

RULES EFFECTIVE IN 1998
[Ohio Administrative Code]

4729-1-01 Public notice of hearing to consider proposed rule changes.

[OAC: 09/10/76, 03/19/87, **04/01/98**]

(Amplifies 119.03, 4729.05)

(A) Reasonable public notice, as required by section 119.03 of the Revised Code, shall be as follows:

- (1) By advertising such notice, one time, in at least one newspaper of general circulation in the state of Ohio at least thirty days prior to the date set for the public hearing.
- (2) By mailing or faxing such notice, one time, to all subscribers on the board's sunshine notice mailing list at least thirty days prior to the date set for the public hearing.
- (3) By mailing or faxing such notice, one time, to all persons who have requested the board to provide notification of any proposed rule changes at least thirty days prior to the date set for the public hearing.
- (4) By placing such notice on the board's world wide web home page at least thirty days prior to the date set for the public hearing, and remaining there until the public hearing record is closed.

(B) The board shall furnish the full text of the proposed rules as follows:

- (1) By mailing to any person who requests such in writing and who pays the cost of copying and mailing.
- (2) By posting on the board's world wide web home page and remaining there until the public hearing record is closed.

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, **02/01/98**]

(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 prescriber 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 prescriber for a patient.
- (E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.
- (F) "To participate with prescribers in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the prescriber(s) involved.
- (G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code.
- (H) "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, 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 prescriber and for whom the prescriber has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional facility as defined in Chapter 4729-17 of the Administrative Code.
- (K) "Standing order" will mean the same as the term "protocol".
- (L) "Protocol" is defined as:
 - (1) A definitive set of treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber 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 prescriber 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 prescriber 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.

4729-5-02 Identification card and signature.

[OAC: 09/10/76, **02/01/98**]

(Amplifies 4729.12, 4729.26)

Each pharmacist and pharmacy intern, to whom an identification card or renewal identification card has been issued, shall immediately sign such identification card.

4729-5-15 Prescriber.

[OAC: 09/10/76, 07/01/84, 07/01/90, 07/01/93, 03/03/95, **02/01/98**]

(Amplifies 3719.01, 3719.04, 3719.05, 3719.06, 3719.07, 3719.28, 4729.02, 4729.51, 4729.55, 4729.66)

- (A) For purposes of division (BB) of section 3719.01 and division (H)(1) of section 4729.02 of the Revised Code, the following persons, maintaining current licenses and in good standing, licensed pursuant to Chapters 4715., 4725., 4731., and 4741. of the Revised Code, are authorized by law to write prescriptions for drugs or dangerous drugs in the course of their professional practice:
- (1) Chapter 4715. of the Revised Code: dentist.
 - (2) Chapter 4725. of the Revised Code: optometrist, if that person holds a current "therapeutic pharmaceutical agents certificate" as defined in division (H) of section 4725.01 of the Revised Code.
 - (3) Chapter 4731. of the Revised Code: doctor of medicine, doctor of osteopathic medicine and surgery, and doctor of podiatry.
 - (4) Chapter 4741. of the Revised Code: doctor of veterinary medicine.
- (B) Those persons pursuing an approved internship, residency, or fellowship program in this state are authorized to write prescriptions only when acting within their scope of employment in the hospital(s) or institution(s). Approved internship and residency programs are those accredited by

the "Accreditation Council for Graduate Medical Education (ACGME)" or the "American Osteopathic Association (AOA)". Approved clinical fellowships are those at institutions which have a residency program in the same or a related clinical field which is accredited by the ACGME or the AOA.

- (C) A non-resident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for drugs in the course of their professional practice in a state other than Ohio is authorized to write prescriptions in that state for drugs to be dispensed in the state of Ohio.
- (D) An advanced practice nurse approved pursuant to section 4723.56 of the Revised Code may, by written or oral prescription, prescribe those drugs which have been approved by the formulary committee for advanced practice nurses and that are included in the collaborative protocol established for that advanced practice nurse pursuant to section 4723.56 of the Revised Code.

4729-5-16 Labeling of drugs dispensed on prescription.

[OAC: 09/10/76, 08/01/84, 09/01/85, 07/01/91, 02/01/98]

(Amplifies 3715.64, 3719.01, 3719.08, 3719.28, 4729.02, 4729.26, 4729.27, 4729.28, 4729.37, 4729.38, 4729.66)

- (A) No drug may be dispensed on prescription unless a label is affixed to the container in which such drug is dispensed and such label includes:
 - (1) The name and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license;
 - (2) The name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner and the species of the animal;
 - (3) The name of the prescriber;
 - (4) Directions for use of the drug;
 - (5) The date of dispensing;
 - (6) Any cautions which may be required by federal or state law;
 - (7) The serial number of the prescription;
 - (8) The name or initials of the pharmacist;
 - (9) The proprietary name, if any, or the generic name and the name of the distributor of the drug dispensed; and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission in writing in the case of a written prescription, or verbally in the case of an orally transmitted prescription;
 - (10) The quantity of drug dispensed.
- (B) The term "affix" means the prescription label must be attached or fastened to the container.
- (C) At least the prescription number and the name of the patient must be placed on all prescription containers too small to bear a complete prescription label and dispensed in a container bearing

a complete prescription label. The label bearing only the prescription number and the name of the patient does not need to be applied to any product whose function would be impaired by such a label. In all cases, a complete prescription label meeting the requirements of paragraph (A) of this rule must be applied to the container in which such product is dispensed.

- (D) This rule does not apply to drugs which are dispensed for use by inpatients of an institutional facility whereby the drug is not in the possession of the ultimate user prior to administration. Such drugs shall be labeled in accordance with rule 4729-17-10 of the Administrative Code.

4729-5-18 Patient profiles.

[OAC: 09/10/76, 09/01/85, 03/01/93, 02/01/98]

(Amplifies 4729.26)

All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy.

- (A) The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made to obtain, record, and maintain at least the following records:
- (1) The patient's data record, which should consist of, but is not limited to, the following information:
 - (a) Full name of the patient for whom the drug is intended;
 - (b) Address and telephone number of the patient;
 - (c) Patient's date of birth or age;
 - (d) Patient's gender;
 - (e) A list of current patient specific data consisting of at least the following:
 - (i) Known drug-related allergies,
 - (ii) Previous drug reactions,
 - (iii) History of or active chronic conditions or disease states,
 - (iv) Other drugs, including over the counter drugs used on a routine basis, or devices;
 - (f) The pharmacist's comments relevant to the individual patient's drug therapy, including any other information peculiar to the specific patient or drug;
 - (g) Any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.
 - (2) The patient's drug therapy record, which shall contain at least the following information for all of the prescriptions that were filled at the pharmacy within the last twelve months showing:
 - (a) Name of the drug or device;

- (b) Prescription number;
- (c) Name and strength of drug;
- (d) Quantity dispensed;
- (e) Date dispensed;
- (f) Name of the prescriber.

(B) The patient profile shall be maintained for a period of not less than one year from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

4729-5-20 Prospective drug utilization review.

[OAC: 09/10/76, 09/01/85, 03/01/93, 02/01/98]

(Amplifies 4729.26)

- (A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:
 - (1) Over-utilization or under-utilization;
 - (2) Therapeutic duplication;
 - (3) Drug-disease state contraindications;
 - (4) Drug-drug interactions;
 - (5) Incorrect drug dosage or duration of drug treatment;
 - (6) Drug-allergy interactions;
 - (7) Abuse/misuse.
- (B) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include consulting with the prescriber and/or counseling the patient.
- (C) Prospective drug utilization review shall be performed using predetermined standards consistent with any of the following:
 - (1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);
 - (2) American hospital formulary service drug information;
 - (3) United States pharmacopeia drug information;
 - (4) American medical association evaluations.

4729-5-22 Patient counseling.

[OAC: 09/10/76, 09/01/85, 03/01/93, 02/01/98]

(Amplifies 4729.26)

- (A) A pharmacist or the pharmacist's designee shall personally offer to counsel the patient or caregiver whenever any prescription, new or refill, is dispensed. In this situation, when counseling is refused, the pharmacist shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document and shall accompany the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.
- (B) A pharmacist, or an intern under the personal supervision of a pharmacist, shall counsel the patient or caregiver. Such counseling may include, but is not limited to, the following:
 - (1) The name and description of the drug;
 - (2) The dosage form, dose, route of administration, and duration of drug therapy;
 - (3) The intended use of the drug and the expected action;
 - (4) Special directions and precautions for preparation, administration, and use by the patient;
 - (5) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;
 - (6) Techniques for self-monitoring drug therapy;
 - (7) Proper storage;
 - (8) Prescription refill information;
 - (9) Action to be taken in the event of a missed dose; and
 - (10) The pharmacist's comments relevant to the individual's drug therapy, including other information peculiar to the specific patient or drug.
- (C) Other forms of drug therapy information may be used when appropriate to supplement the counseling by the pharmacist. Examples of forms that may be used include, but are not limited to, drug product information leaflets, pictogram labels, and video programs.
- (D) Patient counseling shall not be required for inpatients of an institutional facility as defined in rule 4729-17-01 of the Administrative Code.
- (E) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.

4729-5-24 Prescription copy.

[OAC: 10/01/71, 08/01/84, 07/01/90, 07/01/92, 01/17/97, **02/01/98**]

(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. However, pharmacies electronically sharing a real-time, on-line database may transfer a controlled substance prescription up to the maximum number of refills permitted by law and the prescriber's authorization pursuant to paragraph (A)(4) of this rule.
 - (2) The copy transferred shall be an exact duplicate of the original prescription except that it shall also include:
 - (a) Serial prescription number assigned to the prescription;
 - (b) Name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy transferring the copy;
 - (c) Date of issuance of the prescription;
 - (d) Date of original dispensing of the prescription;
 - (e) Original number of refills;
 - (f) Date of last refill;
 - (g) Number of valid refills remaining; and
 - (h) The 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 in such a way as to avoid destroying any of the original information contained on the prescription;
 - (b) Record on the reverse side of the original written prescription:
 - (i) 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.

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, **02/01/98**]

(Amplifies 3719.05, 3719.06, 3719.28, 4729.02, 4729.26, 4729.37)

- (A) A prescription, to be effective, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of 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 prescriber 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 paragraph (N) of this rule and 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 prescriber or the prescriber's agent. 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 prescriber and his/her agent 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 prescriber or the prescriber's agent 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 prescriber.
- (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 prescriber, 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 prescriber 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 prescriber'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 prescriber, 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.
- (N) A schedule II controlled substance prescription for a narcotic substance issued for a patient enrolled in a hospice may be transmitted by the prescriber or the prescriber's agent to the pharmacy by facsimile. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must meet all of the requirements in paragraph (D) of this rule for such a prescription.

4729-9-01 Definitions.

[OAC: 09/10/76, 03/21/88, 07/01/91, 07/01/92, 01/17/97, **02/01/98**]

(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.
- (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.
- (I) "Campus", as used to describe a type of terminal distributor of dangerous drugs license issued pursuant to division (E) of section 4729.51 of the Revised Code, means an establishment or place consisting of multiple buildings where dangerous drugs are stored that are located on a contiguous plot of land. All such buildings and stocks of dangerous drugs shall be under common ownership and control.
- (J) "Certified diabetes 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)".

4729-9-05 Security requirements.

[OAC: 09/10/76, 02/01/98]

(Amplifies 4729.66)

- (A) All registrants shall provide effective and approved controls and procedures to guard against theft and diversion of dangerous drugs. In order to determine whether a registrant has provided effective and approved controls against diversion, the board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the physical security controls and operating procedures necessary to prevent diversion.
- (B) Substantial compliance with the standards set forth in rule 4729-9-11 of the Administrative Code may be deemed sufficient by the board of pharmacy after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the board of pharmacy may consider any of the following factors, as they deem relevant, for strict compliance with security requirements:
 - (1) The type of activity conducted;

- (2) Type and form of dangerous drugs handled;
 - (3) Quantity of dangerous drug handled;
 - (4) Location of the premises and the relationship such location bears on security needs;
 - (5) Type of building construction comprising the facility and the general characteristics of the building or buildings;
 - (6) Type of vaults, safes, and secure enclosures or other storage system (e.g.-automatic storage and retrieval system) used;
 - (7) Type of closures on vaults, safes, and secure enclosures;
 - (8) Adequacy of key control systems and/or combination lock control systems;
 - (9) Adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;
 - (10) Extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
 - (11) Adequacy of supervision over employees having access to manufacturing and storage areas;
 - (12) Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;
 - (13) Availability of local police protection or of the registrant's or applicant's security personnel, and;
 - (14) Adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of dangerous drugs in its operation.
- (C) When physical security controls become inadequate as a result of a significant increase in the quantity of dangerous drugs in the possession of the registrant during normal business operation, the physical security controls shall be expanded and extended accordingly.
- (D) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in rule 4729-9-11 of the Administrative Code may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the board of pharmacy.
- (E) The state board of pharmacy shall be notified of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the registrant before being used or implemented.

4729-9-06 Disposal of dangerous drugs which are controlled substances.

[OAC: 09/10/76, 07/01/93, **02/01/98**]

(Amplifies 3719.05, 3719.06, 3719.07, 3719.28, 4729.66)

- (A) Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances may dispose of such drugs by the following procedure:
- (1) If the person is a registrant or practitioner required to keep records pursuant to Chapters 3719. and 4729. of the Revised Code, the responsible pharmacist or practitioner shall send the state board of pharmacy a list of the dangerous drugs which are controlled substances containing the name and quantity to be disposed of.
 - (2) If the person is not a registrant or practitioner, he shall submit to the board of pharmacy a letter stating:
 - (a) The name and address of the person possessing the dangerous drugs which are controlled substances to be disposed of;
 - (b) The name and quantity of each controlled substance;
 - (c) How the applicant obtained the controlled substances; and
 - (d) The name, address, and registration number of the person who possessed the controlled substances prior to the applicant, if known.
- (B) The executive director shall authorize and instruct the applicant to dispose of the dangerous drugs which are controlled substances in one of the following manners:
- (1) By transfer to persons registered under Chapters 3719. and 4729. of the Revised Code, and authorized to possess the controlled substances;
 - (2) By destruction in the presence of a board of pharmacy officer, agent, or inspector or other authorized person; or
 - (3) By such other means as the board of pharmacy may determine to assure that the controlled substances do not become available to unauthorized persons.
- (C) In the event that a registrant is required regularly to dispose of dangerous drugs which are controlled substances, the executive director may authorize the registrant to dispose of such controlled substances, in accordance with paragraph (B)(1) of this rule, without prior approval of the board of pharmacy in each instance on the condition that the registrant keep records of such disposals and file periodic reports with the board of pharmacy summarizing the disposals made by the registrant. In granting such authority, the executive director may place conditions on the disposal of dangerous drugs which are controlled substances, including but not limited to the method of disposal and the frequency and detail of reports.

4729-9-08 Change in description of terminal or wholesale dangerous drug facility.

[OAC: 09/10/76, 02/01/98]

(Amplifies 4729.51, 4729.52, 4729.54, 4729.66)

For the purpose of division (E) of section 4729.51 and division (D) of section 4729.52 of the Revised Code, any change in the ownership, business or trade name, or address of a terminal or wholesale distributor of dangerous drugs requires a new application and license.

4729-9-09 Security of prescription blanks and D.E.A. controlled substance order forms.

[OAC: 09/10/76, 03/21/88, 07/01/93, 02/01/98]

(Amplifies 3719.09, 3719.28, 4729.51, 4729.66)

For the purpose of aiding compliance with section 2925.23 of the Revised Code, a practitioner, responsible pharmacist, or responsible person shall provide security and control for their prescription blanks and D.E.A. controlled substance order forms by limiting their availability only to authorized persons.

4729-9-13 Distributor of dangerous drug samples.

[OAC: 09/10/76, 02/01/98]

(Amplifies 3719.28, 3719.81)

No manufacturer, manufacturer's representative, or wholesale dealer in pharmaceuticals may furnish a sample of a drug of abuse as defined in section 3719.011 of the Revised Code to a practitioner unless requested by the practitioner and unless the company is registered as a wholesale distributor of dangerous drugs and maintains a record of such distribution which will be available to the state board of pharmacy.

4729-9-18 Availability of terminal, wholesale, or manufacturer license.

[OAC: 07/01/91, 02/01/98]

(Amplifies 4729.51, 4729.66)

Each entity possessing a current license as a terminal distributor of dangerous drugs, wholesale distributor of dangerous drugs, wholesaler of controlled substances, or manufacturer of controlled substances shall maintain such license in a readily available place in the principal location of such business.

4729-17-04 Records: institutional facility pharmacy.

[OAC: 09/10/85, 07/01/91, 01/10/96, 02/01/98]

(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 4729-5-27 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.

4729-17-05 Controlled substance recordkeeping.

[OAC: 02/01/98]

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

- (A) All controlled substances maintained as stock in areas outside of the pharmacy pursuant to paragraph (B) of rule 4729-17-03 of the Administrative Code shall meet the following requirements, unless they are stored in a secure, automated storage system that meets the requirements of paragraph (B) of this rule:
- (1) The drugs shall be stored in a secure location with access limited to authorized individuals;
 - (2) A proof-of-use sheet or other board approved recordkeeping system shall be maintained for each drug and shall include at least, but is not limited to, the following information:
 - (a) Patient name,
 - (b) Date and time of access,
 - (c) Drug name, strength, and quantity obtained,
 - (d) The positive identification of the person doing the administration, and, if applicable,
 - (e) The positive identification of both the person and the witness who waste a partial dose of a controlled substance;
 - (3) At every change of shift, a reconciliation must be conducted by both the leaving and arriving health care professional responsible for the security of these drugs in the area in which they are stored and must include at least the following:
 - (a) A physical count and reconciliation of the controlled substances and proof-of-use sheets, if applicable, to ensure the accountability of all doses,
 - (b) An inspection of the packaging to ensure its integrity,
 - (c) The positive identification of the persons conducting the reconciliation, and
 - (d) The immediate reporting of any unresolved discrepancy to the appropriate people within the institution. The responsible person for the terminal distributor of dangerous drugs license must be one of those notified;
 - (4) All controlled substances shall be packaged in tamper-evident containers except multidose liquids and injectables where unit-of-use packaging is not available.
- (B) All controlled substances maintained as stock in areas outside of the pharmacy pursuant to paragraph (B) of rule 4729-17-03 of the Administrative Code that are stored in a secure, automated storage system shall be handled as in paragraph (A) of this rule unless the automated storage system meets all of the following requirements:
- (1) The drugs shall be stored in a secure location with access limited to authorized individuals;
 - (2) The system shall document the positive identification of every person accessing the system and shall record the date and time of access;

- (3) A recordkeeping system shall be maintained that shall include at least, but is not limited to, the following information:
 - (a) Patient name,
 - (b) Date and time of access,
 - (c) Drug name, strength, and quantity removed,
 - (d) The positive identification of the person removing the drug, and, if applicable,
 - (e) The positive identification of both the person and the witness who waste a partial dose of a controlled substance;
- (4) Periodically, the responsible person shall cause a reconciliation of the automated storage system to be conducted which must include at least the following:
 - (a) A physical count and reconciliation of the controlled substances to ensure the accountability of all doses,
 - (b) An inspection of the packaging to ensure its integrity,
 - (c) The positive identification of the persons conducting the reconciliation, and
 - (d) The immediate reporting of any unresolved discrepancy to the appropriate people within the institution. The responsible person for the terminal distributor of dangerous drugs license must be one of those notified;
- (5) Access to all controlled substances stored in the automated storage system shall be limited to one drug and strength at a time;
- (6) All controlled substances stored in the automated storage system shall be packaged in tamper-evident containers, unless the system only allows access to one dose at a time.

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, **02/01/98**]

(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 patient-specific order issued by a prescriber.
 - (1) 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 verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility.
 - (2) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a facsimile machine to facsimile machine transfer 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 the origin of the order as a part of the drug order record. This facsimile must be maintained if it is the only record showing the pharmacist responsible for dispensing the drug.

- (3) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a board approved paperless automated data processing system may be considered an original order for the dispensing of drugs. Access to such system for entering and transmitting original orders shall be restricted to licensed health care practitioners using positive identification. If the licensed health care practitioner entering the order into the system is not the prescriber, there shall be a system in place requiring the positive identification of the prescriber for each order which shall be available in a readily retrievable fashion. With such a system, the institutional pharmacy director or responsible 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 order of a prescriber. All orders for the dispensing of drugs to outpatients shall, at a minimum, conform to rule 4729-5-30 of the Administrative Code, shall be labeled in accordance with rule 4729-5-16 of the Administrative Code, and the records shall be maintained in accordance with rule 4729-5-27 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.

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