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FULL TEXT SHOWING CHANGES

UNDERLINED = Add New Language

LINED THROUGH = ~~Remove~~ Old Language

4729-3-01 Definitions.

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

- (A) "Pharmacy internship" means the supervised practical experience required for licensure as a registered pharmacist. The purpose of the pharmacy internship program is to provide those individuals, who intend to become registered pharmacists, with the knowledge and practical experience necessary for functioning competently and effectively upon licensure.
- ~~(B)~~ ~~"Supervised practical experience" is the experience obtained at an internship site and which is conducted in accordance with the "National Association of Boards of Pharmacy - American Association of Colleges of Pharmacy" publication "The Internship Experience," or a similar outline and/or manual approved by the board of pharmacy.~~
- ~~(C)~~(B) "Internship site" means a pharmacy licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code, except as provided in paragraph (C) or (D) of rule 4729-3-05 of the Administrative Code, and whose license is in good standing.
- ~~(D)~~(C) "Preceptor" is the individual responsible for seeing that the intern is properly supervised and exposed to all aspects of the an internship program ~~defined as the supervised practical experience.~~
 - (1) A "preceptor" is a pharmacist who holds a current identification card which is in good standing; or, is a person who is of good moral character and is qualified to direct the approved experience in the area approved by the director of internship pursuant to paragraph (D) of rule 4729-3-05 of the Administrative Code.
 - (2) A person may serve as the preceptor for more than one intern. The number of interns engaged in the practice of pharmacy at any time is limited to not more than two for each pharmacist on duty.
 - (3) A preceptor must report to the board on the progress and aptitude of an intern when requested by the director of internship.
- ~~(E)~~(D) "Director of internship" has the same meaning as provided in section 4729.11 of the Revised Code.

~~(F)~~(E) "In good standing" means that the licensee or registrant has not been denied the privilege of supervising interns by the board.

~~(G)~~(F) "Statement of Preceptor" is the form which must be received by the board of pharmacy for each pharmacy intern within thirty days of beginning internship under a preceptor's supervision. A "Statement of Preceptor" form is not required to be submitted to the board when using an academic experience affidavit.

(1) No credit will be given for practical experience obtained prior to thirty days of the date that the "Statement of Preceptor" form is received by the board office; except, that in the event of extraordinary circumstances and when due to no fault of the intern, the board may accept a retroactive date of filing for the "Statement of Preceptor."

(2) The intern must file a "Statement of Preceptor" form whenever he/she changes internship sites and/or preceptors.

~~(H)~~(G) "Practical experience affidavit" is the form which must be used to submit evidence of practical experience for internship credit.

(1) Practical experience reported on the affidavit shall be the total number of actual clock hours worked during the reported time period rounded to the nearest hour. The hours reported must be able to be documented by payroll or other records which may be examined by the board of pharmacy upon reasonable notice.

(2) Practical experience affidavits must be signed by the preceptor on file with the board of pharmacy. In the event of the unavailability of the preceptor's signature due to extraordinary circumstances and due to no fault of the intern, the board may accept an alternative method for verification of a practical experience affidavit.

(3) Practical experience affidavits for a calendar year may be filed at any time, except that they must be received in the board office or postmarked no later than the first day of March of the following year.

~~(I)~~(H) "Academic experience affidavit" is the form that may be used to submit evidence of practical experience obtained from a board approved structured program where academic credit is awarded.

(1) The academic experience coordinator at a school of pharmacy is responsible for assuring that during the time of the experience each practice site and preceptor are currently licensed and are in good standing with the appropriate professional licensing board or have been previously approved by the board of pharmacy.

(2) The preceptor at each practice site must sign the academic experience affidavit certifying the hours of practical experience obtained by the intern.

(3) The academic experience coordinator at a school of pharmacy must submit a signed academic experience affidavit certifying that the intern obtained a passing

grade and that the practice sites and the preceptors are currently licensed and in good standing with the appropriate professional licensing board or have been previously approved by the board of pharmacy.

- (4) The academic experience coordinator at a school of pharmacy is responsible for maintaining records of intern experience at each practice site.
- (5) Academic experience affidavits may be filed at any time, except that they must be received in the board office or postmarked no later than the first day of the July that immediately follows the successful completion of the academic course.

~~(4)~~(1) "School of pharmacy" has the same meaning as a college of pharmacy or a department of pharmacy of a university, which has been recognized and approved by the state board of pharmacy.

4729-5-01 Definitions.

As used in Chapter 4729. of the Revised Code:

- (A) "Practice of pharmacy" is as defined in division (B) of section 4729.01 of the Revised Code.
- (B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular patient will be deemed to have occurred when the pharmacist has given final approval to the patient specific prescription in the system.
- (C) The term "compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.
- (D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a prescriber for a patient.
- (E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.
- (F) "To participate with prescribers in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the prescriber(s) involved.
- (G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code.

- (H) "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, a prescription transmitted by use of a facsimile machine, or a prescription transmitted by a board approved electronic prescription transmission system, each of which is pursuant to rule 4729-5-30 of the Administrative Code.
- (I) "Personal supervision" 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 written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a prescriber are not immediately available; or
 - (2) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases; or
 - (3) A definitive set of written treatment guidelines that include patient specific and dose specific orders for the administration of a specific drug that have been authorized by a prescriber to be used when the services of that prescriber are not immediately available. The state board of pharmacy must approve the treatment guidelines prior to implementation. A list of the board approved drugs used in the treatment guidelines shall be displayed on the pharmacy board web site (www.pharmacy.ohio.gov). To be considered for approval by the board, the treatment guidelines must meet the following requirements:
 - (a) The drugs shall only be administered by an individual authorized by law to administer the drugs that are listed in the treatment guidelines.
 - (b) A prescriber must complete an assessment and make a diagnosis prior to ordering a set of treatment guidelines.

(c) The treatment guidelines:

- (i) Can only be initiated upon the order of a prescriber, and the prescriber, utilizing positive identification, must create an order in the patient record to acknowledge and document an adjustment made pursuant to the treatment guidelines before another dose or frequency adjustment can be made;
- (ii) Shall only apply to adjusting the dose or frequency of the administration of a specific drug that has been previously ordered by a prescriber;
- (iii) Apply only to those drugs that may require calculations for specific dose and frequency adjustments which shall be based on objective measures;
- (iv) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;
- (v) Do not apply to those drugs for which a dosage change selected within the usual normal dose range could cause detrimental adverse effects;
- (vi) Can be performed without requiring the exercise of medical judgment;
- (vii) Will lead to results that are reasonably predictable and safe;
- (viii) Can be performed safely without repeated medical assessments;
- (ix) If performed improperly, would not present a danger of immediate and serious harm to the patient.

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

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

- (M) "Prescriber" means any person authorized by the Revised Code to prescribe dangerous drugs as part of their professional practice.
- (N) "Positive identification" means a method of identifying an individual who prescribes, administers, or dispenses a dangerous drug.
 - (1) A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
 - (a) A manual signature on a hard copy record;

- (b) A magnetic card reader;
 - (c) A bar code reader;
 - (d) A thumbprint reader or other biometric method;
 - (e) A proximity badge reader;
 - (f) A board approved system of randomly generated personal questions;
 - (g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or
 - (h) Other effective methods for identifying individuals that have been approved by the board.
- (2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

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

4729-5-15 Prescriber.

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

~~(D) An advanced practice nurse approved pursuant to section 4723.56 of the Revised Code may 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.~~

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

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

(A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

(B) All prescriptions issued by a prescriber shall:

- (1) Be dated as of and on the day when issued.
- (2) Contain the manually printed, typewritten, or preprinted full name and address of the prescriber.
- (3) Indicate a telephone number where the prescriber can be personally contacted during normal business hours.
- (4) Indicate the full name and address of the patient.
- (5) Indicate the drug name and strength.
- (6) Indicate the quantity to dispense.

- (7) Indicate the appropriate directions for use.
 - (8) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.
 - (9) Not authorize any refills for schedule II controlled substances.
 - (10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.
 - (11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.
 - (12) Identify the trade name or generic name of the drug(s) in a compounded prescription.
 - (13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.
 - (14) For prescriptions issued to a patient by a prescriber, be:
 - (a) Manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document.
 - (b) Issued in compliance with rule 4729-5-13 of the Administrative Code.
 - (15) Be issued in compliance with all applicable federal and state laws, rules, and regulations.
- (C) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that bears the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.
- (D) Oral transmission by the prescriber or the prescriber's agent of original prescriptions and refills authorized by a prescriber, pursuant to the requirements of this rule, may be transmitted by telephone only to:
- (1) A pharmacist.
 - (2) A recording device within the pharmacy if the pharmacist is unavailable. The pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.

- (3) A licensed pharmacy intern if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to receive telephone prescriptions.

The prescriber's agent must provide his/her full name when transmitting an oral prescription.

- (E) Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy pursuant to the following:

- (1) The facsimile of the prescription must include the full name of the prescriber and if applicable the full name of the prescriber's agent transmitting the prescription to the pharmacy.

- (2) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.

- (3) Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:

- (a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.

- (b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.

- (c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-19-02 of the Administrative Code.

- (4) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription.

- (5) The facsimile of the prescription must include header information identifying the origin of the facsimile.

- (F) A prescription may be transmitted by means of a board approved electronic prescription transmission system, without further verification by the pharmacist of the prescriber's identity, provided that:

- (1) The system shall require positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code and the full name of any authorized agent of the prescriber who transmits the prescription.

- (2) The computer data must be retained for a period of three years at the prescriber's office.

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

Successful completion of the "Test of Spoken English (TSE)," pursuant to rules 4729-3-02, 4729-3-03, 4729-3-04, 4729-5-31, and 4729-5-32 of the Administrative Code, shall be a score of fifty or higher. A board approved equivalent of the TSE is the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT). No other administered form of TOEFL will be accepted as a board approved equivalent to TSE. Successful completion of TOEFL iBT shall be the following minimum scores or higher:

- (A) Writing: Twenty-four;
- (B) Speaking: Twenty-six;
- (C) Listening: Eighteen; and
- (D) Reading: Twenty-one.

4729-7-01 Definitions.

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.
- (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 Accreditation 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) "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.

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

- (A) Except as provided in rule 4729-7-08 of the Administrative Code, evidence of six C.E.U.s of approved continuing education shall be submitted by the date indicated on the continuing pharmacy education report form and 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.
- (B) Documentation of the required C.E.U.s shall be submitted on forms provided by the state board of pharmacy.
- (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. Beginning with those pharmacists required to report continuing education in 2004, as long as the continuing pharmacy education report forms are filed in a timely manner, the~~ The C.E.U.s must be obtained on or after March 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. If the continuing pharmacy education report forms are not filed in a timely manner, the C.E.U.s must have been obtained during the three-year period immediately preceding the date that the continuing pharmacy education report form is filed.
- (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."

4729-7-05 Procedure for approval as a provider of continuing pharmacy education.

(A) An individual, institution, organization, association, corporation or agency located in the state of Ohio desiring to be an in-state provider of continuing pharmacy education shall submit an application containing such information as the board of pharmacy may require on forms provided by the board.

(B) An individual, institution, organization, association, corporation or agency located outside the state of Ohio desiring to be an approved out-of-state provider of continuing pharmacy education shall meet the requirements of and be approved by the "~~American~~Accreditation Council on Pharmaceutical Education."

(C) Approval of in-state providers shall be valid for a period of three years at which time re-application is necessary.

4729-9-02 Minimum standards for a pharmacy.

(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) Pharmacy hours

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

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

4729-9-11 Security and control of dangerous drugs.

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 that requires the personal supervision or sale by a pharmacist.
 - (c) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the prescription department.
 - (d) Except as provided in rule 4729-17-03 of the Administrative Code, 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 that requires the personal supervision or sale by a pharmacist.
 - (e) No prescription, dangerous drug, exempt narcotic, hypodermic, nor any other item or product that 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 or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.
 - ~~(g) Notice to the public of operating hours of the prescription department must be posted.~~ If a pharmacy utilizes a board approved delivery system that securely stores and releases a dispensed prescription drug to a patient the pharmacy must be open for business and a pharmacist must be physically present and available for consultation.
- (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.

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

(A) Each prescriber, ~~and terminal distributor of dangerous drugs,~~ 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, including drugs in transit that were either shipped from or to the prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs:

- (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 distributor of dangerous drugs,~~ 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)~~(Q) 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.

4729-9-20 Drugs repackaged by a pharmacy.

(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.

4729-9-25 Drugs compounded for direct administration by a prescriber.

The following requirements do not apply to the compounding of radiopharmaceuticals by a nuclear pharmacy. Radiopharmaceuticals must be prepared pursuant to chapter 4729-15 of the Administrative Code.

A pharmacist may compound a drug pursuant to a request made by a prescriber, or by an agent of the prescriber, for a drug to be used by the prescriber for the purpose of the direct administration to patients in the course of the prescriber's practice pursuant to division (C)(5) of section 4729.01 of the Revised Code and the following:

(A) The drug is compounded and provided to a prescriber as an occasional exception to the normal practice of dispensing drugs pursuant to patient specific prescriptions:

(1) A pharmacy may provide compounded drug preparations to prescribers for direct administration to patients as long as the total value of those compounded preparations does not exceed five percent of the pharmacy's total dollar amount of sales of patient specific compounded prescriptions within the past twelve months.

(2) The pharmacy shall only provide those compounded drugs that are not commercially available to a prescriber which are needed:

(a) To treat an emergency situation;

(b) For an unanticipated procedure for which a time delay would negatively affect a patient outcome;

(c) For diagnostic purposes.

(B) A pharmacy shall not supply more than a seventy-two hour supply of a compounded drug to a prescriber. A prescriber shall not have more than a seventy-two hour supply of a compounded drug on hand at any given time. The seventy-two hour supply provided to the prescriber shall be determined by previous administration patterns provided by a prescriber to the pharmacist. The limitation of a seventy-two hour supply shall not apply to either of the following:

(1) Compounded non-sterile drug preparations for topical administration, pursuant to paragraphs (A)(2)(b) and (A)(2)(c) of this rule, shall be supplied to a prescriber in a single container in which the quantity does not exceed sixty grams or sixty milliliters. A prescriber shall not have more than one full container of sixty grams or sixty milliliters of a compounded drug on hand at any given time; or

(2) Compounded non-sterile drug preparations intended to treat an emergency situation, pursuant to paragraph (A)(2)(a) of this rule, may be provided to a prescriber in a quantity required to sufficiently treat individuals in the event of an emergency situation.

(C) A pharmacy shall not sell a compounded drug to another pharmacy or wholesaler.

(D) Prescribers shall only administer a requested compounded drug directly to their own patients. Prescribers shall not:

(1) Dispense a compounded drug to a patient;

(2) Sell a compounded drug to another prescriber;

(3) Sell a compounded drug to a pharmacy; or

(4) Return a compounded drug to the supplying pharmacy.

(E) Compounded drug preparations shall be assigned beyond use dates that are based on stability and sterility for sterile compounded drug preparations and stability for non-sterile compounded drug preparations pursuant to the following:

(1) Beyond use dates for non-sterile compounded preparations shall be determined by the compounding pharmacy through drug product testing pursuant to acceptable practice standards; by published peer reviewed pharmaceutical literature that have been critically reviewed by unbiased independent experts; or in compliance with requirements in the current edition of an official compendium, such as the "United States Pharmacopoeia/National Formulary".

(2) Beyond use dates for sterile compounded preparations shall be determined by the compounding pharmacy through drug product testing pursuant to acceptable practice standards or shall be based on the following "United States Pharmacopoeia/National Formulary" standards:

(a) Low risk level compounded drug preparations shall be assigned a beyond use date of not more than forty-eight hours when stored at room temperature, or fourteen days when refrigerated at two to eight degrees celsius.

(b) Medium risk level compounded drug preparations shall be assigned a beyond use date of not more than thirty hours when stored at room temperature, or seven days when refrigerated at two to eight degrees celsius.

(c) High risk level compounded drug preparations shall be assigned a beyond use date of not more than twenty-four hours when stored at room temperature, or three days when refrigerated at two to eight degrees celsius.

(F) The labeling of a compounded drug preparation must contain the following:

(1) The statement "For direct patient administration only" displayed prominently;

(2) The statement "Not for resale" displayed prominently;

(3) Proper storage conditions;

(4) Beyond use dates pursuant to paragraph (E) of this rule;

(5) The name(s) of the active and inactive ingredients;

(6) The amount or percentage of active drug ingredients;

(7) The quantity of compounded drug provided;

(8) The route of administration;

(9) The pharmacy name, address, and telephone number;

(10) The pharmacy control number assigned to the compounded drug preparation.

(G) Compounded drug preparation containers that are too small to bear a complete label pursuant to paragraph (F) of this rule must bear a label that contains at least the following information:

- (1) "Not for resale";
- (2) The storage conditions if other than room temperature;
- (3) The beyond use date;
- (4) The drug name(s);
- (5) The drug strength;
- (6) The route of administration;
- (7) The pharmacy control number;
- (8) The pharmacy name.

In all cases, a complete label meeting the requirements of paragraph (F) of this rule must be applied to the outside container in which such compounded preparation is supplied.

(H) The sale of a compounded drug preparation to a prescriber is considered a wholesale sale as defined in section 4729.01 of the Revised Code. A pharmacy is required to follow the record keeping requirements for wholesale sales listed in paragraph (H) of rule 4729-9-16 of the Administrative Code.

(I) A pharmacy must follow the compounding requirements pursuant to rules 4729-5-25 and 4729-9-21 of the Administrative Code, Chapter 4729-19 of the Administrative Code, current professional compounding standards, and all applicable federal and state laws, rules, and regulations.

4729-17-01 Definitions; institutional facility.

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

(A) "Institutional facility" means a hospital as defined in section 3727.01 of the Revised Code, or a facility licensed by the Ohio state board of pharmacy and the Ohio department of health, the Ohio department of rehabilitation and correction, or the Ohio department of mental retardation and developmental disabilities 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)~~(3) Long term care facilities;

~~(5)~~(4) Nursing homes;

~~(6)~~(5) Psychiatric facilities;

~~(7)~~(6) Rehabilitation facilities;

~~(8)~~(7) 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 an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular 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.

(H) "Electronic drug record keeping system" means a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

(I) "Positive identification" has the same meaning as paragraph (N) of rule 4729-5-01 of the Administrative Code except that a specific hospital having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each

user for, but not limited to, the prescribing and administration of a drug if approved by the board of pharmacy.

(1) At a minimum, the following items will be considered during the approval process:

(a) Adequate audit controls are in place to detect and deter drug diversion;

(b) Adequate access controls are in place to assure the identity of a user and to assign accountability of the user for any drug transaction;

(c) Adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;

(d) An ongoing quality assurance program is in place to ensure that (I)(a) through (I)(c) of this rule are being fulfilled and reviewed; and

(e) Appropriate policies and procedures are in place to address all of the items in (I)(a) through (I)(d) of this rule.

(2) Positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code shall always be used to document the:

(a) Dispensing, compounding, or repackaging of a drug;

(b) Removal and possession of a controlled substance to administer to a patient;

(c) Waste of a controlled substance.

(J) "Password" means a private identification that is created by a user to obtain access to an electronic drug record keeping system.

(K) "Personal identifier" means a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as social security number, user identification number, or employee number.

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

(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~~ record keeping procedures to account adequately for the drugs when used and the positive identification of the person 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,~~ and positive identification 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~~ beyond use date;
- (7) Provide adequate ~~recordkeeping~~ record keeping 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.

All drug records shall be maintained for a period of three years pursuant to section 4729.37 of the Revised Code. All drug records must be readily retrievable within three working days, excluding holidays and weekends, of all drug transactions within the

previous three years. Electronic drug record keeping systems, computerized record keeping systems, or subsequent storage of such records, must be readily retrievable via CRT display, hard copy printout, or other mutually agreeable transfer medium. If an electronic drug record keeping system is being utilized as defined in paragraph (H) of rule 4729-17-01 of the Administrative Code the method(s) of achieving positive identification must be approved by the state board of pharmacy prior to implementation pursuant to paragraph (I) of rule 4729-17-01 of the Administrative Code. 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. A log that must be maintained of all changes made to a drug record in an electronic drug record keeping system or a computerized record keeping system after a drug transaction has been made. Such log~~

may be accessible 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) Person making the change.

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

(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.

(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--~~ an electronic drug record keeping 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 within a reasonable period of time 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 pursuant to rules 4729-5-21 and

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.

4729-17-13 D.E.A. numbers for hospital employed ~~physicians~~prescribers.

- (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~~prescriber 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~~prescribers 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.

4729-33-04 ~~Recordkeeping~~Record keeping.

- (A) All emergency medical service (EMS) organizations are required to keep complete and accurate records for at least three years of receipt, use, administration, destruction, and waste of dangerous drugs. These records must be readily available for inspection by state board of pharmacy agents or inspectors as per section 3719.27 of the Revised Code and rule 4729-5-29 of the Administrative Code.
- (B) Records from satellites may be stored at the headquarters if prior notice is sent to the board office. A letter requesting storage of records at the headquarters must be sent to the state board of pharmacy office by verifiable delivery. The board will notify the organization of the board's approval or denial of the request within sixty days.

- (C) Records of oxygen transfilling shall include the manufacturer's lot number of the oxygen used for transfilling the portable oxygen tanks.
- (D) If there is a recall of oxygen by the manufacturer, all portable oxygen tanks that may have any of that lot number shall be dealt with according to the manufacturer's recommendations; but, in all such cases, such portable oxygen tanks must be purged and then refilled.
- (E) A readily retrievable record of controlled substances shall be kept containing documentation of administration, use, or waste of the controlled substances. Such records shall contain at least the following information:
- (1) The name, strength, and quantity of the controlled substance administered, used, or wasted;
 - (2) The date of administration, use, or waste;
 - (3) The name or other means of identifying the patient, such as medical record number or run number;
 - (4) The signature and identification number of the individual administering the controlled substance;
 - (5) In the case of waste, the signatures and identification numbers of both individuals involved in wasting the controlled substance.
- (F) If a computerized record keeping system is being utilized to document any drug transactions, including but not limited to the receipt, use, administration, destruction, and wastage, then the system must have "positive identification", pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code, of the individual responsible for the transaction.

4729-35-01 Definitions.

As used in Chapter 4729-35 of the Administrative Code:

- (A) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code and in rule 4729-9-01 of the Administrative Code.
- (B) "Drug repository program" has the same meaning as in sections 3715.87 to 3715.873 of the Revised Code.
- (C) "Hospital" has the same meaning as in section 3715.87 of the Revised Code.
- (D) "Institutional facility" has the same meaning as in rule 4729-17-01 of the Administrative Code.

- (E) "Licensed health care professional" has the same meaning as in section 3715.872 of the Revised Code.
- (F) "Nonprofit clinic" has the same meaning as in section 3715.87 of the Revised Code.
- (G) "Original sealed and tamper-evident unit dose packaging" includes single unit dose packaging of oral medications from a manufacturer or a repackager licensed with the federal food and drug administration, or from a pharmacy licensed as a terminal distributor of dangerous drugs, and includes injectables, topicals, and aerosols in the manufacturer's or repackager's unopened original tamper-evident packaging.

4729-35-04 Eligible drugs.

All dangerous drugs, except controlled substances and drug samples, may be donated to a pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program if the drugs meet all of the following requirements:

- (A) The drugs are in their original sealed and tamper-evident unit dose packaging. The packaging must be unopened except that the drugs packaged in single unit doses may be accepted and dispensed when the outside packaging is opened if the single unit dose packaging is undisturbed. If the drugs were packaged by a pharmacy the name of the pharmacy and any other pharmacy identifiers must be removed from the packaging prior to dispensing to a recipient patient. This may be accomplished by removing the drug from the pharmacy packaging or by removing the name from the outside packaging of a multiple dose unit dose packaging system.
- (B) The drugs have been in the possession of a licensed healthcare professional and not in the possession of the ultimate user.
- (C) The drugs have been stored according to federal food and drug administration storage requirements.
- (D) The drugs must have an expiration date of six months or greater.
- (E) The packaging must list the lot number and expiration date of the drug.
- (F) The drugs must not have any physical signs of tampering or adulteration.
- (G) The drug packaging must not have any physical signs of tampering.
- (H) All confidential patient information must have been removed from the drug packaging.

4729-36-01 Definitions.

As used in Chapter 4729-36 of the Administrative Code:

- (A) "Charitable pharmacy" means a pharmacy that meets all of the following requirements:
 - (1) Holds a terminal distributor of dangerous drug license issued under section 4729.54 of the Revised Code;
 - (2) Is exempt from federal taxation pursuant to 26 U.S.C. 501(a) and (c)(3); and
 - (3) Is not a hospital as defined in section 3727.01 of the Revised Code.
- (B) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.
- (C) "Manufacturer" means the drug company that manufactures a sample drug.
- (D) "Pharmacist" has the same meaning as in rule 4729-5-01 of the Administrative Code.
- (E) "Sample drug" has the same meaning as in section 2925.01 of the Revised Code.
- (F) "Terminal Distributor" has the same meaning as in section 4729.01 of the Revised Code.
- (G) "Wholesale Distributor" has the same meaning as in section 4729.01 of the Revised Code.

4729-36-02 Licensure of a charitable pharmacy.

A pharmacy that desires to be a charitable pharmacy shall maintain a terminal distributor of dangerous drug license. An application for licensure must include the following:

- (A) A completed application designating the desire to become a charitable pharmacy;
- (B) Documents to support the exemption from federal taxation pursuant to 26 U.S.C. 501(a) and (c)(3); and
- (C) The fee for the appropriate category of licensure.

4729-36-03 Requirements of a charitable pharmacy.

A charitable pharmacy is considered to be a pharmacy pursuant to section 4729.01 of the Revised Code and must follow all federal and state laws, rules, and regulations that pertain to pharmacies and the practice of pharmacy, including, but not limited to, the following:

- (A) Minimum standards for a pharmacy pursuant to rule 4729-9-02 of the Administrative Code;
- (B) Security requirements pursuant to 4729-9-05 of the Administrative Code;
- (C) Security and control of the sample drugs pursuant to rule 4729-9-11 of the Administrative Code;
- (D) Record keeping pursuant to rules 4729-5-27 and 4729-9-22 of the Administrative Code;
- (E) Serial numbering of prescriptions pursuant to rule 4729-5-19 of the Administrative Code;
- (F) Prescription filing pursuant to rule 4729-5-09 of the Administrative Code;
- (G) Confidentiality of patient records pursuant to 4729-5-29 of the Administrative Code;
- (H) Labeling pursuant to 4729-5-16 of the Administrative Code;
- (I) Patient profiles pursuant to rule 4729-5-18 of the Administrative Code;
- (J) Prospective drug utilization review pursuant to 4729-5-20 of the Administrative Code;
- (K) Patient counseling pursuant to rule 4729-5-22 of the Administrative Code;
- (L) Reporting of theft or loss of dangerous drugs pursuant to 4729-9-15 of the Administrative Code; and
- (M) Storage of adulterated drugs pursuant to rule 4729-9-17 of the Administrative Code.

4729-36-04 Sample drug distribution to a charitable pharmacy.

- (A) An eligible sample drug shall only be distributed directly to a charitable pharmacy by a:
 - (1) Manufacturer;
 - (2) Wholesale distributor of dangerous drugs acting on behalf of a manufacturer; or
 - (3) Prescriber practicing in a location that is licensed as a terminal distributor of dangerous drugs.
- (B) If a sample drug is furnished by a prescriber:
 - (1) A record must be created by the prescriber documenting the sample drug transfer. The record shall contain the:

- (a) Name and address of the supplying prescriber;
 - (b) Name, strength, and quantity of the sample drug supplied;
 - (c) Date of the sample drug transfer;
 - (d) Name and address of the charitable pharmacy receiving the sample drug.
- (2) A copy of the original record issued by the manufacturer or the wholesale distributor documenting the transfer of the sample drug to the prescriber must be furnished to the charitable pharmacy upon receiving a sample drug.
- (3) A copy of all required records documenting the transfer of a sample drug must be kept by the prescriber and the charitable pharmacy for a minimum of three years and be stored in a readily retrievable manner.
- (4) The prescriber shall not transfer a sample drug to a charitable pharmacy unless the sample drug meets the eligibility requirements pursuant to rule 4729-36-05 of the Administrative Code.
- (5) The sample drug must not have any physical signs of tampering.
- (6) The sample drug packaging must not have any physical signs of tampering.

4729-36-05 Eligibility requirements for sample drugs received by a charitable pharmacy.

- (A) The sample drug is in the original container in which it was placed by its manufacturer and the container is clearly marked sample;
- (B) Prior to being furnished, the sample drug has been stored under the proper conditions to prevent deterioration or contamination;
- (C) The sample drug is clearly marked with an expiration date and lot number;
- (D) The sample drug is not expired; and
- (E) The sample drug is not a controlled substance.

4729-36-06 Dispensing a sample drug by a charitable pharmacy.

- (A) A pharmacist in a charitable pharmacy must have a valid prescription prior to dispensing a sample drug to a patient pursuant to rules 4729-5-21 and 4729-5-30 of the Administrative Code.

(B) The charitable pharmacy must determine the eligibility requirements for a patient to receive a sample drug.

(C) The sample drug is dispensed to the patient free of charge.

(D) The sample drug may be dispensed:

(1) In the original container in which it was placed by its manufacturer where the container is clearly marked as sample; or

(2) By removing the sample drug from the original container only if the prescription label on the appropriate container, pursuant to rule 4729-9-02 of the Administrative Code, clearly states that the drug dispensed is a sample drug.

4729-37-01 Definitions.

As used in Chapter 4729-37 of the Administrative Code:

(A) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(B) "Outpatient" has the same meaning as in rule 4729-17-01 of the Administrative Code.

(C) "Prescriber" or "licensed health professional authorized to prescribe drugs" have the same meaning as in section 4729.01 of the Revised Code.

(D) "Terminal distributor of dangerous drugs" has the same meaning as in section 4729.01 of the Revised Code.

(E) "Wholesale distributor of dangerous drugs" has the same meaning as in section 4729.01 of the Revised Code.

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

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

(A) All schedule II controlled substances;

(B) All schedule III controlled substances;

(C) All schedule IV controlled substances;

(D) All schedule V controlled substances dispensed pursuant to a prescription;

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

(F) All dangerous drug products containing carisoprodol;

(G) All dangerous drug products containing tramadol.

4729-37-03 Entities required to submit information.

The following entities are required to submit the specified dispensing and wholesale sale information to the board of pharmacy for the drug database:

(A) All pharmacies licensed as a terminal distributor of dangerous drugs that dispense drugs identified in rule 4729-37-02 of the Administrative Code to outpatients residing in this state.

(B) All wholesalers licensed as a wholesale distributor of dangerous drugs that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale to individual prescribers within this state, or to locations other than institutional facilities that are licensed as a terminal distributor of dangerous drugs where prescribers practice.

(C) All pharmacies licensed as a terminal distributor of dangerous drugs that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale to prescribers within this state, or to locations other than institutional facilities that are licensed as a terminal distributor of dangerous where prescribers practice.

The board of pharmacy shall identify the terminal distributors of dangerous drugs locations where prescribers practice and provide this information to all entities required to report sales at wholesale.

4729-37-04 Information required for submission.

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

(1) Pharmacy drug enforcement administration registration number;

(2) Patient full name;

(3) Patient address;

(4) Patient telephone number;

(5) Patient date of birth;

(6) Prescriber's drug enforcement administration registration number;

(7) Date prescription was issued by the prescriber;

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

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

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

(11) Quantity of drug dispensed;

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

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

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

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

(1) Wholesaler or pharmacy drug enforcement administration registration number;

(2) Purchaser's drug enforcement administration registration number;

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

(4) Quantity of the drug sold;

(5) Date of sale.

4729-37-05 Electronic format required for the transmission of dispensing information.

(A) All pharmacy dispensing information required to be submitted to the board of pharmacy pursuant to paragraph (A) of rule 4729-37-04 of the Administrative Code must be transmitted in the format specified by the "American Society for Automation in Pharmacy" (ASAP) for prescription monitoring programs.

(B) In the event that a pharmacy cannot electronically transmit the required information pursuant to paragraph (A) of rule 4729-37-04 of the Administrative Code they must immediately contact the board of pharmacy to determine a mutually acceptable method of reporting. The pharmacy must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

4729-37-06 Electronic format required for the transmission of wholesale drug sales.

- (A) All wholesale data required to be submitted to the board of pharmacy pursuant to paragraph (B) of rule 4729-37-04 of the Administrative Code must be transmitted on a mutually acceptable format such as, but not limited to ASCII delimited, ASCII fixed length, excel spreadsheet.
- (B) In the event that a wholesaler or pharmacy cannot electronically transmit the required information pursuant to paragraph (B) of rule 4729-37-04 of the Administrative Code they must immediately contact the board of pharmacy to determine a mutually acceptable method of reporting. The wholesaler or pharmacy must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

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

- (A) All drug dispensing and wholesale drug sale information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code must be submitted twice a month as follows:
 - (1) During the first through the fifth day of each month; and
 - (2) During the fifteenth through the twentieth day of each month.
- (B) Information reported to the board of pharmacy shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than twenty-one days after the date of the dispensing or wholesale sale.
- (C) In the event that a wholesaler or pharmacy cannot submit the required information as described in this rule they must immediately contact the board of pharmacy to determine a mutually acceptable time for submission of information. The wholesaler or pharmacy must document in writing to the board of pharmacy the reasons for their inability to submit the required information.

4729-37-08 Procedures for obtaining drug database information.

Persons that are permitted pursuant to divisions (A)(1) through (A)(5) of section 4729.79 of the Revised Code to obtain information from the drug database must comply with the following procedures:

- (A) A designated representative of a government entity, a prescriber, or a pharmacist must:
 - (1) Complete a request form giving such information as required by the board of pharmacy;

(2) Submit the completed form to the board of pharmacy in person, by mail, by a verified facsimile transmission, or by other board approved means.

(B) A federal, state, or local officer must:

(1) Complete a request form giving such information as required by the board of pharmacy that will include an active case number assigned by the investigating agency or department and an approval by a supervisor of that agency or department;

(2) Submit the completed form to the board of pharmacy in person, by mail, by a verified facsimile transmission, or by other board approved means.

(C) An individual seeking the individual's own database information must:

(1) Complete a notarized request form giving such information as required by the board of pharmacy;

(2) Submit the completed form in person or by mail;

(3) Receive the information in person at the board of pharmacy office during normal business hours and show proof of identity with a current government issued form of identification that contains a picture such as a current state issued identification card, a current state issued drivers license, or a valid passport;

(4) Pay the cost of printing the document as determined by the board of pharmacy's current per page rate.

4729-37-09 Requesting an extension to the information storage requirements.

A government entity or a law enforcement agency pursuant to section 4729.81 of the Revised Code may request that specific information in the database related to an open investigation be retained beyond the two year information retention requirement. The government entity or law enforcement agency must submit a written request on a form giving such information as required by the board of pharmacy.

4729-37-10 Providing database statistics and law enforcement outcomes.

The board of pharmacy may provide or present database statistics and law enforcement outcomes based on request information pursuant to section 4729.79 of the Revised Code. The information shall not identify a person and will be provided as determined by the board of pharmacy in summary, statistical, or aggregate form.