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**FULL TEXT SHOWING CHANGES**

UNDERLINED = Add New Language

LINED THROUGH = ~~Remove~~ Old Language

**4729-3-02 REGISTRATION AS A PHARMACY INTERN**

- (A) A certificate of registration as a pharmacy intern shall only be issued for the purpose of allowing those individuals who intend to become registered pharmacists the opportunity to obtain the practical experience required for examination and registration as a pharmacist.
- (B) If a person is actively working towards the requirements for licensure as a pharmacist and desires to work as a pharmacy intern in Ohio, he/she must:
  - (1) (a) Have successfully completed at least sixty semester or ninety quarter hours of college, be enrolled in a school of pharmacy, and has begun taking professional classes directly related to the practice of pharmacy; or
  - (b) Have obtained a first professional degree in pharmacy from a program which has been recognized and approved by the state board of pharmacy; or
  - (c) Have established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Commission (FPGEC) certificate, and have established proficiency in spoken English by successfully completing the Test of Spoken English (TSE) or its board approved equivalent pursuant to rule 4729-5-34 of the Administrative Code.
- (2) Submit electronic fingerprint impressions for a criminal records check pursuant to section 4729.071 of the Revised Code and rule 4729-5-12 of the Administrative Code.
- ~~(2)(3)~~Apply to the state board of pharmacy for registration as a pharmacy intern.

**4729-5-08 PHARMACY INTERN PROFESSIONAL FUNCTIONS**

In addition to assisting a pharmacist with technical functions, a pharmacy intern may perform the following professional functions under the direct supervision of a pharmacist. These activities must be documented with positive identification of both the supervising pharmacist and the pharmacy intern.

- (A) The sale of schedule V controlled substances pursuant to rule 4729-11-09 of the Administrative Code.
- (B) The receipt of oral prescriptions pursuant to paragraph (D)(3) of rule 4729-5-21 of the Administrative Code and pursuant to paragraph (D)(3) of rule 4729-5-30 of the Administrative Code.
- (C) The transfer of a prescription copy pursuant to paragraph (G) of rule 4729-5-24 of the Administrative Code.

- (D) The act of patient counseling pursuant to paragraph (B) of rule 4729-5-22 of the Administrative Code.
- (E) The administration of influenza immunizations to individuals eighteen years of age and older pursuant to section 4729.41 of the Revised Code.
- (F) The documentation of informed consent to administer an immunization pursuant to section 4729.41 of the Revised Code and paragraph (O) of rule 4729-5-27 of the Administrative Code.

**4729-5-10 PRESCRIPTION PICK-UP STATION**

- (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 unless such place is a pharmacy as defined in section 4729.01 of the Revised Code, has received board approval to function in such a manner, and all of the following apply:
  - (1) The site is appropriately licensed with the state board of pharmacy as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code;
  - (2) The receipt, storage, control, and distribution of prescriptions are in the full and actual charge of a pharmacist licensed pursuant to Chapter 4729. Of the Revised Code;
  - (3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, and return of all prescriptions;
  - (4) There is a documented method in place to ensure compliance with rule 4729-5-22 of the Administrative Code.
- (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 such place is a pharmacy as defined in section 4729.01 of the Revised Code, has received board approval to function in such a manner, and paragraphs (B)(1) through (B)(4) of this rule apply or, if not a pharmacy, unless all of the following apply:
  - (1) The site is appropriately licensed with the state board of pharmacy as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code.
  - (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 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code.
  - (3) An appropriate recordkeeping system is in place that will provide accountability for proper receipt, delivery, and return 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 PERSON**

- (A) For a pharmacy licensed as a terminal distributor of dangerous drugs:
- (1) 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 person for a pharmacy unless he/she will be physically present in the pharmacy a sufficient amount of time to provide supervision and control.
  - (2) The responsible person 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.
  - (3) The person to whom the terminal distributor of dangerous drugs 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.
- (B) For all locations licensed as a terminal distributor of dangerous drugs:
- (1) A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.
  - (2) The responsible person whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.
  - (3) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within thirty days on a board approved form. This notice to the state board of pharmacy shall be sent by certified regular mail, ~~return receipt requested~~, or by verified facsimile transmission.
  - (4) 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 with the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.

- (5) The responsible person to whom the terminal distributor of dangerous drugs license has been issued is responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs.

**4729-5-12 CRIMINAL RECORDS CHECK FOR PHARMACISTS AND PHARMACY INTERNS**  
**(NEW RULE)**

- (A) Pursuant to section 4729.071 of the Revised Code, an applicant seeking an initial license as a pharmacist by examination or reciprocity, and an applicant seeking an initial license as a pharmacy intern must first submit fingerprint impressions to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check.
- (B) Pursuant to section 4776.02, the criminal records check performed by BCI&I shall consist of both a BCI&I criminal records check and a federal bureau of investigation (FBI) criminal records check. BCI&I shall send the results of the BCI&I and FBI criminal records checks directly to the state board of pharmacy.
- (C) The state board of pharmacy requires that the criminal records check:
  - (1) Be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "WebCheck" provider agency located in Ohio. The state board of pharmacy may accept the results of a criminal records check based on ink impressions from a "WebCheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.
  - (2) Results will only be considered valid if the fingerprint impressions were obtained within the previous twelve months.
- (D) An applicant may submit electronic fingerprint impressions for a criminal records check anytime after he/she has submitted a licensure application to the state board of pharmacy.
- (E) After the state board of pharmacy receives the results from both of the required criminal records checks the licensing process will proceed.

**4729-5-19 SERIAL NUMBERING OF PRESCRIPTIONS**

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 record keeping system is being used pursuant to rule 4729-5-27 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, or authorized pharmacy intern pursuant to rule 4729-5-21 of the Administrative Code, 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 noncontrolled drug through an oral a refill authorization transmitted to a pharmacist, or authorized pharmacy intern pursuant to rule 4729-5-21 of the Administrative Code, provided that no refill may occur beyond one year from the date of issuance of the original prescription.

All additional refills authorized by the prescriber shall be marked on the original prescription listing full name of the authorizing agent, date, number of refills authorized, and pharmacist receiving the authorization. If an alternative record keeping system is used, this information must also be maintained in that system.

- (D) In the case of a board approved central filling operation in which the pharmacies are accessing the same real time, online database, the serial number used may be the original serial number issued at the originating pharmacy if all of the following requirements are met:
  - (1) The computer system maintains the appropriate records for the prescription so that it is possible to determine the identity of every person involved in the dispensing of the prescription who performs an act that would constitute the practice of pharmacy.
  - (2) The computer system assigns a unique internal code to the prescription so that it is possible to determine the location of the personnel involved in the dispensing as well as the location of the drug stock used in the dispensing function.

#### **4729-5-29 CONFIDENTIALITY OF PATIENT RECORDS**

- (A) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction 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~~ Chapters 4730. and 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) An agent who contracts with the pharmacy as a "business associate" in accordance with the regulations promulgated by the secretary of the United States department of health and human services pursuant to the federal standards for privacy of individually identifiable health information.
  - (9) An agent of the state board of nursing when enforcing Chapter 4723. of the Revised Code.
  - (10) Any person, other than those listed in paragraphs (A)(1) to (A)(9) 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) Testimonial privilege is not waived for any communication between a physician, a pharmacist, and a patient pursuant to section 2317.02 of the Revised Code.
- (C) Records relating to the practice of pharmacy, the administration of drugs, or any patient specific drug transaction 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)(9) 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 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, professional title, 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 and explicit 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) For a controlled substance, indicate the drug enforcement administration registration number of the prescriber pursuant to Title 21 CFR 1306.05 (enacted on June 23, 2005).
- (16) If issued by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner with prescriptive authority, contain the nurse's prescriber number found on the certificate to prescribe issued by the state board of nursing pursuant to rule 4723-9-09 of the Administrative Code.
- (17) If issued by a physician assistant with prescriptive authority, contain the certificate number of the physician assistant's certificate to prescribe pursuant to rule 4730-2-07 of the Administrative Code.
- ~~(17)~~(18) 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 provided that:
- (1) The system requires 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 is retained for a period of three years at the prescriber's office.
- (G) Pursuant to section 4729.38 of the Revised Code if a prescriber does not want a pharmacist to select a generically equivalent drug the prescriber must handwrite "dispense as written" or "DAW" on the prescription, or if ordering electronically or orally the prescriber specifies that the prescribed drug is medically necessary.

**4729-5-31 CRITERIA FOR LICENSURE BY EXAMINATION**

- (A) Pursuant to ~~section~~ sections 4729.07 and 4729.13 of the Revised Code regarding pharmacist licensure by examination:
- (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 (NABP)."
  - (2) The minimum passing score is seventy-five on each exam.
    - (a) Any candidate who fails to receive a score of seventy-five on the NAPLEX examination shall make application and remit the fee established by the state board of pharmacy for re-examination.
    - (b) Any candidate who fails to receive a score 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) A candidate may use the NABP process to transfer his/her NAPLEX score to Ohio only after the candidate has met all of the requirements set by the board for examination and licensure in Ohio.

~~(2) (a) The minimum passing score for the NAPLEX is seventy five. Any candidate failing to attain a score 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.~~

~~(b) Pursuant to the procedures established by the NABP, a candidate may transfer his/her NAPLEX score to Ohio only after the candidate has met all of the requirements set by the board for examination and licensure in Ohio.~~

~~(3) The minimum passing score for the jurisprudence examination is seventy five. Any candidate who fails to receive a score 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 regarding the renewal of a pharmacist identification card after a three year lapse:~~

~~(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 (NABP)."~~

~~(2) The minimum passing scores 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 score 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 score 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 regarding graduates of unapproved 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 score 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, "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT), pursuant to rule 4729-5-34 of the Administrative Code.~~

~~(D) Any examination candidate who fails to take both of the required examinations within twelve months from the date the board receives the application materials shall submit a new application for the required examination or examinations and remit the fee established by the state board of pharmacy.~~

~~(E) The record of the passing score for an examination candidate who takes both of the required examinations, but successfully only completes one examination will:~~

~~(1) Be maintained up to three years if no more than twelve months has elapsed between attempts to successfully complete the remaining examination.~~

- (2) Not be maintained if more than twelve months has elapsed between attempts to successfully complete the remaining examination. It will then be necessary for the examination candidate to repeat both examinations for Ohio licensure.
- (F) Any candidate who has requested to transfer their NAPLEX score to Ohio must take the Ohio jurisprudence examination within twelve months from the date the candidate completed the NAPLEX examination or the score transfer will be denied.
- (G) Pursuant to section 4729.071 of the Revised Code and rule 4729-5-12 of the Administrative Code a candidate must submit electronic fingerprint impressions for a criminal records check prior to receiving an initial license to practice as a pharmacist. An examination candidate must submit fingerprint impressions no later than twelve months after the date the board receives the application materials or the scores obtained on NAPLEX and/or MPJE will be denied. After twelve months a candidate must submit a new application, the required fee, fingerprint impressions, and new examination scores.

**4729-5-32 CRITERIA FOR LICENSURE BY RECIPROCITY**

- (A) Pursuant to section 4729.09 of the Revised Code:
  - ~~(A)~~(1) Certification that the credentials of an applicant for registration without examination, filed with the board of the state with which he/she holds a certificate of good standing, are at least the equivalent of those then required by the Ohio board, shall be filed on forms provided by the "National Association of Boards of Pharmacy" or similar forms recognized and approved by the board of pharmacy.
  - ~~(B)~~(2) An applicant who has met the requirements of the state with which he/she holds a certificate of good standing pursuant to a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate shall be required to establish proficiency in spoken English by providing evidence of the successful completion of the "Test of Spoken English (TSE)" or its equivalent.
  - ~~(C)~~(3) Candidates who qualify for licensure by reciprocity shall personally appear before the full board within six months of the date that the application is filed with the board ~~before receiving their identification card to practice pharmacy in Ohio.~~ Candidates who do not appear before the board within the six-month period must file a new application and fee for licensure by reciprocity.
- (B) Pursuant to section 4729.071 of the Revised Code and rule 4729-5-12 of the Administrative Code a candidate must submit electronic fingerprint impressions for a criminal records check prior to receiving an initial license to practice as a pharmacist. A reciprocity candidate must submit fingerprint impressions no later than twelve months after the date the board receives the application materials. After twelve months a candidate must submit a new application, the required fee, fingerprint impressions, and again personally appear before the board as described in this rule.

**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 "Accreditation Council for Pharmacy 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.~~

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

- (A) "Approved continuing education" is defined as participation in an organized and structured continuing pharmacy education experience that has been presented by an approved provider or the state board of pharmacy and that presents information directly related to the practice of pharmacy.
- (B) "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 accredited by the "Accreditation Council for Pharmacy Education" (A.C.P.E.).
- (C) "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.
- (D) "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.
- (E) "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.

**4729-7-06 CRITERIA FOR IN-STATE APPROVED PROVIDERS OF CONTINUING PHARMACY EDUCATION**

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~~ fourteen 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~~ fourteen days after a program has been presented. The notification shall include the name of the presenter(s) and the items noted in paragraphs (D)(1), (D)(2), (D)(4), (D)(5), and (D)(6) of this rule.

**4729-9-01 DEFINITIONS**

- (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. This does not apply to expired drugs that are donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.
- (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 rendering such license void and such license may not be reissued. "Revoke" is an action that 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 rendering 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 suspending some or all of the sanctions imposed by the board against that license. The terms of the probation shall state the period of time covered by the probation and may include other 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**

(A) Library

- (1) ~~Current~~ All pharmacists working in a pharmacy must be able to access all 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.

(G) Personnel

The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code. An employee of a pharmacy that may have contact with patients or the general public must be identified by a nametag that includes the employee's job title.

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

**4729-9-08 CHANGE IN DESCRIPTION OF TERMINAL OR WHOLESALE DANGEROUS DRUG FACILITY**

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

**4729-9-12 VERIFICATION OF LICENSE AS A DISTRIBUTOR OF DANGEROUS DRUGS OR EXEMPT STATUS OF A PRESCRIBER**

(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 pursuant to divisions (B)(1) (a), (j), and (k) of section 4729.51 of the Revised Code 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) as set forth in division (B)(1)(a) of 4729.51 of the Revised Code, an individual prescriber doing business as a sole shareholder of a corporation or a limited liability company pursuant to division (B)(1)(j) of section 4729.51 of the Revised Code, and a dentist pursuant to division (B)(1)(k) of 4729.51 of the Revised Code 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. Also, a prescriber doing business as a sole shareholder of a corporation or a limited liability company must also provide official documentation that states he/she is the sole shareholder;
    - (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.

**4729-9-14 RECORDS OF CONTROLLED SUBSTANCES**

- (A) Each prescriber or terminal distributor of dangerous drugs shall keep a record of all controlled substances received, administered, dispensed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a controlled substance must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.
  - (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 identification 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.
  - (4) Destruction of controlled substances shall be conducted in accordance with rule 4729-9-06 of the Administrative Code.
- (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 may 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)~~
- (C) All records of receipt, distribution, administering, dispensing, inventory, destruction, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located and upon request provided to a state board of pharmacy officer, agent, and/or inspector within three working days, excluding weekends and holidays. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of controlled substances. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.

**4729-9-16 MINIMUM REQUIREMENTS FOR WHOLESALERS**

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.
  - (7) Pursuant to division (A)(1) of section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license will not be issued until the owner(s), or if incorporated the officers, of the wholesale operation submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. Additionally, a criminal records check is required every time there is a change in officers. The criminal records check shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past

twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The owner(s) or officers may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or if located outside of Ohio they may submit ink fingerprint impressions as instructed on a form provided by the board.

- (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. When there is a change in the designated contact person to whom communications with the state board of pharmacy may be directed, the board shall be notified of the new contact person within thirty days on a board approved form. This notice to the board shall be sent by certified mail, return receipt requested, or by verified facsimile transmission.
- (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 dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.

- (M) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

**4729-9-17 STORAGE OF ADULTERATED DRUGS**

To prevent their use, adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for dispensing and administration.

- (A) Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license or two years by those holding a wholesale distributor of dangerous drugs license only.
- (B) Drugs, other than controlled substances, ~~shall~~ may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in rule 4729-9-22 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code.
- (C) Drugs that are controlled substances may be disposed of pursuant to rule 4729-9-06 of the Administrative Code.
- (D) Methods of disposal shall prevent the possession of the drugs by unauthorized persons.

**4729-9-20 DRUGS REPACKAGED OR RELABELED 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~~ seven 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 pharmacist responsible for the repackaging of the drug.

(C) Supplemental labels created by a pharmacy that contain a barcode for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

- (1) The creation of the barcode; and
- (2) Affixing the barcode label to the drug product.

**4729-9-21 DRUGS COMPOUNDED IN A PHARMACY**

- (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 and/or Chapter 4729-15 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~~ seven 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**

Each prescriber or terminal distributor of dangerous drugs shall keep a record of all dangerous drugs received, administered, dispensed, distributed, sold, destroyed, or used. The acts of prescribing, administering, dispensing, and destroying of a dangerous drug must be documented with the positive identification of the responsible individual pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code. These records may be kept electronically if the method is approved by the state board of pharmacy and the records are backed-up each business day.

- (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 identification of the animal for which, the dangerous drug was administered, dispensed, or used.
- (C) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the prescriber or responsible person that performed the destruction, and if used the positive identification of the person that witnessed the destruction.
- ~~(C)~~(D) 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)~~(E) All records of receipt, distribution, administering, dispensing, selling, destroying, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located and upon request provided to a state board of pharmacy officer, agent, and/or inspector within three working days, excluding weekends and holidays. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drug name and license number of the requestor and the name and address of the alternate location. The state board of pharmacy will send written notification to the terminal distributor of dangerous drugs documenting the approval or denial of the request. A copy of the board's approval 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 of dangerous drugs.

**4729-9-24 RETAIL AND WHOLESALE SALES OF DANGEROUS DRUGS ON-LINE**

- (A) All persons selling or offering to sell dangerous drugs at retail or wholesale ~~in~~ into, out of, or within Ohio must be properly 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 under which the 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, pursuant to all federal and state laws, rules, and regulations, 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.

**4729-13-01 DEFINITIONS**

~~As used in Chapter 4729-13 of the Administrative Code:~~

- ~~(A) "Laboratory" means any establishment or place where dangerous drugs are possessed for scientific and clinical purposes and for purposes of instruction that has been approved by the state board of pharmacy.~~
- ~~(B) "Registration numbers" means the numbers assigned to each person registered under the federal drug abuse control laws, sections 4729.52 and/or 4729.54 of the Revised Code.~~
- ~~(C) "Responsible person" means the individual who the licensee has designated as the person who will maintain supervision and control over the possession and custody of such dangerous drugs that may be acquired and utilized by the licensee.~~

~~(D) "D.E.A." means the federal drug enforcement administration.~~

As used in Chapter 4729-13 of the Administrative Code:

- (A) "Controlled substance" has the same meaning as in section 4729.01 of the Revised Code.
- (B) "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.
- (C) "D.E.A." means the federal drug enforcement administration.
- (D) "Laboratory" means any establishment or place where dangerous drugs are possessed for scientific and clinical purposes and for purposes of instruction that has been approved by the state board of pharmacy.
- (E) "Registration numbers" means the numbers assigned to each person registered under the federal drug abuse control laws, sections 4729.52 and/or 4729.54 of the Revised Code.
- (F) "Responsible person" means the individual designated by the licensee as the person who will maintain supervision and control over the possession and custody of such dangerous drugs that may be acquired and utilized by the licensee.

**4729-13-04 ~~RECORDKEEPING~~ RECORD KEEPING**

Each laboratory approved by the state board of pharmacy pursuant to this chapter shall keep records pursuant to paragraph (B) of rule 4729-9-14 of the Administrative Code, and as follows:

- (A) Each approved laboratory conducting chemical analysis with dangerous drugs or controlled substances shall maintain records with the following information for each dangerous drug or controlled substance:
  - (1) The name.
  - (2) The form or forms received or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration in such form (e.g., "C.P.," "U.S.P.," "N.F.," ten-milligram tablet, or ten-milligram concentration per milliliter).
  - (3) The total number of the forms received or manufactured (e.g., one hundred tablets, thirty one-milliliter vials), including the date and quantity of each receipt or manufacture, and the name, address, and registration number, if any, of the person from whom received.
  - (4) The quantity utilized in any manner by the laboratory including the date and manner of utilization, and the name, address, and registration numbers, if any, of each person to whom provided for utilization.
  - (5) Destruction of controlled substances shall be conducted in accordance with rule 4729-9-06 of the Administrative Code.
  - (6) ~~Records relating to known or suspected controlled substances received as evidentiary material for analysis are not required under paragraph (A)(1) of this rule.~~ Destruction of

dangerous drugs, other than controlled substances, shall be conducted in accordance with paragraph (C) of rule 4729-9-22 of the Administrative Code.

- (B) Each approved laboratory conducting research with dangerous drugs or controlled substances shall maintain records with the following information for each dangerous drug or controlled substance:
  - (1) The name.
  - (2) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one-hundred-tablet bottle or five-milliliter vial).
  - (3) The number of commercial containers of each such finished form received from other persons including the date of and the number of containers in each receipt and the name, address, and registration numbers of the persons from whom the containers were received.
  - (4) The number of units or volume of such finished dosage form or commercial containers provided. The date and name and address of the person to whom it was provided. The date and name and address of the person utilizing or administering the drug and the quantity utilized on behalf of the researcher.
  - (5) Destruction of controlled substances shall be conducted in accordance with rule 4729-9-06 of the Administrative Code.
  - (6) Destruction of dangerous drugs, other than controlled substances, shall be conducted in accordance with paragraph (C) of rule 4729-9-22 of the Administrative Code.

**4729-13-06 RESPONSIBLE PERSON FOR APPROVED LABORATORIES**

- (A) The responsible person whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.
- (B) The responsible person is responsible for maintaining adequate supervision and control over the dangerous drugs and controlled substances acquired, utilized, destroyed, or administered by the approved laboratory and maintaining all records required by this chapter and federal law to be kept at the establishment or place described in the license.
- (C) If there is a change in the responsible person, the board of pharmacy shall be notified within thirty days thereof of the date of change and the name of the new responsible person.
  - (1) This notice to the board of pharmacy shall be made by completing, signing, and returning the form supplied by the board by ~~certified regular mail, return receipt requested~~ or by verified facsimile transmission.
  - (2) A complete inventory of the controlled substances on hand shall be taken, pursuant to federal regulations, with the new responsible person. The new responsible person shall be responsible for this inventory.

**4729-14-01 DEFINITIONS**

- ~~(A) "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.~~
- ~~(B) "Registration numbers" means the numbers assigned to each person registered under the federal drug abuse control laws and/or Chapter 4729. of the Revised Code.~~
- ~~(C) "Responsible person" means the individual whom the licensee has designated as the person who will maintain supervision and control over the possession and custody of the dangerous drugs that may be acquired and utilized by the licensee.~~
- ~~(D) "D.E.A." means the federal drug enforcement administration or its successor agency.~~
- ~~(E) "Registered veterinary technician" has the same meaning as given that term in section 4741.01 of the Revised Code.~~
- ~~(F) "Euthanasia technician" is an individual that has successfully completed a euthanasia certification course, the curriculum of which has been approved by the veterinary medical licensing board pursuant to section 4729.532 of the Revised Code, and is in possession of a certificate which documents the successful completion of the certification course.~~

As used in Chapter 4729-14 of the Administrative Code:

- (A) "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.
- (B) "Controlled substance" has the same meaning as in section 4729.01 of the Revised Code.
- (C) "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.
- (D) "D.E.A." means the federal drug enforcement administration.
- (E) "Euthanasia technician" is an individual that has successfully completed a euthanasia certification course, the curriculum of which has been approved by the veterinary medical licensing board pursuant to section 4729.532 of the Revised Code, and is in possession of a certificate which documents the successful completion of the certification course.
- (F) "Registered veterinary technician" has the same meaning as given that term in section 4741.01 of the Revised Code.
- (G) "Registration numbers" means the numbers assigned to each person registered under the federal drug abuse control laws and/or Chapter 4729. of the Revised Code.
- (H) "Responsible person" means the individual designated by the licensee as the person who will maintain supervision and control over the possession and custody of the dangerous drugs that may be acquired and utilized by the licensee.

**4729-14-06 RESPONSIBLE PERSON FOR AN APPROVED ANIMAL SHELTER**

- (A) An individual shall be the responsible person for no more than one such location except with written permission from the board. A written request shall be submitted outlining the circumstances requiring an individual to be responsible for more than one location and the period of time during which the circumstances will exist. An individual shall not be designated the responsible person for a location unless that person shall be physically present in the facility a sufficient amount of time to provide supervision and control.
- (B) The responsible person whose name appears on the limited terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.
- (C) The responsible person is responsible for maintaining adequate supervision and control over the dangerous drugs acquired, utilized, or administered by the approved animal shelter and is responsible for maintaining all required records.
- (D) If there is a change in the responsible person, the board of pharmacy shall be notified within thirty days thereof of the date of change and the name of the new responsible person.
  - (1) This notice to the board of pharmacy shall be made by completing, signing, and returning the form supplied by the board by ~~certified~~ regular mail, ~~return receipt requested~~ or by verified facsimile transmission.
  - (2) Included with this notice to the board shall be a notarized drug list prepared pursuant to paragraph (D) of rule 4729-14-03 of the Administrative Code.
  - (3) A complete inventory of the controlled substances on hand shall be taken, pursuant to federal regulations, with the new responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.

**4729-15-02 RESPONSIBILITY FOR NUCLEAR PHARMACY**

A nuclear pharmacist shall maintain supervision and control of radiopharmaceuticals as provided in division (B) of section 4729.55 of the Revised Code.

- (A) The responsible nuclear pharmacist whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.
- (B) The responsible nuclear pharmacist is responsible for maintaining adequate supervision and control over the dangerous drugs acquired and dispensed by the terminal distributor of dangerous drugs and maintaining all records required by this chapter and federal law to be kept at the establishment or place described in the license.
- (C) If there is a change in the responsible nuclear pharmacist, the board of pharmacy shall be notified within thirty days thereof of the date of change and the name of the new responsible nuclear pharmacist.
  - (1) This notice to the board of pharmacy shall be made by completing, signing, and returning the form supplied by the board by ~~certified~~ regular mail, ~~return receipt requested~~ or by verified facsimile transmission.

- (2) A complete inventory of the controlled substances on hand shall be taken, pursuant to federal regulations, with the new responsible nuclear pharmacist. The new responsible nuclear pharmacist shall be responsible for the accuracy of this inventory.

**4729-15-04 LABELING OF RADIOPHARMACEUTICALS**

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 telephone number of the nuclear pharmacy, and the name and address of the nuclear pharmacy as it appears on the terminal distributor of dangerous drugs license.
  - (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.

**4729-17-02 PHARMACIST-IN-CHARGE OF RESPONSIBLE PERSON FOR AN INSTITUTIONAL PHARMACY**

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~~ person 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~~ responsible person and maintained in a readily available place in the pharmacy.
- (C) The ~~pharmacist-in-charge~~ responsible person 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~~ becomes the ~~pharmacist-in-charge and responsible person~~ 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~~ regular mail, ~~return receipt requested,~~ or by verified facsimile transmission 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~~ became the ~~pharmacist-in-charge~~ responsible person.

- (2) Take a complete inventory, pursuant to federal regulations, of the controlled substances on hand at the pharmacy with the ~~new~~ old or ~~acting pharmacist-in-charge~~ previous responsible person at the time he/she ceases to be ~~pharmacist-in-charge~~ the responsible person.
  - (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~~ responsible person is responsible.

**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~~ responsible person 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 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~~ responsible person.

(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, 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~~ responsible person 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~~ responsible person. 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~~ responsible person, 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 resealed;
- (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 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~~ responsible person shall develop and implement policies and procedures which will detect and deter the diversion and/or adulteration of drugs.

**4729-17-04 RECORDS; INSTITUTIONAL 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~~ responsible person 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.
  - (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 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) 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 PHARMACY**

(A) Library

- (1) ~~Current~~ All pharmacists working in a pharmacy must be able to access all 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.

(C) Personnel

The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code. An employee of a pharmacy that may have contact with patients or the general public must be identified by a nametag that includes the employee's job title.

**4729-17-10 LABELING OF PRESCRIPTIONS FOR PATIENTS OF AN INSTITUTIONAL FACILITY**

(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~~ seven 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.

**4729-31-01 DEFINITIONS**

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.~~
- (A) "Compounded sterile product prescription" shall have the same meaning as in rule 4729-19-01 of the Administrative Code.
- (B) "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.

**4729-31-02 PRESCRIPTIONS FOR STERILE PRODUCTS**

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**

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 telephone number of the pharmacy, and 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 and amount of the drug(s) added;
- (H) The name and volume of the parenteral solution;
- (I) The quantity of drug dispensed, if appropriate;
- (J) Beyond use date;
- (K) Storage conditions.

**4729-33-01 DEFINITIONS**

As used in this chapter:

- ~~(A) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.~~
- ~~(B) "Controlled substance" has the same meaning as in section 4729.01 of the Revised Code.~~
- ~~(C) "Terminal distributor of dangerous drugs" has the same meaning as in section 4729.01 of the Revised Code.~~
- ~~(D) "Emergency medical service (EMS) organization" has the same meaning as in section 4765.01 of the Revised Code.~~
- ~~(E) "Mutual aid" means a formal agreement between two or more EMS organizations to assist in emergency medical coverage in the other's usual area of coverage including having access to dangerous drugs during the emergency situation.~~
- ~~(F) "Posting up" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy.~~
- ~~(G) "Posting up at a special event" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy pursuant to a formal agreement with the sponsors of the special event.~~
- ~~(H) "Special event" means an event requiring EMS coverage for more than twenty four hours including, but not limited to, the following:
 
  - ~~(1) A county fair.~~
  - ~~(2) A weekend festival.~~~~
- ~~(I) "Scope of practice" shall be as defined in section 4765.35 of the Revised Code and rule 4765-12-03 of the Administrative Code for a first responder, section 4765.37 of the Revised Code and rule 4765-15-04 of the Administrative Code for an emergency medical technician basic, section 4765.38 of the Revised Code and rule 4765-16-04 of the Administrative Code for an emergency medical technician intermediate, and section 4765.39 of the Revised Code and rule 4765-17-03 of the Administrative Code for an emergency medical technician paramedic.~~

- ~~(J) "Certificate to practice" means the level to which an individual is trained and licensed as defined in sections 4765.01 and 4765.30 of the Revised Code and rule 4765-1-01 of the Administrative Code.~~
- ~~(K) "Medical director" has the same meaning as in rule 4765-10-06 of the Administrative Code.~~
- ~~(L) "Responsible person" has the same meaning as in rule 4729-13-01 of the Administrative Code.~~
- ~~(M) "Standing order" and "protocol" have the same meanings as in rule 4729-5-01 of the Administrative Code.~~
- ~~(N) "Satellite" means an address licensed by the board as a terminal distributor of dangerous drugs that is separate from the licensed headquarters address of the EMS organization.~~
- ~~(O) "Tamper evident" means the package is sealed in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.~~
- ~~(P) "Readily retrievable" means all records which are required to be maintained must be provided upon request to the inspector or agent of the board of pharmacy within three working days.~~

As used in Chapter 4729-33 of the Administrative Code:

- (A) "Certificate to practice" means the level to which an individual is trained and licensed as defined in sections 4765.01 and 4765.30 of the Revised Code and rule 4765-1-01 of the Administrative Code.
- (B) "Controlled substance" has the same meaning as in section 4729.01 of the Revised Code.
- (C) "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.
- (D) "Emergency medical service (EMS) organization" has the same meaning as in section 4765.01 of the Revised Code.
- (E) "Medical director" has the same meaning as in rule 4765-10-06 of the Administrative Code.
- (F) "Mutual aid" means a formal written agreement between two or more EMS organizations to assist in emergency medical coverage in the other's usual area of coverage including having access to dangerous drugs during the emergency situation.
- (G) "Posting up" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy.
- (H) "Posting up at a special event" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy pursuant to a formal agreement with the sponsors of the special event.
- (I) "Readily retrievable" means all records which are required to be maintained must be provided upon request to the inspector or agent of the board of pharmacy within three working days.
- (J) "Responsible person" has the same meaning as in rule 4729-13-01 of the Administrative Code.

- (K) "Satellite" means an address licensed by the board as a terminal distributor of dangerous drugs that is separate from the licensed headquarters address of the EMS organization.
- (L) "Scope of practice" shall be as defined in section 4765.35 of the Revised Code and rule 4765-12-03 of the Administrative Code for a first responder, section 4765.37 of the Revised Code and rule 4765-15-04 of the Administrative Code for an emergency medical technician-basic, section 4765.38 of the Revised Code and rule 4765-16-04 of the Administrative Code for an emergency medical technician-intermediate, and section 4765.39 of the Revised Code and rule 4765-17-03 of the Administrative Code for an emergency medical technician-paramedic.
- (M) "Special event" means an event requiring EMS coverage for more than twenty-four hours including, but not limited to, the following:
- (1) A county fair.
  - (2) A weekend festival.
- (N) "Standing order" and "protocol" have the same meanings as in rule 4729-5-01 of the Administrative Code.
- (O) "Tamper-evident" means the package is sealed in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.
- (P) "Terminal distributor of dangerous drugs" has the same meaning as in section 4729.01 of the Revised Code.

**4729-33-02 LICENSURE**

- (A) Any emergency medical service (EMS) organization that desires to stock dangerous drugs shall apply for and maintain a license as a terminal distributor of dangerous drugs. The one location that serves as the main station will be deemed the headquarters location. Any other locations associated with this headquarters where dangerous drugs will be stored will be licensed as "satellites". Only the headquarters location will be charged a license fee or renewal license fee.
- (B) Each location, headquarters and satellites, must be licensed as a limited terminal distributor of dangerous drugs and must maintain a current terminal distributor of dangerous drugs license and drug addendum.
- (C) An application for licensure must include all of the following:
- (1) A completed application;
  - (2) A compilation of all protocols involving dangerous drugs that have been signed by the medical director and notarized;
  - (3) A list of drugs referenced in the protocols to be stocked by the EMS organization, signed by the medical director and notarized;

- (4) A list of personnel employed by the EMS organization who may access and administer dangerous drugs, which includes the name of the individual, level of certification, their certification number, and expiration date;
  - (5) A list of any and all formal written mutual aid agreements with other EMS organizations;
  - (6) The fee for the appropriate category of licensure.
- (D) Each location, headquarters and satellite, may only possess those dangerous drugs that are listed on the drug addendum and only at locations licensed by the board of pharmacy.
- (1) A medical director may add dangerous drugs to the drug list by submitting revised, signed and notarized protocols and list of medications, and the addendum update fee.
  - (2) A medical director may delete dangerous drugs from the drug list by submitting a letter listing the drugs to be deleted.
- (E) A new application and fee is required prior to any change of location, addition of a satellite location, change of category, name change, or change of ownership. These changes may be made during the annual renewal period with no additional fee other than the renewal fee.
- (F) The responsible person shall provide supervision and control of all locations where dangerous drugs are stored. The responsible person must be a physician licensed pursuant to Chapter 4731. of the Revised Code or a pharmacist licensed pursuant to Chapter 4729. of the Revised Code.
- (1) To change the responsible person, the new responsible person must complete and return a notification of change of responsible person form within thirty days by regular mail or by verified facsimile transmission.
  - (2) To change the medical director, the new medical director must submit a signed and notarized letter stating that he/she is accepting responsibility for the EMS organization.
    - (a) If the new medical director approves of the current protocol and drug list, a signed and notarized letter must be submitted stating the current protocols and drug list on file have been reviewed and are approved by the medical director for use by this EMS organization, or
    - (b) If the new medical director desires to change the protocols or drug list, the medical director must submit the revised, signed, and notarized protocols and drug list, and the addendum update fee.
- (G) Any changes in protocols that involve dangerous drugs must be submitted to the state board of pharmacy prior to the implementation of the protocols involved. The state board of pharmacy may discuss such protocols with the state board of emergency medical services, state medical board, or other governmental agencies as needed to assure their validity.
- (H) Any change of personnel requires a letter from the organization within thirty days of the change listing the type of change (addition, update, or deletion), names of the personnel involved, level of certification, their certification number, and expiration date.

**4729-33-04 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 drug transaction and be approved by the state board of pharmacy.

**4729-33-05 POSTING UP**

- (A) Except when "posting up at a special event", "posting up" must be a temporary, short-term location of the ~~vehicle~~ EMS unit for less than twenty-four hours where the EMS unit is under constant supervision of the EMS personnel on duty, including but not limited to:
  - (1) Local school sports event;
  - (2) Coverage of a station pursuant to a written mutual aid agreement.

- (B) "Posting up at a special event" requires prior written notification to, and approval from, the state board of pharmacy office. This notification must include the name and location of the event, dates of the event, and name and telephone number of the contact person of the EMS unit.

**4729-35-05 ELIGIBILITY REQUIREMENTS TO RECEIVE DRUGS**

A pharmacy, hospital, or nonprofit clinic that elects to participate in the drug repository program must determine if a person is eligible to receive drugs. A person must meet the following requirements to become an eligible recipient of drugs from the drug repository program:

- (A) Is a resident of Ohio, and
- (B) (1) ~~Has no active third party prescription drug reimbursement coverage~~ reasonable financial means to pay for the drug prescribed; or,
  - (2) Is a patient of a nonprofit clinic.

**4729-35-07 RECIPIENT FORM**

~~Each recipient of~~ Prior to receiving a donated drug ~~drugs from the a drug repository program, each recipient~~ must sign a form stating they understand the immunity provisions of the program pursuant to division (B) of section 3715.872 of the Revised Code. ~~The recipient form must also include at least the following:~~

- ~~(A) The signature of the recipient of the donated drug.~~
- ~~(B) The date the form was signed by the recipient.~~
- ~~(C) The brand name of the drug received, or the generic name and list either the name of the manufacturer or the national drug code number (NDC#).~~
- ~~(D) The strength of the drug received by the recipient.~~
- ~~(E) The quantity of the drug received by the recipient.~~

**4729-35-08 RECORD KEEPING**

- (A) Donor forms must be maintained for a minimum of three years by a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility.
- (B) Recipient forms must be maintained for a minimum of three years by a pharmacy, hospital, or nonprofit clinic.
- (C) An invoice must be created by the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility where the donor resides. The invoice must include at least the following information:
  - (1) The name and address of the donor location.

- (2) The brand name of the drug donated, or the generic name and list either the name of the manufacturer or the national drug code number (NDC#).
  - (3) The strength of the drug.
  - (4) The quantity of the drug.
  - (5) The date the drug was sent to a pharmacy, hospital, or nonprofit clinic.
  - (6) The name and address of the recipient pharmacy, hospital, or nonprofit clinic.
- (D) A prescriber must document the distribution of a donated repository program drug to his/her patient pursuant to rule 4729-9-22 of the Administrative Code and a pharmacy must document the dispensing of a donated repository program drug pursuant to rule 4729-5-27 of the Administrative Code. Both records must indicate that the drug distributed to a patient was from the repository program. If recipient forms are used with each dispensing, this information may be documented on the recipient form.
- ~~(D)~~(E) A copy of the invoice must be maintained for a minimum of three years by both the donor location, which includes a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, or an institutional facility, and the recipient location, which includes a pharmacy, hospital, or nonprofit clinic.

**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; and
  - (3) The information 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.
- (B) All 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 monthly as follows:
  - (1) During the first through the tenth day of each month; and
  - (2) The information shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than forty days after the date of the 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.

**4729-37-11 CORRECTIONS TO THE DRUG DATABASE (NEW RULE)**

- (A) Drug dispensing and wholesale drug sale information must be submitted to the drug database in an accurate and timely manner pursuant to rule 4729-37-07 of the Administrative Code.
- (B) If the omission of drug dispensing or wholesale drug sale information is discovered, the omitted information must be submitted to the board of pharmacy by the licensee during the next scheduled reporting time period after the discovery.
- (C) If erroneous drug dispensing or wholesale drug sale information is discovered, the corrected information must be submitted to the board of pharmacy by the licensee during the next scheduled reporting period after the discovery. If the erroneous information was discovered by the licensee, the licensee must notify the board immediately by telephone of the error and submit written documentation that identifies the erroneous information.
- (D) If the omission of data or erroneous data is the result of a computer programming error, the licensee must notify the board of pharmacy immediately by telephone and submit written documentation. The documentation shall fully describe the error and propose a date for submitting the corrected drug information. The board will review the written documentation to assure compliance with paragraph A of this rule.