy~~terminal distributor, prescriber, or drug distributor must notify the board of pharmacy immediately by telephone and submit written or electronic documentation. The documentation shall fully describe the error and propose a mutually agreed upon date for submitting the corrected ~~drug sales~~ information.

(E) Except as noted in paragraph (D) of this rule, all data must be submitted or corrected electronically unless prior permission for an alternate method is granted by the board's executive director or the director's designee.

4729:8-4-01 Procedures for obtaining drug database information and access by peer review committees.

(A) Persons that are permitted pursuant to section 4729.80 of the Revised Code to obtain information from the drug database shall comply with all application procedures, requirements and acceptable use policies adopted by the board.

(B) An individual seeking the individual's own database information shall comply with the following:

(1) Complete a notarized request form giving such information as required by the board of pharmacy;

(2) Submit the completed form in person or by mail;

(3) Receive the information in person at the board of pharmacy office during normal business hours and show proof of identity with a current government issued form of identification that contains a picture such as a current state issued identification card, a current state issued driver's license, or a valid passport; and

(4) The person may be required to pay the cost of printing the document as determined by the board of pharmacy's current per page rate.

(C) Pursuant to section 4729.80 of the Revised Code, the Board shall provide the following information to a designated representative of a peer review committee relating to a prescriber who is subject to the committee's evaluation, supervision, or discipline:

(1) A summary of the prescriber's prescribing record, if such a record is created by the board.

(2) Information from the database, in a format determined by the board, relating to a current or previous patient of the prescriber who is subject to the committee's evaluation, supervision, or discipline.

4729:4-4-02 Extension to the information storage requirements and the provision of database statistics.

(A) A government entity or a law enforcement agency pursuant to section 4729.82 of the Revised Code may request that specific information in the database related to an open investigation be retained beyond the five-year information retention requirement. The government entity or law enforcement agency must submit a written request on a form giving such information as required by the board of pharmacy.

(B) The board of pharmacy may provide or present database statistics and law enforcement outcomes based on request information pursuant to section 4729.79 of the Revised Code. The information shall not identify a person and will be provided as determined by the board of pharmacy in summary, statistical, or aggregate form.