



Rules Update – February & March 2017

The following rule changes will take effect in February & March 2017:

4729-5-05 (Amend) – Requires pharmacists to report change of name, address or employer within 30 days of the change. Incorporates text from rule 4729-5-06, which is rescinded.

Effective 3/1/2017

4729-5-11 (Amend) – Prohibits persons who have been subject to certain disciplinary actions or criminal convictions from serving as the responsible person on a TDDD or WDDD license, without prior approval from the Board. **Effective 2/17/2017**

4729-5-20 (Amend) – Makes minor updates to the rule on drug utilization review.

Effective 3/1/2017

4729-5-26 (Rescind) – Partial dispensing of schedule II controlled substances rule. Text of this rule is incorporated into the new version of the rule. **Effective 3/1/2017**

4729-5-26 (New) – New partial dispensing of schedule II controlled substances rule that also permits partial fills for patients who are not terminally ill or residing in a long-term care facility.

Effective 3/1/2017

4729-5-29 (Amend) – Permits an agent of any Ohio prescriber regulatory board to have access to patient records (or copy of patient records) when conducting an investigation of a prescriber. **Effective 3/1/2017**

4729-9-09 (New) – Permits inspections of licensed entities and those who submit application for licensure. Provides a licensee or applicant 30 days for to submit notice of corrective action.

Effective 2/17/2017

4729-9-12 (Amend) – Permits the use of the e-licensing system to confirm licensure prior to purchase or sale of a dangerous drug. Clarifies intracompany sales are not wholesale sales. Requires confirmation of licensure before the sale of dangerous drugs between wholesalers.

Effective 3/1/2017



4729-9-17 (Amend) – Updates the requirements for the storage and disposal of adulterated drugs. **Effective 3/1/2017**

4729-9-26 (Amend) – Clarifies the process for conducting criminal records checks for employees of pain management clinics. **Effective 3/1/2017**

4729-27-01 (New) – Consolidates Chapter 4729-27 (Peritoneal Dialysis Solutions) into a single rule. Rescinds the remainder of the Chapter. **Effective 3/1/2017**

4729-33-03 (Amend) – Requires EMS organizations to comply with the new [controlled substance disposal rule](#) (4729-9-06) and [drug theft or significant loss rule](#) (4729-9-15). **Effective 2/17/2017**

A copy of the amended rules is included in this document.

4729-5-05

**Change of name of registrant Pharmacist and pharmacy intern
change of name, address or employment.**

(A) A pharmacist or pharmacy intern, who has a legal change of name, shall ~~report~~ notify 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; or
- (3) A certified copy of a marriage certificate.

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

- (1) The certificate of registration and/or ~~identification card~~ license issued in the original name; and
- (2) The required fee.

~~Upon receipt of the required documents, the board will forward the duplicate certificate of registration and/or identification card issued in the new name.~~

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

(D) A pharmacist or 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) A pharmacist or pharmacy intern who changes their 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.

Effective:

Five Year Review (FYR) Dates: 11/29/2016

Certification

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26
Rule Amplifies: 4729.12
Prior Effective Dates: 9/10/76, 3/21/88, 7/1/93, 11/22/2001

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, the 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~~ governing 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 been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
 - (i) A disciplinary action that resulted in the suspension or revocation of the pharmacist's license or registration; or
 - (ii) A disciplinary action that was based, in whole or in part, on the pharmacist's inappropriate prescribing, dispensing, diverting, administering, storing, compounding, supplying or selling a controlled substance or other dangerous drug.
 - (c) Have been convicted of any of the following:
 - (i) a felony;
 - (ii) a misdemeanor related to, or committed in, the practice of pharmacy;

(iii) an act of moral turpitude; or

(iv) a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(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 adequate supervision.
- (2) All employees of the facility, including the responsible person, shall submit to a criminal records check in accordance with section 4776.02 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.~~
 - (b) Have been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
 - (i) A disciplinary action that resulted in the suspension or revocation of the physician's license or registration; or
 - (ii) A disciplinary action that was based, in whole or in part, on the physician's inappropriate prescribing, personally furnishing, diverting, administering, storing, compounding, supplying or

selling a controlled substance or other dangerous drug.

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

(i) a felony;

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

(iii) an act of moral turpitude; or

(iv) a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

- (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~~ governing 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~~ section 1304.11 of the Code of Federal Regulations (9/9/2014) 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~~ location licensed as ~~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~~ governing 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, the 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 dangerous drugs.
- (7) The board of pharmacy shall issue a resolution providing the credential types required for the responsible person of each classification/business type of terminal distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for that classification/business type. The resolution shall be updated as necessary and available on the ~~board's~~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 been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
- (i) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or
- (ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.
- (c) Have been convicted of any of the following:
- (i) a felony;
- (ii) a misdemeanor related to, or committed in, the person's professional practice;
- (iii) an act of moral turpitude; or

(iv) a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(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 (9/19/2015/2014) ~~shall~~ and rule 4729-9-14 of the Administrative Code, 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~~ location licensed as 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~~ governing 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/business type of wholesale distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for that classification/business type. The resolution shall be updated as necessary and available on the ~~board's~~ 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 been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

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

(i) a felony;

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

(iii) an act of moral turpitude; or

(iv) a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(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 sixty 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.

Effective:

Five Year Review (FYR) Dates: 09/01/2021

Certification

Date

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1/1/09, 04/01/2015, 9/1/2016

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; and
 - (9) Food-nutritional supplements-drug interactions.
- (B) Upon ~~recognizing~~ identifying any issue listed in paragraph (A) of this rule ~~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; and
 - (3) United States ~~pharmacopoeia~~ pharmacopoeia 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~~three 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 an OARRS 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 a 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.

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10/27/11, 2/1/2016

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 (03/31/2010), 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 dispensings 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 dispensings 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.

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

(C) 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 or other form of positive identification of the dispensing pharmacist.

(D) 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.

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Rule Amplifies: 3719.05, 3719.07, 3719.13, 3719.27

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 or registration of a health professional authorized to prescribe drugs as defined in section 4729.01 when enforcing that agency's chapter of the Revised Code.
 - ~~(5) An agent of 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, upon request, 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.

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4/27/07, 1/1/09, 11/22/2011

4729-9-09

Inspections and Corrective Actions.

(A) Pursuant to section 3719.13, an entity licensed or registered by the state board of pharmacy is subject to an on-site inspection by the board. An authorized board agent may, without notice, carry out an on-site inspection or investigation of an entity licensed or registered by the board. Upon verification of the board agent's credentials, the agent shall be permitted to enter the licensed or registered entity.

(B) Submission of an application for a license or registration with the state board of pharmacy 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, registration or application. The licensee, registrant 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, registrant or applicant shall submit to the board within thirty days, in a manner prescribed by the board, either of the following:

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

(2) An explanation disputing the observed violations.

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Rule Amplifies: 4729.25, 3719.18, 3719.13

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 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 the wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code or the terminal distributor license number for occasional wholesale sales conducted in accordance with rule 4729-9-10 of the Administrative Code.

(1) 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.

(2) 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~~ accordance with paragraph (C) (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.

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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, personally furnishing, compounding 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) ~~Drugs~~ 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) ~~Drugs~~ 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.~~

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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 as described in 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.

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. BCI&I shall send the results of the BCI&I criminal records check directly to the employer or potential employer. BCI&I shall provide a letter regarding the FBI criminal records check to the employer or potential employer stating that there is either no record of any conviction or a letter stating that the request may not meet the criteria. When an employer or potential employer receives a letter stating that the request may not meet the criteria, they may share this information with the employee or potential employee. In order to complete the criminal records check, the employee or potential employee must then complete a "Request for Release-FBI Rapsheet" and send it to BCI&I to request a copy of the FBI criminal record results be sent directly to the employee or potential employee. The employee or potential employee must provide the results to the employer or potential employer. The employee or potential employee must provide the results to the employer or potential employer in the original sealed envelope received from BCI&I. The criminal records check shall be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "WebCheck" provider agency located in Ohio. The employer may accept the results of a criminal records check based on ink impressions from a "WebCheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

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4729-27-01

Peritoneal Dialysis Solutions.

- (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 or III 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, 4729-9-12 and 4729-9-17 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 authorized 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 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.

Replaces:

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4729-27-05

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1/17/97, 11/22/2011

4729-33-03

Security and storage of dangerous drugs.

- (A) ~~Overall~~ Pursuant to rule 4729-5-11, the 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, ~~Tampertamper~~-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, emergency medical technicians-intermediate (advanced emergency medical technicians), registered nurses, physicians, and pharmacists who are associated with ~~that~~ the 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 emergency medical technicians-intermediate (advanced emergency medical technician) as defined in Chapter ~~4765-16~~ 4765.01 of the ~~Administrative~~ Revised 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~~ shall 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 emergency medical technicians-intermediate (advanced emergency medical technician), as defined in Chapter ~~4765-16~~4765.01 of the Administrative Revised Code, level of training.
- (K) Any theft or significant loss ~~or theft~~ of dangerous drugs ~~must~~ shall be reported in accordance with rule 4729-9-15 of the Administrative Code. ~~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~~ a vehicle or storage ~~cabinets~~ cabinet 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.

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