Common Sense Initiative

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

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NOTE: This Business Impact Analysis is being re-issued to incorporate a change to proposed OAC 4729:8-3-03, which extends the deadline to move to ASAP 5.0 from May 1, 2025 to December 1, 2025. The comment period has been extended to December 13, 2024.

UPDATE 12/10/24: On December 9, 2024, the Board voted to withdraw rule 4729:8-3-02.1 (Supplemental information required for submission) from CSI review. References to the rule have been removed from this document.

Comments on the proposed rules will be accepted until close of business on December 13, 2024. Please send all comments to the following email address:
RuleComments@pharmacy.ohio.gov

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

Business Impact Analysis

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

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Regulation/Package Title (a general description of the rules' substantive content):
Ohio Automated Rx Reporting System (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, 4729:8-4-03.

Date of Submission for CSI Review: 11/4/2024 (reissued 11/15/2024 & 12/10/2024)

Public Comment Period End Date: 12/13/2024

Rule Type/Number of Rules:

New/_2_ rules

No Change/_3_ rules (FYR? __Y_)

Amended/_7_ 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Rescinded/_1_ rules (FYR?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.

4729:8-1-01 - Ohio Automated Rx Reporting System – Definitions: Provides the definition section for the division of the OAC. Adds references to central fill and originating pharmacy. Also adds references to dispensaries for the purposes of medical marijuana reporting.

4729:8-2-01 - List of drugs to be reported: Provides a listing of the controlled substances required to be reported to OARRS. No changes are being proposed to this rule.

4729:8-2-02 - Additional drugs to be reported: Provides a listing of the additional drugs that are not controlled substances that are required to be reported to OARRS. No changes are being proposed to this rule.

4729:8-3-01 - Entities required to submit information: Lists the entities required to submit data to OARRS. Adds references to medical marijuana dispensaries and exempts OTPs from having to report patient data as this data is reported via the state's central registry.

4729:8-3-02 - Information required for submission: Provides the data that are required to be submitted to the Board for outpatient prescriptions that meet the requirements of the rules. The rule is being amended to add additional data fields that are part of the ASAP 5.0 data standard to improve data quality.

4729:8-3-03 - Electronic format required for the transmission of drug sales: Rescinds current rule and replaces with new rule requiring all reporting be conducted in accordance with the ASAP 5.0 data standard by December 1, 2025. Permits the Board's Executive Director to grant extensions to the requirements of this rule.

4729:8-3-04 - Frequency requirements for submitting drug database information: Includes the requirements for the frequency of reporting patient information to OARRS. Makes minor grammatical updates to the rule.

4729:8-3-05 - Corrections to the drug database: Specifies the process for making corrections to data reported to OARRS. Adds specific requirements for making corrections if a pharmacy utilizes a central fill pharmacy to dispense prescriptions.

4729:8-4-01 - Procedures for obtaining drug database information and access by peer review committees: Establishes standards for hospital peer review committees to access OARRS. Also, sets requirements to obtain one's own OARRS report. Makes a minor grammatical update.

4729:8-4-02 - Extension to the information storage requirements and the provision of database statistics: Establishes the process for OARRS data retention and the provision of statistics from the system. This is a no change rule.

4729:8-4-03 - Access to opioid treatment program data provided by the Ohio department of mental health and addiction services: Specifies who can access data provided by the Ohio Department of Mental Health and Addiction Services that is reported to OARRS. Updates the language to reflect statutory changes in ORC 4729.80 and makes one minor grammatical update.

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 4729.26, 3719.28 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, 4729.80, 4729.81, 4729.82 and 4729.83.

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.
   N/A.

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 these proposed regulations do not implement a federal requirement.

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 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 4729.83 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 that is subject to abuse and diversion.

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 and prescribers 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.

   N/A.

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.

   Prior to filing with CSI, these rules were distributed for public comment and were also reviewed and approved by the Ohio 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?**

The Board received concerns regarding requirements to report specific data regarding secondary payment sources. That provision was removed from the rule.

Additionally, the Board simplified the process for reporting the animal species code to be either large animal or small animal as commenters were concerned about not knowing the specific species of animal.

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 were not used to develop or review the rules.

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 health and safety by ensuring uniform collection of data on drugs that may be the subject of abuse, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

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 other Ohio Board of Pharmacy 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 website, 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 staff 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 internal newsletters, 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

The rule package impacts the following:

- Pharmacies licensed as Terminal Distributors of Dangerous Drugs that dispense OARRS reportable drugs to patients in this state.
- Distributors of Dangerous Drugs that ship OARRS reportable drugs into or within Ohio.
- Prescribers who personally furnish (i.e. dispense) controlled substances from their offices.
- Ohio 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.

4729:8-1-01 - Ohio Automated Rx Reporting System – Definitions: Provides the definition section for the division of the OAC. Adds references to central fill and originating pharmacy. Also adds references to dispensaries for the purposes of medical marijuana reporting. This is a definition section and should not result in any adverse impacts.

4729:8-2-01 - List of drugs to be reported: Provides a listing of the controlled substances required to be reported to OARRS. No changes are being proposed to this rule. This rule does not have any adverse impact because the Ohio Revised Code already requires the reporting of these drugs to OARRS.

4729:8-2-02 - Additional drugs to be reported: Provides a listing of the additional drugs that are not controlled substances that are required to be reported to OARRS. No changes are being proposed to this rule. This rule does require the reporting of a drug not listed in the Ohio Revised Code, gabapentin, as a drug of concern. This has been a requirement since 2016 and therefore should not add any additional administrative costs to existing licensees who are reporting.

4729:8-3-01 - Entities required to submit information: Lists the entities required to submit data to OARRS. Adds references to medical marijuana dispensaries (who are already required to report under ORC 4729.771) and exempts OTPs from having to

report patient data as this data is reported via the state's central registry. This rule should not have an adverse impact because the entities listed are required to report under existing law.

4729:8-3-02 - Information required for submission: Provides the data that are required to be submitted to the Board for outpatient prescriptions that meet the requirements of the rules. The rule is being amended to add additional data fields that are part of the ASAP 5.0 data standard to improve data quality. This rule will result in an increase in administrative costs for all pharmacies and prescriber clinics who are required to report to OARRS. Pharmacies will experience IT enhancement costs and administrative costs to ensure they capture this data. Prescribers will also experience these costs, however, only 27 prescribers reported to OARRS in 2021 so the impact should be limited.

4729:8-3-03 - Electronic format required for the transmission of drug sales: Rescinds current rule and replaces with new rule requiring all reporting be conducted in accordance with the ASAP 5.0 data standard by December 1, 2025. Permits the Board's Executive Director to grant extensions to the requirements of this rule. While pharmacies will experience increased IT develop costs to adopt this updated data standard, some states have already adopted it as a requirement. For example, Nebraska requires the use of the ASAP 5.0 data standard effective 9.1.2024.

4729:8-3-04 - Frequency requirements for submitting drug database information: Includes the requirements for the frequency of reporting patient information to OARRS. Makes minor grammatical updates to the rule. These frequency with which data must be submitted has not changed since 2015. Additionally, the time it takes to file an exception to the reporting requirements is between 10-15 minutes.

4729:8-3-05 - Corrections to the drug database: Specifies the process for making corrections to data reported to OARRS. Adds specific requirements for making corrections if a pharmacy utilizes a central fill pharmacy to dispense prescriptions. Adds administrative costs to the reporting pharmacy to develop a process to submit corrections if utilizing a central fill pharmacy.

4729:8-4-01 - Procedures for obtaining drug database information and access by peer review committees: Establishes standards for hospital peer review committees to access OARRS. Also sets process for requesting one's own OARRS report. Makes a minor grammatical update. The cost of obtaining a person's OARRS report is free, however, they will experience certain costs to obtain their report (notary, coming in-person to obtain the report, showing identification, etc.).

4729:8-4-02 - Extension to the information storage requirements and the provision of database statistics: Establishes the process for OARRS data retention and the provision of statistics from the system. This is a no change rule. Requires submission of a form by law enforcement. Completion of this form takes between 10-15 minutes.

4729:8-4-03 - Access to opioid treatment program data provided by the Ohio department of mental health and addiction services: Specifies who can access data provided by the Ohio Department of Mental Health and Addiction Services that is reported to OARRS. Updates the language to reflect statutory changes in ORC 4729.80 and makes one minor grammatical update. As this rule specifies who can access certain data, it should not have an 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).***

    Yes. The Board exempts opioid treatment programs (OTPs) from having to report to OARRS, as they already report this data to the system via a central registry managed by the Ohio Department of Mental Health and Addiction Services.

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 regulation protects and promotes public safety by ensuring uniform reporting of controlled substance and other drugs of concern to the Ohio Automated Rx Reporting System.

Regulatory Flexibility

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

    Yes. In the event that a drug distributor or terminal distributor cannot electronically transmit the required information, the drug distributor or terminal distributor 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.

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 Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure to report controlled substances or other drugs of concern to OARRS 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.

Rule 4729:8-1-01 | Ohio Automated Rx Reporting System - Definitions. (AMEND)

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) "Central fill pharmacy" has the same meaning as in rule 4729:5-5-19 of the Administrative Code.

(~~B~~ **C**) "Distributor of dangerous drugs" or "drug distributor" means the following persons licensed in accordance with section 4729.52 of the Revised Code and division 4729:6 of the Administrative Code:

(1) Wholesale distributors of dangerous drugs, including virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(D) "Designated representative" means the dispensary key employee responsible for acting in compliance with agency 3796 of the Administrative Code.

(E) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(F) "Dispensary" means a holder of a valid retail dispensary license in accordance with Chapter 3796. of the Revised Code.

(G) "Originating pharmacy" has the same meaning as in rule 4729:5-5-19 of the Administrative Code.

(H) "Opioid treatment program" has the same meaning as in Chapter 4729:5-21 of the Administrative Code.

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

(~~D~~ **G**) "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~~ **H**) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.

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

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

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

(~~I~~ **L**) "Sale" and "sell" has the same meaning as in section 4729.01 of the Revised Code.

(~~J~~ **M**) "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, as defined in rule 4729:6-3-08 of the Administrative Code, to a prescriber or terminal distributor;

(3) The transfer or sale of a non-patient specific dangerous drug to a prescriber or terminal distributor.

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

(N) "Zero report" means either:

(1) A report documenting that none of the drugs listed in Chapter 4729:8-2 of the Administrative Code were sold, dispensed or personally furnished during the required reporting period; or

(2) For a dispensary, a report documenting that no medical marijuana was sold or dispensed.

Rule 4729:8-2-01 | List of drugs to be reported. (NO CHANGE)

Pursuant to section 4729.75 of the Revised Code, the required information for the following 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 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.

Rule 4729:8-2-02 | Additional drugs to be reported. (NO CHANGE)

(A) Pursuant to section 4729.75 of the Revised Code, the required information for the following drugs pursuant to an outpatient prescription, personally furnished by a prescriber, or sold at wholesale to a prescriber or 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.

(B) Pursuant to section 4729.75 of the Revised Code, the required information for the following drugs pursuant to an outpatient prescription shall be submitted to the state board of pharmacy in accordance with section 4729.77 of the Revised Code and this division of the Administrative Code:

All dangerous drug products containing naltrexone that are indicated for the treatment of alcohol dependence or the prevention of relapse to opioid dependence.

Rule 4729:8-3-01 | Entities required to submit information. (AMEND)

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 state board of pharmacy for the operation of the drug database:

(A) All pharmacies 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.

(B) All pharmacies 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) Except as provided in rule 4729:8-2-02 of the Administrative Code, 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) Except as provided in rule 4729:8-2-02 of the Administrative Code, 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 shall report those drug transactions in accordance with the wholesale reporting requirements of this chapter.

(E) Except as provided in rule 4729:8-2-02 of the Administrative Code, all prescribers, except veterinarians, located within this state shall report all drugs listed in Chapter 4729:8-2 of the Administrative Code that are personally furnished to patients.

(F) A retail dispensary licensed under Chapter 3796. of the Revised Code in accordance with section 4729.771 of the Revised Code.

(G) An opioid treatment program licensed as a terminal distributor of dangerous drugs is exempted from the reporting requirements of this division.

(1) An opioid treatment program shall report patient information via the central registry established in rule 5122-40-08 of the Administrative Code.

(2) Reporting of patient information pursuant to paragraph (G)(1) of this rule shall be made in compliance with 42 CFR Part 2.

Rule 4729:8-3-02 | Information required for submission. (AMEND)

(A) Pharmacies 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 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) Pharmacy dispensing software vendor;

(6) Pharmacy license number, if both the drug enforcement administration registration and national provider identifier are not provided;

(7) Type of pharmacy or dispenser;

(8) Indication if entity is a mail order pharmacy;

(~~5~~ **9**) Patient full name;

(~~6~~ **10**) Patient residential address;

(~~7~~ **11**) Patient telephone number;

(~~8~~ **12**) Patient date of birth;

(~~9~~ **13**) Patient gender;

(14) Species code;

(15) Owner's name for veterinary patients;

(16) Owner's date of birth for veterinary patients;

(17) Owner's gender for veterinary patients;

(18) Name of animal;

(19) Veterinary species code for veterinary patients that is either:

(a) For small animals: 03;

(b) For large animals, including livestock: 06.

(~~10~~ **20**) Prescriber's full name (first name and last name);

(21) Transmission form of prescription (e.g., written, verbal, electronic, etc.);

(~~11~~ **22**) Prescriber's drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(~~12~~ **23**) Date prescription was issued by the prescriber;

(~~13~~ **24**) Date the prescription was dispensed ~~**or sold**~~ by the pharmacy;

(25) Date the prescription was sold by the pharmacy, which shall be the date the prescription is sold, picked up, or otherwise left the pharmacy;

(~~14~~ **26**) Indication of whether the prescription dispensed is new or a refill;

(~~15~~ **27**) Number of the refill being dispensed;

(~~16~~ **28**) National drug code of the drug dispensed;

(29) Indication if the product is compounded in accordance with division 4729:7 of the Administrative Code;

(~~17~~ **30**) Quantity of the drug prescribed;

(~~18~~ **31**) Quantity of drug dispensed;

(~~19~~ **32**) Number of days' supply of the 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 the 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 the drug dispensed.

(~~20~~ **33**) Serial or prescription number assigned to the prescription order;

(~~21~~ **34**) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation. Use of discount cards shall be reported as private pay;

(~~22~~ **35**) Pharmacy national provider identification (NPI) number;

(~~23~~ **36**) Prescriber's national provider identification (NPI) number, if prescriber does not have an NPI**, then the prescriber's state license number or** another mutually acceptable identifier;

(37) Pharmacist national provider identifier (NPI).

(a) If a pharmacist other than the dispensing pharmacist conducted the drug utilization review per rule 4729:5-5-08 of the Administrative Code, report the NPI of the pharmacist who conducted the drug utilization review;

(b) If a pharmacist does not have an NPI, report the pharmacist's license number or another mutually acceptable identifier;

(38) Name of pharmacist. If a pharmacist other than the dispensing pharmacist conducted the drug utilization review per rule 4729:5-5-08 of the Administrative Code, report the full name of the pharmacist who conducted the drug utilization review;

(~~24~~ **39**) 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 drug personally furnished;

(12) Quantity of drug personally furnished;

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

(14) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation. Use of discount cards shall be reported as private pay;

(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 terminal distributors pursuant to paragraphs (C) and (D) 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) Drug distributor or 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 drug sold;

(4) Quantity of the drug sold;

(5) Date of sale; and

(6) Transaction identifier or invoice number.

(D) Drug distributors shall report suspicious orders and customer information pursuant to rule 4729:6-3-05 of the Administrative Code to the drug database established in section 4729.75 of the Revised Code.

Rule 4729:8-3-02.1 | Supplemental information required for submission. (NEW)

This rule was withdrawn from CSI consideration by the Board on December 9, 2024.

Rule 4729:8-3-03 | Electronic format required for the transmission of drug sales. (RESCIND CURRENT / NEW)

(A) All prescription dispensing information or prescriber personally furnishing information required to be submitted to the board 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:

(1) ASAP Version 5.0 Standard for Prescription Drug Monitoring Programs (1/1/2024); or

(2) Until December 1, 2025, ASAP Version 4.2A Standard for Prescription Drug Monitoring Programs (3/15/2017).

(B) The board's executive director or the director's designee may authorize up to a six-month extension to the implementation of ASAP Version 5.0 beyond April 1, 2025. Such extensions may only be considered if the pharmacy or prescriber has made all reasonable and prudent attempts to meet the deadline.

(C) 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.

(D) All wholesale data required to be submitted to the board of pharmacy pursuant to rule 4729-8-3-02 of the Administrative Code shall 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.

(E) In the event that a drug distributor or terminal distributor cannot electronically transmit the required information pursuant to paragraph (D) of this rule, the drug distributor or terminal distributor 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.

Rule 4729:8-3-04 | Frequency requirements for submitting drug database information. (AMEND)

(A) A 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 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 pursuant to this division of the Administrative Code.

(2) A zero report, if a 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 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 or prescriber's non-business days.

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

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

(F) A drug distributor that has been in possession of a drug listed in Chapter 4729:8-2 of the Administrative Code for sale at wholesale within the previous three years shall submit to the board of pharmacy, at least monthly, either of the following:

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

(2) A zero report, if a drug distributor has no drug sale information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code.

(G) All wholesale sale information required to be submitted to the board of pharmacy pursuant to this division of the Administrative Code shall be submitted at least monthly. 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.

(H) If a drug distributor, prescriber, or terminal distributor cannot submit the required information at the required intervals specified in this rule, the drug distributor, terminal distributor or prescriber may request an extension from the **board's** ~~**boards**~~ executive director or the ~~**directors**~~ **director's** designee to submit the required information in a mutually acceptable time frame.

Rule 4729:8-3-05 | Corrections to the drug database. (AMEND)

(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 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, drug distributor or prescriber shall notify the board of pharmacy within twenty-four hours of the discovery. The corrected information must be submitted to the board of pharmacy by the terminal distributor, prescriber**,** or drug distributor within seven days of the discovery.

(D) If the omission of data or erroneous data is the result of a computer programming error, the 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 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** ~~**boards**~~ executive director or the ~~**directors**~~ **director's** designee.

(F) If utilizing a central fill pharmacy to report to the drug database in accordance with this division of the Administrative Code, the central fill pharmacy and the originating pharmacy shall implement a process to submit a correction if the drug is returned to stock pursuant to rule 4729:5-5-22 of the Administrative Code. It shall be the responsibility of the reporting pharmacy to ensure this process is completed in accordance with this rule.

Rule 4729:8-4-01 | Procedures for obtaining drug database information and access by peer review committees. (AMEND)

(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** ~~**committees**~~ evaluation, supervision, or discipline.

Rule 4729:8-4-02 | Extension to the information storage requirements and the provision of database statistics. (NO CHANGE)

(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 4729.80 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.

Rule 4729:8-4-03 | Access to opioid treatment program data provided by the Ohio department of mental health and addiction services. (AMEND)

(A) Pursuant to ~~**division (A)(23) of**~~ section 4729.80 of the Revised Code, the following persons shall be permitted to access opioid treatment program data provided by the Ohio department of mental health and addiction services in accordance with section 4729.772 of the Revised Code:

(1) Prescriber and prescriber delegates as authorized in ~~**division (A)(5) of section**~~ **under** 4729.80 of the Revised Code;

(2) Pharmacist and pharmacist delegates as authorized ~~**in division (A)(6) of**~~ **under** section 4729.80 of the Revised Code;

(3) The director of health as authorized ~~**in division (A)(13) of**~~ **under** section 4729.80 of the Revised Code;

(4) An individual listed in paragraphs (A)(1) and (A)(2) of this rule who is from or participating with another state's prescription monitoring program; and

~~**(4) An individual listed in division (A)(5) or (A)(6) of section 4729.80 who is from or participating with another states prescription monitoring program; and**~~

(5) A coroner, deputy coroner, or coroner's delegate as authorized ~~**in division (A)(17) of**~~ **under** section 4729.80 of the Revised Code.

(B) Nothing in this rule shall be construed to limit the state board of ~~**pharmacys**~~ **pharmacy's** access and use of data collected by the drug database to carry out its responsibilities in accordance with section 4729.81 of the Revised Code.