# OHIO STATE BOARD OF PHARMACY

**77 South High Street, Room 1702; Columbus, OH 43215-6126**

-Equal Opportunity Employer and Service Provider-

*TEL:* **614-466-4143** *E-MAIL:* **exec@bop.ohio.gov** *FAX:* **614-752-4836**

*TTY/TDD:* Use the Ohio Relay Service: 1-800-750-0750 *URL:* http://www.pharmacy.ohio.gov


## Rule Changes Effective May 22, 2014

The following rule changes will take effect on May 22, 2014:

- 4729-3-03: Removes the requirement that a pharmacy intern submit an original transcript when applying for a license.

- 4729-5-01: Permits the use of protocols for administration of vitamin K for prevention of Vitamin K deficient bleeding in newborns and administration of erythromycin for the prevention of ophthalmia neonatorum. The rule also removes the specific requirement that a thumbprint reader must be used to provide positive identification. Instead, the rule allows for a number of different biometric identification methods.

- 4729-5-38: Removes the requirement that an individual obtain a prescription prior to the administration of the zoster (shingles) vaccine by a pharmacist. This rule would still require that all pharmacists ensure that the patient meets the age criteria specified by the F.D.A. (50+) approved labeling for the vaccine and that the pharmacist has met the training required by 4729-5-36. More information about this rule can be accessed here: http://pharmacy.ohio.gov/Documents/LawsRules/RuleChanges/Guidance%20Document%20for%20Pharmacist%20Administration%20of%20Zostavax%20(Herpes%20Zoster%20Vaccine).pdf

- 4729-5-15: Corrects a reference to the Ohio Revised Code that authorizes prescribers to write prescriptions.

- 4729-5-17: Amends the section to correspond with recent changes to Ohio Revised Code 4729.291 that limits personally furnishing controlled substances to a seventy-two hour supply and, in any thirty-day period, personally furnishing quantities supplied to all patients not to exceed two thousand five hundred dosage units. More information about this rule can be accessed here: http://www.pharmacy.ohio.gov/Documents/Pubs/Special/Regulatory%20Policy%20Statement%20-%204729-5-17%20-%20Personally%20Furnishing%20Controlled%20Substances.pdf

- 4729-5-21: Removes the requirement that pharmacies file prescriptions serially in sequential order. Prescriptions must still be printed out and filed according to rule 4729-5-09 of the Administrative Code. (i.e. Prescriptions may be filed by date, or in another readily retrievable manner, not only by numeric order or something to that gist).

- 4729-5-24: Amends this section to allow the board of pharmacy the ability to approve the transfer of a copy of a prescription that does not meet the requirements provided in this section of rule.
- 4729-7-02: Changes the submission date for pharmacist continuing education requirements from March 1st to September 15th.
- 4729-7-03: Removes the requirement that a pharmacist submit original continuing education documentation.
- 4729-9-02: Removes the requirement that all pharmacies possess a paper copy of the references necessary to conduct the practice of pharmacy. The regulation would require the pharmacy to either have a paper copy or ensure access to the appropriate references via electronic means.
- 4729-10-01: Makes a technical correction to correspond with an updated section of the Ohio Revised Code.
- 4729-15-05: Corrects a spelling error in a section of code that prohibits certain activities when working with radiopharmaceuticals.
- 4729-29-07: Removes the requirement that long-term-care facilities submit consult agreements to the Board of Pharmacy prior to implementation. ORC 4729.39 authorizes a pharmacist practicing under a consult agreement with a physician to manage an individual's drug therapy under specified conditions.
- 4729-31-04: Updates the rule to reflect current technology by removing references to outdated equipment.
- 4729-33-03: Updates the rule for the storage of dangerous drugs by an emergency medical service organization to reflect changes in terminology adopted by the Ohio Department of Public Safety regarding advanced emergency medical technicians (formally known as emergency medical technician-intermediate).
- 4729-37-02: Removes redundant language requiring the reporting of carisoprodol to the Ohio Automated Rx Reporting System (OARRS), as it has recently been classified by the DEA as a schedule IV controlled substance.
- 4729-37-04: Requires pharmacies to report Pharmacy National Provider Information number and Prescriber's National Provider Identification number to OARRS. The National Provider Identification number is a standard number that all prescribers and pharmacies will have.
- 4729-37-07: Requires daily reporting of controlled substances and tramadol dispensed by pharmacies and prescribers to the Ohio Automated Rx Reporting System (OARRS).
- 4729-37-11: Removes the requirement that correction to the OARRS system be made in writing and allows for electronic corrections to the system.

For any questions regarding these changes or any additional administrative rules, please contact the Ohio State Board of Pharmacy at 614-466-4143.

4729-3-03 **Application for registration as a pharmacy intern.**

(A) Every person desiring to register as a pharmacy intern for the purpose of obtaining the practical experience required for examination and registration as a pharmacist shall submit the following to the state board of pharmacy:

(1) A completed application form (form #0100 version 09/12) as provided by the board, which can be accessed by visiting http://www.pharmacy.ohio.gov;

(2) A head and shoulders photograph taken within the previous six months;

(3) Fee;

(4) ~~An original transcript certifying~~Documentation, as determined by the state board of pharmacy, that the applicant has in fact successfully completed a minimum of sixty semester or ninety quarter hours of college work; and

(5) A certificate of enrollment from a school of pharmacy certifying that the person is enrolled in a school of pharmacy and has begun taking professional classes directly related to the practice of pharmacy; or

(6) All items listed in paragraphs (A)(1) to (A)(3) of this rule and:

(a) Certification of having obtained a first professional degree in pharmacy from a program that has been recognized and approved by the state board of pharmacy; or

(b) Certification of having established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the "Test of Spoken English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729-5-34 of the Administrative Code.

(B) The state board of pharmacy may register an applicant as a pharmacy intern as soon as the state board of pharmacy receives all the required items set forth in paragraphs (A)(1) to (A)(5) or paragraph (A)(6) of this rule.

(C) The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny the issuance of a certificate of registration or an identification card to practice as a pharmacy intern.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26
Rule Amplifies: 4729.08 , 4729.11 , 4729.12, 4729.15
Prior Effective Dates: 9/10/76, 8/1/84, 9/1/85, 7/1/91, 7/1/92, 7/1/94, 1/17/97, 2/1/02, 2/1/03, 2/1/05, 4/27/07, 1/1/11

4729-5-01 **Definitions.**

As used in Chapter 4729. of the Revised Code:

(A) "Practice of pharmacy" is as defined in division (B) of section 4729.01 of the Revised Code.

(B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular patient will be deemed to have occurred when the pharmacist has given final approval to the patient specific prescription in the system.

(C) The term "compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.

(D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a prescriber for a patient.

(E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.

(F) "To participate with prescribers in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the prescriber(s) involved.

(G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code.

(H) "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, a prescription transmitted by use of a facsimile machine, or a prescription transmitted by a board approved electronic prescription transmission system, each of which is pursuant to rule 4729-5-30 of the Administrative Code.

(I) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional activities.

(J) "Preprinted order" is defined as a patient specific, definitive set of drug treatment

directives to be administered to an individual patient who has been examined by a prescriber and for whom the prescriber has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional facility as defined in Chapter 4729-17 of the Administrative Code.

(K) "Standing order" will mean the same as the term "protocol".

(L) "Protocol" is defined as:

(1) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a prescriber are not immediately available; or

(2) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases; or

(3) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed healthcare professionals when administering vitamin K for prevention of vitamin K deficient bleeding in newborns; or

(4) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed healthcare professionals when administering erythromycin for prevention of ophthalmia neonatorum; or

~~(3)~~(5) A definitive set of written treatment guidelines that include patient specific and dose specific orders for the administration of a specific drug that have been authorized by a prescriber to be used when the services of that prescriber are not immediately available. The state board of pharmacy must approve the treatment guidelines prior to implementation. ~~A list of the board~~

~~approved drugs used in the treatment guidelines shall be displayed on the pharmacy board web site (www.pharmacy.ohio.gov).~~ To be considered for approval by the board, the treatment guidelines must meet the following requirements:

(a) The drugs shall only be administered by an individual authorized by law to administer the drugs that are listed in the treatment guidelines.

(b) A prescriber must complete an assessment and make a diagnosis prior to ordering a set of treatment guidelines.

(c) The treatment guidelines:

(i) Can only be initiated upon the order of a prescriber, and the prescriber, utilizing positive identification, must create an order in the patient record to acknowledge and document an adjustment made pursuant to the treatment guidelines before another dose or frequency adjustment can be made;

(ii) Shall only apply to adjusting the dose or frequency of the administration of a specific drug that has been previously ordered by a prescriber;

(iii) Apply only to those drugs that may require calculations for specific dose and frequency adjustments which shall be based on objective measures;

(iv) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;

(v) Do not apply to those drugs for which a dosage change selected within the usual normal dose range could cause detrimental adverse effects;

(vi) Can be performed without requiring the exercise of medical judgment;

(vii) Will lead to results that are reasonably predictable and safe;

(viii) Can be performed safely without repeated medical assessments;

(ix) If performed improperly, would not present a danger of immediate and serious harm to the patient.

A protocol may be used only by individuals authorized by law to administer the drugs and to perform the procedures included in the protocol.

Protocols submitted for approval by the state board of pharmacy may be reviewed with the appropriate health care related board prior to any approval by the state board of pharmacy.

(M) "Prescriber" means any person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.

(N) "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug.

(1) A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A ~~thumbprint reader or other~~ biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

(O) "Originating pharmacy", as it relates to central fill pharmacies, means the pharmacy that received the original prescription.

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

(Q) "OARRS report" means a report of information related to a specific person generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(R) "Reported drugs" means all the drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26
Rule Amplifies: 4729.01 , 4729.27 , 4729.28 , 4729.54
Prior Effective Dates: 9/10/76, 5/15/87, 7/1/92, 7/1/93, 9/1/96, 1/17/97, 2/1/98, 3/1/99, 2/1/03, 1/1/04, 2/1/05, 1/1/06, 10/19/07

4729-5-15 **Prescriber.**

(A) For purposes of division (~~Z~~Y) of section 3719.01 and division (I) of section 4729.01 of the Revised Code, the following persons, maintaining current licenses and in good standing, licensed pursuant to Chapters 4715., 4725., 4731., and 4741. of the Revised Code, are authorized by law to write prescriptions for drugs or dangerous drugs in the course of their professional practice:

(1) Chapter 4715. of the Revised Code: dentist.

(2) Chapter 4725. of the Revised Code: optometrist, if that person holds a current "therapeutic pharmaceutical agents certificate" as defined in division (H) of section 4725.01 of the Revised Code.

(3) Chapter 4731. of the Revised Code: doctor of medicine, doctor of osteopathic medicine and surgery, and doctor of podiatry.

(4) Chapter 4741. of the Revised Code: doctor of veterinary medicine.

(B) Those persons pursuing an approved internship, residency, or fellowship program in this state are authorized to write prescriptions only when acting within their scope of employment in the hospital(s) or institution(s). Approved internship and residency programs are those accredited by the "Accreditation Council for Graduate Medical Education (ACGME)" or the "American Osteopathic Association (AOA)". Approved clinical fellowships are those at institutions which have a residency program in the same or a related clinical field which is accredited by the ACGME or the AOA.

(C) A nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for drugs in the course of their professional practice in a state, as defined in division (G) of section 1.59 of the Revised Code, other than Ohio is authorized to write prescriptions in that state for drugs to be dispensed in the state of Ohio.

(D) An advanced practice nurse approved pursuant to section 4723.48 of the Revised Code may prescribe those drugs which have been approved by the committee on prescriptive governance for advanced practice nurses and pursuant to the standard care agreement for that advanced practice nurse.

(E) A physician assistant approved pursuant to section 4730.44 of the Revised Code may prescribe those drugs approved in rule by the medical board and pursuant to the physician supervisory plan for that physician assistant.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3719.28, 4729.26
Rule Amplifies: 3719.01, 3719.04, 3719.05, 3719.06, 3719.07, 4729.01, 4729.51, 4729.55
Prior Effective Dates: 9/10/76, 7/1/84, 7/1/90, 7/1/93, 3/3/95, 2/1/98, 3/1/99, 2/1/03, 2/1/05, 1/1/06

4729-5-17 **Labeling by prescribers who personally furnish dangerous drugs to their patients.**

(A) Whenever a prescriber personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, the prescriber shall affix to the container a label showing:

(1) The name and address of the prescriber.

(2) The name of the patient for whom the drug is intended. If the patient is an animal, the name of the owner and identification of the animal.

(3) Name and strength of the dangerous drug.

(4) Directions for use.

(5) Date furnished.

(B) Whenever a prescriber personally furnishes a dangerous drug, labeled as a sample pursuant to section 3719.81 of the Revised Code and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide, in written format, the following:

(1) Name of the prescriber.

(2) Name of the patient. If the patient is an animal, the name of the owner and identification of the animal.

(3) Directions for use.

(C) For controlled substances, personally furnishing quantities are limited to a seventy-two hour supply and in any thirty day period the personally furnishing quantities supplied to all patients shall not exceed two thousand five hundred dosage units pursuant to section 4729.291 of the Revised Code.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3715.69 , 3719.28 , 4729.26
Rule Amplifies: 3715.64 , 3719.06 , 3719.08 , 3719.81 , 4729.29 , 4729.51, 4729.291
Prior Effective Dates: 06/01/99, 03/31/00

4729-5-21 **Manner of processing a prescription.**

(A) 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. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) A pharmacist when dispensing a prescription must:

(1) Ensure that patient information is profiled pursuant to rule 4729-5-18 of the Administrative Code;

(2) Perform prospective drug utilization review pursuant to rule 4729-5-20 of the Administrative Code;

(3) Ensure that the drug is labeled pursuant to rule 4729-5-16 of the Administrative Code;

(4) Ensure that a patient is given an offer to counsel pursuant to rule 4729-5-22 of the Administrative Code;

(5) Ensure that a prescription is filed pursuant to rule 4729-5-09 of the Administrative Code.

(C) Prescriptions:

(1) A pharmacist may receive a signed hard copy prescription, an oral prescription, a facsimile of a signed prescription, or a prescription sent using a board approved electronic prescription transmission system. The pharmacist shall follow the prescription record keeping processes noted in paragraphs (C), (D), (E), and (F) of this rule for each of these types of prescriptions received unless utilizing an alternate record keeping system pursuant to rule 4729-5-27 of the Administrative Code that has been approved by the board.

(2) When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her positive identification into the computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code. If an

alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, the record of dispensing must also be recorded in the alternate record keeping system.

(3) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or enter such information in an alternate record keeping system or, if approved by the state board of pharmacy, enter his/her positive identification into a computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code.

(D) Oral prescriptions:

(1) The pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, on the original prescription and, if used, on the alternate system of record keeping. The pharmacist is responsible for assuring the validity of the source of the oral prescription.

(2) Upon receiving a prescription from a recording device, the pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

(3) A licensed pharmacy intern may receive telephone prescriptions and remove prescriptions from a recording device if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to perform this function.

(a) The intern shall immediately reduce the prescription to writing, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the oral order.

(b) The supervising pharmacist on duty is responsible for the accuracy of the prescription.

(c) The supervising pharmacist on duty must be immediately available to answer questions or discuss the prescription with the caller.

(E) Facsimile prescriptions:

(1) A facsimile shall only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record including the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile.

(2) The pharmacist must record the prescription in writing pursuant to section 4729.37 of the Revised Code or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(F) Electronic prescriptions:

(1) Electronic prescriptions may be received by a pharmacy if the electronic prescription transmission system has been approved by the state board of pharmacy.

(2) A pharmacy desiring to receive electronic prescriptions directly into its computer system must obtain approval from the state board of pharmacy. The original prescription information received from the prescriber must be saved and a hardcopy prescription must be printed to document the dispensing. The hardcopy prescription must be filed ~~serially~~ in the prescription file pursuant to rule 4729-5-09 of the Administrative Code.

(3) A pharmacy computer system meeting the requirements of 21 C.F.R. 1311 (04/01/13) shall be considered approved by the state board of pharmacy.

(G) A pharmacist may not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription.

(H) The quantity dispensed shall be considered the quantity prescribed unless the quantity dispensed on a:

(1) New prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription. If the quantity dispensed on a new prescription is greater than the quantity prescribed, the pharmacist

shall also record on the original prescription the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(2) Refill prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription or enter the quantity dispensed on an alternate record pursuant to paragraph (F) of rule 4729-5-27 of the Administrative Code. If the quantity dispensed on a refill prescription is greater than the quantity prescribed, the pharmacist shall also record the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(I) Where a prescription is written using a generic name, or where the pharmacist dispenses an equivalent drug product pursuant to the provisions of sections 4729.38 and 4729.381 of the Revised Code, the brand name or drug name and name of the manufacturer or distributor of the drug or the national drug code (NDC) number of the drug dispensed must be recorded on the record of dispensing by the pharmacist.

(J) A pharmacist who modifies a patient's drug therapy pursuant to a consult agreement and is:

(1) Also responsible for the dispensing of the drug to the patient must include on the drug order the name of the physician who originally prescribed the drug, sign the pharmacist's full name, and be in compliance with this rule in the same manner as the prescriber.

(2) Not responsible for the dispensing of the drug to the patient may transmit the order to a pharmacy by acting as an agent of the physician. Such pharmacist must personally transmit the order verbally or by facsimile to another pharmacist and be in compliance with this rule.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28
Rule Amplifies: 4729.28 , 4729.37 , 4729.38 , 4729.381 , 4729.39 , 3719.05
Prior Effective Dates: 2/1/05, 4/27/07, 1/1/10

4729-5-24 **Prescription copy.**

(A) A pharmacist may transfer a copy of a prescription; a pharmacist may refill a copy of a prescription; such actions must be in accordance with the following unless otherwise approved by the state board of pharmacy:

(1) Copies of prescriptions shall be transferred only between pharmacists except as provided in paragraph (G) of this rule; copies of prescriptions for controlled substances pursuant to sections 3719.41, 3719.43, and 3719.44 of the Revised Code shall be communicated directly between two pharmacists and shall be transferred only one time. However, pharmacies electronically sharing a real time, online database may transfer a controlled substance prescription up to the maximum number of refills permitted by law and the prescriber's authorization pursuant to paragraph (A)(4) of this rule.

(2) The copy transferred shall be an exact duplicate of the original prescription except that it shall also include:

(a) Serial prescription number assigned to the prescription;

(b) Name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy transferring the copy;

(c) Date of issuance of the prescription;

(d) Date of original dispensing of the prescription;

(e) Original number of refills;

(f) Date of last refill;

(g) Number of valid refills remaining; and

(h) The full name of the transferring pharmacist.

(3) Copies transferred for nonrefillable prescriptions shall be marked on the face of the prescription or orally noted by the transferring pharmacist "For Information Purposes Only" and are not valid prescriptions for the dispensing of drugs.

(4) The pharmacist transferring a copy of a prescription must:

(a) Cancel the original prescription by writing the word "void" on the face of the prescription in such a way as to avoid destroying any of the original information contained on the prescription;

(b) Record on the reverse side of the original written prescription:

(i) The date of transfer;

(ii) His/her signature; and

(iii) The name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy receiving the prescription and the full name of the pharmacist receiving the prescription.

(c) Except, if an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, copies of prescriptions may be transferred by a pharmacist if the prescription record in the system is invalidated to prevent further dispensing at the original site. The prescription record in the system must contain the date of transfer, full name of pharmacist making transfer, full name of pharmacist receiving the prescription, and the name and address of the pharmacy receiving the copy. Also, original written prescriptions for controlled substances must be canceled as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule.

(5) The pharmacist receiving a copy of a prescription must:

(a) Exercise reasonable diligence to determine validity of the copy;

(b) Reduce an oral prescription to writing by recording all of the information transferred (must include all information required in paragraph (A)(2) of this rule) and write the word "transfer" on the face of the prescription;

(c) Record date of transfer on the face of the prescription.

(B) A prescription copy may be transferred between two pharmacies if the two pharmacies are accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. The computerized systems must satisfy all information requirements of paragraphs (A)(2) and (A)(4)(c) of this rule.

This shall include invalidation of the prescription record in the system to prevent further dispensing at the original site and, if a controlled substance prescription, the canceling of the original written prescription as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule. A system must be in place that will allow only authorized access to these computerized prescription records by a pharmacist and indicate on the prescription record when and by whom such access was made.

(C) A prescription copy may be transferred between two pharmacists by the use of a facsimile machine. This facsimile may be considered to be a copy of a prescription if all information requirements of paragraph (A) of this rule, including invalidation of the original prescription or computer records, are met. A system must be in place that will show on the facsimile positive identification of the transferring and receiving pharmacists which must become a part of the prescription record. Facsimile copies must be recorded in writing pursuant to section 4729.37 of the Revised Code, or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(D) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient. Original copies of prescriptions shall be maintained by pharmacies for the purpose of documenting the dispensing of drugs to a particular patient.

(1) In the event that the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacist shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient.

(2) No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.

(E) Prescriptions entered into a computer system but not dispensed may be transferred to another pharmacy if all of the following conditions are met:

(1) The complete prescription information has been entered into the computer system;

(2) The information is displayed on the patient's profile;

(3) There is positive identification, either in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the

prescription information into the system;

(4) The original prescription is filed in accordance with rule 4729-5-09 of the Administrative Code;

(5) All requirements of this rule are met for the transfer of the prescription.

(F) Transfer of prescription information between two pharmacies which are accessing the same real time, online database pursuant to the operation of a board approved central filling operation shall not be considered a prescription copy and, therefore, is not subject to the requirements of this rule.

(G) A licensed pharmacy intern may send or receive copies of prescriptions pursuant to the following:

(1) The pharmacist on duty who is supervising the activity of the intern will determine if the intern is competent to send or receive a prescription copy.

(2) The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription copy that is sent or received by an intern.

(3) The supervising pharmacist must be immediately available to answer questions or discuss the prescription copy that is sent or received by an intern.

(4) The intern may not send or receive a prescription copy for a controlled substance.

(5) The pharmacist or intern receiving a prescription copy from an intern must document the full names of the sending intern and his/her supervising pharmacist. The receiving intern shall immediately reduce the prescription copy to writing and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the copy.

(6) The pharmacist or intern sending a prescription copy to an intern must document the full names of the receiving intern and his/her supervising pharmacist. There must be documented positive identification of the sending intern and his/her supervising pharmacist who authorized the transfer of the prescription copy.

(7) The approved intern and the supervising pharmacist must meet all the requirements of this rule.

Effective: 05/22/2014

R.C. 119.032 review dates: 01/31/2016

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3719.28 , 4729.26
Rule Amplifies: 3719.05 , 4729.37
Prior Effective Dates: 10/1/1971, 8/1/1984, 7/1/1990, 7/1/1992, 1/17/1997, 7/1/1997, 2/1/1998, 3/1/1999, 3/31/2000, 2/1/2002, 2/1/2003, 2/1/2005, 4/27/2007, 1/1/2010, 1/1/2011

4729-5-38 **Immunization administration.**

In addition to the immunizations and medications listed in section 4729.41 of the Revised Code and pursuant to the requirements noted in section 4729.41 of the Revised Code and rules 4729-5-36 and 4729-5-37 of the Administrative Code, a pharmacist may administer the zoster vaccine according to the following requirements:

~~(A) The pharmacist must receive a patient specific prescription prior to administration of the drug;~~

~~(B) The vaccine must be administered within thirty days of the issuance of the prescription;~~

~~(C)~~(A) The patient must meet the age criteria specified in the F.D.A. approved labeling; and

~~(D)~~(B) The pharmacist must be able to document meeting the training criteria required by rule 4729-5-36.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 4729.41
Rule Amplifies: 4729.41
Prior Effective Dates: 06/21/2009

4729-7-02 **Requirements for renewal of a pharmacist identification card.**

(A) Except as provided in rule 4729-7-08 of the Administrative Code, evidence of six C.E.U.s of approved continuing education shall be submitted to the board no later than September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. ~~by the date indicated on the continuing pharmacy education report form and at intervals.~~ At least 0.3 C.E.U.s of the total required C.E.U.s must be obtained from Ohio state board of pharmacy approved programs in jurisprudence.

~~(B) Documentation of the required C.E.U.s shall be submitted on forms provided by the state board of pharmacy.~~

~~(C)~~(B) The C.E.U.s must be obtained ~~on or after March first of the year that is~~within a period of time that is no more than three years prior to ~~May~~ September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal. A pharmacist shall be subject to further action of the board if the continuing pharmacy education is not submitted to the board by September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal.~~report forms are not filed by the date indicated on the continuing pharmacy education report form, or if the hours submitted are incomplete.~~ If reporting continuing education is required after a pharmacist's license has lapsed or where the license is being renewed after board action, continuing education must be obtained during the three year period immediately preceding the date the renewal application is filed with the board office.

~~(D)~~(C) C.E.U.s obtained in excess of the required C.E.U.s at the time the continuing education is required for identification card renewal, may not be transferred and applied to future requirements.

(D) For the first three C.E.U. reporting years following the adoption of this rule, the board may accept C.E.U.s within a period of time from March first, three years prior to September fifteenth of the year in which evidence of the continuing pharmacy education is required for identification card renewal.

(E) A pharmacist whose identification card has lapsed or has been suspended may renew his/her identification card, if he/she qualifies for renewal pursuant to section 4729.12 or section 4729.13 of the revised Code, by paying the required fee, completing the application for renewal, and, if he/she would have been required to report continuing pharmacy education during the period of lapse or suspension, by providing evidence of having obtained the number of C.E.U.s required at the time of renewal by submitting the certificates of participation obtained during the three-year period immediately preceding the date of applying for renewal.

(F) Ohio-registered pharmacists who hold a current license in states where continuing education is mandatory, have met the continuing pharmacy education requirements of that state, and who do not practice pharmacy in Ohio, may renew their identification card by paying the required fee, completing the application for renewal, and submitting the following signed statement on their continuing pharmacy education report form:

"I declare under penalties of falsification that I hold a current and valid pharmacist license, number (insert license number), in the state of (insert name of state), that I have met the continuing pharmacy education requirements of this state and I do not presently practice pharmacy in the state of Ohio. I hereby agree to immediately notify the Ohio state board of pharmacy if I return and commence the practice of pharmacy in the state of Ohio."

(G) The state board of pharmacy may grant extension periods and waivers for the completion of license renewal and continuing education requirements for active military service members and their spouses. If a current pharmacist or their spouse is called to active duty for military service, the time period allowed for completion of any continuing education requirements will be extended by the amount of time that the pharmacist or the pharmacist’s spouse was on active duty. A pharmacist seeking an extension period or waiver must provide documentation to the board demonstrating active-duty service.

(H) If a pharmacist is a member of the armed forces, reserves, the Ohio national guard, the Ohio military reserve, or the Ohio naval militia, the state board of pharmacy shall consider relevant military education, training or service that has been completed by the license holder when determining the fulfillment of any continuing education requirements.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26
Rule Amplifies: 4729.12 , 4729.13, 4729.15
Prior Effective Dates: 11/20/1972, 09/15/1979, 02/15/1982, 07/01/1984, 09/01/1985, 03/21/1988, 07/01/1994, 02/15/1995, 04/15/1999, 02/01/2002, 01/01/2006, 04/27/2007

4729-7-03 **Evidence of continuing pharmacy education experiences.**

(A) Registered pharmacists shall keep all certificates and other documented evidence of participation which have been issued for approved C.E.U.s for which the pharmacist has claimed continuing education units towards renewal of his/her Ohio registered pharmacist identification card for a period of one year following the year in which evidence was required for renewal.

(B) ~~The original certificates or documents~~Documentation, as determined by the state board of pharmacy, shall be submitted ~~to the state board of pharmacy~~ only when requested by the board.

(C) The board will monitor compliance by auditing a random sample of registrants each reporting period.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26
Rule Amplifies: 4729.12
Prior Effective Dates: 11/20/1972, 09/15/1979, 03/01/1999

4729-9-02 **Minimum standards for a pharmacy.**

(A) Library

(1) All pharmacists working in a pharmacy must be able to access all current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio;

(2) The pharmacy shall ~~carry~~have access to and utilize the references necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws; and

(3) Telephone number of a poison control center.

(B) Equipment

The pharmacy shall carry and utilize the equipment necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws.

(C) Stock of drugs

The stock of drugs shall include such chemicals, drugs, and preparations sufficient to compound and prepare all types of prescriptions offered by the pharmacy.

(D) Prescription containers

The stock of prescription containers shall include such containers as are necessary to dispense drugs in accordance with federal and state laws, including the provisions of the federal Poison Prevention Act of 1970 and compendial standards, or as recommended by the manufacturer or distributor for non-compendial drug products.

(E) Space and fixtures

(1) The stock, library, and equipment shall be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings primarily used for the compounding and preparing of prescriptions and for the manufacture of pharmaceutical preparations.

(2) All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of

the drugs prior to their dispensing as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise indicated by the board.

(3) All storage areas shall provide adequate physical security for all dangerous drugs in accordance with rules 4729-9-05 and 4729-9-11 of the Administrative Code.

(F) Pharmacy hours

Notice to the public of operating hours of the pharmacy department must be posted.

(G) Personnel

The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code. An employee of a pharmacy that may have contact with patients or the general public must be identified by a nametag that includes the employee's job title.

(H) Additional minimum standards are required for specialized pharmacy practices pursuant to Chapters 4729-15, 4729-17, and 4729-19 of the Administrative Code.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26
Rule Amplifies: 4729.54, 4729.55
Prior Effective Dates: 9/10/1976, 9/1/1985, 3/21/1988, 7/1/1990, 7/1/1992, 7/1/1994, 3/1/1999, 1/1/2006

4729-10-01 **Definitions.**

As used in Chapter 4729-10 of the Administrative Code:

(A) "Nonresident pharmacy" means any pharmacy, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into Ohio;

(B) "Nonresident terminal distributor of dangerous drugs" means any person, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers in any manner, dangerous drugs at retail into Ohio;

(C) "Pharmacist," as used in division (B)~~(2)~~ of section 4729.55 of the Revised Code, means an individual who holds a current license to practice pharmacy in the state where he/she is practicing.

(D) "Licensed health professional authorized to prescribe drugs" or "prescriber" as used in division (B) of section 4729.55 of the Revised Code means an individual who is authorized by law to prescribe drugs or dangerous drugs in the state where the individual is practicing.

(E) "Dangerous drug" has the same meaning as given that term in section 4729.01 of the Revised Code.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26
Rule Amplifies: 4729.01
Prior Effective Dates: 8/16/94 (Emer), 12/15/94, 3/1/99

4729-15-05 **Prohibitions.**

(A) No person shall receive, possess, or transfer radiopharmaceuticals except in accordance with section 4729.51 of the Revised Code.

(B) No person, other than a nuclear pharmacist, shall be personally in full and actual charge of a nuclear pharmacy.

(C) No person shall conduct a nuclear pharmacy except in accordance with section 4729.28 of the Revised Code, state board of pharmacy rules, regulations of the United States nuclear regulatory commission or the appropriate state nuclear regulatory agencies, and regulations of other appropriate state agencies.

(D) No person shall utilize ~~resuable~~reusable unit dose transport containers for radioactive dosages without either an effective process to decontaminate the transport container of blood or other biohazardous substances or an effective mechanism to avoid contamination of the transport container.

(E) No person shall re-use a unit dose transport container that remains contaminated with blood or other biohazardous substances. Any unit dose transport container that is returned with the tamper-evident seal broken and the unit dose syringe included must be considered to be contaminated.

(F) This rule does not apply to:

(1) An individual prescriber who prepares radiopharmaceuticals for administration to the prescriber's patients as provided in section 4729.29 of the Revised Code.

(2) The transfer of radioactive material not intended for use as a drug to authorized persons.

(3) The occasional transfer of bulk quantities of radiopharmaceuticals to other authorized persons to meet shortages.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3715.69 , 3719.28 , 4729.26
Rule Amplifies: 3715.63 , 3719.09 , 4729.27 , 4729.28 , 4729.51
Prior Effective Dates: 4/1/1978, 9/1/1989, 7/1/1994, 3/1/1999, 4/27/2007

4729-29-07 **Board review of the institutional policy for consult agreements.**

An institutional policy for consult agreements developed pursuant to division (C) of section 4729.39 of the Revised Code shall be subject to review by the state board of pharmacy as follows:

(A) Upon the request of the state board of pharmacy, a hospital or long-term care facility shall immediately make available its policy for consult agreements. The state board of pharmacy, after review, may approve the policy or return it to the hospital or long-term care facility for revision without approval.

~~(B) Each long-term care facility's policy for consult agreements shall be submitted to the state board of pharmacy for review prior to implementation. The state board of pharmacy shall approve the policy only after the board is satisfied that the policy complies with all appropriate laws and rules. Any subsequent revisions to the policy, after the initial approval, must be submitted to the state board of pharmacy and approved prior to implementation.~~

~~(C)~~(B) If a policy for consult agreements has been returned for revision without approval to a hospital or long-term-care facility by the state board of pharmacy, such policy may not be implemented until it has been approved by the board.

~~(D)~~(C) Policies for consult agreements that are requested by, or that are required to be submitted to, the state board of pharmacy may be reviewed with the state medical board, as appropriate.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.29, 4729.39
Rule Amplifies: 4729.39
Prior Effective Dates: 6/1/2001

4729-31-04 **Recordkeeping.**

In a fluid therapy pharmacy, the responsible pharmacist shall be responsible for maintaining the following records:

(A) A record of all drugs purchased, the quantity received, and the name, address, and wholesale or terminal distributor of dangerous drugs license number of the person from whom the drugs were purchased.

(B) All drug orders and records relating to the practice of pharmacy. Such drug orders and records may be ~~microfilmed or~~ retained by any process providing an exact duplicate of the original order. In addition, if an alternate recordkeeping system is utilized, these records may be stored on any storage medium that meets industry standards for quality and has stability for a period of at least three years. Records on an automated data processing system, or subsequent storage of such records, must be readily retrievable ~~(via CRT display or hard copy printout)~~, within seventy-two hours.

(1) Records of drugs dispensed shall include, but are not limited to:

(a) The name, strength, and quantity of drugs dispensed;

(b) The date of dispensing;

(c) The name of the patient to whom, or for whose use, the drug was dispensed;

(d) Positive identification of all pharmacists involved in each function of the dispensing; and

(e) Disposal record of any unused drug(s).

(2) All other records relating to the practice of pharmacy other than dispensing shall include, but not limited to:

(a) The name of the inpatient to whom, or for whose benefit the activity was performed;

(b) The practice of pharmacy activity performed;

(c) The results of the activity, if applicable; and

(d) Positive identification of all pharmacists involved in each function of the activity.

(C) A record of all drugs compounded which shall include at least the following:

(1) Name of drug, strength, and dosage form;

(2) Quantity of drug(s) added to each container;

(3) Disposition of unused drug(s) and amount;

(4) Manufacturer's or distributor's control number;

(5) Manufacturer's or distributor's name, if a generic drug is used;

(6) Pharmacy control number, if prepared in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(7) Date of compounding;

(8) Manufacturer's or distributor's expiration date;

(9) The pharmacy's expiration date or beyond-use date;

(10) Positive identification of the registered pharmacist responsible for the compounding or repackaging of each drug product.

(D) All records must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber. All records shall be readily retrievable and uniformly maintained in an unalterable and secure manner for at least three years from the date of the last dispensing.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3719.28 , 4729.26
Rule Amplifies: 3719.07 , 4729.37 , 4729.55
Prior Effective Dates: 3/1/1999

4729-37-11 **Corrections to the drug database.**

(A) Drug dispensing and wholesale drug sale information must be submitted to the drug database in an accurate and timely manner pursuant to rule 4729-37-07 of the Administrative Code.

(B) If the ~~ommission~~omission of drug dispensing or wholesale drug sale information is discovered, the omitted information must be submitted to the board of pharmacy by the pharmacy, prescriber, or wholesaler during the next reporting time period after the discovery.

(C) If erroneous drug dispensing or wholesale drug sale information is discovered, the corrected information must be submitted to the board of pharmacy by the pharmacy, prescriber or wholesaler during the next reporting time period after the discovery. ~~If the erroneous information was discovered by the licensee, the licensee must notify the board immediately by telephone of the error and submit written documentation that identifies the erroneous information.~~

(D) If the omission of data or erroneous data is the result of a computer programming error, the pharmacy, prescriber, or wholesaler must notify the board of pharmacy immediately by telephone and submit written documentation. The documentation shall fully describe the error and propose a date for submitting the corrected drug information. The board will review the written documentation to assure compliance with paragraph (A) of this rule.

(E) Except as noted in paragraph (D), all data must be submitted or corrected electronically unless prior permission for an alternate method is approved by the board of pharmacy.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3719.28 , 4729.26 , 4729.83
Rule Amplifies: 4729.75 , 4729.76 , 4729.77 , 4729.78 , 4729.79 , 4729.80 , 4729.81 , 4729.82 , 4729.83 , 4729.84
Prior Effective Dates: 1/1/09

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, ~~emergency medical technician-intermediates~~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 ~~emergency medical technician-intermediate~~advanced emergency medical technician as defined in ~~rules~~ Chapter 4765-16~~-01 and 4765-16-02~~ 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.

(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 technician-intermediate~~advanced emergency medical technician, as defined in ~~rules~~ Chapter 4765-16~~-01 and 4765-16-02~~ of the Administrative Code, level of training.

(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.

Effective: 05/22/2014

R.C. 119.032 review dates: 03/07/2014 and 05/22/2019

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28
Rule Amplifies: 4729.51 , 4729.54 , 4729.55
Prior Effective Dates: 8/15/2000, 1/1/2004

4729-37-02 **List of drugs to be reported.**

Pursuant to section 4729.75 of the Revised Code required information for the following list of drugs must be submitted to the board of pharmacy pursuant to sections 4729.77, ~~and~~ 4729.78 and 4729.79 of the Revised Code:

(A) All schedule II controlled substances;

(B) All schedule III controlled substances;

(C) All schedule IV controlled substances;

(D) All schedule V controlled substances dispensed pursuant to a prescription or personally furnished by a prescriber;

(E) All schedule V controlled substances sold to a prescriber at wholesale;

~~(F) All dangerous drug products containing carisoprodol;~~

~~(G)~~(F) All dangerous drug products containing tramadol.

Effective: 05/22/2014

R.C. 119.032 review dates: 10/01/2015

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3719.28 , 4729.26 , 4729.83
Rule Amplifies: 4729.75 , 4729.76 , 4729.77 , 4729.78 , 4729.79 , 4729.80 , 4729.81 , 4729.82 , 4729.83 , 4729.84
Prior Effective Dates: 1/1/06

4729-37-04 **Information required for submission.**

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

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

(2) Pharmacy name;

(3) Pharmacy address;

(4) Pharmacy telephone number;

(5) Patient full name;

(6) Patient residential address;

(7) Patient telephone number;

(8) Patient date of birth;

(9) Patient gender;

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

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

(12) Date prescription was issued by the prescriber;

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

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

(15) Number of the refill being dispensed;

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

(17) Quantity of drug dispensed;

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

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

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

(21) Pharmacy National Provider Identification (NPI) number; and

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

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

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

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

(3) Prescriber address;

(4) Prescriber telephone number;

(5) Patient full name;

(6) Patient residential address;

(7) Patient telephone number;

(8) Patient date of birth;

(9) Patient gender;

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

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

(12) Quantity of drug dispensed;

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

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

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

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

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

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

(4) Quantity of the drug sold;

(5) Date of sale; and

(6) Transaction identifier or invoice number.

Effective: 05/22/2014

R.C. 119.032 review dates: 12/01/2015

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3719.28 , 4729.26 , 4729.83
Rule Amplifies: 4729.75 , 4729.76 , 4729.77 , 4729.78 , 4729.79 , 4729.80 , 4729.81 , 4729.82 , 4729.83 , 4729.84
Prior Effective Dates: 1/1/06, 4/27/07, 10/19/07, 1/1/11

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

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

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

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

(B) The dispensing report, the personally furnishing information, or the "Zero Report" shall be consecutive and inclusive from the last date and time that information was submitted and shall be reported no later than ~~eight days~~thirty-six hours after the last ~~date~~time reported on a previous report.

(C) Any record of a dispensed or personally furnished reportable drug shall be reported to the board of pharmacy within 24 hours of being dispensed or personally furnished.

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

~~(C)~~(E) If a pharmacy or prescriber ceases to possess for the purpose of dispensing or personally furnishing any reported drug (including a sample drug), the responsible person may notify the board of pharmacy in writing. If the board is notified of the change, the pharmacy or prescriber is not required to submit a "Zero Report" until the pharmacy or prescriber possesses for the purpose of dispensing or personally furnishing a reported drug (including a sample drug).

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

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

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

after the date of the wholesale sale.

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

Effective: 05/22/2014

R.C. 119.032 review dates: 12/01/2015

CERTIFIED ELECTRONICALLY

Certification

05/12/2014

Date

Promulgated Under: 119.03
Statutory Authority: 3719.28 , 4729.26 , 4729.83
Rule Amplifies: 4729.75 , 4729.76 , 4729.77 , 4729.78 , 4729.79 , 4729.80 , 4729.81 , 4729.82 , 4729.83 , 4729.84
Prior Effective Dates: 1/1/06, 10/19/07, 1/1/09, 6/21/09, 1/1/11