

RULES EFFECTIVE IN 1999
[Ohio Administrative Code]

4729-5-01 Definitions. [OAC: 03/01/99]

Amplifies: 4729.01, 4729.26, 4729.27, 4729.28, 4729.54, 4729.66

Review Date(s): 02/01/98, 02/01/03

History: 10/01/71, 09/10/76, 05/15/87, 07/01/92, 07/01/93, 09/01/96, 01/17/97, 02/01/98

As used in Chapter 4729. of the Revised Code:

- (A) "Practice of pharmacy" is as defined in division (B) of section 4729.01 of the Revised Code.
- (B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug.
- (C) The term "compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.
- (D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a prescriber for a patient.
- (E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.
- (F) "To participate with prescribers in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the prescriber(s) involved.
- (G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code.
- (H) "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, 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 state 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 state 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 state board of pharmacy may be reviewed with the medical and/or nursing board, as appropriate, prior to any approval by the state board of pharmacy.

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

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

A magnetic card reader or a bar code reader system of identification must also include a private personal identifier, such as a password, for entry into a mechanical or automated system.

4729-5-10 Prescription pick-up station. [OAC: 03/01/99]

Amplifies: 4729.26, 4729.27, 4729.28

Review Date(s): 03/01/99, 03/01/04

History: 07/25/61, 03/19/87, 07/01/94, 02/15/95

- (A) No pharmacist shall accept prescriptions obtained from a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled.
- (B) No pharmacist shall dispense dangerous drugs to a place which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered unless all of the following apply:
 - (1) The site is licensed with the state board of pharmacy as a terminal distributor of dangerous drugs.

- (2) The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4723., 4729., or 4731. of the Revised Code.
- (3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt and delivery of all prescription medications.
- (4) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.
- (5) The state board of pharmacy has approved the site for such activity due to clear and convincing evidence that delivery of prescription medication directly to the patient would result in:
 - (a) Danger to public health or safety, or
 - (b) Danger to the patient without increased involvement by a health care professional in the patient's drug therapy.

4729-5-11 Responsible pharmacist. [OAC: 03/01/99]

Amplifies: 3719.28, 4729.26, 4729.27, 4729.28, 4729.55, 4729.60, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 03/21/88, 07/01/90, 02/15/95

- (A) Only a pharmacist may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for a pharmacy as defined in division (A) of section 4729.01 of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy except with written permission from the state board of pharmacy. A written request shall be submitted outlining the circumstances requiring a pharmacist to be responsible for more than one pharmacy and the period of time during which the circumstances will exist. A pharmacist shall not be designated the responsible pharmacist for a pharmacy unless he/she will be physically present in the pharmacy a sufficient amount of time to provide supervision and control.
- (B) The responsible pharmacist shall be responsible for the practice of the profession of pharmacy, including but not limited to "supervision and control" of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, "adequate safeguards" as required in division (C) of section 4729.55 of the Revised Code, and maintaining all drug records otherwise required.
- (C) If there is a change in the responsible pharmacist, the state board of pharmacy shall be notified on a board approved form within thirty days thereof of the effective date of the change and the name of the new responsible pharmacist.
 - (1) This notice to the state board of pharmacy shall be by certified mail, return receipt requested, or by verified facsimile transmission.
 - (2) A complete inventory, pursuant to federal regulations and rule 4729-9-14 of the Administrative Code, shall be taken of the controlled substances on hand at the pharmacy with the new responsible pharmacist. The new responsible pharmacist shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.
- (D) The person to whom the terminal dangerous drug license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs and the practice of pharmacy.

4729-5-13 Prescription format. [OAC: 03/01/99]

Amplifies: 3719.06, 3719.28, 4729.37, 4729.66

Review Date(s): 04/30/01

History: 07/01/94, 01/10/96

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

4729-5-15 Prescriber. [OAC: 03/01/99]

Amplifies: 3719.01, 3719.04, 3719.05, 3719.06, 3719.07, 3719.28, 4729.01, 4729.51, 4729.55, 4729.66

Review Date(s): 02/01/98, 02/01/03

History: 09/10/76, 07/01/84, 07/01/90, 07/01/93, 03/03/95, 02/01/98

- (A) For purposes of division (Z) of section 3719.01 and division (I) of section 4729.01 of the Revised Code, the following persons, maintaining current licenses and in good standing, licensed pursuant to Chapters 4715., 4725., 4731., and 4741. of the Revised Code, are authorized by law to write prescriptions for drugs or dangerous drugs in the course of their professional practice:
 - (1) Chapter 4715. of the Revised Code: dentist.
 - (2) Chapter 4725. of the Revised Code: optometrist, if that person holds a current "therapeutic pharmaceutical agents certificate" as defined in division (H) of section 4725.01 of the Revised Code.
 - (3) Chapter 4731. of the Revised Code: doctor of medicine, doctor of osteopathic medicine and surgery, and doctor of podiatry.

- (4) Chapter 4741. of the Revised Code: doctor of veterinary medicine.
- (B) Those persons pursuing an approved internship, residency, or fellowship program in this state are authorized to write prescriptions only when acting within their scope of employment in the hospital(s) or institution(s). Approved internship and residency programs are those accredited by the "Accreditation Council for Graduate Medical Education (ACGME)" or the "American Osteopathic Association (AOA)". Approved clinical fellowships are those at institutions which have a residency program in the same or a related clinical field which is accredited by the ACGME or the AOA.
- (C) A 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: 03/01/99]

Amplifies: 3715.64, 3715.69, 3719.01, 3719.08, 3719.28, 4729.01, 4729.26, 4729.27, 4729.28, 4729.37, 4729.38, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 08/01/84, 09/01/85, 07/01/91, 02/01/98

- (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 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;
 - (9) 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.

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

[OAC: 06/01/99]

Amplifies: 3715.64, 3715.69, 3719.06, 3719.08, 3719.28, 3719.81, 4729.29, 4729.51, 4729.66

Review Date(s): 03/01/04

- (A) Whenever a prescriber personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, the prescriber shall affix to the container a label showing:
- (1) The name and address of the prescriber.
 - (2) The name of the patient for whom the drug is intended. If the patient is an animal, the name of the owner and the species of the animal.
 - (3) Name and strength of the dangerous drug.
 - (4) Directions for use.
 - (5) Date furnished.
- (B) Whenever a prescriber personally furnishes a dangerous drug, labeled as a sample pursuant to section 3719.81 of the Revised Code and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide, in written format, the following:
- (1) Name of the prescriber.
 - (2) Name of the patient. If the patient is an animal, the name of the owner and the species of the animal.
 - (3) Directions for use.

4729-5-18 Patient profiles. [OAC: 03/01/99]

Amplifies: 4729.26

Review Date(s): 02/01/98, 02/01/03

History: 09/10/76, 09/01/85, 03/01/93, 02/01/98

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;

- (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 and nutritional supplements, including non-prescription 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 and strength of the drug or device;
 - (b) Prescription number;
 - (c) Quantity dispensed;
 - (d) Date dispensed;
 - (e) 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.

4729-5-19 Serial numbering of prescriptions. [OAC: 03/01/99]

Amplifies: 3715.64, 3715.69, 3719.05, 3719.07, 3719.13, 3719.27, 3719.28, 4729.26, 4729.37, 4729.55, 4729.66

Review Date(s): 04/30/02

History: 03/01/92, 01/17/97

All outpatient prescriptions must be serially numbered when entered into the computer system or when dispensed under a manual system.

- (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 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 prescriber to continue the medication, except:
 - (1) The prescriber 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 prescriber 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 prescriber 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.

4729-5-20 Prospective drug utilization review. [OAC: 03/01/99]

Amplifies: 4729.26

Review Date(s): 02/01/98, 02/01/03

History: 09/10/76, 09/01/85, 03/01/93, 02/01/98

- (A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:
 - (1) Over-utilization or under-utilization;
 - (2) Therapeutic duplication;
 - (3) Drug-disease state contraindications;
 - (4) Drug-drug interactions;
 - (5) Incorrect drug dosage;
 - (6) Drug-allergy interactions;
 - (7) Abuse/misuse;
 - (8) Inappropriate duration of drug treatment;
 - (9) Documented food-nutritional supplements-drug interaction.
- (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, but not limited to, any of the following:
 - (1) Peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);
 - (2) American hospital formulary service drug information;
 - (3) United States pharmacopoeia drug information;
 - (4) American medical association evaluations.

4729-5-24 Prescription copy. [OAC: 03/01/99]

Amplifies: 3719.05, 3719.28, 4729.26, 4729.37

Review Date(s): 04/30/02

History: 10/01/71, 08/01/84, 07/01/90, 07/01/92, 01/17/97, 07/01/97, 02/01/98

- (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 canceled as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule.
 - (5) The pharmacist receiving a copy of a prescription must:

- (a) Exercise reasonable diligence to determine validity of the copy;
 - (b) Reduce an oral prescription to writing by recording all of the information transferred (must include all information required in paragraph (A)(2) of this rule) and write the word "transfer" on the face of the prescription;
 - (c) Record date of transfer on the face of the prescription.
- (B) A prescription copy may be transferred between two pharmacies if the two pharmacies are accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner. The computerized systems must satisfy all information requirements of paragraphs (A)(2) and (A)(4)(c) of this rule. This shall include invalidation of the prescription record in the system to prevent further dispensing at the original site and, if a controlled substance prescription, the canceling of the original written prescription as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule. A system must be in place that will allow only authorized access to these computerized prescription records by a pharmacist and indicate on the prescription record when and by whom such access was made.
- (C) A prescription copy may be transferred between two pharmacists by the use of a facsimile machine. This facsimile may be considered to be a copy of a prescription if all information requirements of paragraph (A) of this rule, including invalidation of the original prescription or computer records, are met. A system must be in place that will show on the facsimile positive identification of the transferring and receiving pharmacists which must become a part of the prescription record. Facsimile copies must be recorded in writing pursuant to section 4729.37 of the Revised Code, or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.
- (D) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient. Original copies of prescriptions shall be maintained by pharmacies for the purpose of documenting the dispensing of drugs to a particular patient.
- (1) In the event that the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacist shall, upon the request of the patient, transfer the prescription information to the pharmacy designated by the patient.
 - (2) No pharmacy shall refuse to transfer information about a previously dispensed prescription to another pharmacy when requested by the patient. Prescription information shall be transferred in accordance with this rule as soon as possible in order to assure that the patient's drug therapy is not interrupted.
- (E) Prescriptions entered into a computer system but not dispensed may be transferred to another pharmacy if all of the following conditions are met:
- (1) The complete prescription information has been entered into the computer system;
 - (2) The information is displayed on the patient's profile;
 - (3) There is positive identification, either in the computer system or on the hard-copy prescription, of the pharmacist who is responsible for entering the prescription information into the system;
 - (4) The original prescription is filed in accordance with rule 4729-5-09 of the Administrative Code;
 - (5) All requirements of this rule are met for the transfer of the prescription.

4729-5-25 Dispensing of drugs and compounding of prescriptions. [OAC: 03/01/99]

Amplifies: 4729.26, 4729.27, 4729.28

Review Date(s): 04/30/02

History: 04/01/65, 10/01/71, 03/19/87

- (A) Only a pharmacist or pharmacy intern under the personal supervision of a pharmacist is permitted to engage in dispensing and compounding.
- (B) A person, not a pharmacist or intern under the personal supervision of a pharmacist, may assist a pharmacist in the compounding of prescriptions and dispensing of drugs in accordance with section 4729.01 of the Revised Code and according to the following requirements:
 - (1) May not engage in any procedure requiring professional judgment. The pharmacist is responsible for the drug dispensed.
 - (2) The system of drug distribution must provide exact control and assign immediate responsibility only to a pharmacist accountable at every point in the system between receipt of the order for a drug and final delivery for administration or use by the patient.
 - (3) May not engage in any procedure contrary to the intent of the statutes and rules regulating the dispensing of drugs and compounding of prescriptions.
 - (4) All such persons must not have any pending charges or prior convictions of any state or federal pharmacy or drug laws, or be addicted to or abusing alcohol or drugs, or impaired physically or mentally to such a degree as to render him/her unfit.
- (C) No dangerous drug, as defined in section 4729.01 of the Revised Code, shall be sold, offered for sale, or dispensed by means of any mechanical device unless such device is approved by the state board of pharmacy.

4729-5-26 Partial dispensing of schedule II controlled substances. [OAC: 03/01/99]

Amplifies: 3719.05, 3719.07, 3719.13, 3719.27, 3719.28

Review Date(s): 04/30/02

History: 03/01/92, 01/17/97

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 prescriber.

4729-5-27 Recordkeeping. [OAC: 03/01/99]

Amplifies: 3719.05, 3719.07, 3719.13, 3719.27, 3719.28, 4729.26, 4729.27, 4729.37

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

The following recordkeeping requirements do not apply to records relating to the practice of pharmacy for an inpatient as defined in rule 4729-17-01 of the Administrative Code.

- (A) There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:
 - (1) Prescription information entered into the recordkeeping system;
 - (2) Prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code;
 - (3) Dispensing;
 - (4) Patient counseling.
- (B) When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her positive identification into the computerized 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 alternate recordkeeping system.
- (C) 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.
- (D) The quantity dispensed shall be considered the quantity prescribed unless:
 - (1) If the quantity dispensed on a new prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription. If the quantity dispensed on a new prescription is greater than the quantity prescribed, the pharmacist shall also record on the original prescription the date and time that the prescriber was contacted and approval obtained.
 - (2) If the quantity dispensed on a refill prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription or enter the quantity dispensed on an alternate record meeting the requirements of this rule. If the quantity dispensed on a refill prescription is greater than the quantity prescribed, the pharmacist shall also record the date and time that the prescriber was contacted and approval obtained.

- (E) 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.
- (F) 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.
- (G) 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.
- (H) All records relating to the practice of pharmacy shall be readily available, and promptly produced, upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours.
- (I) All prescriptions or other records relating to the practice of pharmacy, 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.
- (J) Any pharmacy intending to maintain records relating to the practice of pharmacy at a location other than the place licensed with the state board of pharmacy must first send written notification to the state board of pharmacy by certified mail, return receipt requested. If not contested within sixty days of receipt by the state board of pharmacy office, such request will stand as approved.

4729-5-28 Computerized recordkeeping systems. [OAC: 03/01/99]

Amplifies: 3719.05, 3719.07, 3719.13, 3719.27, 3719.28, 4729.26, 4729.27, 4729.37

Review Date(s): 04/30/02

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

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 prescriber;
 - (3) Date of dispensing by the pharmacist;
 - (4) Full name and address of the patient;
 - (5) Full name and address of the prescriber;
 - (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 pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code, and the pharmacist responsible for dispensing, if a board approved system;
 - (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 and strength of the drug dispensed;
 - (3) The date of refill;
 - (4) The quantity dispensed;
 - (5) The positive identification of the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code and the pharmacist responsible for dispensing for each refill, if a board approved system;
 - (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 the 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) Prescriptions entered into a computer system but not dispensed must meet all of the following conditions:
 - (1) The complete prescription information must be entered in the computer system;
 - (2) The information must appear in the patient's profile;
 - (3) There is positive identification, in the computer system or on the hard-copy prescription, of the pharmacist who is responsible for entering the prescription information into the system; and
 - (4) The original prescription is filed according to rule 4729-5-09 of the Administrative Code.
- (F) 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.

(G) 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 prescriber;
- (4) Date of original dispensing by the pharmacist;
- (5) Full name and address of the patient;
- (6) Full name and address of the prescriber;
- (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 prescriber;
- (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.

(H) 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.

4729-5-29 Confidentiality of patient records. [OAC: 03/01/99]

Amplifies: 3719.05, 3719.07, 3719.13, 3719.27, 3719.28, 4729.26, 4729.27, 4729.37, 4729.39

Review Date(s): 04/30/02

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

(A) Records relating to the practice of pharmacy 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 prescriber who issued the prescription or medication order.
- (3) Certified/licensed health care personnel who are responsible for the care of the patient.

- (4) A member, inspector, agent, or investigator of the state board of pharmacy or any federal, state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug.
 - (5) An agent of 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)(7) 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) Any communication between a physician, a pharmacist, and a patient, pursuant to a consult agreement, except when requested by a federal, a state, or a local government entity, is privileged from discovery or other use and disclosure in civil process.
- (C) Records relating to the practice of pharmacy or administering drugs which may be required as evidence of a violation shall be released to a member, inspector, agent, or investigator of the state board of pharmacy or any state, county, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person or drug upon his request. Such person shall furnish a receipt to the person having legal custody of the records. If the record is a prescription, the receipt shall list the following information:
- (1) Prescription identification number; or, if an order for medication, the name of the patient;
 - (2) The drugs prescribed;
 - (3) Quantity of drugs prescribed and dispensed;
 - (4) Name of the prescriber;
 - (5) Date, name of agency, and signature of person removing the records.
- (D) All such records, including consents, memoranda of emergency disclosures, and written requests pursuant to paragraph (A)(8) of this rule, shall be kept on file at the pharmacy for a period of three years in a readily retrievable manner.

4729-5-30 Manner of issuance of prescription. [OAC: 03/01/99]

Amplifies: 3719.05, 3719.06, 3719.28, 4729.01, 4729.26, 4729.281, 4729.37, 4729.39

Review Date(s): 04/30/01

History: 04/01/78, 01/01/81, 02/15/82, 07/01/90, 07/01/94, 11/25/94, 09/01/96, 02/01/98

- (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 except in accordance with section 4729.281 of the Revised Code.
- (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. A pharmacist who modifies a patient's drug therapy, pursuant to a consult agreement, must personally transmit the facsimile or oral order to another pharmacist, if the drug is not dispensed by the pharmacist who modified the drug order.

- (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.
- (O) When a pharmacist, acting as an agent of the physician, modifies a patient's drug therapy pursuant to a consult agreement, the pharmacist must comply with this rule in the same manner as a prescriber and include the name of the physician who originally prescribed the drug and sign the pharmacist's full name.

4729-5-31 Criteria for licensure by examination. [OAC: 03/01/99]

Amplifies: 4729.07, 4729.08, 4729.13, 4729.26

Review Date(s): 03/01/99, 03/01/04

History: 02/15/82, 09/01/85, 03/21/88, 07/01/90, 01/26/93, 03/01/94, 09/01/96, 07/01/97

- (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 state board of pharmacy 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 and remit the fee established by the state board of pharmacy for re-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 and remit the fee established by the state board of pharmacy for re-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 state board of pharmacy 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 state board of pharmacy 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 state board of pharmacy 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.

4729-7-01 Definitions. [OAC: 03/01/99]

Amplifies: 4729.01, 4729.12, 4729.26

Review Date(s): 04/30/00

History: 11/20/72, 09/15/79, 02/15/95

As used in Chapter 4729-7 of the Administrative Code:

- (A) "Continuing pharmacy education", as required in section 4729.12 of the Revised Code, is defined as post-registration pharmacy education of approved quality undertaken to maintain professional competency to practice pharmacy, improve professional skills, and preserve uniform qualifications for continuing the practice of the profession for the purpose of protecting public health and welfare.
- (B) "Continuing education unit (C.E.U.)" is defined as ten contact hours of participation in an organized continuing pharmacy education experience presented by an approved provider.
- (C) "Approved continuing education" is defined as participation in an organized and structured continuing pharmacy education experience which has been presented by an approved provider or the state board of pharmacy and which presents information directly related to the practice of pharmacy in the area of patient care, pharmacy jurisprudence, or pharmacy management.
- (D) "Approved provider" is defined as an individual, institution, organization, association, corporation, or agency that has been approved by the state board of pharmacy and/or the "American Council on Pharmaceutical Education" (A.C.P.E.).
- (E) "Evidence of approved C.E.U.s" is defined as a certificate or other document certifying that the pharmacist has satisfactorily participated in an organized and structured continuing pharmacy education experience which was presented by an approved provider.
- (F) "Patient care" related continuing education shall include continuing pharmacy education experiences dealing with the properties and actions of drugs and dosage forms; the etiology, characteristics, therapeutics and prevention of disease states; and the monitoring and management of patients by the pharmacist.
- (G) "Pharmacy jurisprudence" related continuing education shall include Ohio state board of pharmacy approved continuing pharmacy education experiences that deal with current laws, rules, and regulations dealing with the practice of pharmacy and the recent changes that have occurred to those laws, rules, and regulations.

- (H) "Pharmacy management" related continuing education shall include continuing pharmacy education experiences that deal with professional practice management or the behavioral, social, or economic aspects of health care.

4729-7-02 Requirements for renewal of a pharmacist identification card. [OAC: 04/15/99]

Amplifies: 4729.12, 4729.13, 4729.26

Review Date(s): 04/30/00

History: 11/20/72, 09/15/79, 02/15/82, 07/01/84, 09/01/85, 03/21/88, 07/01/94, 02/15/95

- (A) Except as provided in rule 4729-7-08 of the Administrative Code, evidence of four and one-half C.E.U.s of approved continuing education shall be submitted with the application for renewal of a pharmacist identification card at intervals not to exceed three years. At least 0.3 C.E.U.s of the total required C.E.U.s must be obtained from Ohio state board of pharmacy approved programs in jurisprudence. Beginning with those pharmacists required to report continuing education in 2001, evidence of six C.E.U.s of approved continuing education shall be submitted with the application for renewal of a pharmacist identification card at intervals not to exceed three years. Beginning with those pharmacists required to report continuing education in 2001, at least four and one-half C.E.U.s of the total required C.E.U.s must be obtained in patient care related programs and at least 0.3 C.E.U.s of the total required C.E.U.s must be obtained from board approved programs in jurisprudence.
- (B) Documentation of the required C.E.U.s shall be submitted on forms provided by the state board of pharmacy and in the manner required for renewal of the pharmacist identification card.
- (C) The C.E.U.s must be obtained on or after July first of the year that is three years prior to the year in which evidence of the continuing pharmacy education is required for identification card renewal.
- (D) C.E.U.s obtained in excess of the required C.E.U.s at the time the continuing education is required for identification card renewal may not be transferred and applied to future requirements.
- (E) A pharmacist whose identification card has lapsed or has been suspended may renew his/her identification card, if he/she qualifies for renewal pursuant to section 4729.12 or section 4729.13 of the Revised Code, by paying the required fee, completing the application for renewal, and, if he/she would have been required to report continuing pharmacy education during the period of lapse or suspension, by providing evidence of having obtained the number of C.E.U.s required at the time of renewal by submitting the certificates of participation obtained during the three-year period immediately preceding the date of applying for renewal.
- (F) Ohio-registered pharmacists who hold a current license in states where continuing education is mandatory, have met the continuing pharmacy education requirements of that state, and who do not practice pharmacy in Ohio, may renew their identification card by paying the required fee, completing the application for renewal, and submitting the following signed statement on their continuing pharmacy education report form:

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

4729-7-03 Evidence of continuing pharmacy education experiences. [OAC: 03/01/99]

Amplifies: 4729.12, 4729.26

Review Date(s): 04/30/00

History: 06/01/72, 11/20/72, 09/15/79

- (A) Registered pharmacists shall keep all certificates and other documented evidence of participation which have been issued for approved C.E.U.s for which the pharmacist has claimed continuing education units towards renewal of his/her Ohio registered pharmacist identification card for a period of one year following the year in which evidence was required for renewal.
- (B) The original certificates or documents shall be submitted to the state board of pharmacy only when requested by the board.
- (C) The board will monitor compliance by auditing a random sample of registrants each reporting period.

4729-7-06 Criteria for in-state approved providers of continuing pharmacy education.

[OAC: 03/01/99]

Amplifies: 4729.12, 4729.26

Review Date(s): 04/30/00

History: 09/15/79, 03/21/88

In-state providers who desire to become approved by the state board of pharmacy must demonstrate ability and willingness to offer quality continuing pharmacy education in a responsible manner and shall submit evidence of this on applications supplied by the board. The minimal criteria include:

- (A) There shall be a responsible person charged with the administration of the continuing pharmacy education program and liaison with the board. Unless otherwise approved by the board, the responsible person shall be a pharmacist licensed to practice pharmacy in Ohio.
- (B) Providers shall award continuing pharmacy education credit to successful participants in terms of C.E.U.s.
- (C) Providers shall send a list of successful participants and their Ohio registration numbers to the board within thirty days of the experience or maintain such records for a five-year period to be made available to the board on request.
- (D) Providers shall award a certificate to each successful participant containing at least the following information:
 - (1) The name of the provider;
 - (2) The completion date of the experience;
 - (3) The name of the participant;
 - (4) The title of the experience;
 - (5) The number of C.E.U.s the experience has been assigned;
 - (6) The experience identification number according to the numbering system designated by the board; and
 - (7) The positive identification of the responsible person.
- (E) Providers shall develop and employ evaluation techniques that will assess the effectiveness of the continuing pharmacy education experiences with the goal of continual improvement.
- (F) Providers should utilize an evaluation mechanism for the purpose of allowing each participant to assess the achievement of personal objectives.
- (G) Providers shall send notification to the board before or within ten days after a program has been presented.

4729-7-08 Alternative methods of proving continuing competency. [OAC: 03/01/99]

Amplifies: 4729.12, 4729.13, 4729.26

Review Date(s): 03/01/04

- (A) As an alternative to providing evidence of all of the required C.E.U.s of approved continuing education as required by rule 4729-7-02 of the Administrative Code except for the 0.3 C.E.U.s of Ohio state board of pharmacy approved jurisprudence, a pharmacist may satisfy the continuing pharmacy education requirements by providing evidence at the time of renewal that he/she has met the requirements of and is currently certified by a board approved pharmacy practice specific specialty certification program. At a minimum, such pharmacy practice specific specialty certification programs shall consist of:
- (1) Periodic recertification examinations;
 - (2) Documentation by the certification program that the pharmacist is currently certified by the program;
 - (3) Other requirements as determined by the board.
- (B) Pharmacists who choose to meet their continuing pharmacy education requirements in the manner described in paragraph (A) of this rule are still required to provide evidence of having completed at least 0.3 C.E.U.s of Ohio state board of pharmacy approved pharmacy jurisprudence related continuing education.

4729-9-01 Definitions. [OAC: 03/01/99]

Amplifies: 3719.01, 3719.03, 3719.28, 4729.01, 4729.16, 4729.26, 4729.56, 4729.57, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 03/21/88, 07/01/91, 07/01/92, 01/17/97, 02/01/98

- (A) "Dangerous drug," as defined in section 4729.01 of the Revised Code, means any drug or drug product whose commercial package bears a label containing the symbol "Rx only", 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) As used in Chapters 3719. and 4729. of the Revised Code, "registered" and "licensed" mean that an individual or facility has met the initial qualifications for registration and licensure with the state 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 state 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 state 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 state board of pharmacy during

a period of good behavior for a period of time and under such conditions as determined by the state 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 state 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 state 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)".

4729-9-02 Minimum standards for a pharmacy. [OAC: 03/01/99]

Amplifies: 4729.54, 4729.55, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 01/01/63, 02/15/82, 03/21/88, 07/01/90, 07/01/92, 07/01/94

(A) Library

- (1) Current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio;
- (2) The pharmacy shall carry and utilize the references necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws; and
- (3) Telephone number of a poison control center.

(B) Equipment

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

(C) Stock of drugs

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

(D) Prescription containers

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

(E) Space and fixtures

- (1) The stock, library, and equipment shall be housed in a suitable, well-lighted and well-ventilated room or department with clean and sanitary surroundings primarily used for the compounding and preparing of prescriptions and for the manufacture of pharmaceutical preparations.
 - (2) All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise indicated by the board.
 - (3) All storage areas shall provide adequate physical security for all dangerous drugs in accordance with rules 4729-9-05 and 4729-9-11 of the Administrative Code.
- (F) Additional minimum standards are required for specialized pharmacy practices pursuant to Chapters 4729-15, 4729-17, and 4729-19 of the Administrative Code.

4729-9-03 Minimum standards for a first-aid department. [OAC: 03/01/99]

Amplifies: 4729.54, 4729.55, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 09/01/85, 07/01/90

- (A) A first-aid department is any entity which stocks, administers, and/or uses dangerous drugs in conjunction with the treatment of medical emergencies, except that this does not include the offices of a prescriber as defined in section 4729.01 of the Revised Code or an entity licensed in any other manner as a terminal distributor of dangerous drugs pursuant to section 4729.54 of the Revised Code.
- (B) Each first-aid department which stocks, administers, and/or provides dangerous drugs must obtain a limited category I, II, or III terminal distributor of dangerous drugs license pursuant to section 4729.54 of the Revised Code. The license and the addendum shall be maintained in a readily available place in the principal location of such business for inspection by a state board of pharmacy designated agent. The application and license shall be signed by a person licensed pursuant to Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery. This person shall maintain supervision and control over the possession and custody of the dangerous drugs and is responsible for their legal use and distribution in accordance with state and federal laws and rules.
- (C) When one first-aid department purchases dangerous drugs for first-aid departments in other locations and redistributes them, this supplying first-aid department must also be registered as a wholesale distributor of dangerous drugs.

All purchase, sale, and distribution records for dangerous drugs and inventory for controlled substances shall be kept for at least three years and shall be available for inspection during regular business hours by a state board of pharmacy designated agent. The first-aid department must be able to account for the acquisition, administration, and distribution of all dangerous drugs.
- (D) All purchase orders or requisitions for dangerous drugs must be signed by the responsible person who signed the dangerous drug license pursuant to paragraph (B) of this rule and who is in charge of the first-aid department.
- (E) Dangerous drugs which are not controlled substances shall be administered only by certified/-licensed health care personnel who are functioning within the scope of their practice in accordance with written standing orders or protocol filed with the state board of pharmacy pursuant to section 4729.54 of the Revised Code. Controlled substances may be administered only after personally contacting a prescriber and obtaining an oral order. No dangerous drugs are to be administered except pursuant to the written standing orders or protocol or where a written or

oral order is issued by such prescriber for the particular patient. Oral orders shall be immediately recorded in writing including the name and strength of drug, dosage form, quantity used, name of patient, name of prescriber, name of person receiving order, name of person administering drug, time of administration, and the date. This record shall be kept on file at the first-aid department and be co-signed by the prescriber within thirty days.

- (F) All dangerous drugs are to be kept in a safe and secure place, such as an enclosure or cabinet, which is to be kept locked.
- (G) The responsible prescriber shall visit the first-aid department at least once each month and shall review the records, accountability procedures, controls, and security.

4729-9-04 Returned drugs. [OAC: 03/01/99]

Amplifies: 3715.63, 3715.69, 3719.05, 3719.28, 4729.26, 4729.66

Review Date(s): 04/30/02

History: 09/10/76, 07/01/91, 07/01/92, 01/17/97

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

4729-9-05 Security requirements. [OAC: 03/01/99]

Amplifies: 4729.66

Review Date(s): 02/01/98, 02/01/03

History: 09/10/76, 02/01/98

- (A) All registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion.
- (B) Substantial compliance with the standards set forth in rule 4729-9-11 of the Administrative Code may be deemed sufficient by the state 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 state 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 drugs 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 areas containing dangerous drugs;
 - (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 state 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: 03/01/99]

Amplifies: 3719.05, 3719.06, 3719.07, 3719.28, 4729.66

Review Date(s): 02/01/98, 02/01/03

History: 09/10/76, 07/01/93, 02/01/98

- (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 prescriber required to keep records pursuant to Chapters 3719. and 4729. of the Revised Code, the responsible pharmacist or prescriber 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 prescriber, he shall submit to the state 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 state board of pharmacy officer, agent, or inspector or other authorized person; or
 - (3) By such other means as the state 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 state board of pharmacy in each instance on the condition that the registrant keep records of such disposals and file periodic reports with the state 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.

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

[OAC: 03/01/99]

Amplifies: 3719.09, 3719.28, 4729.51, 4729.66

Review Date(s): 02/01/98, 02/01/03

History: 09/10/76, 03/21/88, 07/01/93, 02/01/98

For the purpose of aiding compliance with section 2925.23 of the Revised Code, a prescriber, 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.

4729-9-10 Occasional sale. [OAC: 03/01/99]

Amplifies: 4729.51, 4729.66

Review Date(s): 04/30/99, 02/01/03

History: 04/01/65, 03/19/87, 07/01/93

The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a drug by a pharmacist who is a terminal distributor of dangerous drugs or is employed by a terminal distributor of dangerous drugs and the buyer shall be a wholesale distributor of dangerous drugs, a terminal distributor of dangerous drugs, or a prescriber as defined in section 4729.01 of the Revised Code.

The total value of all dangerous drugs distributed by the terminal distributor of dangerous drugs pursuant to this rule shall not exceed five per cent of the total value of dangerous drugs purchased by the terminal distributor of dangerous drugs during the same calendar year. In addition, the total amount of controlled substances sold pursuant to this rule shall not exceed the allowable amount as specified in section 1307.11 of the Code of Federal Regulations.

The value of the dangerous drugs shall be based on the cost of the dangerous drugs to the terminal distributor of dangerous drugs.

4729-9-11 Security and control of dangerous drugs. [OAC: 03/01/99]

Amplifies: 3719.05, 3719.09, 3719.28, 4729.26, 4729.27, 4729.28, 4729.51, 4729.531, 4729.55, 4729.57, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 04/01/78, 04/01/89, 07/01/94, 08/16/94, 11/25/94

A pharmacist, prescriber, or responsible person pursuant to paragraph (C) of rule 4729-13-01 or paragraph (C) of rule 4729-14-01 of the Administrative Code, who has signed as being responsible for a terminal distributor of dangerous drugs license, shall provide "supervision and control" of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, and "adequate safeguards" to assure that dangerous drugs are being distributed in accordance with all state and federal laws as required in section 4729.55 of the Revised Code, by the following procedures:

(A) In a pharmacy.

- (1) Personal supervision by a pharmacist of the dangerous drugs at all times to deter and detect theft or diversion; except,
- (2) Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:
 - (a) The prescription department or stock of dangerous drugs must be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time the pharmacist is not present. Such a barrier, before being put into use, must be approved by the state board of pharmacy.
 - (b) The prescription department must contain all dangerous drugs, exempt narcotics, hypodermics, poisons, and every other item or product which requires the personal supervision or sale by a pharmacist.
 - (c) No item, product, record, or equipment which must be accessible to anyone other than a pharmacist may be stored in the prescription department.
 - (d) Only a pharmacist may have access to the prescription department or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, exempt narcotics, hypodermics, poisons, and any other item or product which requires the personal supervision or sale by a pharmacist.
 - (e) No prescription, dangerous drug, exempt narcotic, hypodermic, nor any other item or product which requires the personal supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the prescription department is closed.
 - (f) New prescriptions received from the patient or by mail, or refill prescription orders received from the patient or by phone or by mail, may be dropped into the prescription department by slot when a pharmacist is not present.
 - (g) Notice to the public of operating hours of the prescription department must be posted.
- (3) Areas designated for the dispensing, compounding, and storage of dangerous drugs shall meet the security requirements in rule 4729-9-05 of the Administrative Code. No person may be within the physical confines of the area designated for the dispensing, compounding, and storage of dangerous drugs unless under the personal supervision of a pharmacist.

(B) In other terminal distributors of dangerous drugs, including but not limited to, emergency medical services pursuant to division (C) of section 4729.54 of the Revised Code, first-aid departments pursuant to rule 4729-9-04 of the Administrative Code, approved laboratories

pursuant to paragraph (A) of rule 4729-13-01 of the Administrative Code, and animal shelters pursuant to paragraph (A) of rule 4729-14-01 of the Administrative Code, dangerous drugs must be stored in an area secured by either a physical barrier with suitable locks and/or an electronic barrier to deter and detect unauthorized access.

- (C) A pharmacist, prescriber, or responsible person for a terminal distributor of dangerous drugs license pursuant to paragraph (C) of rule 4729-13-01 or paragraph (C) of rule 4729-14-01 of the Administrative Code who has signed as being responsible for a terminal distributor of dangerous drugs license is responsible to monitor for suspicious orders, unusual usage, or questionable disposition of dangerous drugs.

4729-9-12 Verification of license as a distributor of dangerous drugs or exempt status of a prescriber. [OAC: 03/01/99]

Amplifies: 3719.04, 3719.28, 4729.51, 4729.60, 4729.66

Review Date(s): 04/30/01

History: 07/01/91, 03/13/95, 01/10/96

- (A) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a terminal distributor of dangerous drugs, the wholesale distributor must obtain a copy of the current certificate of license as a terminal distributor from the purchaser pursuant to division (A) of section 4729.60 of the Revised Code.
 - (1) The purchaser shall furnish a copy of the certificate of license as a terminal distributor to the wholesale distributor of dangerous drugs. If the certificate of license indicates a limited category I, II, or III license, the terminal distributor shall furnish the wholesale distributor a copy of the current license addendum listing those drugs the purchaser is authorized to possess.
 - (2) If no certificate of license as a terminal distributor is obtained or furnished before the sale, both the seller and the purchaser shall be considered to be in violation of section 4729.60 of the Revised Code.
- (B) Before a terminal distributor of dangerous drugs may make a purchase of dangerous drugs at wholesale, the purchaser must obtain from the seller the wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code.
 - (1) The seller shall furnish the wholesale distributor registration number and registration expiration date to the terminal distributor of dangerous drugs.
 - (2) If no registration number of the wholesale distributor is obtained or furnished before the purchase, both the purchaser and the seller shall be considered to be in violation of section 4729.60 of the Revised Code.
- (C) Before a wholesale distributor of dangerous drugs may make a sale of a dangerous drug to a prescriber as defined in division (I) of section 4729.01 of the Revised Code, the wholesale distributor must obtain:
 - (1) A copy of the current certificate of license as a terminal distributor from the prescriber pursuant to division (A) of section 4729.60 of the Revised Code and, if the license is limited, a copy of the addendum listing the drugs the licensee is authorized to purchase and possess; or
 - (2) Copies of all documents required to establish that the prescriber is exempt from licensure as a terminal distributor of dangerous drugs and is authorized by federal and state laws to purchase the dangerous drugs for use in the course of his/her professional practice. The required documents are as follows:
 - (a) An individual prescriber doing business as a sole proprietor (not incorporated in any manner) must provide a copy of his/her current license to practice and the license

must authorize the use of the drugs requested from the wholesaler in his/her practice;

- (b) The address of all sites of practice where the drugs will be delivered to and stored for use by the prescriber in his/her professional practice pursuant to federal and state laws;
 - (c) Verification from the licensing board that the prescriber's license is in good standing and that there are no restrictions on his/her license to practice and use drugs in his/her practice. If the license has been restricted by the licensing board, a copy of the official documents restricting the license to practice and use drugs in the course of professional practice must be furnished to the wholesaler and maintained by the wholesaler with all other documents establishing the prescriber's exemption from licensure as a terminal distributor of dangerous drugs;
 - (d) If an exempted prescriber wishes to purchase and possess dangerous drugs which are also controlled substances, the prescriber must submit a copy of his/her current registration with the federal drug enforcement administration and provide verification that the DEA registration and authority to use controlled substances in the course of professional practice has not been restricted by the appropriate professional licensing board or the federal drug enforcement administration.
- (D) Dangerous drugs may not be shipped by a wholesale distributor of dangerous drugs to any address other than those listed by the business entity meeting the definition of a prescriber and filed with the wholesale distributor in paragraph (B) of this rule. Controlled substances may only be shipped to those addresses registered with the federal drug enforcement administration for the purpose of storing controlled substances.
- (E) All documents establishing the fact that a prescriber is exempt from licensure as a terminal distributor of dangerous drugs shall be current and maintained for a period of three years by the wholesale distributor of dangerous drugs.
- (F) Copies of licenses to practice and verification that there are no restrictions on a prescriber's license by either the appropriate professional licensing board or the federal drug enforcement administration shall be obtained within fifteen days of the date of renewal of such licenses. No dangerous drugs may be sold and delivered to a prescriber until the required documentation has been obtained by the wholesale distributor.
- (G) Each wholesale distributor of dangerous drugs registered with the state board of pharmacy shall report any suspicious purchases of any dangerous drugs by a prescriber exempted from licensure as a terminal distributor of dangerous drugs. A suspicious purchase includes, but is not limited to, any drugs that the prescriber is not authorized to use in the course of his/her professional practice.

4729-9-13 Distributor of dangerous drugs samples. [OAC: 03/01/99]

Amplifies: 3719.28, 3719.81, 4729.66

Review Date(s): 02/01/98, 02/01/03

History: 09/10/76, 02/01/98

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 prescriber unless requested by the prescriber 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.

4729-9-14 Records of controlled substances. [OAC: 03/01/99]

Amplifies: 3719.07, 3719.28

Review Date(s): 03/01/99, 03/01/04

History: 04/01/78, 01/01/81, 07/01/89

- (A) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, dispensed, sold, or used.
- (1) Records of receipt shall contain a description of all controlled substances received, the kind and quantity of controlled substances received, the name and address of the persons from whom received, and the date of receipt.
 - (2) Records of administering, dispensing, or using controlled substances shall contain a description of the kind and quantity of the controlled substance administered, dispensed, or used, the date, the name and address of the person to whom, or for whose use, or the owner and species of the animal for which the controlled substance was administered, dispensed, or used.
 - (3) Records of drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the name and address requirements of paragraph (A)(2) of this rule.
- (B) Each prescriber or terminal distributor of dangerous drugs shall maintain an inventory of all controlled substances as follows:
- (1) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken.
 - (a) The name of the substance.
 - (b) The total quantity of the substance.
 - (i) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter).
 - (ii) The number of units or volume of each finished form in each commercial container (e.g., one-hundred-tablet bottle or ten-milliliter vial).
 - (iii) The number of commercial containers of each such finished form (e.g., three one-hundred-tablet bottles or ten one-milliliter vials).
 - (c) If the substance is listed in schedule I or II, the prescriber or terminal distributor of dangerous drugs shall make an exact count or measure of the contents.
 - (d) If the substance is listed in schedule III, IV, or V, the prescriber or terminal distributor of dangerous drugs shall make an estimated count or measure of the contents, unless the container holds more than one thousand tablets or capsules in which an exact count of the contents must be made.
 - (2) A separate inventory shall be made for each place or establishment where controlled substances are in the possession or under the control of the prescriber or terminal distributor. Each inventory for each place or establishment shall be kept at the place or establishment.
 - (3) An inventory of all stocks of controlled substances on hand on the date the prescriber or terminal distributor first engages in the administering, dispensing, or use of controlled substances. In the event the prescriber or terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

- (4) Each prescriber or terminal distributor of dangerous drugs shall take a new inventory of all stocks of controlled substances on hand every two years following the date on which the initial inventory is taken.
- (5) When a substance is added to the schedule of controlled substances by the federal drug enforcement administration or the state board of pharmacy, each prescriber or terminal distributor of dangerous drugs shall take an inventory of all stock of such substance on hand at that time.
- (6) All records of receipt, distribution, administering, dispensing, inventory, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any prescriber or terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send notification to the state board of pharmacy; if not contested by the board within sixty days, it will stand as approved.

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

[OAC: 03/01/99]

Amplifies: 3719.07, 3719.28, 4729.55, 4729.66

Review Date(s): 04/30/01

History: 04/01/78, 02/15/82, 07/01/90, 02/15/95, 01/17/97

- (A) Each prescriber 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 state 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 state 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 prescriber 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 state 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 state board of pharmacy and law enforcement authorities, and the drug enforcement administration (DEA) pursuant to section 1305.12(b), Code of Federal Regulations.

4729-9-16 Minimum requirements for wholesalers. [OAC: 03/01/99]

Amplifies: 3719.03, 3719.28, 4729.53, 4729.66

Review Date(s): 04/30/01

History: 06/01/82, 07/01/90, 07/01/92, 01/17/97

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 state board of pharmacy 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 state board of pharmacy. 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 state 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 state board of pharmacy 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 pharmacopoeia/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 operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.
 - (i) The wholesaler shall inform the state board of pharmacy 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 state board of pharmacy 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 state 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 state 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 state 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 state 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 dan-

gerous 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.

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

[OAC: 03/01/99]

Amplifies: 3719.03, 3719.28, 4729.53, 4729.55, 4729.66

Review Date(s): 04/30/01

History: 07/01/91, 01/10/96

- (A) The state board of pharmacy may consider as evidence of a person not meeting the requirements provided in sections 4729.53 and 4729.55 of the Revised Code, and may deny a person registration as a wholesale distributor of dangerous drugs or licensure as a terminal distributor of dangerous drugs in Ohio if such person:
- (1) Has been convicted of a felony;
 - (2) Has been convicted of violating any state or federal pharmacy or drug law;
 - (3) Is not of good moral character and habits;
 - (4) Is addicted to or abusing liquor or drugs;
 - (5) Has been disciplined by the Ohio state board of pharmacy pursuant to section 4729.16 of the Revised Code; or
 - (6) Has been disciplined by any board of pharmacy.
- (B) When a request for licensure as a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or as a wholesaler or manufacturer of controlled substances is made, the state board of pharmacy may consider as evidence of the facility not meeting the requirements for licensure as provided in Chapters 3719. and 4729. of the Revised Code, or may deny issuance of such licensure, if:
- (1) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked by the state board of pharmacy to the spouse or other family member;
 - (2) The ownership of such facility, or pharmacy previously located in such facility, has been transferred from a licensee whose license has been revoked by the state board of pharmacy to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed.
 - (3) The facility knowingly employs a person who has been denied the right to work in such a facility by the state board of pharmacy as part of an official order of the board.

4729-9-20 Drugs repackaged by a pharmacy. [OAC: 03/01/99]

Amplifies: 3715.521, 3715.63, 3715.64, 3715.69, 3719.07, 3719.08, 3719.28, 4729.66

Review Date(s): 04/30/01

History: 07/01/91, 01/10/96

- (A) Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following:
- (1) Name of drug, strength, and dosage form;

- (2) The identification of the repackager by name or by the final six digits of their terminal distributor of dangerous drugs license number;
 - (3) Pharmacy control number;
 - (4) Pharmacy's expiration date or beyond-use date, which shall be within the proven period of stability of the drug. This expiration or beyond-use date shall be no later than the manufacturer's expiration date of a not previously opened manufacturer's container.
- (B) A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include at least the following:
- (1) Name of drug, strength, dosage form, and quantity;
 - (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 repackaging of the drug.

4729-9-21 Drugs compounded in a pharmacy. [OAC: 03/01/99]

Amplifies: 3715.521, 3715.63, 3715.64, 3715.69, 3719.05, 3719.28, 4729.26, 4729.28, 4729.55, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 07/01/94

- (A) In order to compound prescriptions, a pharmacy shall meet the minimum standards for a pharmacy pursuant to rule 4729-9-02 of the Administrative Code.
- (B) Parenteral and sterile product prescriptions shall be compounded in accordance with Chapter 4729-19 of the Administrative Code.
- (C) For all compounded prescriptions, the pharmacist shall:
 - (1) Inspect and approve the compounding process;
 - (2) Perform the final check of the finished product.
- (D) For all compounded prescriptions, the pharmacist shall be responsible for:
 - (1) All compounding records;
 - (2) The proper maintenance, cleanliness, and use of all equipment used in compounding.
- (E) Personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.
- (F) A prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

- (G) A compounded prescription that is dispensed to a patient must be labeled according to rule 4729-5-16 of the Administrative Code.
- (H) Labels for a compounded prescription that is prepared in anticipation of a prescription drug order shall contain, but not be limited to, the following:
 - (1) The name, strength, and quantity of each drug used in the compounded prescription;
 - (2) The identification of the repackager by name or by the final six digits of its terminal distributor of dangerous drugs license number;
 - (3) Pharmacy control number;
 - (4) The pharmacy's expiration date or beyond-use date.

4729-9-22 Records of dangerous drugs. [OAC: 03/01/99]

Amplifies: 4729.26, 4729.37, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 07/01/94

Each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, distributed, sold, or used.

- (A) Records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt.
- (B) Records of administering, dispensing, or using dangerous drugs shall contain a description of the kind and quantity of the dangerous drugs administered, dispensed, sold, or used, the date, the name and address of the person to whom, or for whose use, or the owner and species of the animal for which the dangerous drug was administered, dispensed, or used.
- (C) Records of dangerous drugs, other than controlled substances, administered, dispensed, or used which become a permanent part of the patient's medical record shall be deemed to meet the requirements of paragraph (B) of this rule.
- (D) All records of receipt, distribution, administering, dispensing, selling, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send notification to the state board of pharmacy by certified mail, return receipt requested; if not contested by the board within sixty days, it will stand as approved. A copy of the request with the return receipt shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor.

4729-9-23 Dispensing of multiple drugs in single-dose containers. [OAC: 03/01/99]

Amplifies: 3715.521, 3715.63, 3715.64, 3715.69, 4729.26, 4729.66

Review Date(s): 03/01/04

Multiple drugs may be packaged in the same container such that the different drugs are in contact with each other only under the following conditions:

- (A) The number of drugs placed in one package cannot exceed the capability of the receptacle to prevent damage to the dosage forms.
- (B) The quantity dispensed may not be more than a thirty-one-day supply.
- (C) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required by state and federal law including accessory labels.

- (D) Each individual package must include a beyond-use date of not more than sixty days from the date the drugs were placed in the package.
- (E) Medications which have been packaged in multi-dose packaging are considered adulterated if returned to the pharmacy for any reason and may not be returned to stock or re-dispensed.
- (F) The packaging is tamper-evident.
- (G) Any pharmacist or pharmacy using multi-dose packaging must implement policies and procedures which will exclude drugs having the following characteristics from such packaging:
 - (1) The U.S.P. monograph or official labeling requires dispensing in the original container;
 - (2) The drugs or dosage forms are incompatible with packaging components or each other;
 - (3) The drugs are therapeutically incompatible when administered simultaneously;
 - (4) The drug products require special packaging.

4729-9-24 Retail and wholesale sales of dangerous drugs on-line. [OAC: 03/01/99]

Amplifies: 3715.69, 3719.04, 3719.05, 3719.28, 4729.26, 4729.51, 4729.551, 4729.66

Review Date(s): 03/01/04

- (A) All persons selling or offering to sell dangerous drugs at retail or wholesale in Ohio must be licensed or registered with the Ohio state board of pharmacy as a dangerous drug distributor.
- (B) All dangerous drug distributors registered or licensed with the Ohio state board of pharmacy and who sell or offer to sell dangerous drugs at retail or wholesale on the "Internet" to persons located in Ohio or any other state must make such sales only in compliance with all state and federal laws governing the legal distribution of dangerous drugs.
- (C) "Internet" sites owned and/or maintained by Ohio registered or licensed dangerous drug distributors must provide the following information to the public on the "Internet" site and no drugs are to be shipped at wholesale or retail except in accordance with Ohio's drug laws:
 - (1) Name dangerous drug distributor is licensed to do business as in Ohio.
 - (2) Full address of licensed or registered site.
 - (3) Name of responsible person as it appears on the dangerous drug distributor license.
 - (4) Telephone number where responsible person may be contacted.
 - (5) A list of the states in which the dangerous drug distributor may legally sell prescription drugs at wholesale or retail.
 - (6) The name, address, and how the drug law enforcement agency may be contacted in each state in which the person is authorized to do business. This may include a link to the drug law enforcement agency's "Internet" site and/or their e-mail address.
- (D) Any Ohio licensed or registered dangerous drug distributor requesting personal information from the public by way of the "Internet" site (questionnaire forms or e-mail) must provide for security and confidentiality of the information. This portion of the "Internet" site must also provide information regarding how the personal information will be used and ensure that such information is not used for purposes not disclosed without the written informed consent of the patient or person submitting personal information.

4729-10-01 Definitions. [OAC: 03/01/99]

Amplifies: 4729.01, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 08/16/94, 12/15/94

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

- (A) "Nonresident pharmacy" means any pharmacy, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into Ohio;
- (B) "Nonresident terminal distributor of dangerous drugs" means any person, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers in any manner, dangerous drugs at retail into Ohio;
- (C) "Pharmacist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice pharmacy in the state where he is practicing.
- (D) "Dentist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice dentistry in the state where he is practicing.
- (E) "Optometrist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice optometry in the state where he is practicing.
- (F) "Physician," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice medicine in the state where he is practicing.
- (G) "Veterinarian," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice veterinary medicine in the state where he is practicing.
- (H) "Dangerous drug" has the same meaning as given that term in section 4729.01 of the Revised Code.

4729-11-09 Sale of schedule V controlled substance products without a prescription.

[OAC: 03/01/99]

Amplifies: 3719.05, 3719.28, 4729.26, 4729.28, 4729.51, 4729.66

Review Date(s): 04/30/00

History: 08/16/94(Emer), 11/25/94

A schedule V controlled substance product which is not a prescription drug as determined under the "Federal Food, Drug and Cosmetic Act" may be sold at retail by a pharmacist without a prescription to a purchaser at retail, provided that:

- (A) The sale is made only by a pharmacist and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities in this section, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist).
- (B) The purchaser is at least eighteen years of age.
- (C) The pharmacist requires every purchaser of a controlled substance under this rule not known to him to furnish suitable identification (including proof of age where appropriate).
- (D) A bound record book is maintained which contains the true name and complete address of the purchaser, the legible signature of the purchaser, the name and quantity of controlled substances sold, the date of each sale, and the name and legible initials of the pharmacist who sold the controlled substance at retail. This book shall be maintained for a period of three years

from the date of the last transaction and must be made available for inspection and copying by persons authorized to enforce the federal and state drug laws.

- (E) The schedule V controlled substance product is sold at retail.
- (F) Not more than two hundred forty milliliters (eight ounces) nor more than forty-eight solid dosage units of any schedule V controlled substance product containing opium, nor more than one hundred twenty milliliters (four ounces) nor more than twenty-four solid dosage units of any other narcotic controlled substance may be sold at retail to the same purchaser in any consecutive forty-eight-hour period.
- (G) Not more than one hundred solid dosage units of any schedule V controlled substance stimulant product may be sold to any one person in any consecutive thirty-day period.
- (H) The schedule V controlled substance is sold at retail for a legitimate medical need and the purchaser furnishes information to the pharmacist which establishes the legitimate medical need for the controlled substance.

4729-13-02 Procedure for state board of pharmacy approval as a laboratory. [OAC: 03/01/99]

Amplifies: 4729.54, 4729.55, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 04/01/78, 07/01/89, 07/01/94

- (A) A person, as defined in division (S) of section 4729.01 of the Revised Code, desiring to be approved by the state board of pharmacy as a laboratory shall file with the state board of pharmacy a completed application containing information relative to the qualifications for approval as set forth in rule 4729-13-03 of the Administrative Code.
- (B) The state board of pharmacy shall issue a terminal distributor of dangerous drugs license to purchase, possess, and utilize dangerous drugs for scientific and clinical purposes and for purposes of instruction at the establishment or place described in the application to each person who has submitted an application and has paid the required license fee if the board determines that such applicant meets the requirements set forth in this chapter.
- (C) All licenses issued pursuant to this rule shall be effective for a period of twelve months from the first day of January of each year. A license shall be renewed by the state board of pharmacy for a like period, annually, according to the provisions of this rule, and the standard renewal procedure of sections 4745.01 to 4745.03 of the Revised Code.
- (D) The fee required for issuance of the license shall be the same as that required in section 4729.54 of the Revised Code.
- (E) A person desiring to renew the license shall submit a completed application for such renewal and pay the required fee before the fifteenth day of December each year.
- (F) The state board of pharmacy, within thirty days after receipt of an application filed in the form and manner set forth in this rule for the issuance of a new or renewal license, shall notify the applicant whether or not such license will be issued or renewed. If the board determines that such license will not be issued or renewed, such notice to the applicant shall set forth the reason or reasons that such license will not be issued or renewed.

4729-13-03 Qualifications for a laboratory. [OAC: 03/01/99]

Amplifies: 4729.55, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 04/01/78, 07/01/89, 07/01/94

A laboratory to be approved by the state board of pharmacy to be entrusted with the custody and utilization of dangerous drugs and controlled substances for scientific and clinical purposes and for purposes of instruction must furnish satisfactory proof to the state board of pharmacy that:

- (A) The applicant is qualified to conduct the business of an approved laboratory.
- (B) The applicant will, on behalf of the applicant, the applicant's agents, and employees, submit to the jurisdiction of the state board of pharmacy and to the laws of this state for the purposes of the enforcement of Chapters 3719. and 4729. of the Revised Code.
- (C) Adequate safeguards are assured to prevent the illegal acquisition, distribution, or utilization of dangerous drugs or their diversion into illicit channels.

4729-13-05 Security controls for laboratories. [OAC: 03/01/99]

Amplifies: 3719.09, 3719.28, 4729.51, 4729.55, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 04/01/78, 07/01/89, 07/01/94

- (A) Areas designated for the storage of dangerous drugs shall meet the security requirements in paragraph (B) of rule 4729-9-11 of the Administrative Code.
- (B) Controlled substances shall be stored in a securely locked, substantially constructed cabinet.
- (C) Etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. government class V security container.
- (D) The responsible person shall notify the state board of pharmacy, law enforcement authorities, and the regional office of the drug enforcement administration in his region of the theft or significant loss of any dangerous drugs or controlled substances upon discovery of such loss or theft pursuant to rule 4729-9-15 of the Administrative Code.

4729-14-02 Procedure for licensure as an animal shelter. [OAC: 03/01/99]

Amplifies: 4729.531, 4729.532, 4729.54, 4729.55, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 08/16/94(Emer), 11/25/94

- (A) A person, as defined in division (S) of section 4729.01 of the Revised Code, desiring to be licensed by the state board of pharmacy as an animal shelter shall file with the state board of pharmacy a completed application containing information relative to the qualifications for approval as set forth in rule 4729-14-03 of the Administrative Code.
- (B) The state board of pharmacy shall issue a limited terminal distributor of dangerous drugs license, pursuant to sections 4729.531 and 4729.532 of the Revised Code, at the establishment or place described in the application to each person who has submitted an application and has paid the required license fee if the board determines that such applicant meets the requirements set forth in Chapter 4729-14 of the Administrative Code.
- (C) All licenses issued pursuant to this rule shall be effective for a period of twelve months from the first day of January of each year. A license shall be renewed by the state board of pharmacy for a like period, annually, according to the provisions of this rule, and the standard renewal procedure of sections 4745.01 to 4745.03 of the Revised Code.

- (D) The fee required for issuance of the license shall be the same as that required in section 4729.54 of the Revised Code.
- (E) A person desiring to renew the license shall submit a completed application for such renewal and pay the required fee on or before the last day of December each year.
- (F) The state board of pharmacy, within thirty days after receipt of a complete application filed in the form and manner set forth in this rule for the issuance of a new or renewal license, shall notify the applicant whether or not such license will be issued or renewed. If the board determines that such license will not be issued or renewed, such notice to the applicant shall set forth the reason or reasons that such license will not be issued or renewed.

4729-15-01 Definitions. [OAC: 03/01/99]

Amplifies: 3719.01, 3719.28, 4729.01, 4729.26, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 04/01/78, 09/01/89, 07/01/94

As used in Chapter 4729-15 of the Administrative Code:

- (A) "Nuclear pharmacy" is a pharmacy where prescriptions for radiopharmaceuticals are filled or where radiopharmaceuticals are compounded or dispensed by a pharmacist licensed by the proper authorities to receive, possess, and use such drugs. A nuclear pharmacy shall be licensed by the United States "Nuclear Regulatory Commission" or the appropriate state nuclear regulatory agencies, other appropriate state agencies, and by the state board of pharmacy.
- (B) "Radiopharmaceutical," a dangerous drug as defined in division (D) of section 4729.01 of the Revised Code, shall include any article that exhibits spontaneous decay or disintegration of an unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such article.
- (C) "Nuclear pharmacist" shall be a licensed pharmacist holding a current identification card in the state of Ohio, and meets the following standards:
 - (1) Be certified as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or
 - (2) Meet minimal standards of training for an "authorized user" of radioactive material or for an "authorized nuclear pharmacist (ANP)" designation by the proper nuclear regulatory agency, the United States Nuclear Regulatory Commission, or the appropriate state agency including:
 - (a) Have received a minimum of two hundred contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy or a program approved by the nuclear regulatory commission, with emphasis in the following areas:
 - (i) Radiation physics and instrumentation (eighty-five hours);
 - (ii) Radiation protection (forty-five hours);
 - (iii) Mathematics of radioactivity (twenty hours);
 - (iv) Radiation biology (twenty hours);
 - (v) Radiopharmaceutical chemistry (thirty hours).
 - (b) Attain a minimum of five hundred hours of clinical nuclear pharmacy training under the supervision of a pharmacist trained in nuclear pharmacy and who is an "authorized user" or an "authorized nuclear pharmacist" as defined by the nuclear regulatory commission.

4729-15-04 Labeling of radiopharmaceuticals. [OAC: 03/01/99]
Amplifies: 3715.64, 3715.69, 3719.08, 3719.28, 4729.26, 4729.66
Review Date(s): 03/01/99, 03/01/04
History: 04/01/78, 09/01/89, 07/01/94

All radiopharmaceuticals dispensed for use by inpatients of an institutional facility are exempt from the labeling requirements of rule 4729-17-10 of the Administrative Code. All radiopharmaceuticals dispensed for use by outpatients are exempt from the labeling requirements of rule 4729-5-16 of the Administrative Code.

- (A) No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing the following information:
 - (1) The standard radiation symbol.
 - (2) The words "Caution - Radioactive Material."
 - (3) The prescription number.
 - (4) The radionuclide and chemical form.

- (B) No radiopharmaceutical may be dispensed unless a tamper-evident seal is applied and a label is affixed to the outer or delivery container of each dose bearing the following information:
 - (1) The standard radiation symbol.
 - (2) The words "Caution - Radioactive Material."
 - (3) The radionuclide and chemical form.
 - (4) The volume if in liquid form.
 - (5) The requested activity and the calibration date and time.
 - (6) The prescription number.
 - (7) Labels for radiolabeled blood components and therapeutic dosages must always contain the patient's name at the time of dispensing. Where the patient's name is not available at the time of dispensing for diagnostic dosing, a seventy-two-hour exemption is allowed to obtain the name of the patient. No later than seventy-two hours after dispensing the radiopharmaceutical, the patient's name must be associated with the prescription in a readily retrievable manner and must be retained for a period of three years.
 - (8) The name and address of the nuclear pharmacy.
 - (9) The name of the end authorized user, who must also be a prescriber as defined in section 4729.01 of the Revised Code.
 - (10) The lot number of the preparation.

4729-15-05 Prohibitions. [OAC: 03/01/99]
Amplifies: 3715.63, 3715.69, 3719.09, 3719.28, 4729.26, 4729.27, 4729.28, 4729.51, 4729.66
Review Date(s): 03/01/99, 03/01/04
History: 04/01/78, 09/01/89, 07/01/94

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

- (B) No person, other than a nuclear pharmacist, shall be personally in full and actual charge of a nuclear pharmacy.
- (C) No person shall conduct a nuclear pharmacy except in accordance with section 4729.28 of the Revised Code, state board of pharmacy rules, regulations of the United States nuclear regulatory commission or the appropriate state nuclear regulatory agencies, and regulations of other appropriate state agencies.
- (D) No person shall utilize unit-dose transport containers for radioactive dosages without an effective mechanism to avoid contamination of the transport container with blood or other biohazardous substances.
- (E) No person shall re-use a unit-dose transport container that has been contaminated with blood or other biohazardous substances. Any unit-dose transport container that is returned with the tamper-evident seal broken and the unit-dose syringe included must be considered to be contaminated.
- (F) This rule does not apply to:
 - (1) An individual prescriber who prepares radiopharmaceuticals for administration to the prescriber's patients as provided in section 4729.29 of the Revised Code.
 - (2) The transfer of radioactive material not intended for use as a drug to authorized persons.
 - (3) The occasional transfer of bulk quantities of radiopharmaceuticals to other authorized persons to meet shortages.

4729-17-01 Definitions: institutional facility. [OAC: 03/01/99]

Amplifies: 3719.01, 3719.28, 4729.01, 4729.26, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 09/01/85, 07/01/91, 03/13/95, 01/10/96

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

- (A) "Institutional facility" means a facility licensed by the Ohio state board of pharmacy and either the Ohio department of health or the Ohio department of rehabilitation and correction at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including but not limited to:
 - (1) Convalescent homes;
 - (2) Developmental facilities;
 - (3) Hospitals;
 - (4) Long-term care facilities;
 - (5) Nursing homes;
 - (6) Psychiatric facilities;
 - (7) Rehabilitation facilities;
 - (8) Mental retardation facilities.
- (B) "Inpatient" means any person who receives drugs for use while within the institutional facility.
- (C) "Inpatient prescription" means a written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient.

- (D) "Dispensing of a drug pursuant to an inpatient prescription" means the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of a computerized automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given final approval to the patient-specific order in the system.
- (E) "Contingency drugs" are those drugs which may be required to meet the therapeutic needs of inpatients when a licensed pharmacist is not available and personally in full and actual charge of the institutional pharmacy.
- (F) "Emergency drugs" are those drugs which are required to meet the immediate therapeutic needs of inpatients in order to sustain life in an emergency crisis.
- (G) "Outpatient" means any person who receives drugs for use outside of the institutional facility.

4729-17-02 Pharmacist-in-charge of an institutional pharmacy. [OAC: 03/01/99]

Amplifies: 3719.05, 3719.07, 3719.28, 4729.26, 4729.27, 4729.55, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 11/01/85, 07/01/90, 07/01/91, 01/10/96

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

- (A) The institutional pharmacy director or designated pharmacist shall be the pharmacist-in-charge pursuant to section 4729.27 of the Revised Code, the responsible pharmacist pursuant to rule 4729-5-11 of the Administrative Code, and the pharmacist responsible for maintaining supervision and control over the possession and custody of all dangerous drugs acquired by the institutional facility pursuant to division (B) of section 4729.55 of the Revised Code.
- (B) The terminal distributor of dangerous drugs license issued to the institutional facility shall be signed by the pharmacist-in-charge and maintained in a readily available place in the pharmacy.
- (C) The pharmacist-in-charge shall:
 - (1) Be responsible for the practice of pharmacy performed within the institution;
 - (2) Develop, implement, supervise, and coordinate all services provided by the pharmacy;
 - (3) In conjunction with the appropriate interdisciplinary committees, be responsible for the development of written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs, assure adherence to these policies and procedures in order to provide for the safe and efficient distribution of drugs in all areas of the institution, and make available a current copy of these written policies and procedures for inspection and/or copying by an employee of the state board of pharmacy;
 - (4) Be responsible for the security and control of all drugs within the institution;
 - (5) Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs.
- (D) An institutional pharmacy director or designated pharmacist, who ceases to be the pharmacist-in-charge and responsible pharmacist pursuant to section 4729.27 and division (B) of section 4729.55 of the Revised Code, shall:
 - (1) File a written notice to the state board of pharmacy by certified mail, return receipt requested, within thirty days. This notice shall include:

- (a) The name, address, and dangerous drug distributor license number(s) of the institutional pharmacy;
 - (b) His/her name and pharmacist registration identification number; and
 - (c) The date on which he/she was no longer the pharmacist-in-charge.
- (2) Take a complete inventory, pursuant to federal regulations, of the controlled substances on hand at the pharmacy with the new or acting pharmacist-in-charge at the time he/she ceases to be pharmacist-in-charge.
- (a) The original copy of the inventory shall be maintained in the pharmacy with all other required controlled substance records;
 - (b) This inventory shall serve as the inventory of controlled substances for which the new or acting pharmacist-in-charge is responsible.

4729-17-03 Security and control of drugs in an institutional facility. [OAC: 03/01/99]

Amplifies: 3719.09, 3719.28, 4729.26, 4729.28, 4729.51, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 09/01/85, 07/01/91, 01/10/96

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

- (i) Identify the personnel authorized to access the pharmacy and the conditions under which access may be gained to the pharmacy;
 - (ii) Ensure a minimum of two employees of the institution, one of whom shall be a health care professional licensed pursuant to Chapter 4723. (Nursing Practice Act) or 4731. (Medical Practice Act) of the Revised Code and authorized by such chapter to administer drugs in the course of their professional practice, to accompany each other when accessing the pharmacy;
 - (iii) Provide a written record documenting emergency access to the pharmacy. Such record shall include the names and titles of all institutional personnel accessing the pharmacy, date and time of access, the name and quantity of drugs obtained, the name of the patient, and the name of the ordering prescriber.
- (b) The written record of each access to the institutional pharmacy when it is closed and a pharmacist is not present shall be filed, within twenty-four hours, with the pharmacist-in-charge and maintained in the pharmacy for three years.

(B) Supplies of dangerous drugs may be maintained in patient care areas according to written policies and procedures developed and implemented by the pharmacist-in-charge. The policies and procedures shall:

- (1) Provide for a limited quantity of dangerous drugs to be maintained at any one location;
- (2) Provide for the proper storage and labeling of all such drugs;
- (3) Provide for storage in a secure area. If dangerous drugs cannot be stored in a secure area, they shall be stored in a container which is sealed with a tamper-evident seal that must be broken to gain access to the drugs;
- (4) Provide for notification of the pharmacist-in-charge, or designated pharmacist, when the dangerous drug supply has been accessed and/or drugs used;
- (5) Provide for replacement of the drugs used, and the dangerous drug supply to be re-sealed;
- (6) Provide for inspection of the dangerous drug supply, on a regular basis, to detect unauthorized use of such drugs and which drugs have exceeded their expiration or beyond-use date;
- (7) Provide adequate recordkeeping procedures to document the disposition of drugs from the supply.

(C) Security

- (1) All areas occupied by an institutional pharmacy shall be capable of being secured by key, or other effective mechanism, so as to prevent access by unauthorized personnel.
- (2) In the absence of a licensed pharmacist, all areas occupied by an institutional pharmacy shall be secured so as to prevent access by unauthorized personnel.
- (3) The pharmacist-in-charge shall develop and implement policies and procedures which will detect and deter the diversion and/or adulteration of drugs.

4729-17-04 Records; institutional facility pharmacy. [OAC: **03/01/99**]

Amplifies: 3719.09, 3719.28, 4729.26, 4729.28, 4729.51, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 09/01/85, 07/01/91, 01/10/96

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 records relating to the practice of pharmacy. Such drug orders and records may be microfilmed or retained by any process providing an exact duplicate of the original order. In addition, if an alternate recordkeeping system is utilized these records may be stored on any storage medium that meets industry standards for quality and has stability for a period of at least three years. Records on an automated data processing system, or subsequent storage of such records, must be readily retrievable (via CRT display or hard-copy printout), within seventy-two hours.
 - (1) Records of drugs dispensed shall include, but are not limited to:
 - (a) The name, strength, and quantity of drugs dispensed;
 - (b) The date of dispensing;
 - (c) The name of the inpatient to whom, or for whose use, the drug was dispensed; and
 - (d) Positive identification of all pharmacists involved in the dispensing.
 - (2) All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
 - (a) The name of the inpatient to whom, or for whose benefit, the activity was performed;
 - (b) The practice of pharmacy activity performed;
 - (c) The results of the activity, if applicable; and
 - (d) Positive identification of all pharmacists involved in the activity, identifying the function performed by each pharmacist.
 - (3) 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, quantity, 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 licensed 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: 03/01/99]

Amplifies: 3719.07, 3719.28, 4729.26, 4729.37, 4729.55, 4729.66

Review Date(s): 02/01/03

History: 02/01/98

- (A) All controlled substances dispensed to inpatients in an institutional facility in quantities exceeding a seventy-two-hour supply shall be dispensed and maintained according to the following requirements:
- (1) All controlled substances dispensed in quantities exceeding a seventy-two-hour supply shall be packaged in tamper-evident, unit-of-use containers except multidose liquids and injectables where unit-of-use packaging is not available;
 - (2) The drugs shall be stored in a secure location with access limited to authorized individuals;
 - (3) 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;
 - (4) 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. A pharmacist at the pharmacy department responsible for the terminal distributor of dangerous drugs license must be one of those notified.
- (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 shall meet the following requirements, unless they are stored in a secure, automated storage system that meets the requirements of paragraph (C) 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. A pharmacist at the pharmacy department responsible 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.
- (C) 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 (B) 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. A pharmacist at the pharmacy department responsible 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.

4729-17-08 Minimum standards for an institutional facility pharmacy. [OAC: 03/01/99]

Amplifies: 4729.55, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 09/01/85, 07/01/90, 01/10/96

(A) Library

- (1) Current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio;
- (2) The pharmacy shall carry and utilize the references necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws; and
- (3) Telephone number of a poison control center.

(B) Drug inventory, fixtures, and space

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

4729-17-09 Drug orders for patients of an institutional facility. [OAC: **03/01/99**]

Amplifies: 3719.05, 3719.06, 3719.07, 3719.28, 4729.26, 4729.28, 4729.37, 4729.55, 4729.66

Review Date(s): 04/30/01

History: 09/10/76, 09/01/85, 07/01/90, 07/01/91, 11/25/94, 01/10/96, 02/01/98

- (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 state board of pharmacy 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 professionals using positive identification. If the licensed health care professional 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.

4729-17-10 Labeling of prescriptions for patients of an institutional facility. [OAC: 03/01/99]

Amplifies: 3715.64, 3715.69, 3719.08, 3719.28, 4729.26, 4729.66

Review Date(s): 04/30/01

History: 09/01/85, 07/01/91, 01/10/96

- (A) All dangerous drugs dispensed for use by inpatients in an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:
- (1) The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include:
 - (a) The non-proprietary or proprietary name of the drug;
 - (b) The route of administration, if other than oral;
 - (c) The strength and volume, where appropriate, expressed in the metric system whenever possible;
 - (d) The control number and expiration date;
 - (e) Identification of the manufacturer, packer or distributor, or if the repackager is the dispensing pharmacy identification of the repackager, shall be by name or by the final six digits of their terminal distributor of dangerous drugs license number, and such identification shall be clearly distinguishable from the rest of the label;
 - (f) Special storage conditions, if required.
 - (2) When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:
 - (a) Identification of the dispensing pharmacy;
 - (b) The patient's name;
 - (c) The date of dispensing;
 - (d) The non-proprietary and/or proprietary name of the drug;
 - (e) The strength, expressed in the metric system whenever possible.
 - (3) Multiple drugs may be packaged in the same container such that the different drugs are in contact with each other only under the following conditions:
 - (a) The number of drugs placed in one package cannot exceed the capability of the receptacle to prevent damage to the dosage forms.
 - (b) The quantity dispensed may not be more than a thirty-one-day supply.
 - (c) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required by state and federal law including accessory labels.
 - (d) Each individual package must include a beyond-use date of not more than sixty days from the date the drugs were placed in the package.

- (e) Medications which have been packaged in multi-dose packaging may not be returned to stock or redispensed when returned to the pharmacy for any reason.
 - (f) When the drugs are not in the possession of the ultimate user and any one drug within each individual package has been discontinued, all drugs in the individual package are deemed adulterated and they may not be administered.
 - (g) The packaging is tamper-evident.
 - (h) Any pharmacist/pharmacy using multi-dose packaging must implement policies and procedures which will exclude drugs having the following characteristics from such packaging:
 - (i) The U.S.P. monograph or official labeling requires dispensing in the original container;
 - (ii) The drugs or dosage forms are incompatible with packaging components or each other;
 - (iii) The drugs are therapeutically incompatible when administered simultaneously;
 - (iv) The drug products require special packaging.
- (4) At least the name of the patient must be placed on all medication containers too small to bear a complete label and dispensed in a container bearing a complete label.
- (B) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code.
- (C) Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:
- (1) The patient's name;
 - (2) The name and amount of the parenteral solution;
 - (3) The name and amount of the drug(s) added;
 - (4) The expiration date or beyond-use date;
 - (5) The name and address of the institutional facility pharmacy;
 - (6) Cautionary statements, if required.

4729-17-13 D.E.A. numbers for hospital employed physicians. [OAC: 03/01/99]

Amplifies: 3719.06, 3719.28, 4729.51, 4729.66

Review Date(s): 04/30/01

History: 07/01/91, 11/25/94

- (A) A person authorized to write prescriptions pursuant to paragraph (B) of rule 4729-5-15 of the Administrative Code who is employed as a staff physician of a hospital, is not individually registered under the provisions of the controlled substances act and, therefore, does not possess a "Drug Enforcement Administration" (D.E.A.) number, may administer, dispense, and prescribe controlled substances under the registration of the hospital.
- (B) A person pursuing an approved training program within the jurisdiction of the hospital and authorized to write prescriptions pursuant to paragraph (B) of rule 4729-5-15 of the Administrative Code may administer, dispense, or prescribe controlled substances under the registration of the hospital. Persons pursuing such approved training programs may function in sites outside the physical confines of the hospital only if such sites are part of the training

program and the persons are under the employment and jurisdiction of the hospital administering the approved program. While functioning in the outside sites, such persons may continue to use the internal code assigned by the hospital administering the approved program, upon mutual agreement of the hospital and the outside site.

- (C) The administering, dispensing, or prescribing must be done in the usual course of his/her professional practice and only within the scope of his/her employment.
- (D) Each person so authorized must be assigned a specific internal code number by the hospital which will be used as a suffix to the hospital D.E.A. registration number. Such internal code number shall consist of numbers, letters, or a combination thereof and shall be preceded by a hyphen. A list of the internal codes and the corresponding individual physicians must be kept by the hospital and made available at all times to other registrants, state board of pharmacy designated agents, investigators of the state medical board, and federal, state, county, or municipal law enforcement agencies for verification.

4729-19-01 Definitions. [OAC: 03/01/99]

Amplifies: 3719.01, 3719.28, 4729.01, 4729.26, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 07/04/88, 07/01/93

- (A) As used in the Administrative Code:
 - (1) "Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment according to "National Sanitation Foundation (NSF) Standard 49".
 - (2) "Class 100 environment" means an atmospheric environment which contains less than one hundred particles of 0.5 microns in diameter per cubic foot of air according to "Federal Standard 209D."
 - (3) "Compounding facility" means a site licensed as a terminal distributor of dangerous drugs where the compounding of sterile product prescriptions occurs.
 - (4) "Cytotoxic" means a drug that has been shown to be carcinogenic or mutagenic to humans through active or passive exposure.
 - (5) "Parenteral" means a sterile preparation of drugs for injection through one or more layers of the skin.
 - (6) "Sterile product" means a dosage form free of living microorganisms (aseptic).
- (B) Compounded sterile product prescriptions include, but are not limited to, the following preparations:
 - (1) Total parenteral nutrition (TPN) solutions;
 - (2) Parenteral analgesic drugs;
 - (3) Parenteral antibiotics;
 - (4) Parenteral antineoplastic agents;
 - (5) Parenteral electrolytes;
 - (6) Parenteral vitamins;
 - (7) Irrigating fluids;
 - (8) Ophthalmic preparations.

- (C) Sterile product prescriptions shall not include commercially manufactured products that do not require compounding prior to dispensing.

4729-19-02 Prescriptions for sterile products. [OAC: 03/01/99]

Amplifies: 3719.06, 3719.07, 3719.28, 4729.26, 4729.37, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 11/25/94

- (A) Sterile product prescriptions must meet the requirements of rule 4729-5-30 of the Administrative Code, except that a sterile product prescription prepared in accordance with federal and state requirements that is for a schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion 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 paragraphs (D) and (K) of rule 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.
- (B) The requirements for sterile product prescriptions received by a fluid therapy pharmacy are as specified in rule 4729-31-02 of the Administrative Code.

4729-19-03 Labeling. [OAC: 03/01/99]

Amplifies: 3715.64, 3715.69, 3719.08, 3719.28, 4729.26, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 07/04/88, 07/01/93

- (A) No sterile product prescription may be dispensed to an outpatient unless the container in which such prescription is dispensed is labeled pursuant to rule 4729-5-16 of the Administrative Code nor to an inpatient unless the container in which such prescription is dispensed is labeled pursuant to rule 4729-17-10 of the Administrative Code. In addition, the label shall include the beyond-use date of the final preparation.
- (B) The requirements for the labeling of sterile product prescriptions in a fluid therapy pharmacy are as specified in rule 4729-31-03 of the Administrative Code.

4729-19-04 Minimum standards for compounding parenteral or sterile product prescriptions. [OAC: 03/01/99]

Amplifies: 4729.55, 4729.66

Review Date(s): 03/01/99, 03/01/04

History: 07/04/88, 07/01/93

- (A) A compounding facility shall meet the minimum standards for institutional facility pharmacies pursuant to rule 4729-17-08 of the Administrative Code.
- (B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile product prescriptions.
- (1) The policy and procedure manual shall include a quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education.
 - (2) The policy and procedure manual shall include policies and procedures for cytotoxic waste, if applicable.
 - (3) The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy designated agent.

(C) Physical requirements

- (1) The facility shall have a designated area with access limited to authorized personnel for preparing parenteral and sterile products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- (2) The facility compounding parenteral and sterile product prescriptions shall have:
 - (a) Appropriate environmental control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;
 - (b) Appropriate disposal containers for used needles, syringes, etc. and, if applicable, for cytotoxic waste from the preparation of chemotherapy agents;
 - (c) Appropriate environmental control including approved biohazard cabinetry when cytotoxic drug products are prepared;
 - (d) Infusion devices and equipment, if appropriate;
 - (e) Appropriate temperature-controlled transport containers.
- (3) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.
- (4) The facility shall have sufficient current reference materials related to sterile products to meet the needs of the facility staff.
- (5) The compounding of sterile products shall be done within a class 100 environment except in an emergency situation when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized.

(D) Delivery service

The responsible person shall assure the environmental control of all products shipped to the patient.

(E) Disposal of cytotoxic and/or hazardous waste

The responsible person shall assure that there is a system for the disposal of cytotoxic and/or hazardous waste in a manner so as not to endanger the public health.

(F) Cytotoxic drugs

The following requirements are necessary for those facilities that prepare cytotoxic drugs to ensure the protection of the personnel involved:

- (1) All cytotoxic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet. Other products should not be compounded in this cabinet.
- (2) Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include at least gloves and gowns with tight cuffs.

- (3) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.
- (4) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.
- (5) Written procedures for handling both major and minor spills of cytotoxic agents shall be developed and shall be included in the policy and procedure manual.
- (6) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(G) Patient training

Whenever possible, a pharmacist shall be involved in discussing with each patient receiving an outpatient parenteral or sterile product prescription, or the caregiver of such individual, the following matters:

- (1) Dosage form, dosage, route of administration, and duration of drug therapy;
- (2) Special directions and precautions for preparation and administration;
- (3) Proper storage; and
- (4) Stability or incompatibilities of the medication.

(H) Quality assurance

There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and facilities.

- (1) All clean rooms and laminar flow hoods shall be certified for operational efficiency at least every six months. Appropriate records shall be maintained.
- (2) There shall be written procedures developed requiring appropriate sampling if microbial contamination is suspected.
- (3) If bulk compounding of parenteral or sterile products is performed using non-sterile chemicals, extensive end-product testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.
- (4) There shall be written justification for the chosen beyond-use dates of compounded products.

4729-29-01 Reasonable attempt to contact and confer. [OAC: 03/01/99]

Amplifies: 4729.01, 4729.26, 4729.39

Review Date(s): 03/01/04

As used in section 4729.39 of the Revised Code, a "reasonable attempt to contact and confer" shall be deemed to have occurred if the pharmacist provides the physician with notification of the intended action to be taken pursuant to the consult agreement and provides the physician with the opportunity to respond in a timely manner. Such notification may include, but is not limited to, one of the following methods:

- (A) Personally meeting with the physician;
- (B) Telephone discussion with the physician;

- (C) Facsimile in a manner that confirms delivery;
- (D) Electronic mail that confirms delivery;
- (E) Any other method in writing that reaches the physician in a timely manner; or
- (F) Any other method of notification as outlined in the consult agreement between the pharmacist and physician that might reasonably be expected to allow for the notification of the physician prior to the implementation of the intended action.

4729-29-02 Pharmacist as agent. [OAC: 03/01/99]

Amplifies: 4729.26, 4729.39

Review Date(s): 03/01/04

For the purpose of implementing any actions initiated as a result of a consult agreement whereby the consulting pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, the consulting pharmacist shall be deemed to be acting as the agent of the consulting physician as the term agent is used in rule 4729-5-30 of the Administrative Code unless the physician has specified otherwise in the consult agreement. The pharmacist's copy of the signed consult agreement shall be made available to the dispensing pharmacist or the person administering the dosage ordered if it is requested in order to prove the right of the pharmacist to act in this manner.

4729-29-03 Records. [OAC: 03/01/99]

Amplifies: 4729.26, 4729.39

Review Date(s): 03/01/04

As required by section 4729.39 of the Revised Code, all consult agreements and the records of actions taken pursuant to such consult agreements shall be in writing. The pharmacist shall maintain these records in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the consult. Such consult agreements shall be considered confidential patient records and are therefore subject to the requirements of rule 4729-5-29 of the Administrative Code.

4729-29-04 Therapy management by formulary. [OAC: 03/01/99]

Amplifies: 4729.26, 4729.39

Review Date(s): 03/01/04

The requirements of section 4729.39 of the Revised Code do not apply within an institutional facility as defined in rule 4729-17-01 of the Administrative Code when the pharmacists are following the requirements of a formulary system that was developed pursuant to section 4729.381 of the Revised Code.

4729-29-05 Signatures required on a consult agreement. [OAC: 03/01/99]

Amplifies: 4729.26, 4729.39

Review Date(s): 03/01/04

To be effective, a consult agreement must bear the signatures of one patient or caregiver, one physician, and one pharmacist. The consult agreement must define the diagnosis or diagnoses that affect the drug therapy that is covered by the agreement. Where there is a group of physicians or pharmacists who may be caring for the patient, the consult agreement shall be signed by the primary physician and the primary pharmacist. In this case, the consult agreement shall designate one other pharmacist who may be covering for the primary pharmacist. This designation of an alternate pharmacist for coverage purposes must be made prior to the consult agreement receiving the signature of the patient or the patient's caregiver.

4729-31-01 Definitions. [OAC: 03/01/99]

Amplifies: 3719.01, 3719.28, 4729.01, 4729.26, 4729.66

Review Date(s): 03/01/04

As used in this chapter of the Administrative Code:

- (A) "Fluid therapy pharmacy" means a pharmacy where the primary purpose is to compound and dispense parenteral compounded sterile product prescriptions. Such a pharmacy must comply with the minimum standards for compounding parenteral or sterile product prescriptions as defined in rule 4729-19-04 of the Administrative Code.
- (B) "Compounded sterile product prescription" shall have the same meaning as in rule 4729-19-01 of the Administrative Code.

4729-31-02 Prescriptions for sterile products. [OAC: 03/01/99]

Amplifies: 3719.06, 3719.07, 3719.28, 4729.26, 4729.37, 4729.66

Review Date(s): 03/01/04

When prepared in a fluid therapy pharmacy, drugs shall be dispensed by a pharmacist pursuant to an original patient-specific order issued by a prescriber.

- (A) Oral orders, where permitted by law, issued by a prescriber for patients of a fluid therapy pharmacy may be transmitted to a pharmacist by a prescriber or a prescriber's agent. Such orders shall be recorded by the pharmacist noting the full name of the authorized personnel transmitting the order. The original signed prescriptions must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.
- (B) Drug orders for patients of a fluid therapy pharmacy transmitted to a pharmacist by the use of a facsimile machine shall only be valid if permitted by law and if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the patient's records including the positive identification of the prescriber and the prescriber's agent as well as 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 drug order for three years from the date of the last transaction. The original signed drug order from which the facsimile is produced shall not be issued to the patient. The original signed drug order must remain with the patient's records at the prescriber's office or the institutional facility where it was issued. A facsimile of a drug order 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.
- (C) All drug orders for patients of a fluid therapy pharmacy shall include, but are not limited to, at least the following:
 - (1) Name and address of the patient;
 - (2) Name, strength, and dosage form of the drug;
 - (3) Directions for use, including route of administration if other than oral;
 - (4) Date prescribed;
 - (5) Prescriber's positive identification;
 - (6) Length of therapy or total quantity to be dispensed.

4729-31-03 Labeling. [OAC: 03/01/99]

Amplifies: 3715.64, 3715.69, 3719.08, 3719.28, 4729.26, 4729.66

Review Date(s): 03/01/04

When prepared in a fluid therapy pharmacy, no compounded parenteral product prescription may be dispensed unless a label is affixed to the container in which such drug is dispensed and such label includes:

- (A) The name and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license;
- (B) The name of the patient for whom the drug is prescribed;
- (C) The name of the prescriber;
- (D) Directions for use of the drug which must include route of administration;
- (E) The date of dispensing;
- (F) Any cautions which may be required by federal or state law;
- (G) The name or initials of the pharmacist;
- (H) The name and amount of the drug(s) added;
- (I) The name and volume of the parenteral solution;
- (J) The quantity of drug dispensed, if appropriate;
- (K) Beyond use date;
- (L) Storage conditions.

4729-31-04 Recordkeeping. [OAC: 03/01/99]

Amplifies: 3719.07, 3719.28, 4729.26, 4729.37, 4729.55, 4729.66

Review Date(s): 03/01/04

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

- (A) A record of all drugs purchased, the quantity received, and the name, address, and wholesale or terminal distributor of dangerous drugs license number of the person from whom the drugs were purchased.
- (B) All drug orders and records relating to the practice of pharmacy. Such drug orders and records may be microfilmed or retained by any process providing an exact duplicate of the original order. In addition, if an alternate recordkeeping system is utilized, these records may be stored on any storage medium that meets industry standards for quality and has stability for a period of at least three years. Records on an automated data processing system, or subsequent storage of such records, must be readily retrievable (via CRT display or hard-copy printout), within seventy-two hours.
 - (1) Records of drugs dispensed shall include, but are not limited to:
 - (a) The name, strength, and quantity of drugs dispensed;
 - (b) The date of dispensing;
 - (c) The name of the patient to whom, or for whose use, the drug was dispensed;
 - (d) Positive identification of all pharmacists involved in each function of the dispensing; and

- (e) Disposal record of any unused drug(s).
- (2) All other records relating to the practice of pharmacy other than dispensing shall include, but not limited to:
 - (a) The name of the inpatient to whom, or for whose benefit the activity was performed;
 - (b) The practice of pharmacy activity performed;
 - (c) The results of the activity, if applicable; and
 - (d) Positive identification of all pharmacists involved in each function of the activity.
- (C) A record of all drugs compounded which shall include at least the following:
 - (1) Name of drug, strength, and dosage form;
 - (2) Quantity of drug(s) added to each container;
 - (3) Disposition of unused drug(s) and amount;
 - (4) Manufacturer's or distributor's control number;
 - (5) Manufacturer's or distributor's name, if a generic drug is used;
 - (6) Pharmacy control number, if prepared in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;
 - (7) Date of compounding;
 - (8) Manufacturer's or distributor's expiration date;
 - (9) The pharmacy's expiration date or beyond-use date;
 - (10) Positive identification of the registered pharmacist responsible for the compounding or repackaging of each drug product.
- (D) All records must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber. All records shall be readily retrievable and uniformly maintained in an unalterable and secure manner for at least three years from the date of the last dispensing.

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