

RULES EFFECTIVE IN 1996
[Ohio Administrative Code]

Rule 4729-5-01 Definitions.

[OAC: 10/01/71, 09/10/76, 05/15/87, 07/01/92, 07/01/93, **09/01/96**]
(Amplifies: 4729.02, 4729.26, 4729.27, 4729.28, 4729.54, 4729.66)

As used in Chapter 4729. of the Revised Code:

- (A) To "practice pharmacy" is as defined in division (B) of section 4729.02 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 practitioner and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug.
- (C) "Compound" means the professional judgment of a pharmacist associated with the measuring and mixing of one or more drugs, and also includes the reconstitution of a drug by the measuring and mixing of a diluent, pursuant to a prescription.
- (D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a practitioner 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 practitioners in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the practitioner(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 and, where applicable, has met the continuing pharmacy education requirements in accordance with Chapter 4729-7 of the Administrative Code.
- (H) "Original prescription" means the prescription issued by the practitioner in writing, or an oral prescription recorded in writing by the pharmacist, or a prescription transmitted by use of a facsimile machine, each of which is pursuant to rule 4729-5-30 of the Administrative Code.
- (I) "Personal supervision" means a pharmacist shall be physically present in the pharmacy and provide personal review and approval of all professional pharmaceutical 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 practitioner and for whom the practitioner 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 or health care 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 treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a practitioner as defined in rule 4729-5-15 of the Administrative Code and have been approved by the board of pharmacy to be used by certified or licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a practitioner are not immediately available; or
- (2) A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a practitioner as defined in rule 4729-5-15 of the Administrative Code and have been approved by the board of pharmacy to be used by certified or licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases.

A protocol may be used only by licensed or certified individuals acting within the scope of their license or certification who have been adequately trained in the safe administration and use of the drugs and other procedures included in the protocol.

Protocols submitted for approval by the board of pharmacy may be reviewed with the medical and/or nursing board, as appropriate, prior to any approval by the 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. Such method may include a password access to a mechanical or automated system, but must also include a physical means of identification such as, but not limited to, the following:
- (1) A manual signature on a hard-copy record;
 - (2) A magnetic card reader;
 - (3) A bar code reader;
 - (4) A thumbprint reader or other biometric method; or
 - (5) A daily printout of every transaction that is verified and manually signed within twenty-four hours 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.

Rule 4729-5-13 Prescription format.

[OAC: 07/01/94, **01/10/96**]

(Amplifies 3719.06, 3719.28, 4729.02, 4729.37, 4729.66)

- (A) No pharmacist shall dispense dangerous drugs pursuant to a written outpatient prescription unless the following conditions are met:
- (1) The prescription is issued in compliance with rule 4729-5-30 of the Administrative Code.
 - (2) If preprinted with multiple drug name and strength combinations:
 - (a) There are no controlled substances among the choices;

- (b) There is only one prescription order selected per form.
- (B) No practitioner shall write and no pharmacist shall dispense controlled substances pursuant to a written outpatient prescription unless the following conditions are met:
 - (1) The prescription has been issued in compliance with rule 4729-5-30 of the Administrative Code.
 - (2) The prescription contains only one prescription order per prescription form, whether handwritten or preprinted.
 - (3) The quantity has been written both numerically and alphabetically.
 - (4) If preprinted, there is only one drug and strength combination printed on the form.
- (C) A prescription issued by a medical intern, resident, or fellow as defined in paragraph (B) of rule 4729-5-15 of the Administrative Code may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.
- (D) A prescription issued by a staff practitioner of a hospital may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.

Rule 4729-5-30 Manner of issuance of prescription.

[OAC: 04/01/78, 01/01/81, 02/15/82, 07/01/90, 07/01/94, 11/25/94, **09/01/96**]

(Amplifies: 3719.06, 3719.28, 4729.02, 4729.37, 4729.66)

- (A) A prescription, to be effective, must be issued for a legitimate medical purpose by an individual practitioner or advanced practice nurse approved pursuant to section 4723.56 of the Revised Code 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 professional treatment or in legitimate and authorized research 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 provided for violations of the provisions of law.
- (B) All prescriptions shall be dated as of and signed on the day when issued, and shall bear the full name and address of the patient.
- (C) All written prescriptions issued by a practitioner or advanced practice nurse approved pursuant to section 4723.56 of the Revised Code shall bear the full name and address of the prescriber and shall be manually signed by the prescriber in the same manner as he/she would sign a check or legal document.
- (D) An original signed prescription (for other than a schedule II controlled substance except as noted in rules 4729-17-09 and 4729-19-02 of the Administrative Code) may be transmitted as an "other means of communication" to a pharmacist by the use of a facsimile machine only by a practitioner, the practitioner's agent, or an advanced practice nurse approved pursuant to section 4723.56 of the Revised Code. Such 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 positive identification of the practitioner and his/her agent or of the advanced practice nurse, as well as positive identification of the origin of the facsimile. 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. The original signed prescription from which the facsimile is produced shall not be issued to the patient. The original signed prescription must remain with the patient's records at the prescriber's office or the institutional facility where it was issued. A facsimile of a prescription received by a pharmacist in any manner other than transmission directly from the practitioner, the practitioner's agent, or the advanced practice nurse approved pursuant to section 4723.56 of the Revised Code shall not be considered a valid prescription, except as a copy of a prescription pursuant to rule 4729-5-24 of the Administrative Code.

- (E) All prescriptions shall specify the number of times or the period of time for which the prescription may be refilled. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.
- (F) Prescriptions for dangerous drugs may not be dispensed for the first time beyond six months from the date of issuance by a practitioner or an advanced practice nurse approved pursuant to section 4723.56 of the Revised Code.
- (G) Prescriptions for dangerous drugs and controlled substances in schedule V may not be authorized for refill beyond one year from the date of issuance. Prescriptions for controlled substances in schedules III and IV shall be authorized for refill only as permitted by section 3719.05 of the Revised Code. Prescriptions for controlled substances in schedule II may not be refilled.
- (H) A prescription may be refilled only as expressly authorized by the practitioner or the advanced practice nurse approved pursuant to section 4723.56 of the Revised Code, either in writing or orally. If no such authorization is given, the prescription may not be refilled.
- (I) The drug(s) in a compounded prescription or drug product shall be identified by the product trade name or generic name.
- (J) No prescription shall be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice. A "coded prescription" is one which bears letters, numbers, words or symbols, or any other device used in lieu of the name, quantity, strength and directions for its use, other than those normal letters, numbers, words, symbols, or other media recognized by the profession of pharmacy as a means of conveying information by prescription. No symbol, word, or any other device shall be used in lieu of the name of said preparation.
- (K) The agent of a practitioner who transfers a facsimile of an original prescription or transmits an oral prescription or authorization of a refill for a dangerous drug must identify themselves by full name and the pharmacist shall make a record of the practitioner's agent on the original prescription and, if used, on the alternate system of recordkeeping.
- (L) When forms are used that create multiple copies of a prescription issued to a patient by a practitioner or an advanced practice nurse approved pursuant to section 4723.56 of the Revised Code, the original prescription which also bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.
- (M) A pharmacist may accept, without further verification of the prescriber's identity required, a prescription that has been transmitted by means of a board approved automated paperless system. The system shall require positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code as well as the full name of any authorized agent of the prescriber who transmits the prescription.

Rule 4729-5-31 Criteria for licensure by examination.

(Amplifies: 4729.07, 4729.08, 4729.13, 4729.26)

[OAC: 02/15/82, 09/01/85, 03/21/88, 07/01/90, 01/26/93, 03/01/94, **09/01/96**]

- (A) Pursuant to section 4729.07 of the Revised Code:

- (1) The examination shall consist of the "National Association of Boards of Pharmacy Licensure Examination (NABPLEX)" and a jurisprudence examination compiled by the board or the "National Association of Boards of Pharmacy."
- (2) The minimum passing grade for the "National Association of Boards of Pharmacy Licensure Examination (NABPLEX)" is seventy-five. Any candidate failing to attain a grade of seventy-five on the NABPLEX examination will be required to repeat the NABPLEX examination.
- (3) The minimum passing grade for the jurisprudence examination is seventy-five. Any candidate who fails to receive a grade of seventy-five on the jurisprudence examination will be required to repeat the jurisprudence examination.

(B) Pursuant to section 4729.13 of the Revised Code:

- (1) The examination shall consist of the "National Association of Boards of Pharmacy Licensure Examination (NABPLEX)" and a jurisprudence examination compiled by the board or the "National Association of Boards of Pharmacy."
- (2) The minimum passing grades for renewal of the pharmacist's identification card is a seventy-five on each exam.
 - (a) Any candidate for renewal of an identification card who fails to receive a grade of seventy-five on the jurisprudence examination shall make application and remit the fee established by the board for re-examination.
 - (b) Any candidate for renewal of an identification card who fails to receive a grade of seventy-five on the NABPLEX examination shall make application and remit the fee established by the board for re-examination.

(C) Pursuant to section 4729.08 of the Revised Code:

Applicants for examination and registration as a pharmacist who are graduates of schools or colleges of pharmacy located outside the United States and who are using an approved examination to establish equivalency of their education shall:

- (1) Obtain a grade no lower than seventy-five on the "Foreign Pharmacy Graduate Equivalency Examination (FPGEE)"; and
- (2) Show oral proficiency in English by successful completion of the "Test of Spoken English (TSE)" or its equivalent, pursuant to rule 4729-5-34 of the Administrative Code.

Rule 4729-5-34 Successful completion of the "Test of Spoken English".

[OAC: 03/21/88, **01/10/96**]

(Amplifies 4729.08, 4729.26)

Successful completion of the "Test of Spoken English (TSE)," pursuant to rules 4729-3-02, 4729-3-03, 4729-3-04, 4729-5-31, and 4729-5-32 of the Administrative Code, shall be a score of fifty or higher.

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

[OAC: 07/01/91, 03/13/95, **01/10/96**]

(Amplifies 3719.04, 3719.28, 4729.51, 4729.60, 4729.66)

- (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.
- (1) The purchaser shall furnish a copy of the certificate of license as a terminal distributor to the wholesale distributor of dangerous drugs. 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 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 the wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code.
- (1) The seller shall furnish the wholesale distributor registration number and registration expiration date to the terminal distributor of dangerous drugs.
 - (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 practitioner as defined in division (H) of section 4729.02 of the Revised Code, the wholesale distributor must obtain:
- (1) A copy of the current certificate of license as a terminal distributor from the practitioner pursuant to division (A) of section 4729.60 of the Revised Code and, if the license is limited, a copy of the addendum listing the drugs the licensee is authorized to purchase and possess; or
 - (2) Copies of all documents required to establish that the practitioner is exempt from licensure as a terminal distributor of dangerous drugs 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 practitioner doing business as a sole proprietor (not incorporated in any manner) 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;
 - (b) The address of all sites of practice where the drugs will be delivered to and stored for use by the practitioner in his/her professional practice pursuant to federal and state laws;
 - (c) Verification from the licensing board that the practitioner'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 practitioner's exemption from licensure as a terminal distributor of dangerous drugs;

- (d) If an exempted practitioner wishes to purchase and possess dangerous drugs which are also controlled substances, the practitioner 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) If the exempted business entity is a corporation, partnership, limited partnership, or limited liability company, the following documents must be provided to the wholesale distributor of dangerous drugs to validate the business entity's exemption from licensure as a terminal distributor of dangerous drugs and that the incorporators or partners are authorized to use the dangerous drugs requested in their professional practice:
 - (1) Copies of the documents filed with the secretary of state or other government agencies to establish the corporation, partnership, limited partnership, or limited liability company;
 - (2) Copies of the documents required in paragraphs (C)(2)(a) to (C)(2)(d) of this rule for each of the incorporators or partners of the business entity.
- (E) 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 practitioner and filed with the wholesale distributor in paragraph (B) of this rule. Controlled substances may only be shipped to those addresses registered with the federal drug enforcement administration for the purpose of storing controlled substances.
- (F) All documents establishing the fact that a business entity is exempt from licensure as a practitioner shall be current and maintained for a period of three years by the wholesale distributor of dangerous drugs.
- (G) Copies of licenses to practice and verification that there are no restrictions on a practitioner'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 practitioner until the required documentation has been obtained by the wholesale distributor.
- (H) Each wholesale distributor of dangerous drugs registered with the board of pharmacy shall report any suspicious purchases of any dangerous drugs by a practitioner exempted from licensure as a terminal distributor of dangerous drugs. A suspicious purchase includes, but is not limited to, any drugs that the practitioner is not authorized to use in the course of his/her professional practice.

Rule 4729-9-19 Violations as evidence for denial of terminal, wholesale, or manufacturer license.

[OAC: 07/01/91, 01/10/96]

(Amplifies 3719.03, 3719.28, 4729.53, 4729.55, 4729.66)

- (A) The board of pharmacy may consider as evidence of a person not meeting the requirements provided in sections 4729.53 and 4729.55 of the Revised Code, and may deny a person registration as a wholesale distributor of dangerous drugs or licensure as a terminal distributor of dangerous drugs in Ohio if such person:
 - (1) Has been convicted of a felony;
 - (2) Has been convicted of violating any state or federal pharmacy or drug law;
 - (3) Is not of good moral character and habits;

- (4) Is addicted to or abusing liquor or drugs;
 - (5) Has been disciplined by the Ohio state board of pharmacy pursuant to section 4729.16 of the Revised Code; or
 - (6) Has been disciplined by any board of pharmacy.
- (B) When a request for licensure as a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or as a wholesaler or manufacturer of controlled substances is made, the board of pharmacy may consider as evidence of the facility not meeting the requirements for licensure as provided in Chapters 3719. and 4729. of the Revised Code, or may deny issuance of such licensure, if:
- (1) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked by the board to the spouse or other family member;
 - (2) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked by the board to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed.
 - (3) The facility knowingly employs a person who has been denied the right to work in such a facility by the board as part of an official order of the board.

Rule 4729-9-20 Drugs repackaged by a pharmacy.

[OAC: 07/01/91, 01/10/96]

(Amplifies 3719.07, 3719.08, 3719.28, 4729.66)

Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following:

- (A) Name of drug, strength, and dosage form;
- (B) The identification of the repackager by name or by the final six digits of their terminal distributor of dangerous drugs license number;
- (C) Pharmacy control number;
- (D) Pharmacy's expiration date or beyond-use date, which shall be within the proven period of stability of the drug. This expiration or beyond-use date shall be no later than the manufacturer's expiration date of a not previously opened manufacturer's container.

Rule 4729-12-09 Exceptions.

[OAC: 08/24/94, 12/15/94, 01/10/96]

(Amplifies 3719.28, 3719.44, 4729.66)

Pursuant to division (K) of section 3719.44 of the Revised Code, each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is declared to be exempt from classification as a schedule V controlled substance:

- (A) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts.
- (B) "Breathe Easy®" herb tea.

- (C) "Bronkaid® Dual Action" caplets.
- (D) "Hydrosal®" hemorrhoidal ointment.
- (E) "Primatene® Dual Action Formula" tablets.
- (F) "Primatene®" tablets.

Rule 4729-17-01 Definitions; institutional facility.

[OAC: 09/10/76, 09/01/85, 07/01/91, 03/13/95, **01/10/96**]

(Amplifies 3719.01, 3719.28, 4729.02, 4729.26, 4729.55, 4729.66)

As used in Chapter 4729-17 of the Administrative Code:

- (A) "Institutional facility" means a facility whose primary purpose is to provide medical care and treatment to inpatients, including but not limited to:
 - (1) Convalescent homes;
 - (2) Developmental facilities;
 - (3) Hospitals;
 - (4) Long-term care facilities;
 - (5) Nursing homes;
 - (6) Psychiatric facilities;
 - (7) Rehabilitation facilities;
 - (8) Mental retardation facilities.
- (B) "Inpatient" means any person who receives drugs for use while within the institutional facility.
- (C) "Inpatient prescription" means a written or oral order for a drug to be dispensed for use in treating an inpatient.
- (D) "Dispensing of a drug pursuant to an inpatient prescription" means the professional pharmaceutical review required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a practitioner. In the case of a computerized 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 inpatient will be deemed to have occurred when the pharmacist has given final approval to the patient-specific order in the system.
- (E) "Contingency drugs" are those drugs which may be required to meet the therapeutic needs of inpatients when an Ohio registered pharmacist is not available and personally in full and actual charge of the institutional pharmacy.
- (F) "Emergency drugs" are those drugs which are required to meet the immediate therapeutic needs of inpatients in order to sustain life in an emergency crisis.
- (G) "Outpatient" means any person who receives drugs for use outside of the institutional facility.

Rule 4729-17-02 Pharmacist-in-charge of an institutional pharmacy.

[OAC: 09/10/76, 11/01/85, 07/01/90, 07/01/91, **01/10/96**]

(Amplifies 3719.05, 3719.07, 3719.28, 4729.26, 4729.27, 4729.55, 4729.66)

Each institutional pharmacy shall be directed by a pharmacist who holds a current identification card to practice pharmacy in Ohio pursuant to the provisions of section 4729.12 of the Revised Code.

- (A) The institutional pharmacy director or designated pharmacist shall be the pharmacist-in-charge pursuant to section 4729.27 of the Revised Code, the responsible pharmacist pursuant to rule 4729-5-11 of the Administrative Code, and the pharmacist responsible for maintaining supervision and control over the possession and custody of all dangerous drugs acquired by the institutional facility pursuant to division (B) of section 4729.55 of the Revised Code.
- (B) The terminal distributor of dangerous drugs license issued to the institutional facility shall be signed by the pharmacist-in-charge and conspicuously displayed in the pharmacy.
- (C) The pharmacist-in-charge shall:
 - (1) Be responsible for all pharmaceutical activities performed by all institutional pharmacy personnel;
 - (2) Develop, implement, supervise, and coordinate all services provided by the pharmacy;
 - (3) Be responsible for the development of, in conjunction with the appropriate interdisciplinary committees, and assure adherence to policies and procedures for the safe and efficient distribution of drugs in all areas of the institution;
 - (4) Be responsible for the security and control of all drugs within the institution;
 - (5) Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs;
 - (6) Develop and implement written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs. A current copy of the written policies and procedures shall be available for inspection and/or copying by an employee of the board of pharmacy.
- (D) An institutional pharmacy director or designated pharmacist, who ceases to be the pharmacist-in-charge and responsible pharmacist pursuant to section 4729.27 and division (B) of section 4729.55 of the Revised Code, shall:
 - (1) File a written notice to the board of pharmacy by certified mail, return receipt requested, within thirty days. This notice shall include:
 - (a) The name, address, and dangerous drug distributor license number(s) of the institutional pharmacy;
 - (b) His/her name and pharmacist registration identification number; and
 - (c) The date on which he/she was no longer the pharmacist-in-charge.
 - (2) Take a complete inventory, pursuant to federal regulations, of the controlled substances on hand at the pharmacy with the new or acting pharmacist-in-charge at the time he/she ceases to be pharmacist-in-charge.
 - (a) The original copy of the inventory shall be maintained in the pharmacy with all other required controlled substance records;
 - (b) This inventory shall serve as the inventory of controlled substances for which the new or acting pharmacist-in-charge is responsible.

Rule 4729-17-03 Security and control of drugs in an institutional facility.

[OAC: 09/10/76, 09/01/85, 07/01/91, **01/10/96**]

(Amplifies 3719.05, 3719.07, 3719.28, 4729.26, 4729.27, 4729.55, 4729.66)

- (A) In the absence of a registered pharmacist, drugs ordered by a practitioner for patient treatment may be obtained in the following manner:
- (1) Where a registered pharmacist is not present twenty-four hours-a-day, drugs for patient treatment may be made available to health care professionals licensed pursuant to Chapter 4723. (Nursing Practice Act) or 4731. (Medical Practice Act) of the Revised Code and authorized by such chapters to administer drugs in the course of their professional practice by the use of contingency drug supplies pursuant to the provisions of paragraph (A)(2) of this rule. A registered pharmacist shall be available for emergencies when the institutional pharmacy is closed.
 - (2) Contingency drugs shall be used only in the absence of a registered pharmacist, and shall be stored in a locked cabinet(s) or other enclosure(s) constructed and located outside of the institutional pharmacy. The storage area must be sufficiently secure to deny access, without obvious damage, to unauthorized persons. The pharmacist-in-charge shall:
 - (a) Designate those who may obtain access to the drug supply;
 - (b) Determine, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included in the contingency drug supply;
 - (c) Ensure that such drugs are properly labeled and packaged in sufficient quantities to provide drug therapy during the period when the institutional pharmacy is not open;
 - (d) Provide controls adequate to prevent diversion of the drugs, and institute recordkeeping procedures to account adequately for the drugs when used and who obtained the drugs from the drug supply;
 - (e) Provide procedures for the inspection of the contingency drug inventory to assure proper utilization and replacement of the drug supply.
 - (3) For a pharmacy located on the premises of the institutional facility, when a drug is not available from the contingency drug supply and such drug is required to treat the immediate needs of an inpatient or outpatient whose health would otherwise be jeopardized, such drug may be obtained from the institutional pharmacy pursuant to written policies and procedures implemented by the pharmacist-in-charge.
 - (a) The policies and procedures shall:
 - (i) Identify the personnel authorized to access the pharmacy and the conditions under which access may be gained to the pharmacy;
 - (ii) Ensure a minimum of two employees of the institution, one of whom shall be a health care professional licensed pursuant to Chapter 4723. (Nursing Practice Act) or 4731. (Medical Practice Act) of the Revised Code and authorized by such chapter to administer drugs in the course of their professional practice, to accompany each other when accessing the pharmacy;

- (iii) Provide a written record documenting emergency access to the pharmacy. Such record shall include the names and titles of all institutional personnel accessing the pharmacy, date and time of access, the name and quantity of drugs obtained, the name of the patient, and the name of the ordering practitioner.
 - (b) The written record of each access to the institutional pharmacy when it is closed and a pharmacist is not present shall be filed, within twenty-four hours, with the pharmacist-in-charge and maintained in the pharmacy for three years.
- (B) Supplies of dangerous drugs may be maintained in patient care areas according to written policies and procedures developed and implemented by the pharmacist-in-charge. The policies and procedures shall:
 - (1) Provide for a limited quantity of dangerous drugs to be maintained at any one location;
 - (2) Provide for the proper storage and labeling of all such drugs;
 - (3) Provide for storage in a secure area. If dangerous drugs cannot be stored in a secure area, they shall be stored in a container which is sealed with a tamper-evident seal that must be broken to gain access to the drugs;
 - (4) Provide for notification of the pharmacist-in-charge, or designated pharmacist, when the dangerous drug supply has been accessed and/or drugs used;
 - (5) Provide for replacement of the drugs used, and the dangerous drug supply to be re-sealed;
 - (6) Provide for inspection of the dangerous drug supply, on a regular basis, to detect unauthorized use of such drugs and which drugs have exceeded their expiration or beyond-use date;
 - (7) Provide adequate recordkeeping procedures to document the disposition of drugs from the supply.
- (C) Security
 - (1) All areas occupied by an institutional pharmacy shall be capable of being secured by key, or other effective mechanism, so as to prevent access by unauthorized personnel.
 - (2) In the absence of a registered pharmacist, such area shall be secured so as to prevent access by unauthorized personnel.
 - (3) The pharmacist-in-charge shall develop and implement policies and procedures which will prevent the diversion and/or adulteration of drugs.

Rule 4729-17-04 Records; institutional facility pharmacy.

[OAC: 09/01/85, 07/01/91, **01/10/96**]

(Amplifies 3719.07, 3719.28, 4729.26, 4729.37, 4729.55, 4729.66)

The pharmacist-in-charge shall be responsible for maintaining the following records:

- (A) A record of all drugs purchased, the quantity received, and the name, address, and wholesale distributor registration number of the person from whom the drugs were purchased.

- (B) All drug orders and dispensing records for drugs for patients. Such drug orders and dispensing 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 electronic, magnetic, light, laser, or optic media. Any such storage media must meet industry standards for quality and have 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. Records of drugs dispensed shall include, but is not limited to, the name, strength, and quantity of drugs dispensed; the date of dispensing; the name of the inpatient to whom, or for whose use, the drug was dispensed; and positive identification of the dispensing pharmacist. Records of drugs dispensed for outpatients shall be maintained pursuant to rule 4729-5-17 of the Administrative Code.
- (C) A record of all drugs compounded or repackaged for use only within the institution, which shall include at least the following:
- (1) Name of drug, strength, and dosage form;
 - (2) Manufacturer's or distributor's control number;
 - (3) Manufacturer's or distributor's name, if a generic drug is used;
 - (4) Pharmacy control number;
 - (5) Manufacturer's or distributor's expiration date;
 - (6) The pharmacy's expiration date or beyond-use date;
 - (7) Positive identification of the registered pharmacist responsible for the compounding or repackaging of the drug.
- (D) A record of the distribution of dangerous drugs to other areas of the institution for administration or use as described in paragraph (B) of rule 4729-17-03 of the Administrative Code, which shall include at least the following:
- (1) The name, strength, dosage form, and amount of drug distributed;
 - (2) The area receiving the drug;
 - (3) The date distributed;
 - (4) Positive identification of the individual receiving the drug if it is a controlled substance;
 - (5) The area of the institution receiving the dangerous drug shall make a record of all such drugs administered to patients. Such records shall include at least the following:
 - (a) Name of the patient;
 - (b) Name, dosage form, and strength when applicable of the drug;
 - (c) Date and time the drug was administered;
 - (d) Quantity administered;
 - (e) Positive identification of the personnel administering the drug.

- (E) All records shall be maintained for a period of three years in a readily retrievable manner, pursuant to section 4729.37 of the Revised Code.

Rule 4729-17-05 **Definitions; health care facility.**

Rule rescinded effective 01/10/96.

Rule 4729-17-06 **Responsible pharmacist for a health care facility pharmacy and the contingency and emergency drug supply.**

Rule rescinded effective 01/10/96.

Rule 4729-17-07 **Security and control of drugs in a health care facility.**

Rule rescinded effective 01/10/96.

Rule 4729-17-08 **Minimum standards for an institutional facility pharmacy.**

[OAC: 09/10/76, 09/01/85, 07/01/90, **01/10/96**]

(Amplifies 4729.55, 4729.66)

(A) Library

- (1) Current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio;
- (2) The pharmacy shall carry 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 the nearest poison control center.

(B) Drug inventory, fixtures, and space

- (1) The inventory of drugs and equipment shall be commensurate with the scope of pharmacy services provided, and housed in suitable, well-lighted and well-ventilated room(s), in a clean and sanitary area.
- (2) All areas where drugs are stored shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing or administration as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.
- (3) All areas where drugs are stored shall provide adequate physical security to prevent their diversion and/or adulteration.

Rule 4729-17-09 **Drug orders for patients of an institutional facility.**

[OAC: 09/10/76, 09/01/85, 07/01/90, 07/01/91, 11/25/94, **01/10/96**]

(Amplifies 3719.05, 3719.06, 3719.07, 3719.28, 4729.26, 4729.28, 4729.37, 4729.55, 4729.66)

- (A) Drugs shall be dispensed by a pharmacist for inpatients pursuant to an original written order issued by a prescriber, or a direct carbonized copy or a facsimile of such order. Oral orders issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacist by personnel authorized by, and in accordance with, written policies and procedures of

the facility. Such orders shall be recorded by the pharmacist, noting the full name(s) of the authorized personnel transmitting the order. Oral orders issued by a prescriber and transmitted by authorized personnel shall be countersigned by the prescriber within the allotted time required by the written policies and procedures. Drug orders for inpatients of an institutional facility transferred to a pharmacist by use of a facsimile machine shall be transmitted by personnel authorized by, and in accordance with, written policies and procedures of the facility. The pharmacist receiving the facsimile shall have in place written policies and procedures allowing only authorized personnel access to the drug order facsimile. The pharmacist shall maintain the facsimile showing positive identification of the person authorized to transmit the order and the origin of the order as a part of the drug order record. In an institutional facility, this facsimile must be maintained if it is the only record showing the pharmacist responsible for dispensing the drug. Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a paperless automated data processing system may be considered an original order for the dispensing of drugs, only if a prescriber has input the order into the system. Access to such system for inputting original orders shall be restricted to prescribers in accordance with written policies and procedures of the facility. With such a system, the institutional pharmacy director or designated pharmacist shall have in place written policies and procedures allowing only authorized personnel in the pharmacy access to the drug orders.

- (B) All orders for drugs for inpatients shall include, but are not limited to, at least the following:
 - (1) Name of patient;
 - (2) Name, strength, and dosage form of drug;
 - (3) Directions for use, including route of administration if other than oral;
 - (4) Date prescribed; and
 - (5) Prescriber's positive identification.
- (C) Drugs shall be dispensed for outpatients pursuant to an original written order of a prescriber or an order transmitted by a prescriber to a pharmacist. All orders for the dispensing of drugs to outpatients shall, at a minimum, contain all of the items required by rule 4729-5-30 of the Administrative Code, shall be labeled in accordance with rule 4729-5-16 of the Administrative Code, and records maintained in accordance with rule 4729-5-17 of the Administrative Code.
- (D) An original signed prescription for a schedule II controlled substance prepared in accordance with federal and state requirements and issued for a resident in a long term care facility may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be received and maintained as in paragraph (D) of rule 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at either the prescriber's office or the long term care facility.

Rule 4729-17-10 Labeling of prescriptions for patients of an institutional facility.

[OAC: 09/01/85, 07/01/91, **01/10/96**]

(Amplifies 3719.08, 3719.28, 4729.26, 4729.37, 4729.55, 4729.66)

- (A) All dangerous drugs dispensed for use by inpatients in an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:
 - (1) The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include:
 - (a) The non-proprietary or proprietary name of the drug;

- (b) The route of administration, if other than oral;
 - (c) The strength and volume, where appropriate, expressed in the metric system whenever possible;
 - (d) The control number and expiration date;
 - (e) Identification of the manufacturer, packer or distributor, or if the repackager is the dispensing pharmacy identification of the repackager, shall be by name or by the final six digits of their terminal distributor of dangerous drugs license number, and such identification shall be clearly distinguishable from the rest of the label;
 - (f) Special storage conditions, if required.
- (2) When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:
- (a) Identification of the dispensing pharmacy;
 - (b) The patient's name;
 - (c) The date of dispensing;
 - (d) The non-proprietary and/or proprietary name of the drug;
 - (e) The strength, expressed in the metric system whenever possible.
- (3) Multiple drugs may be packaged in the same container such that the different drugs are in contact with each other only under the following conditions:
- (a) The number of drugs placed in one package cannot exceed the capability of the receptacle to prevent damage to the dosage forms.
 - (b) The quantity dispensed may not be more than a thirty-one-day supply.
 - (c) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required by state and federal law including accessory labels.
 - (d) Each individual package must include a beyond-use date of not more than forty-five days from the date the drugs were placed in the package.
 - (e) Medications which have been dispensed in multi-dose packaging may not be returned to stock or redispensed when returned to the pharmacy for any reason.
 - (f) When any one drug within each individual package has been discontinued, all drugs in the individual package are deemed adulterated and they may not be used.
 - (g) The packaging is such that it discloses whether or not it has been opened prior to administration by the patient or caregiver.
 - (h) Any pharmacist/pharmacy using multi-dose packaging must implement policies and procedures which will exclude drugs having the following characteristics from such packaging:

- (i) The U.S.P. monograph or official labeling requires dispensing in the original container;
 - (ii) The drugs or dosage forms are incompatible with packaging components or each other;
 - (iii) The drugs are therapeutically incompatible when administered simultaneously;
 - (iv) The drug products require special packaging.
- (4) At least the name of the patient must be placed on all medication containers too small to bear a complete label and dispensed in a container bearing a complete label.
- (B) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code.
- (C) Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:
- (1) The patient's name;
 - (2) The name and amount of the parenteral solution;
 - (3) The name and amount of the drug(s) added;
 - (4) The expiration date or beyond-use date;
 - (5) The name and address of the institutional facility pharmacy;
 - (6) Cautionary statements, if required.

Rule 4729-17-11 Labeling of prescriptions for outpatients.

[OAC: 09/01/85, 07/01/91, **01/10/96**]

(Amplifies 3719.08, 3719.28, 4729.26, 4729.37, 4729.55, 4729.66)

All drugs dispensed for use by outpatients of an institutional facility shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code except as noted in paragraph (A) of rule 4729-17-10 of the Administrative Code.

Rule 4729-17-12 Records; health care facility pharmacy.

Rule rescinded effective 01/10/96.

(09/09/96)