2/11/16

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.

Amended Rules

- **4729-37-04:** Provides the required information that must be submitted by a pharmacy or prescriber to the Ohio Automated Rx Reporting System (OARRS). Updates a cross reference to proposed new rule 4729-37-12.
- **4729-37-03:** Lists the entities required to submit data to OARRS. Updates a cross reference to proposed new rule 4729-37-12.
- **4729-37-07:** Specifies the frequency required for submitting data to OARRS. Updates a cross reference to proposed new rule 4729-37-12.

New

- **4729-37-12:** Requires the submission to OARRS of dispensing and personal furnishing information for drugs containing gabapentin.

Comments on the proposed rules will be accepted until close of business on February 24, 2016. Please send all comments to the following email address:
Cameron.mcnamee@pharmacy.ohio.gov

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Drug Database - OARRS

Rule Number(s): Amended: 4729-37-03; 4729-37-04; 4729-37-07

New: 4729-37-12

Date: 02/11/2016

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Amended	Rescinded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.

Amended Rules

- **4729-37-04:** Provides the required information that must be submitted by a pharmacy or prescriber to the Ohio Automated Rx Reporting System (OARRS). Updates a cross reference to proposed new rule 4729-37-12.
- **4729-37-03:** Lists the entities required to submit data to OARRS. Updates a cross reference to proposed new rule 4729-37-12.

- **4729-37-07:** Specifies the frequency required for submitting data to OARRS. Updates a cross reference to proposed new rule 4729-37-12.

New

- **4729-37-12:** Requires the submission to OARRS of dispensing and personal furnishing information for drugs containing gabapentin.

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

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.

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 regulation of the pharmacy profession has 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 maintenance of the state's prescription monitoring program (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 4729.83 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.

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.

OAC 4729-37-12 was developed in response to receiving a number of requests from pharmacists and prescribers reporting the abuse of gabapentin. The Board also consulted with the State Medical Board, Department of Health and Bureau of Workers' Compensation.

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?

Rule 4729-37-12 was initially included in 4729-37-02 but the proposal was moved to a separate rule to avoid impact on current rules adopted by state licensing boards.

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?

The Board used the following data to support the proposed adoption of OAC 4729-37-12:

Ohio Department of Health – 2014 Drug Overdose Data

- Gabapentin (Neurontin®) was found in the system of 44 unintentional drug overdose decedents in 2014.

Ohio Substance Abuse Monitoring Network – June 2015 Report

- Neurontin® (anti-convulsants) was reported highly available by participants in Athens, Cincinnati and Dayton regions.
- Participants in Cincinnati shared that users will often use this sort of medication illicitly to avoid withdrawal symptoms. Athens participants reported that Lyrica® 75 mg pill sells for $1.50 and Neurontin® 300 mg sells for $2.
- Participants indicated that these pills are easily prescribed and are purchased from dealers, adding that they are found among incarcerated populations. Oral consumption was the only route of administration mentioned by participants.

Ohio Substance Abuse Monitoring Network – Southeast Regional June 2015 Report

Participants most often reported the current availability for Lyrica® and Neurontin® as '10' on a scale of '0' (not available, impossible to get) to '10' (highly available, extremely easy to get). Participants reported that the availability of these drugs has increased during the past six months. Reports of current street prices for Lyrica® and Neurontin® were consistent among participants with experience buying these drugs. Reportedly, Lyrica® 75 mg sells for $1.50; Neurontin® 300 mg sells for $2. The most common route of administration for either drug is oral ingestion.

Ohio Substance Abuse Monitoring Network – Dayton Regional June 2015 Report

Neurontin® (an analgesic, anti-epileptic agent) was reported again by law enforcement, who rated current street availability as '10' for availability on a scale of '0' (not available, impossible to get) to '10' (highly available, extremely easy to get). A law enforcement officer commented, "They get that stuff all the time. They get it by the bottles." Law enforcement reported that the availability of Neurontin® has remained the same during the past six months.

Ohio Substance Abuse Monitoring Network – Columbus Regional January 2015 Report

Neurontin® (an analgesic, anti-epileptic agent) is highly available in the region. Participants most often reported the drug's current availability as '10' on a scale of '0' (not available,

impossible to get) to '10' (highly available, extremely easy to get); treatment providers most often reported current availability as '8-10.' Participants reported no change in availability of Neurontin® during the past six months, while treatment provider indicated an increase. Treatment providers purported that an increase in prescription writing of Neurontin® has led to increased street availability of the drug. A pharmacist remarked, "I'm blown away that [Neurontin® is] not controlled."

Participants with experience purchasing the drug said it sells for $0.50-1 per pill (unspecified dosage). In addition to obtaining Neurontin® on the street from dealers, participants also reported getting personal prescriptions from doctors, as one participant stated, "They're easy to get prescribed, too." Participants reported using Neurontin® to avoid withdrawal from other drugs. Participants described typical Neurontin® users as individuals on probation, because most drug screens do not detect this drug, or people who illicitly use prescription opioids. A treatment provider described typical users as males and females in their twenties.

Ohio Substance Abuse Monitoring Network – Dayton Regional January 2015 Report

Neurontin® (an analgesic, anti-epileptic agent) was mentioned by law enforcement professionals, who reported, "That's the big one right now." Although not much information was available, officers reported that Neurontin® is most often snorted or orally consumed.

Lastly, Neurontin® (an analgesic, anti-epileptic agent) was mentioned by law enforcement professionals, who reported that the drug seems to be gaining in popularity right now. Although not much information was available, officers reported that Neurontin® is most often snorted or orally consumed.

Other Sources of Scientific Data:

- Misuse and Abuse of Pregabalin and Gabapentin: Cause for Concern? CNS Drugs June 2014, Volume 28, Issue 6, pp 491-496 First online: 24 April 2014
- Neurontin® [package insert]. New York: Pfizer, Inc.; 2012.
- Smith BH, Higgins C, Baldacchino A, Kidd B, Bannister J. Substance misuse of gabapentin. Br J Gen Pract. 2012;62:406-407. Abstract
- Reccoppa L, Malcolm R, Ware M. Gabapentin abuse in inmates with prior history of cocaine dependence. Am J Addict. 2004;13:321-323. Abstract
- Del Paggio D. Psychotropic medication abuse in correctional facilities. Bay Area Psychopharmacology Newsletter. 2005;8:1- http://www.acbhcs.org/Psychopharmacology/2005/June2005.pdf Accessed June 10, 2014.

- Victorri-Vigneau C, Guerlais M, Jolliet P. Abuse, dependency and withdrawal with gabapentin: a first case report. Pharmacopsychiatry. 2007;40:43-44. Abstract
- Norton JW. Gabapentin withdrawal syndrome. Clin Neuropharmacol. 2001;24:245-246. Abstract
- Pittenger C, Desan PH. Gabapentin abuse, and delirium tremens upon gabapentin withdrawal [letter]. J Clin Psychiatry. 2007;68:483-484. Abstract
- Baird CR, Fox P, Colvin LA. Gabapentinoid abuse in order to potentiate the effect of methadone: a survey among substance misusers. Eur Addict Res. 2014;20:115-118.

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 drugs that may be the subject 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, b*ut 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, biannual 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 that ship controlled substances.
- Prescribers who personally furnish (i.e. dispense) controlled substances from their offices.

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 for a pharmacist, pharmacy intern, terminal distributor of dangerous drugs and wholesale distributors of dangerous drugs. Discipline might include reprimand, suspension of a license, required course work (pharmacists/interns), monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

- **4729-37-03:** Lists the entities required to submit data to OARRS. The overall cost of the rule includes administrative and technological costs incurred by the listed entities to submit the data to OARRS.
- **4729-37-07:** Specifies the frequency required for submitting data 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. 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.

- **4729-37-04:** Provides the required information that must be submitted by a pharmacy or prescriber to OARRS. The cost of the rule is administrative and technological costs incurred by the pharmacies and prescribers to submit the data to OARRS. This only impacts a small proportion of prescribers who normally write prescriptions to be dispensed at pharmacies. Pharmacies in Ohio have developed an automated process to provide dispensing data to OARRS.

  4729-37-12: Requires the submission to OARRS of dispensing and personal furnishing information for drugs containing gabapentin. This will require pharmacies to update their systems to send data to the Board within 24 hours if they dispense gabapentin. Pharmacies that already send data to OARRS for controlled substances will need to update their systems to add gabapentin as a reported drug. Pharmacies that do not report (because they do not currently dispense controlled substances) will need to begin reporting information on gabapentin dispensing to OARRS. This may result in an upgrade cost to their pharmacy dispensing software.

  It will also require physicians to provide this information to the Board within 24-hours of personally furnishing a drug. It is estimated this will cost a physician who personally furnishes gabapentin 2-3 times per week an additional 30 minutes of staff time to report.

  Wholesalers that sell gabapentin will also be required to report their sales information for gabapentin.

Regulatory Flexibility

15. 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.

16. 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.

17. 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.

4729-37-12 Dangerous Drug Monitoring. (NEW)

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

(A) All dangerous drug products containing gabapentin.

4729-37-04 Information required for submission.

(A) Pharmacies pursuant to paragraphs (A) and (B) of rule 4729-37-03 of the Administrative Code that dispense drugs identified in rules 4729-37-02 and 4729-37-12 of the Administrative Code to outpatients residing in this state must report the following dispensing information to the board of pharmacy:

(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 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 drug dispensed;

(18) Number of days' supply of drug dispensed;

(19) 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; and

(22) Prescriber's national provider identification (NPI) number, unless the prescriber is a licensed veterinarian as defined in section 4741.01 of the Revised Code.

(B) Prescribers pursuant to paragraph (E) of rule 4729-37-03 of the Administrative Code that personally furnish drugs identified in rules 4729-37-02 and 4729-37-12 of the Administrative Code to outpatients must report the following dispensing information to the board of pharmacy:

(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 dispensed;

(12) Quantity of drug dispensed;

(13) Number of days' supply of drug dispensed; and

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

(C) Wholesalers and pharmacies pursuant to paragraphs (C) and (D) of rule 4729-37-03 of the Administrative Code that sell drugs identified in rules 4729-37-02 and 4729-37-12 of the Administrative Code at wholesale must at least report the following information to the board of pharmacy in the format described in rule 4729-37-06 of the Administrative Code:

(1) Wholesaler or pharmacy 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.

4729-37-03 Entities required to submit information.

The following entities are required to submit the specified dispensing, personal furnishing, or wholesale sale information to the board of pharmacy for the drug database:

(A) All pharmacies located outside this state and licensed as a terminal distributor of dangerous drugs shall report all drugs identified in rules 4729-37-02 and 4729-37-12 of the Administrative Code that are dispensed to outpatients residing in this state.

(B) All pharmacies located within this state and licensed as a terminal distributor of dangerous drugs shall report all drugs identified in rules 4729-37-02 and 4729-37-12 of the Administrative Code that are dispensed to all outpatients.

(C) All wholesalers licensed as a wholesale distributor of dangerous drugs that sell drugs identified in rules 4729-37-02 and 4729-37-12 of the Administrative Code at wholesale shall report those drug transactions.

(D) All pharmacies licensed as a terminal distributor of dangerous drugs that sell drugs identified in rules 4729-37-02 and 4729-37-12 of the Administrative Code at wholesale shall report those drug transactions.

(E) All prescribers, except veterinarians, located within this state shall report all drugs identified in rules 4729-37-02 and 4729-37-12 of the Administrative Code that are personally furnished to outpatients.

4729-37-07 Frequency requirements for submitting drug database information.

(A) A pharmacy or prescriber that has possessed for the purpose of dispensing or personally furnishing a reported drug (including a sample drug) within the previous two years shall submit to the board of pharmacy, at least daily, either of the following:

(1) All drug dispensing and personally furnishing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02, 4729-37-12 and 4729-37-04 of the Administrative Code.

(2) A "Zero Report", if a pharmacy has no drug dispensing information or a prescriber has no personally furnishing information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02, 4729-37-12 and 4729-37-04 of the Administrative Code.

(B) The dispensing report, the personally furnishing information, 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.

(C) Any record of a dispensed or personally furnished reportable drug shall be reported to the board of pharmacy within twenty-four hours of being dispensed or personally furnished.

(D) Any pharmacy or prescriber whose normal business hours are not seven days per week shall electronically indicate their normal business hours to the board and a "Zero Report" will be automatically submitted on their behalf on non-business days.

(E) If a pharmacy or prescriber ceases to possess for the purpose of dispensing or personally furnishing any reported drug (including a sample drug), the responsible person shall notify the board of pharmacy electronically or in writing. The board shall be notified if the pharmacy or prescriber resumes dispensing or personally furnishing a reportable drug, including a sample drug.

(F) All wholesale drug sale information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02, 4729-37-12 and 4729-37-04 of the Administrative Code must be submitted monthly as follows:

(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) In the event that a wholesaler, prescriber, or pharmacy cannot submit the required information as described in this rule, the responsible person must immediately contact the board of pharmacy to determine a mutually acceptable time for submission of information. The reasons

for the inability of the wholesaler, prescriber, or pharmacy to submit the required information must be documented in writing to the board of pharmacy.