

RULES EFFECTIVE IN 1997
[Ohio Administrative Code]

Rule 4729-1-02 Notice of meetings.
[OAC: 04/01/78, 04/01/89, 01/17/97]
(Amplifies 121.22)

Any person may determine the time and place of all regularly scheduled meetings and the time, place, and purpose of all special meetings of the state board of pharmacy, as required by division (F) of section 121.22 of the Revised Code, by:

- (A) Written request to the state board of pharmacy.
 - (1) Written requests shall include the name, mailing address, and telephone number of the person making the request.
 - (2) Written requests shall be accompanied by a service fee of twenty-five dollars which shall be valid for the fiscal year of July first through June thirtieth.
 - (3) Notice for the annual renewal of this request will be sent by the board of pharmacy by June first of each year and shall be due no later than July thirty-first of each year.
- (B) Calling the telephone number of the state board of pharmacy between the normal business hours of eight a.m. to four-thirty p.m., Monday through Friday, legal holidays excepted.
- (C) Consulting the official record of all board of pharmacy regularly scheduled and special meetings located at office of the state board of pharmacy.

Rule 4729-3-01 Definitions.
[OAC: 06/01/72, 09/10/76, 03/19/87, 07/01/94, 01/17/97]
(Amplifies 4729.08, 4729.11, 4729.26)

As used in Chapter 4729-3 of the Administrative Code:

- (A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.
- (B) "Supervised practical experience" is the experience obtained at an internship site and which is conducted in accordance with the "National Association of Boards of Pharmacy - American Association of Colleges of Pharmacy" publication "The Internship Experience," or a similar outline and/or manual approved by the board of pharmacy.
- (C) "Internship site" means a pharmacy licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code, except as provided in paragraph (C) or (D) of rule 4729-3-05 of the Administrative Code, and whose license is in good standing.

- (D) "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of the internship program defined as the supervised practical experience.
- (1) A "preceptor" is a pharmacist who holds a current identification card which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship pursuant to rule 4729-3-05 of the Administrative Code.
 - (2) A person may serve as the preceptor for more than one intern. The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty.
 - (3) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship.
- (E) "Director of internship" has the same meaning as provided in section 4729.11 of the Revised Code.
- (F) "In good standing" means that the licensee or registrant has not been denied the privilege of supervising interns by the board.
- (G) "Statement of Preceptor" is the form which must be received by the board of pharmacy for each pharmacy intern within thirty days of beginning internship under a preceptor's supervision.
- (1) No credit will be given for practical experience obtained prior to thirty days of the date that the "Statement of Preceptor" form is received by the board office; except, that in the event of extraordinary circumstances and when due to no fault of the intern, the board may accept a retroactive date of filing for the "Statement of Preceptor."
 - (2) The intern must file a "Statement of Preceptor" form whenever he/she changes internship sites and/or preceptors.
- (H) "Practical experience affidavit" is the form which must be used to submit practical experience for internship credit.
- (1) Practical experience must be itemized to the nearest half hour on the affidavit by the total number of hours obtained each week. The hours reported must be able to be documented by payroll or other records which may be examined by the board of pharmacy upon reasonable notice.
 - (2) Practical experience affidavits must be signed by the preceptor on file with the board of pharmacy. In the event of the unavailability of the preceptor's signature due to extraordinary circumstances and due to no fault of the intern, the board may accept an alternative method for verification of a practical experience affidavit.
 - (3) Practical experience affidavits for a calendar year may be filed at any time, except that they must be received in the board office or postmarked no later than the first day of March of the following year.

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

[OAC: 09/10/76, 08/01/84, 09/01/85, 07/01/91, 07/01/92, 07/01/94, 01/17/97]

(Amplifies 4729.08, 4729.11, 4729.12, 4729.26)

- (A) Every person desiring to register as a pharmacy intern shall submit the following to the state board of pharmacy:

- (1) A completed application form as provided by the board;
 - (2) A three- by four-inch head and shoulders photograph taken within the previous six months;
 - (3) Fee;
 - (4) A transcript certifying that the applicant has in fact successfully completed a minimum of forty-eight semester or seventy-two quarter hours of college work; and
 - (5) A certificate of acceptance into a school or college of pharmacy or a department of pharmacy of a university recognized and approved by the state board of pharmacy.
- or
- (6) All items listed in paragraphs (A)(1) to (A)(3) of this rule and certification of having obtained a first professional degree in pharmacy from a program which has been recognized and approved by the state board of pharmacy; or 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 (TSE)" or its equivalent.
- (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.

Rule 4729-3-04 Pharmacy intern identification card renewal.

[OAC: 09/10/76, 08/01/84, 09/01/85, 07/01/91, 07/01/92, 01/17/97]

(Amplifies 4729.08, 4729.11, 4729.12, 4729.26, 5903.10)

A pharmacy intern may renew his/her identification card each year provided he/she is actively working toward the requirements for licensure as a pharmacist and otherwise meets the requirements and rules of the state board of pharmacy. The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny the issuance of an identification card to practice pharmacy as an intern.

- (A) An intern shall be considered to be actively working towards licensure as a pharmacist if he/she has complied with all of the statutes and rules regarding internship since registration as a pharmacy intern, and:
- (1) He/she is enrolled in a college of pharmacy or is able to provide evidence that he/she has been, or will be, accepted for enrollment or re-enrollment in a college of pharmacy; or
 - (2) He/she is a member of the armed forces and can provide evidence that he/she has been, or will be, accepted for enrollment or re-enrollment in a college of pharmacy upon his/her release from the armed forces; or
 - (3) He/she is able to provide evidence of obtaining a first professional degree in pharmacy from a school or college of pharmacy or a department of pharmacy of a university recognized and approved by the state board of pharmacy; or

- (4) He/she is able to provide evidence of obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and can provide evidence of successful completion of the "Test of Spoken English (TSE)" or its equivalent.
- (B) An intern who has obtained a first professional degree in pharmacy from a school or college of pharmacy or a department of pharmacy of a university recognized and approved by the state board of pharmacy, or who has established equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, may renew his/her license only once. In the event of extraordinary circumstances and when due to no fault of the intern, the board may approve additional renewals.

Rule 4729-3-05 Internship credit.

[OAC: 09/10/76, 02/15/82, 03/19/87, 07/01/90, 07/01/92, 07/01/94, 01/17/97]

(Amplifies 4729.08, 4729.11, 4729.26)

- (A) No internship credit shall be granted by the board for practical experience obtained before registration as an intern or during a period when the intern's registration has lapsed.
- (B) Internship credit may be granted for practical experience obtained when the intern is registered and attending classes in the academic program of a school of pharmacy, other than the structured academic program as provided for in paragraph (C) of this rule.
- (C) Internship credit may be gained for practical experience obtained in a structured program for which academic credit is awarded (e.g., externship, clerkship). Such credit shall be limited to the number of hours for which the structured program has been approved by the state board of pharmacy. Internship credit shall be granted only when the intern obtains a passing grade for the course involved. A school or college of pharmacy which desires to conduct such structured programs eligible for approval shall make a written request on forms provided by the board.
- (D) Up to five hundred hours of internship credit may be obtained at a site other than a pharmacy licensed as a terminal distributor of dangerous drugs (e.g., manufacturing, research, consulting, drug information, and drug utilization review). To receive credit for such experience, a formal request must be submitted to the director of internship for approval prior to beginning the experience in these areas. The request shall include a detailed description of the contemplated internship with respect to time, place, duties, responsibilities, professional supervision, and the person supervising the experience.
- (E) Internship credit may be denied for the practical experience accumulated when an intern is found to be guilty of violation(s) pursuant to section 4729.16 of the Revised Code.
- (F) The pharmacy internship requirement for the licensure examination shall be deemed satisfactorily completed when the intern has filed affidavits certifying that he/she has obtained a total of one thousand five hundred hours of supervised practical experience and such affidavits have been accepted by the board of pharmacy.

Rule 4729-5-01 Definitions.

[OAC: 10/01/71, 09/10/76, 05/15/87, 07/01/92, 07/01/93, 09/01/96, 01/17/97]

(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, an oral or electronically transmitted 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 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.
- (O) "Certified diabetic educator", as used in Chapters 3719. and 4729. of the Revised Code, means a person who has been certified to conduct diabetes education by the "National Certification Board for Diabetes Educators (NCBDE)".

Rule 4729-5-07 Recognized and approved colleges of pharmacy.

[OAC: 09/10/76, 09/01/85, 07/01/92, 01/17/97]

(Amplifies 4729.08, 4729.11, 4729.12, 4729.26)

- (A) To be recognized and approved by the state board of pharmacy, a school or college of pharmacy or a department of pharmacy of a university shall meet the requirements as set forth by the board. The board may utilize the reports, requirements, and recommendations of any recognized accrediting organization or higher education governing board in determining the requirements. The board of pharmacy shall take into consideration, but not be bound by, accreditation standards established by the "American Council on Pharmaceutical Education".
- (B) For the purpose of satisfying the requirements of division (C) of section 4729.08 of the Revised Code, graduates of a school or college of pharmacy or a department of pharmacy of a university located outside the United States shall establish educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and by establishing proficiency in spoken English by obtaining the score required by rule 4729-5-34 of the Administrative Code on the "Test of Spoken English (TSE)".
- (C) The term "United States," as used in paragraph (B) of this rule, shall be deemed to include all states of the United States, the District of Columbia, and all territories and any commonwealths.

Rule 4729-5-17 Recordkeeping.

Rule rescinded effective 01/17/97. (See new rules 4729-5-27, 4729-5-28, and 4729-5-29)

Rule 4729-5-19 Serial numbering of prescriptions.

[OAC: 03/01/92, 01/17/97] (Also see Rule 4729-5-26)

(Amplifies 3719.05, 3719.07, 3719.13, 3719.27, 3719.28, 4729.26, 4729.37, 4729.55, 4729.66)

All outpatient prescriptions dispensed by a pharmacy must be serially numbered.

- (A) This number must appear on the original prescription. If an alternate recordkeeping system is being used pursuant to rules 4729-5-27 and 4729-5-28 of the Administrative Code, the serial number must also appear on the records in this alternate system.
- (B) There must be a complete and consecutive accounting of all numbers used in the serial numbering system.
- (C) All prescriptions which are not refillable, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon authorization by the practitioner to continue the medication, except:
 - (1) The prescribing practitioner may authorize additional refills of a schedule III or IV controlled substance through an oral refill authorization transmitted to a pharmacist, provided the additional refills do not exceed five refills of the original prescription nor does any refill occur beyond six months from the date of issuance of the original prescription; or
 - (2) The prescribing practitioner may authorize additional refills of a schedule V controlled substance or a non-controlled drug through an oral refill authorization transmitted to a pharmacist provided that no refill may occur beyond one year from the date of issuance of the original prescription.
 - (3) All additional refills authorized by the prescribing practitioner shall be marked on the original prescription listing authorizing agent, date, number of refills authorized, and pharmacist receiving the authorization. If an alternative recordkeeping system is used, this information must also be maintained in that system.

Rule 4729-5-24 Prescription copy.

[OAC: 10/01/71, 08/01/84, 07/01/90, 07/01/92, 01/17/97, 07/01/97]

(Amplifies 3719.05, 3719.28, 4729.26, 4729.37)

- (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:
 - (1) Copies of prescriptions shall be transferred only between pharmacists; 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.
 - (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 name of the transferring pharmacist.

(3) Copies transferred for non-refillable 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;
- (b) Record on the reverse side of the original written prescription:
 - (i) Date of transfer;
 - (ii) His/her signature; and
 - (iii) When transferring an oral prescription, the name and address (and "D.E.A." number for controlled substance prescriptions) and name of the pharmacist at the receiving pharmacy.
- (c) Except, if an automated data processing system is being used as an alternate system of recordkeeping for prescriptions pursuant to rules 4729-5-27 and 4729-5-28 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, name of pharmacist making transfer, and the name and address of the pharmacy receiving the copy. Also, original written prescriptions for controlled substances must be cancelled 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 cancelling 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.

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

[OAC: 03/01/92, 01/17/97] (Replaces: Part of Rule 4729-5-19)
(Amplifies 3719.05, 3719.07, 3719.13, 3719.27, 3719.28)

At the time of partial dispensing of a schedule II controlled substance prescription for a "terminally ill" patient or a patient residing in a "long term care facility", in accordance with section 1306.13 of the Code of Federal Regulations, the following must be observed:

- (A) Prior to a partial dispensing of a schedule II controlled substance, the pharmacist must confirm that the patient is "terminally ill" or a patient residing in a "long term care facility" and note this on the prescription.
- (B) The partial dispensing of a schedule II prescription can only occur at the pharmacy where the original prescription is on file.
- (C) At the time of partial dispensing of a schedule II controlled substance, the following must be noted on the back of the original prescription: the date dispensed, quantity dispensed, remaining quantity authorized to be dispensed, prescription number of this partial dispensing if different, and the manual initials of the dispensing pharmacist.
- (D) If an alternate recordkeeping system utilizing an automated data processing system is used and the automated data processing system will not permit refills of schedule II controlled substances, a new prescription number for the partial dispensing must be assigned.
 - (1) A notation must also be made in the database that identifies this new prescription number as a partial dispensing and provides the serial number of the original prescription.

- (2) A prescription bearing the new serial number must be placed in the schedule II file. The prescription for each partial filling must also show the serial number of the original prescription.
- (E) The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed.
- (F) All partial dispensings of schedule II controlled substances must occur within sixty days from the date of issuance of the prescription by the practitioner.

Rule 4729-5-27 Recordkeeping.

[OAC: 10/01/71, 09/10/76, 04/01/78, 07/01/84, 03/19/87, 09/01/89, 07/01/93, **01/17/97**]

(Replaces: Part of Rule 4729-5-17)

(Amplifies 3719.05, 3719.07, 3719.13, 3719.27, 3719.28, 4729.26, 4729.27, 4729.37)

The following recordkeeping requirements do not apply to drugs dispensed pursuant to an inpatient prescription as defined in rule 4729-17-01 of the Administrative Code.

- (A) 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 board, enter his/her positive identification into the computerized recordkeeping system as required in rule 4729-5-28 of the Administrative Code. If an alternate recordkeeping system is being used pursuant to this rule, the record of dispensing the original prescription must also be recorded in the recordkeeping system.
- (B) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, he/she must record the date of such dispensing and manually record his/her name or initials on the original prescription or enter such information on an alternate record meeting the requirements of this rule. If an alternate recordkeeping system is being used pursuant to this rule, this alternate record must be used to record the dispensing of all prescriptions.
- (C) 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.
- (D) Records of dispensing drugs must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber. All recordkeeping systems shall provide records which are readily retrievable and uniformly maintained for a period of three years from the date of the last dispensing.
- (E) If an alternate recordkeeping system is being used pursuant to this rule, such record shall include at a minimum the following data:
 - (1) The serial number assigned to and recorded on the original prescription preserved on file at the pharmacy in accordance with section 4729.37 of the Revised Code.
 - (2) Name, strength, and dosage form of the drug dispensed.
 - (3) Date of dispensing (filling or refilling).

- (4) Quantity dispensed. If the quantity dispensed is greater than that prescribed, the pharmacist must record the date and time that he/she contacted the prescriber and obtained approval.
- (5) The positive identification of the dispensing pharmacist. If the pharmacist merely initials and dates the record of dispensing, he/she shall be deemed to have dispensed the quantity prescribed on the original prescription. Only the pharmacist responsible for filling or refilling the prescription or medication order shall make this record.
- (F) All records of dispensing drugs shall be readily available, and promptly produced, upon request for inspection by a board of pharmacy officer, agent, and/or inspector during regular business hours.
- (G) All prescriptions or other records of dispensing, which are required to be kept for three years according to section 4729.37 of the Revised Code, may be microfilmed or placed on electronic, magnetic media. The microfilm or electronic, magnetic media used for this purpose must comply with the "International Standards Organization" standards of quality approved for permanent records. Such records are subject to all other paragraphs of this rule.
- (H) Any pharmacy intending to maintain records of dispensing at a location other than the place licensed with the board of pharmacy must first send written notification to the board by certified mail, return receipt requested. If not contested within sixty days of receipt by the board office, such request will stand as approved.

Rule 4729-5-28 Computerized recordkeeping systems.

[OAC: 10/01/71, 09/10/76, 04/01/78, 07/01/84, 03/19/87, 09/01/89, 07/01/93, 01/17/97]

(Replaces: Part of Rule 4729-5-17)

(Amplifies 3719.05, 3719.07, 3719.13, 3719.27, 3719.28, 4729.26, 4729.27, 4729.37)

If a computerized recordkeeping system is being used as an alternate recordkeeping system pursuant to rule 4729-5-27 of the Administrative Code, the following requirements must be met:

- (A) The system must be capable of providing immediate retrieval (via CRT display and hard-copy printout or other mutually agreeable transfer medium) of patient profile information for all prescriptions filled within the previous twelve months and retrieval within three working days, excluding weekends and holidays, of all prescriptions dispensed within the previous thirty-six months. This information shall include at least, but is not limited to, the following data:
 - (1) The original prescription number;
 - (2) Date of issuance of the original prescription order by the practitioner;
 - (3) Date of dispensing by the pharmacist;
 - (4) Full name and address of the patient;
 - (5) Full name and address of the practitioner;
 - (6) Directions for use;
 - (7) The name, strength, dosage form, and quantity of the drug prescribed;
 - (8) The quantity dispensed if different from the quantity prescribed;
 - (9) Positive identification of the dispensing pharmacist;
 - (10) The total number of refills authorized by the prescriber;
 - (11) The refill history of the prescription as defined in paragraph (B) of this rule.

- (B) The refill history of the prescription must include, but is not limited to:
- (1) The prescription number;
 - (2) The name of the drug dispensed;
 - (3) The date of refill;
 - (4) The quantity dispensed;
 - (5) The name or initials of the dispensing pharmacist for each refill;
 - (6) The total number of refills dispensed to date for that prescription order.
- (C) Documentation of the fact that the prescription refill information entered into the automated data processing system is correct must be provided by each individual pharmacist who makes use of such system by one of the following methods:
- (1) Positive identification, as defined in rule 4729-5-01 of the Administrative Code, of the pharmacist responsible for each data entry. If this method is used, the automated data processing system must have a daily backup;
 - (2) A hard-copy printout of each day's prescription refill data that shall include, at a minimum, the following data:
 - (a) Date of dispensing;
 - (b) Prescription number;
 - (c) Patient name;
 - (d) Name, strength (if applicable), and quantity of drug;
 - (e) Identification of pharmacy and pharmacist;
 - (f) Identification of controlled substances.

This printout must be verified, dated, and signed by each individual pharmacist who dispensed a prescription that day. The pharmacist must verify that the data on the printout is complete and correct and sign a statement to that effect on the document as he/she would sign a check or legal document (e.g., J. H. Smith or Jane H. Smith). These documents must be maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing. If the printout is prepared at a location other than that where the drug was dispensed, the printout must be provided to the licensed location within three working days, excluding holidays and weekends, of the date on which the drugs were dispensed. Such printouts must be verified and signed by each pharmacist who dispensed drugs within twenty-four hours of the date the printout is received;
 - (3) A tamper-evident log book in which shall be entered, at a minimum, the date of dispensing and prescription number. The dispensing pharmacist must manually record his/her name or initials on each log book entry at the time of dispensing each refill; or
 - (4) Each individual pharmacist involved in dispensing drugs must enter into a tamper-evident log book, at a minimum, the following data for each prescription refilled:
 - (a) Date of dispensing;
 - (b) Prescription number;

- (c) Patient name;
- (d) Name, strength (if applicable), and quantity of drug;
- (e) Identification of pharmacy and pharmacist;
- (f) Identification of controlled substances.

Each individual pharmacist involved in dispensing drugs must review this information at the end of each day and then must sign a statement in the log book attesting to the fact that the prescription information entered into the computer that day and recorded in the log book has been reviewed by him/her and is correct as shown.

- (D) Any such computerized recordkeeping system must have the capability of producing a printout of any prescription data which the user pharmacy is responsible for maintaining pursuant to federal and state laws and their implementing regulations and rules within three working days of a request being submitted by an individual authorized by law to access such records.
- (E) In the event that the computerized recordkeeping system experiences down-time, a record of all refills dispensed during such time must be recorded on the back of the original prescription. The refill information must be entered into the computerized recordkeeping system as soon as it is available for use. During the time the computerized recordkeeping system is not available, prescriptions may be refilled only if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.
- (F) A pharmacy purging a computerized recordkeeping system of prescription records must develop a method of recordkeeping capable of providing retrieval (via CRT display, hard-copy printout, or other mutually agreeable transfer medium) within three working days, excluding holidays and weekends, of prescription order information for all prescriptions filled or refilled within the previous three years. This information shall include, at a minimum, the following data:
 - (1) Pharmacy name and address;
 - (2) Original prescription number;
 - (3) Date of issuance of the original prescription order by the practitioner;
 - (4) Date of original dispensing by the pharmacist;
 - (5) Full name and address of the patient;
 - (6) Full name and address of the practitioner;
 - (7) Directions for use;
 - (8) Name, strength, dosage form, and quantity of the drug prescribed;
 - (9) Quantity dispensed if different from the quantity prescribed;
 - (10) Total number of refills authorized by the prescribing practitioner;
 - (11) Total number of refills dispensed to date for that prescription order;
 - (12) Date of each refill;
 - (13) Name or initials of the dispensing pharmacist.

Such data must be accessible by patient profile, alphabetically, or serially by prescription number.

(G) A log must be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited to, the following:

- (1) Date and time of change;
- (2) Changes made;
- (3) Pharmacist making the change.

Rule 4729-5-29 Confidentiality of patient records.

[OAC: 10/01/71, 09/10/76, 04/01/78, 07/01/84, 03/19/87, 09/01/89, 07/01/93, **01/17/97**]

(Replaces: Part of Rule 4729-5-17)

(Amplifies 3719.05, 3719.07, 3719.13, 3719.27, 3719.28, 4729.26, 4729.25, 4729.37)

(A) Records of dispensing or administering of drugs are not a public record. A person having custody of, or access to, such records shall not divulge the contents thereof, or provide a copy thereof, to anyone except:

- (1) The patient for whom the prescription or medication order was issued.
- (2) The practitioner who issued the prescription or medication order.
- (3) Certified/licensed health care personnel who are responsible for the care of the patient.
- (4) A member, inspector, agent, or investigator of the board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.
- (5) An agent of the state medical board when enforcing Chapter 4731. of the Revised Code.
- (6) An agency of government charged with the responsibility of providing medical care for the patient upon a written request by an authorized representative of the agency requesting such information.
- (7) An agent of a medical insurance company who provides prescription insurance coverage to the patient upon authorization and proof of insurance by the patient or proof of payment by the insurance company for those medications whose information is requested.
- (8) Any person, other than those listed in paragraphs (A)(1) to (A)(6) of this rule, only when the patient has given consent for such disclosure in writing, except where a patient requiring medication is unable to deliver a written consent to the necessary disclosure. Any consent must be signed by the patient and dated. Any consent for disclosure is valid until rescinded by the patient. In an emergency, the pharmacist may disclose the prescription information when, in the professional judgment of the pharmacist, it is deemed to be in the best interest of the patient. A pharmacist making an oral disclosure in an emergency situation must prepare a written memorandum showing the patient's name, the date and time the disclosure was made, the nature of the emergency, and the names of the individuals by whom and to whom the information was disclosed.

(B) Records of dispensing or administering drugs which may be required as evidence of a violation shall be released to a member, inspector, agent, or investigator of the board of pharmacy or

any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug upon his request. Such person shall furnish a receipt to the person having legal custody of the records. The receipt shall list the records removed and shall include the following information:

- (1) Prescription identification number; or, if an order for medication, the name of the patient;
 - (2) The drugs prescribed;
 - (3) Quantity of drugs prescribed and dispensed;
 - (4) Name of the prescribing practitioner;
 - (5) Date, name of agency, and signature of person removing the records.
- (C) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A)(7) of this rule, shall be kept on file at the pharmacy for a period of three years in a readily retrievable manner.

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

[OAC: 02/15/82, 09/01/85, 03/21/88, 07/01/90, 01/26/93, 03/01/94, 09/01/96, **07/01/97**]

(Amplifies 4729.07, 4729.08, 4729.13, 4729.26)

- (A) Pursuant to section 4729.07 of the Revised Code:
- (1) The examination shall consist of the "North American Pharmacist Licensure Examination (NAPLEX)" and a jurisprudence examination compiled by the board or the "National Association of Boards of Pharmacy."
 - (2) The minimum passing grade for the NAPLEX is seventy-five. Any candidate failing to attain a grade of seventy-five on the NAPLEX examination will be required to repeat the NAPLEX 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 "North American Pharmacist Licensure Examination (NAPLEX)" 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 NAPLEX 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 4729-9-01 Definitions.

[OAC: 09/10/76, 03/21/88, 07/01/91, 07/01/92, 01/17/97]

(Amplifies 3719.01, 3719.03, 3719.28, 4729.02, 4729.16, 4729.26, 4729.56, 4729.57, 4729.66)

- (A) "Dangerous drug," as defined in division (D)(1) of section 4729.02 of the Revised Code, means any drug or drug product whose commercial package bears a label containing the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian" or any similar restrictive statement.
- (B) A dangerous drug is adulterated if beyond the expiration date as stated by the manufacturer, packer, or distributor in its labeling or if it is not stored or dispensed according to the requirement of the federal act as indicated in the product labeling.
- (C) "Psychiatric outpatient facility" means a facility where psychiatric evaluation and treatment is provided on an outpatient basis.
- (D) "Registered" and "licensed", as used in Chapters 3719. and 4729. of the Revised Code, have the same meaning. "Registered" and "licensed" mean that an individual or facility has met the initial qualifications for registration and licensure with the board of pharmacy and, if they are still actively practicing pharmacy or distributing drugs, have complied with annual renewal procedures, including payment of applicable fees.
- (E) "Revoke", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license which renders such license void and such license may not be reissued. "Revoke" is an action which is permanent against the license and licensee except that after twelve months or such period of time as the individual board order may require, a licensee whose license has been revoked may make application to the board for issuance of a new license. A pharmacist whose license has been revoked must pass any examination required by the board prior to the issuance of any new license.
- (F) "Suspend", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license which renders such license without force and effect for a period of time as determined by the board of pharmacy. The board may require that an individual whose license has been suspended may not be employed by or work in a facility licensed by the board of pharmacy to possess or distribute dangerous drugs during such period of suspension.
- (G) "Place on probation", as used in Chapter 4729. of the Revised Code, means to take action against a license which suspends the sanctions imposed by the board of pharmacy during a period of good behavior for a period of time and under such conditions as determined by the board of pharmacy.
- (H) "Refuse to grant or renew", as used in Chapter 4729. of the Revised Code, means to deny original or continued licensure for a period of at least twelve months. After twelve months or

such period of time as the individual board order may require, a pharmacist, a pharmacy intern, a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, a wholesaler of controlled substances, a manufacturer of controlled substances, or an individual or facility who desires to attain such status by licensure, and whose license the board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A pharmacist, or an individual who desires to attain such status by licensure, whose license the board of pharmacy has refused to grant or renew must meet any requirements established by the board or must pass any examination required by the board.

Rule 4729-9-04 Returned drugs.

[OAC: 09/10/76, 07/01/91, 07/01/92, 01/17/97]

(Amplifies 3719.05, 3719.28, 4729.26, 4729.66)

No drug or drug product, which has been sold at retail and has left the physical premises of the terminal distributor of dangerous drugs, shall be dispensed again except drugs dispensed for inpatients pursuant to paragraph (C) of rule 4729-17-01 of the Administrative Code or non-controlled drugs dispensed and delivered for outpatients to a psychiatric outpatient facility licensed with the board of pharmacy and provided by a government entity that are packaged in unopened, single-dose or tamper-evident containers and whereby the drug has not been in the possession of the ultimate user. Drugs that have been dispensed or possessed not in accordance with this rule are considered to be adulterated.

Rule 4729-9-15 Report of theft or loss of dangerous drugs, controlled substances, and drug documents.

[OAC: 04/01/78, 02/15/82, 07/01/90, 02/15/95, 01/17/97]

(Amplifies 3719.07, 3719.28, 4729.55, 4729.66)

- (A) Each practitioner and terminal or wholesale distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance:
- (1) The board of pharmacy, by telephone immediately upon discovery of the theft or significant loss;
 - (2) If a controlled substance, the drug enforcement administration (DEA) pursuant to section 1301.76(b), Code of Federal Regulations;
 - (3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.
- (B) Controlled substance thefts must also be reported by using the federal DEA report form whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them. A copy of the federal form regarding such theft or loss shall be filed with the board of pharmacy within thirty days following the discovery of such theft or loss.
- (1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.
 - (2) A request for a waiver of the thirty-day limit must be requested in writing.
- (C) Each practitioner and terminal or wholesale distributor of dangerous drugs immediately upon discovery of any theft or loss of:

- (1) Uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed, shall notify the board of pharmacy and law enforcement authorities.
- (2) Official written order form(s) as defined in division (U) of section 3719.01 of the Revised Code shall notify the board of pharmacy and law enforcement authorities, and the drug enforcement administration (DEA) pursuant to section 1305.12(b), Code of Federal Regulations.

Rule 4729-9-16 Minimum requirements for wholesalers.

[OAC: 06/01/82, 07/01/90, 07/01/92, 01/17/97]

(Amplifies 3719.03, 3719.28, 4729.53, 4729.66)

The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio.

- (A) The following information shall be required on a form supplied by the board from each person making application for a license as a wholesale distributor of dangerous drugs:
 - (1) The name, full business address (not a post office box), and telephone number;
 - (2) All trade or business names used by the licensee, any trade or business names under which licensee was previously or is presently licensed;
 - (3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs;
 - (4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency);
 - (5) The name(s) of the owner and/or operator of the licensee, including:
 - (a) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity;
 - (b) If a partnership, the name of each partner, and the name of the partnership;
 - (c) If a corporation, the name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, the corporation number, and a copy of the corporation papers;
 - (d) If a government agency, the name of the agency, and the name of each officer and director of the agency.
 - (6) If the entity making application for a wholesale distributor of dangerous drugs license is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to distribute dangerous drugs in that state and the experience the licensing authority has had with the entity. This information will be used as part of the consideration in licensing the entity by the Ohio board. The Ohio board will respond to inquiries of a similar nature from other states about licensees in Ohio.

- (B) Prior to the end of the licensing period, a renewal application requesting such information as the board of pharmacy may require will be sent to the address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the established deadline.
- (C) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:
 - (1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (3) Have a quarantine area for storage of dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored no longer than two years pursuant to rule 4729-9-17 of the Administrative Code;
 - (4) Be maintained in a clean and orderly condition;
 - (5) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- (D) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
 - (1) Access from outside the premises shall be kept to a minimum and be well controlled.
 - (2) The outside perimeter of the premises shall be well lighted.
 - (3) Entry into areas where dangerous drugs are held shall be limited to authorized personnel.
 - (4) All facilities where dangerous drugs are held shall be equipped with a board approved alarm system to detect unauthorized entry after hours.
 - (5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (E) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopeia/national formulary (USP/NF).
 - (1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
 - (2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.
 - (3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all stored drugs.
- (F) All shipments of dangerous drugs shall be examined in accordance with the following:

- (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;
 - (2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions;
 - (3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all incoming and outgoing dangerous drugs.
- (G) All returned, damaged, and outdated dangerous drugs shall be handled in the following manner:
- (1) Dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to their supplier.
 - (2) Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.
 - (3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.
 - (4) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated dangerous drugs.
- (H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.
- (1) These records shall include but not be limited to the following information:
 - (a) The source of the drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped.
 - (b) The identity and quantity of the drugs received and distributed or disposed of.
 - (c) The dates of receipt and distribution of the drugs.
 - (d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized by division (B) of section 4729.51 of the Revised Code.
 - (e) A system of procedures shall be designed and, when required, operated to disclose orders for controlled substances and other dangerous drugs subject to abuse, as

designated by the board of pharmacy. The board shall furnish wholesalers with the name and identification numbers of drug products subject to abuse at least fourteen days prior to the date that such system is required to commence or when a product is deleted from such requirements.

- (i) The wholesaler shall inform the board of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.
 - (ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, shall be furnished to the board within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.
- (2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of two years following disposition of the drugs.
- (3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.
 - (a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized board of pharmacy designated agents, federal, state, or local law enforcement agency officials.
 - (b) Wholesalers intending to maintain records, described in this rule, at a location other than the place licensed by the board of pharmacy must first send notification to the board.
- (I) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:
 - (1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.
 - (2) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:
 - (a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;
 - (b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

- (c) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.
- (3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.
- (4) A procedure to ensure that any outdated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated dangerous drugs. This documentation shall be maintained for two years after disposition of the outdated drugs.
- (J) Wholesale distributors of dangerous drugs shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.
- (K) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.
- (L) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.
 - (1) Wholesale drug distributors shall permit properly identified and authorized board of pharmacy designated agents, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law.
 - (2) Any entity making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.
- (M) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

Rule 4729-12-09 Exceptions.

[OAC: 08/24/94, 12/15/94, 01/10/96, 07/01/97]

(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 excepted 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.
- (G) "SnoreStop™" tablets.

Rule 4729-27-01 Definitions.

[OAC: 01/17/97]

(Amplifies 4729.02, 4729.66)

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

Rule 4729-27-02 Licensure.

[OAC: 01/17/97]

(Amplifies 4729.51, 4729.54, 4729.55, 4729.551, 4729.66)

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

Rule 4729-27-03 Security, storage, and sale.

[OAC: 01/17/97]

(Amplifies 4729.51, 4729.54, 4729.55, 4729.551, 4729.66)

- (A) Peritoneal dialysis solutions may be sold at retail to patients only pursuant to an order from a person authorized to prescribe peritoneal dialysis solutions in the course of professional practice.
- (B) Peritoneal dialysis solutions may be sold at retail and must be maintained in accordance with Chapters 3715. and 4729. of the Revised Code; rules 4729-9-04, 4729-9-05, 4729-9-11, and 4729-9-12 of the Administrative Code; and applicable federal laws and regulations.

Rule 4729-27-04 Records.

[OAC: 01/17/97]

(Amplifies 4729.51, 4729.54, 4729.55, 4729.551, 4729.66)

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

Rule 4729-27-05 Prescriber's order.

[OAC: 01/17/97]

(Amplifies 4729.51, 4729.54, 4729.55, 4729.551, 4729.66)

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

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