9/28/2016

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New Rules

- 4729-9-09: Requires response for violations found during an inspection within 30 days of notification.
- 4729-27-01: Consolidates Peritoneal Dialysis Solution Chapter (4729-27) into a single rule. Rescinds current chapter.

Amended

- 4729-9-17: Rule requires adulterated drugs to be stored separately from inventory. Clarifies that controlled substances shall be disposed in accordance with rule 4729-9-06.
- 4729-5-10: Changes the pick-up station rule to require the pharmacy and pick-up station to retain a copy of the pick-up station agreement rather than submitting notification directly to the Board.
- 4729-5-29: Authorizes the release of patient records to any Ohio agency responsible for licensure of a health professionals authorized to prescribe drugs.
- 472-5-05: Requires a pharmacist or pharmacy intern to report within 30 days any legal name change, change of mailing address or change of employment. Rescinds 4729-5-06.
- 4729-33-03: Updates cross reference to the updated controlled substance destruction rule.
- 4729-9-26: Clarifies that all criminal records checks for pain management clinics shall consist of a BCI&I and FBI records check.
- 4729-9-12: Allows for wholesaler and terminal distributors to validate licensure within the e-licensing system prior to conducting a sale rather than requesting a copy of license itself. Includes federal language permitting transfer of drugs among common ownership.
- 4729-5-20: Corrects typo and removes reference to outdated references for drug utilization review by a pharmacist.
- 4729-5-11: Prohibits persons from acting as a responsible person if they have previous administrative discipline or have been convicted of a crime.

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- 4729-5-26: Changes partial dispensing rule to conform with recent changes in federal law to allow for partial fills of schedule II controlled substances for all patients.

Comments on the proposed rules will be accepted until close of business on October 12, 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: Pharmacists & Dangerous Drugs

Rule Number(s): New: 4729-9-09; 4729-27-01

Amend: 4729-9-17; 5-10; 5-29; 5-05; 33-03; 9-26; 9-12; 5-20; 5-11; 5-26

Date: 05/09/2016

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.

New Rules

- 4729-9-09: Requires response for violations found during an inspection within 30 days of notification.
- 4729-27-01: Consolidates Peritoneal Dialysis Solution Chapter (4729-27) into a single rule. Rescinds current chapter.

Amended

- 4729-9-17: Rule requires adulterated drugs to be stored separately from inventory. Clarifies that controlled substances shall be disposed in accordance with rule 4729-9-06.
- 4729-5-10: Changes the pick-up station rule to require the pharmacy and pick-up station to retain a copy of the pick-up station agreement rather than submitting notification directly to the Board.
- 4729-5-29: Authorizes the release of patient records to any Ohio agency responsible for licensure of a health professionals authorized to prescribe drugs.
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- 4729-33-03: Updates cross reference to the updated controlled substance destruction rule.
- 4729-9-26: Clarifies that all criminal records checks for pain management clinics shall consist of a BCI&I and FBI records check.
- 4729-9-12: Allows for wholesaler and terminal distributors to validate licensure within the e-licensing system prior to conducting a sale rather than requesting a copy of license itself. Includes federal language permitting transfer of drugs among common ownership.
- 4729-5-20: Corrects typo and removes reference to outdated references for drug utilization review by a pharmacist.
- 4729-5-11: Prohibits persons from acting as a responsible person if they have previous administrative discipline or have been convicted of a crime.
- 4729-5-26: Changes partial dispensing rule to conform with recent changes in federal law to allow for partial fills of schedule II controlled substances for all patients.

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

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

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?

Rules 4729-5-26 and 4729-9-12 include recent changes made in federal law.

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 dangerous drugs and 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.

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.

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 State of Ohio Board of Pharmacy would not be able to:

- Ensure timely responses to violations of laws and rules identified during an inspection;
- Regulate the distribution of dialysis solution;
- Require the removal of outdated and expired drugs from inventory;
- Track the dispensing of dangerous drugs that are not directly provided to the patient;
- Ensure confidentiality of patient records;
- Maintain current information on licensees;
- Ensure proper destruction of controlled substances by EMS;
- Provide background checks for pain management owners;
- Require validation of licensure prior to the sale of dangerous drugs;
- Require pharmacists to conduct a thorough review of patient information prior to the dispensing of dangerous drugs;
- Prohibit individuals convicted of crimes and disciplinary action from having access to dangerous drugs; and
- Allow for the partial filling of controlled substances in accordance with federal law.

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 rules in this package were reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings, is responsible for reviewing and approving all rules prior to their legislatively mandated five-year review date.

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

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

The rules review committee provided the following input that was incorporated into the draft regulations:

- 4729-9-09: Extended the notification period from 20 days to 30 days.
- 4729-9-17: Included requirement to prohibit access to adulterated drugs by unauthorized persons.
- 4729-5-29: Added language authorizing access to all Ohio prescriber regulatory agencies.
- 4729-5-20: Removal of outdated reference.

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 or review this 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 regulations related to the practice of pharmacy and distribution of dangerous drugs, 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 agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform regulations across Ohio. At this juncture, it was the determination of the Board and the Rules Review Committee 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 Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, 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:

- Pharmacists and Pharmacy Interns;
- EMS Agencies;
- Dialysis solution distributors;
- Terminal distributors of dangerous drugs;
- Pain Management clinics;
- Prescribers; and
- Wholesale distributors of dangerous drugs.

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, intern, terminal or wholesale distributor 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.

New Rules

- 4729-9-09: Requires response for violations found during an inspection within 30 days of notification. Adverse impact of this regulation is the time it takes to prepare a response to violations identified by a Board inspector. The time to respond is dependent on the number of violations observed.
- 4729-27-01: Consolidates Peritoneal Dialysis Solution Chapter (4729-27) into a single rule. Rescinds current chapter. This is a consolidation of existing rules into a single rule. Those in compliance with this rule, should not have experience any adverse impacts. This rule requires licensure as a Category II terminal distributor of dangerous drugs. The cost of the license is 112.50 per year and its takes approximately 30 minutes to complete the application.

Amended

- 4729-9-17: Rule requires adulterated drugs to be stored separately from inventory. Clarifies that controlled substances shall be disposed in accordance with rule 4729-9-06. The adverse impact of this regulation is the time it takes to regularly review inventory to identify and remove expired and adulterated drugs. Additional costs may be incurred for the destruction of these drugs.

- 4729-5-10: Changes the pick-up station rule to require the pharmacy and pick-up station to retain a copy of the pick-up station agreement rather than submitting notification directly to the Board. This rule removes the requirement to submit paperwork to the Board and wait for approval. Instead, the cost associated with compliance is the completion the pick-up station form. This two-page form takes approximately 15 minutes to complete.
- 4729-5-29: Authorizes the release of patient records to any Ohio agency responsible for licensure of a health professionals authorized to prescribe drugs. The adverse impact of this regulation may be the cost associated with having to assist investigators and other approved entities to retrieve patient records.
- 472-5-05: Requires a pharmacist or pharmacy intern to report within 30 days any legal name change, change of mailing address or change of employment. Rescinds 4729-5-06. It takes approximately 3-5 minutes to complete each form required. Individuals changing their name will have to pay to obtain the required documents (i.e. marriage certificate) in the rule for submission to the Board.
- 4729-33-03: Updates cross reference to the updated controlled substance destruction rule. Removes the requirement that prior approval be obtained by the Board before destroying controlled substance inventory. This reduces the regulatory burden on EMS providers.
- 4729-9-26: Clarifies that all criminal records checks for pain management clinics shall consist of a BCI&I and FBI records check. Requires FBI and Ohio Bureau of Criminal Identification and Investigation (BCI&I) background checks for owners of pain management clinics. The cost of this regulation includes the following fees: BCI&I - $22, FBI - $24, and some agencies may charge a processing fee (e.g. $5-$40).
- 4729-9-12: Allows for wholesaler and terminal distributors to validate licensure within the e-licensing system prior to conducting a sale rather than requesting a copy of license itself. Includes federal language permitting transfer of drugs among common ownership. This rule reduces regulatory burden by only requiring the check in the e-licensing system (rather than obtaining documentation from the seller or buyer) prior to selling or purchasing dangerous drugs. The time it takes to verify licensure online is 2-3 minutes.
- 4729-5-20: Corrects typo and removes outdated references for drug utilization review by a pharmacist. This rule requires a drug utilization review be conducted by a pharmacist. This may take upwards of 2-3 minutes per prescription.
- 4729-5-11: Prohibits persons from acting as a responsible person if they have previous administrative discipline or have been convicted of a crime. This rule does require submission of a new form if there is a change in the responsible person on a license. This form takes approximately 10 minutes to complete and does not require a fee.

- 4729-5-26: Changes partial dispensing rule to conform with recent changes in federal law to allow for partial fills of schedule II controlled substances for all patients. There are documentation requirements associated with this rule that may increase the administrative burden of processing partial fill prescriptions.

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 are intended to protect and promote public safety. In particular, they ensure uniform regulations that allow for:

- Timely responses and corrections to violations of laws and rules identified during an inspection;
- Oversight of the distribution of dialysis solution;
- Removal of outdated and expired drugs from inventory to prevent patient harm;
- Tracking of the dispensing of dangerous drugs that are not directly provided to the patient to preserve the integrity of the drug product;
- The confidentiality of patient records and access to authorized users, including those conducting criminal and administrative investigations;
- The Board to have the most up-to-date information on licensees;
- EMS to properly destroy their controlled substance inventory;
- Pain management clinic owners to obtain and submit comprehensive background checks;
- Validation of licensure prior to the sale of dangerous drugs to prevent illegal sales and diversion;
- A thorough review of patient information by pharmacists prior to the dispensing of dangerous drugs; and
- Preventing individuals convicted of crimes and disciplinary action from having access to dangerous drugs.

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 or the preparation/distribution of dangerous drugs 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 specialists and agents) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-9-09 Inspections and Corrective Actions (NEW)

(A) A location licensed as a terminal or wholesale distributor of dangerous drugs is subject to on-site inspection by the state board of pharmacy. An authorized board agent may enter a terminal or wholesale distributor of dangerous drugs without notice in order to carry out an on-site inspection or investigation.

(B) Submission of an application for a license as a terminal or wholesale distributor of dangerous drugs constitutes permission for entry and on-site inspection by an authorized board agent.

(C) If an agent of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the agent may provide written notice, in a manner prescribed by the board, of the nature of the observed violations to the responsible person on the license. The licensee or applicant may also be subject to disciplinary actions pursuant to sections 4729.16, 4729.56 and 4729.57 of the Revised Code.

(D) Violations may include any of the following:

(1) Violating any rule of the board;

(2) Violating any provision of Chapter 4729. of the Revised Code;

(3) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code;

(4) Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code.

(E) The licensee shall submit notification to the board within ~~twenty~~ thirty days, in a manner prescribed by the board, either of the following:

(1) The action the licensee has taken to correct the violations and the date of implementation of the corrective action; or

(2) An explanation disputing the observed violations.

4729-9-17 Storage of adulterated drugs.

To prevent their use, adulterated drugs, as defined in rule 4729-9-01 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing and administration.

(A) Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license or two years by those holding a wholesale distributor of dangerous drugs license only. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

(B) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in rule 4729-9-22 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession of the drugs by unauthorized persons.

(C) Dangerous drugs that are controlled substances ~~may~~ shall be disposed of pursuant to rule 4729-9-06 of the Administrative Code.

~~(D) Methods of disposal shall prevent the possession of the drugs by unauthorized persons.~~

4729-27-01 ~~Definitions.~~ Peritoneal Dialysis Solutions.

(RESCIND 4729-27-02, 03, 04, 05)

(A) For the purpose of Chapter 4729. of the Revised Code, the term "peritoneal dialysis solutions" shall mean the commercially available, unopened, sterile solutions whose only purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis.

(B) Each person, whether located within or outside this state, who sells peritoneal dialysis solutions in original packages labeled as required by applicable federal and state laws, rules, and regulations to persons residing in this state, shall obtain a limited category II terminal distributor of dangerous drugs license from the board of pharmacy pursuant to the provisions of sections 4729.54, 4729.55, and 4729.551 of the Revised Code. This requirement shall not apply to persons already licensed to purchase, possess, and sell unlimited category II dangerous drugs at retail.

(C) Peritoneal dialysis solutions may be sold at retail to patients only pursuant to an order from a person authorized to prescribe peritoneal dialysis solutions in the course of professional practice.

(D) Peritoneal dialysis solutions may be sold at retail and must be maintained in accordance with Chapters 3715. and 4729. of the Revised Code; rules 4729-9-04, 4729-9-05, 4729-9-11, and 4729-9-12 of the Administrative Code; and applicable federal laws and regulations.

(E) All retail sellers of peritoneal dialysis solutions shall maintain records of purchase of peritoneal dialysis solutions at wholesale and sale of peritoneal dialysis solutions at retail for three years at the licensed location, or an alternate site approved by the board, for inspection and copying by board of pharmacy agents. The record of sale must include, but is not limited to, the order issued by the person authorized to prescribe peritoneal dialysis solutions in the course of professional practice.

(F) Before making an initial sale of peritoneal dialysis solutions to a patient, the retail seller must have an order issued by a person authorized to prescribe peritoneal dialysis solutions in the course of the prescriber's professional practice. The order must include the full name and address of the patient, the name and address of the prescriber, and the complete and accurate identification of each such product to be provided to the patient.

4729-5-10 Prescription pick-up station.

(A) No pharmacist shall accept prescriptions obtained from a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled unless such place is a pharmacy as defined in section 4729.01 of the Revised Code and all of the following apply:

(1) The site is appropriately licensed pursuant to Chapter 4729. of the Revised Code;

(2) The receipt, storage, control, and distribution of prescriptions are in the full and actual charge of a pharmacist licensed pursuant to Chapter 4729. of the Revised Code;

(3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, and return of all prescriptions;

(4) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.

(5) The following documentation is submitted in a manner prescribed by the board:

(a) If the pharmacy shipper and receiver are not within the same corporation, then the pick-up station and the pharmacy shall maintain ~~submit notification to the board in a manner prescribed by the board~~ an executed copy of the pick-up station agreement; or

(b) If the shipper and receiver are within the same corporation, then the pick-up station and the pharmacy shall maintain ~~submit notification to the board in a manner prescribed by the board~~ an executed copy of the pick-up station agreement.

(B) No pharmacist shall dispense dangerous drugs to a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered unless such place is a pharmacy as defined in section 4729.01 of the Revised Code or, if not a pharmacy, all of the following apply:

(1) The site is appropriately licensed pursuant to Chapter 4729. of the Revised Code, unless a waiver is granted by the board.

(2) There is clear and convincing evidence that delivery of a prescription medication directly to the patient would result in:

(a) Danger to public health or safety, or

(b) Danger to the patient without increased involvement by a health care professional in the patient's drug therapy.

(3) The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code.

(4) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, and return of all prescription medications.

(5) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.

(6) The following documentation is submitted in a manner prescribed by the board:

(a) If the pharmacy shipper and receiver are not within the same corporation, then the pick-up station and the pharmacy shall maintain ~~submit notification to the board in a manner prescribed by the board~~ an executed copy of the pick-up station agreement; or

(b) If the shipper and receiver are within the same corporation, then the pick-up station must and the pharmacy shall maintain ~~submit notification to the board in a manner prescribed by the board~~ an executed copy of the pick-up station agreement.

(C) The state board of pharmacy may restrict a site from acting as a pick-up station if it has clear and convincing evidence that the activities of the pick-up station present the following:

(1) Danger to public health or safety, or

(2) Danger to the patient.

(D) The agreement described in this rule shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy agents for a period of three years following the termination of the agreement.

(E) The board shall make available on its website the pick-up station agreement referenced in this rule.

4729-5-29 Confidentiality of patient records.

(A) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction are not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone except:

(1) The patient for whom the prescription or medication order was issued.

(2) The prescriber who issued the prescription or medication order.

(3) Certified/licensed health care personnel who are responsible for the care of the patient.

(4) A member, inspector, agent, or investigator of the state board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.

(5) An agent of an Ohio licensing agency that is responsible for the licensure of a health professional authorized to prescribe drugs as defined in section 4729.01 when enforcing that agency's chapter of the Revised Code. ~~the state medical board when enforcing Chapters 4730. and 4731. of the Revised Code~~.

(6) An agency of government charged with the responsibility of providing medical care for the patient upon a written request by an authorized representative of the agency requesting such information.

(7) An agent of a medical insurance company who provides prescription insurance coverage to the patient upon authorization and proof of insurance by the patient or proof of payment by the insurance company for those medications whose information is requested.

(8) An agent who contracts with the pharmacy as a "business associate" in accordance with the regulations promulgated by the secretary of the United States department of health and human services pursuant to the federal standards for privacy of individually identifiable health information.

~~(9) An agent of the state board of nursing when enforcing Chapter 4723. of the Revised Code.~~

(~~10~~9) Any person, other than those listed in paragraphs (A)(1) to (A)(8) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient requiring medication is unable to deliver a written consent to the necessary disclosure. Any consent must be signed by the patient and dated. Any consent for disclosure is valid until rescinded by the patient. In an emergency, the pharmacist may disclose the prescription information when, in the

professional judgment of the pharmacist, it is deemed to be in the best interest of the patient. A pharmacist making an oral disclosure in an emergency situation must prepare a written memorandum showing the patient's name, the date and time the disclosure was made, the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.

(B) Testimonial privilege is not waived for any communication between a physician, a pharmacist, and a patient pursuant to section 2317.02 of the Revised Code.

(C) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction which may be required as evidence of a violation shall be released to a member, inspector, agent, or investigator of the state board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug upon his request. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a prescription, the receipt shall list the following information:

(1) Prescription identification number; or, if an order for medication, the name of the patient;

(2) The drugs prescribed;

(3) Quantity of drugs prescribed and dispensed;

(4) Name of the prescriber;

(5) Date, name of agency, and signature of person removing the records.

(D) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A)(9) of this rule, shall be kept on file at the pharmacy for a period of three years in a readily retrievable manner.

4729-5-05 ~~Change of name of registrant~~ Pharmacist and pharmacy intern change of name, address and/or employment.

(A) A pharmacist or pharmacy intern, who has a legal change of name, shall report the change to the board of pharmacy within ~~sixty~~ thirty days from the effective date of such change. Such notification of a name change shall be accompanied by one of the following:

(1) A notarized affidavit;

(2) A certified copy of a court record;

(3) A certified copy of a marriage certificate.

(B) Requests for duplicate certificate of registration and/or an identification card, to be issued in the new name, shall be accompanied by the following:

(1) The certificate of registration and/or identification card issued in the original name; and

(2) The required fee.

(C) Upon receipt of the required documents in paragraphs (A) and (B) of this rule, the board will forward the duplicate certificate of registration and/or identification card issued in the new name.

(D) Every pharmacist and pharmacy intern who changes their mailing address shall notify the board of pharmacy of the new address within thirty days after the effective date of such change.

(E) Every pharmacist and pharmacy intern who changes his/her place of employment shall notify the board of pharmacy of the address of the principal place where they practice their profession, including pharmacist placement services, within thirty days after they have commenced such practice.

RESCIND 4729-5-06

4729-33-03 Security and storage of dangerous drugs.

(A) Overall supervision and control of dangerous drugs is the responsibility of the responsible person. The responsible person may delegate the day-to-day tasks to the emergency medical service (EMS) organization personnel who hold appropriate certification to access the dangerous drugs for which they are responsible.

(B) All dangerous drugs must be secured in a tamper-evident setting with access limited to EMS personnel based on their certification status except for sealed, Tamper-evident solutions labeled for irrigation use. All registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs.

(C) Only emergency medical technician-paramedics, advanced emergency medical technicians, registered nurses, physicians, and pharmacists who are associated with that EMS organization may have access to any controlled substances maintained by the EMS organization. Other persons employed by the EMS organization may have access to controlled substances only under the direct and immediate supervision of an emergency medical technician-paramedic, an advanced emergency medical technician as defined in Chapter 4765-16 of the Administrative Code, a registered nurse, or a physician in emergency situations.

(D) Administration of dangerous drugs by EMS personnel is limited to the scope of practice, as determined by the state board of emergency medical services, for the individual's certification level and the protocols as established by the medical director or when the individual is acting within their certification level pursuant to direct prescriber's orders received over an active communication link.

(E) All dangerous drugs will be maintained in a clean and temperature-controlled environment.

(F) Any dangerous drug that reaches its expiration date is considered adulterated and must be separated from the active stock to prevent possible administration to patients.

(G) Any non-controlled dangerous drug that is outdated may be returned to the supplier where the drug was obtained or may be disposed of in the proper manner.

(H) Any controlled substance that is outdated may be returned to the supplier where the drug was obtained.

(I) Destruction of outdated controlled substances ~~may only be done by a state board of pharmacy agent or by prior written permission from the state board of pharmacy office~~ shall be done in accordance with rule 4729-9-06 of the Administrative Code.

(J) Destruction of partially used controlled substances can be accomplished, with the appropriate documentation, by two licensed health care personnel, one of which must have at least an advanced emergency medical technician, as defined in Chapter 4765-16 of the Administrative Code, level of training and shall be done in accordance with rule 4729-9-06 of the Administrative Code.

(K) Any loss or theft of dangerous drugs must be reported upon discovery, by telephone, to the state board of pharmacy, local law enforcement and, if controlled substances are involved, to the drug enforcement administration. A report must be filed with the state board of pharmacy of any loss or theft of the vehicle or storage cabinets containing dangerous drugs used by the EMS organization.

(L) Any dangerous drug showing evidence of damage or tampering shall be removed from stock and replaced immediately.

4729-9-26 Criminal records check for pain management clinics.

Pursuant to division (B) of section 4729.552 of the Revised Code, a new terminal distributor of dangerous drug license with a pain management clinic classification will not be issued until the physician owner(s), or if incorporated the physician officers, of the pain management clinic submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. Additionally, a criminal records check is required every time there is a change in ownership for each new owner(s) or officer(s). ~~The~~ All criminal records checks conducted in accordance with this rule shall consist of both a BCI&I criminal records check and a federal bureau of investigations (FBI) records check. The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The physician owner(s) or physician officers must submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code. Physician owner(s) or physician officers are required to have all employees submit to a BCI&I and FBI criminal records check to ensure that no person has been previously convicted of, or pleaded guilty to a theft offense that would constitute a felony as described in division (K)(3) of section 2913.01 of the Revised Code or a felony drug abuse offense as defined in section 2925.01 of the Revised Code. Employees must submit electronic fingerprint impressions to the physician owner(s) or physician officers pursuant to rule 4729-4-04 of the Administrative Code.

4729-9-12 Verification of license as a distributor of dangerous drugs or exempt status of a prescriber.

(A) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code or may utilize the board's online registry to confirm licensure.

(1) The purchaser shall furnish a copy of the certificate of license as a terminal distributor to the wholesale distributor of dangerous drugs or the wholesale distributor may utilize the board's online registry to confirm licensure. If the certificate of license or online registry indicates a limited category I, II, or III license, the terminal distributor shall furnish the wholesale distributor a copy of the current license addendum listing those drugs the purchaser is authorized to possess.

(2) If no certificate of license or confirmation of licensure as a terminal distributor is obtained or furnished before the sale, both the seller and the purchaser shall be considered to be in violation of section 4729.60 of the Revised Code.

(B) Before a terminal distributor of dangerous drugs may make a purchase of dangerous drugs at wholesale, the purchaser must obtain from the seller or the board's online registry either of the following:

(1) The wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code; or

(2) The terminal distributor license number for occasional wholesale sales conducted in accordance with rule 4729-9-10.

(a) The seller shall furnish the wholesale distributor registration number and registration expiration date to the terminal distributor of dangerous drugs or the purchaser may utilize the board's online registry to confirm licensure.

(b) If no registration number of the wholesale distributor is obtained or furnished before the purchase, both the purchaser and the seller shall be considered to be in violation of section 4729.60 of the Revised Code.

(C) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a prescriber as defined in division (I) of section 4729.01 of the Revised Code, the wholesale distributor must obtain:

(1) A copy of the current certificate of license as a terminal distributor from the prescriber pursuant to division (A) of section 4729.60 of the Revised Code or the wholesale distributor may utilize the board's online registry to confirm licensure as a terminal distributor of dangerous drugs and, if the license is limited, a copy of the addendum listing the drugs the licensee is authorized to purchase and possess; or

(2) Unless the prescriber meets the terminal distributor of dangerous drugs licensing requirements in section 4729.541 of the Revised Code, copies of all documents required to establish that the prescriber is exempt from licensure as a terminal distributor of dangerous drugs pursuant to divisions (B)(1)(a), (B)(1)(j), and (B)(1)(k) of section 4729.51 of the Revised Code and is authorized by federal and state laws to purchase the dangerous drugs for use in the course of his/her professional practice. The required documents are as follows:

(a) An individual prescriber doing business as a sole proprietor (not incorporated in any manner) as set forth in division (B)(1)(a) of 4729.51 of the Revised Code, an individual prescriber doing business as a sole shareholder of a corporation or a limited liability company pursuant to division (B)(1)(j) of section 4729.51 of the Revised Code, and a dentist pursuant to division (B)(1)(k) of 4729.51 of the Revised Code must provide a copy of his/her current license to practice and the license must authorize the use of the drugs requested from the wholesaler in his/her practice. Also, a prescriber doing business as a sole shareholder of a corporation or a limited liability company must also provide official documentation that states he/she is the sole shareholder;

(b) The address of all sites of practice where the drugs will be delivered to and stored for use by the prescriber in his/her professional practice pursuant to federal and state laws;

(c) Verification from the licensing board that the prescriber's license is in good standing and that there are no restrictions on his/her license to practice and use drugs in his/her practice. If the license has been restricted by the licensing board, a copy of the official documents restricting the license to practice and use drugs in the course of professional practice must be furnished to the wholesaler and maintained by the wholesaler with all other documents establishing the prescriber's exemption from licensure as a terminal distributor of dangerous drugs;

(d) If an exempted prescriber wishes to purchase and possess dangerous drugs which are also controlled substances, the prescriber must submit a copy of his/her current registration with the federal drug enforcement administration and provide verification that the DEA registration and authority to use controlled substances in the course of professional practice has not been restricted by the appropriate professional licensing board or the federal drug enforcement administration.

(D) Dangerous drugs may not be shipped by a wholesale distributor of dangerous drugs to any address other than those listed by the business entity meeting the definition of a prescriber and

filed with the wholesale distributor in paragraph (B) of this rule. Controlled substances may only be shipped to those addresses registered with the federal drug enforcement administration for the purpose of storing controlled substances.

(E) All documents establishing the fact that a prescriber is exempt from licensure as a terminal distributor of dangerous drugs shall be current and maintained for a period of three years by the wholesale distributor of dangerous drugs.

(F) Copies of licenses to practice and verification that there are no restrictions on a prescriber's license by either the appropriate professional licensing board or the federal drug enforcement administration shall be obtained within fifteen days of the date of renewal of such licenses. No dangerous drugs may be sold and delivered to a prescriber until the required documentation has been obtained by the wholesale distributor.

(G) Each wholesale distributor of dangerous drugs registered with the state board of pharmacy shall report any suspicious purchases of any dangerous drugs by a prescriber exempted from licensure as a terminal distributor of dangerous drugs. A suspicious purchase includes, but is not limited to, any drugs that the prescriber is not authorized to use in the course of his/her professional practice.

(H) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729-16-07 of the Administrative Code, the terminal distributor of dangerous drugs must confirm a current certificate of license as a terminal distributor from the purchaser. The seller may utilize the board's online registry to confirm licensure.

(I) Before a wholesale distributor of dangerous drugs may purchase a dangerous drug from another wholesale distributor of dangerous drugs, the purchaser must confirm the seller has a current license as a wholesale distributor of dangerous drugs. The purchaser may utilize the board's online registry to confirm licensure.

(J) Before a terminal distributor of dangerous drugs may make a sale of dangerous drugs pursuant to rule 4729-9-10 of the Administrative Code, the seller must confirm the purchaser has a current certificate of license as a terminal distributor from the purchaser or the purchaser is exempted from licensure as a terminal distributor of dangerous drugs pursuant to section 4729.51 of the Revised Code. The seller may utilize the board's online registry to confirm licensure.

(K) Use of the board's online registry pursuant to this rule shall be documented and such documentation shall be maintained for a period of three years by the wholesale or terminal distributor of dangerous drugs.

(L) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery. Such transfer or delivery includes either of the following:

(1) Intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control.

(2) The sale, purchase, or transfer of a drug or an offer to sell, purchase, or transfer of a drug among hospitals or other health care entities that are under common control. Common control means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise.

4729-5-20 Prospective drug utilization review.

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment;

(9) Food-nutritional supplements-drug interactions.

(B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing an OARRS report or another state's report, pursuant to paragraph (D) of this rule, and/or consulting with the prescriber and/or counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information;

(3) United States ~~pharmacopoeia~~ pharmacopeia drug information.~~;~~

~~(4) American medical association evaluations.~~

(D) Prior to dispensing an outpatient prescription for a reported drug as listed in rule 4729-37-02 of the Administrative Code, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period, including a border state's information when the

pharmacist is practicing in a county bordering another state if that state's information is available, in any of the following circumstances:

(1) A patient adds a different or new reported drug to their therapy that was not previously included;

(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;

(3) A prescriber is located outside the usual pharmacy geographic area;

(4) A patient is from outside the usual pharmacy geographic area;

(5) A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding 3 months, unless the prescriptions are from prescribers who practice at the same physical location;

(6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks.

(E) In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.

(F) A pharmacist may use a delegate to request an OARRS report.

(G) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. Based upon information obtained during prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist is not required to dispense a prescription of doubtful, questionable, or suspicious origin.

4729-5-11 Responsible person.

(A) For a pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Only a pharmacist may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for a pharmacy as defined in division (A) of section 4729.01 of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy unless granted permission in accordance with paragraph (E) of this rule.

(2) The responsible person shall be responsible for the practice of the profession of pharmacy, including but not limited to supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs as required in rule 4729-9-11 of the Administrative Code and maintaining all drug records otherwise required.

(3) The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs and the practice of pharmacy.

(4) Unless otherwise approved by the Board, no responsible person for locations licensed as a pharmacy shall:

(a) Have ever been denied a license by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(b) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the pharmacist's inappropriate prescribing, dispensing, personally furnishing, diverting, administering, supplying, or selling a controlled substance or other dangerous drug.

(c) Have been the subject of disciplinary action by any licensing entity.

(d) Have been convicted of any of the following:

(i) a felony;

(ii) a misdemeanor related to, or committed in, the practice of pharmacy; or

(iii) a crime of moral turpitude.

(B) For locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revised Code:

(1) Only a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may be the responsible person whose name appears on the category III terminal distributor of dangerous drugs with a pain management classification license as defined in section 4729.552 of the Revised Code. A physician shall be the responsible person for no more than one such location unless granted permission in accordance with paragraph (E) of this rule. A physician shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with a pain management classification unless he/she will be physically present at the location for a sufficient amount of time to provide supervision.

(2) All employees of the facility, including the responsible person, shall submit to a criminal records check in accordance with section4776.02 of the Revised Code.

(3) The responsible person for locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revised Code must meet one of the following requirements:

(a) Hold current subspecialty certification in pain management by the American board of medical specialties, or hold a current certificate of added qualification in pain management by the American osteopathic association bureau of osteopathic specialists; or

(b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists; or

(c) Hold current board certification by the American board of pain medicine; or

(d) Hold current board certification by the American board of interventional pain physicians; or

(e) Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists.

(4) No responsible person for locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revised Code shall:

(a) Have ever been denied a license to prescribe, dispense, personally furnish, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, personally furnishing, diverting, supplying or selling a controlled substance or other dangerous drug.

(b) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, personally furnishing, diverting, administering, supplying, or selling a controlled substance or other dangerous drug.

(c) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, diverting, administering, personally furnishing, ~~diverting,~~ supplying or selling a controlled substance or other dangerous drug.

(d) Have been convicted of any of the following:

(i) a felony;

(ii) a misdemeanor related to, or committed in, the practice of medicine; or

(iii) a crime of moral turpitude.

(5) The person to whom the category III terminal distributor of dangerous drugs license with a pain management classification has been issued, the responsible person and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the operation of a pain management clinic and prescribing of controlled substances.

(C) For all locations licensed as a terminal distributor of dangerous drugs:

(1) A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.

(2) When there is a change of responsible person, the state board of pharmacy shall be notified within ten days of the effective date of the appointment of the new responsible person in a manner prescribed by the board. For an animal shelter licensed as a terminal distributor of dangerous drugs, the notification shall include a notarized drug list prepared pursuant to paragraph (D) of rule 4729-14-03 of the Administrative Code.

(3) A complete inventory, pursuant to federal regulations and rule 4729-9-14 of the Administrative Code, shall be taken of the controlled substances on hand with the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.

(4) The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of dangerous drugs.

(5) A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.

(6) The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs as required in rule 4729-9-11 of the Administrative Code and maintaining all records relating to the distribution of dangerous drugs.

(7) The board of pharmacy shall issue a resolution providing the credential types required for the responsible person of each classification of terminal distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for that classification type. The resolution shall be updated as necessary and available on the board's web site, www.pharmacy.ohio.gov.

(8) Unless otherwise approved by the Board, no responsible person for locations licensed as a terminal distributor of dangerous drugs shall:

(a) Have ever been denied a license by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(b) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the person’s inappropriate prescribing, dispensing, personally furnishing, diverting, administering, supplying, or selling a controlled substance or other dangerous drug.

(c) Have been the subject of disciplinary action by any licensing entity.

(d) Have been convicted of any of the following:

(i) a felony;

(ii) a misdemeanor related to, or committed in, the person's professional practice; or

(iii) a crime of moral turpitude.

(D) For all locations licensed as a wholesale distributor of dangerous drugs:

(1) A location licensed as a wholesale distributor of dangerous drugs must have a responsible person at all times.

(2) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within ten days of the effective date of the appointment of the new responsible person in a manner prescribed by the board.

(3) A responsible person shall not be designated the responsible person for more than one location licensed as a wholesale distributor of dangerous drugs unless granted permission in accordance with paragraph (E) of this rule.

(4) A complete inventory pursuant to section 1304.11 of the code of federal regulations (9/1/2015) shall be taken of the controlled substances on site by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the wholesale distributor of dangerous drugs.

(5) The person to whom the wholesale distributor of dangerous drugs license has been issued and the responsible person are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of dangerous drugs.

(6) The board of pharmacy shall issue a resolution providing the credential types or qualifications required for the responsible person of each classification of wholesale distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for that classification type. The resolution shall be updated as necessary and available on the board's web site,www.pharmacy.ohio.gov.

(7) Unless otherwise approved by the Board, no responsible person for locations licensed as a wholesale distributor of dangerous drugs shall:

(a) Have ever been denied a license by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(b) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the person's

inappropriate prescribing, dispensing, personally furnishing, diverting, administering, supplying, or selling a controlled substance or other dangerous drug.

(c) Have been the subject of disciplinary action by any licensing entity.

(d) Have been convicted of any of the following:

(i) a felony;

(ii) a misdemeanor related to, or committed in, the distribution of dangerous drugs; or

(iii) a crime of moral turpitude.

(E) Written requests for being a responsible person at more than one location pursuant to paragraphs (A), (B) and (D) of this rule must be submitted to the state board of pharmacy in a manner prescribed by the board. The executive director or designee shall have the authority to temporarily approve or deny a request for being a responsible person at more than one location for a period not to exceed 60 days. The full Board will review requests the executive director or designee has temporarily approved at the next scheduled Board meeting. A terminal or wholesale distributor of dangerous drugs whose request has been denied either by the executive director, the executive director's designee or the board will be provided with a written explanation of denial and allowed one opportunity to resubmit its request to address the identified concerns. If the Board approves a request for being a responsible person at more than one location, the request will be good for a period of up to one year, unless otherwise indicated by the board.

4729-5-26 Partial dispensing of schedule II controlled substances.

(A) A valid prescription for a schedule II controlled substance may be partially dispensed if all of the following apply:

(1) For a terminally ill patient or a patient residing in a long term care facility, in accordance with 21 C.F.R. 1306.13, the following must be observed:

(a) Prior to a partial dispensing of a schedule II controlled substance, the pharmacist must confirm that the patient is "terminally ill" or a patient residing in a "long term care facility" and note this on the prescription;

(b) The total quantity dispensed in all partial dispensing shall not exceed the total quantity prescribed; and

(c) The remaining portions of a partially dispensed schedule II controlled substance prescription shall be filled not later than sixty days after the date on which the prescription is written.

(2) For a patient who is not terminally ill or residing in a long term care facility, the following must be observed:

(a) The partial dispensing shall be requested by the patient or the prescriber that issued the prescription;

(b) The total quantity dispensed in all partial dispensing shall not exceed the total quantity prescribed; and

(c) The remaining portions of a partially dispensed schedule II controlled substance prescription shall be filled not later than thirty days after the date on which the prescription is written.

~~At the time of partial dispensing of a schedule II controlled substance prescription for a "terminally ill" patient or a patient residing in a "long term care facility", in accordance with 21 C.F.R.1306.13, the following must be observed:~~

~~(A) Prior to a partial dispensing of a schedule II controlled substance, the pharmacist must confirm that the patient is "terminally ill" or a patient residing in a "long term care facility" and note this on the prescription.~~

(C) The partial dispensing of a schedule II prescription can only occur at the pharmacy where the original prescription is on file.

(D) At the time of partial dispensing of a schedule II controlled substance, the following must be noted on the back of the original prescription or within an alternate record keeping system pursuant to rule 4729-5-27 of the Administrative Code: the date dispensed, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of this partial dispensing if different, and the manual initials of the dispensing pharmacist.

(E) If an alternate record keeping system is being used and the system will not permit refills of schedule II controlled substances, a new prescription number for the partial dispensing must be assigned.

(1) A notation must also be made in the database that identifies this new prescription number as a partial dispensing and provides the serial number of the original prescription.

(2) A prescription bearing the new serial number must be placed in the schedule II file. The prescription for each partial filling must also show the serial number of the original prescription.

~~(F) The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.~~

~~(G) All partial dispensings of schedule II controlled substances must occur within sixty days from the date of issuance of the prescription by the prescriber.~~