

<u>Page</u>	<u>Rule No.</u>	<u>Rule Title</u>
	<b>4729-</b>	
		<b><u>CHAPTER 4729-1 [ADMINISTRATIVE PROCEDURES]</u></b>
1	1-02	Notice of meetings.
		<b><u>CHAPTER 4729-5 [PHARMACY PRACTICE]</u></b>
1	5-01	Definitions.
4	5-08	Pharmacy intern professional functions. (NEW)
5	5-10	Prescription pick-up station.
5	5-13	Prescription format.
6	5-15	Prescriber.
7	5-27	Record keeping.
12	5-30	Manner of issuance of a prescription.
15	5-36	Course requirements in the administration of adult immunizations.
16	5-37	Protocols for the administration of adult immunizations.
		<b><u>CHAPTER 4729-9 [DANGEROUS DRUGS]</u></b>
17	9-11	Security and control of dangerous drugs.
18	9-14	Records of controlled substances.
20	9-22	Records of dangerous drugs.
		<b><u>CHAPTER 4729-10 [NONRESIDENT TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS]</u></b>
20	10-01	Definitions.
21	10-02	Licensure.
23	10-03	Compliance.
		<b><u>CHAPTER 4729-36 [CHARITABLE PHARMACIES]</u></b>
24	36-04	Sample drug distribution to a charitable pharmacy.
		<b><u>CHAPTER-37 [DRUG DATABASE]</u></b>
24	37-03	Entities required to submit information.
25	37-04	Information required for submission.
26	37-06	Electronic format required for the transmission of wholesale drug sales.
26	37-07	Frequency requirements for submitting drug database information.

**FULL TEXT SHOWING CHANGES**

UNDERLINED = Add New Language

LINED THROUGH = ~~Remove~~ Old Language

**4729-1-02 Notice of meetings.**

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

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

**4729-5-01 Definitions.**

As used in Chapter 4729. of the Revised Code:

- (A) "Practice of pharmacy" is as defined in division (B) of section 4729.01 of the Revised Code.
- (B) The term "dispense" means the final association of a drug with a particular patient pursuant to the prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for: interpreting, preparing, compounding, labeling, and packaging a specific drug. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular patient will be deemed to have occurred when the pharmacist has given final approval to the patient specific prescription in the system.
- (C) The term "compounding" has the same meaning as defined in division (C) of section 4729.01 of the Revised Code.
- (D) "Interpret prescriptions" means the professional judgment of a pharmacist when reviewing a prescription order of a prescriber for a patient.

- (E) "To participate in drug selection" means selecting and dispensing a drug product pursuant to sections 4729.38 and 4729.381 of the Revised Code.
- (F) "To participate with prescribers in reviews of drug utilization" means monitoring the appropriate use of drugs through communication with the prescriber(s) involved.
- (G) "Pharmacist" means an individual who holds a current pharmacist identification card pursuant to section 4729.08 or 4729.09 of the Revised Code; or, pursuant to section 4729.12 of the Revised Code.
- (H) "Original prescription" means the prescription issued by the prescriber in writing, an oral or electronically transmitted prescription recorded in writing by the pharmacist, a prescription transmitted by use of a facsimile machine, or a prescription transmitted by a board approved electronic prescription transmission system, each of which is pursuant to rule 4729-5-30 of the Administrative Code.
- (I) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional ~~pharmaceutical~~ activities.
- (J) "Preprinted order" is defined as a patient specific, definitive set of drug treatment directives to be administered to an individual patient who has been examined by a prescriber and for whom the prescriber has determined that the drug therapy is appropriate and safe when used pursuant to the conditions set forth in the preprinted order. Preprinted orders may be used only for inpatients in an institutional facility as defined in Chapter 4729-17 of the Administrative Code.
- (K) "Standing order" will mean the same as the term "protocol".
- (L) "Protocol" is defined as:
  - (1) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a prescriber are not immediately available; or
  - (2) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber and have been approved by the state board of pharmacy pursuant to section 4729.54 of the Revised Code. A protocol may be used only by licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases; or
  - (3) A definitive set of written treatment guidelines that include patient specific and dose specific orders for the administration of a specific drug that have been authorized by a prescriber to be used when the services of that prescriber are not immediately available. The state board of pharmacy must approve the treatment guidelines prior to implementation. A list of the board approved drugs used in the treatment guidelines shall be displayed on the pharmacy board web site ([www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)). To be considered for approval by the board, the treatment guidelines must meet the following requirements:

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

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

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

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

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

**4729-5-08 Pharmacy intern professional functions. (NEW)**

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 4729-5-30 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 licensed with the state board of pharmacy as a terminal distributor of dangerous drugs;
  - (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 licensed with the state board of pharmacy as a terminal distributor of dangerous drugs.
  - (2) The receipt, storage, control, and distribution of prescriptions or drugs are in the full and actual charge of a health care professional licensed pursuant to Chapter 4715., 4723., 4729., 4730., ~~or 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.

**4729-5-13 Prescription format.**

Except as provided in rule 4729-5-14 of the Administrative Code:

- (A) No pharmacist shall dispense dangerous drugs pursuant to a written outpatient prescription unless the following conditions are met:

- (1) The prescription is issued in compliance with rule 4729-5-30 of the Administrative Code.
- (2) If handwritten or typewritten, there are no more than three noncontrolled substance prescription orders per prescription form.
- (3) If preprinted with multiple drug names or strength combinations:
  - (a) There are no controlled substances among the choices;
  - (b) There is only one prescription order selected per form.
- (B) No prescriber shall write and no pharmacist shall dispense controlled substances pursuant to a written outpatient prescription unless the following conditions are met:
  - (1) The prescription has been issued in compliance with rule 4729-5-30 of the Administrative Code.
  - (2) The prescription contains only one prescription order per prescription form, whether handwritten, typewritten, or preprinted.
  - (3) The quantity has been written both numerically and alphabetically.
  - (4) If preprinted, there is only one drug and strength combination printed on the form.
- (C) A prescription for a controlled substance issued by a medical intern, resident, or fellow as defined in paragraph (B) of rule 4729-5-15 of the Administrative Code may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.
- (D) A prescription for a controlled substance issued by a staff prescriber of a hospital may not be dispensed unless the prescription is issued in compliance with this rule and rule 4729-17-13 of the Administrative Code and unless it bears the identification number issued by the employing hospital or institution pursuant to rule 4729-17-13 of the Administrative Code.
- (E) If a board approved electronic prescription transmission system is used to fax a prescription to a pharmacy, the faxed order is exempt from paragraphs (A) and (B) of this rule. The faxed order must comply with rule 4729-5-30 of the Administrative Code and must be filed in the most restrictive file according to rule 4729-5-09 of the Administrative Code.

**4729-5-15 Prescriber.**

- (A) For purposes of division (Z) of section 3719.01 and division (I) of section 4729.01 of the Revised Code, the following persons, maintaining current licenses and in good standing, licensed pursuant to Chapters 4715., 4725., 4731., and 4741. of the Revised Code, are authorized by law to write prescriptions for drugs or dangerous drugs in the course of their professional practice:
  - (1) Chapter 4715. of the Revised Code: dentist.

- (2) Chapter 4725. of the Revised Code: optometrist, if that person holds a current "therapeutic pharmaceutical agents certificate" as defined in division (H) of section 4725.01 of the Revised Code.
- (3) Chapter 4731. of the Revised Code: doctor of medicine, doctor of osteopathic medicine and surgery, and doctor of podiatry.
- (4) Chapter 4741. of the Revised Code: doctor of veterinary medicine.
- (B) Those persons pursuing an approved internship, residency, or fellowship program in this state are authorized to write prescriptions only when acting within their scope of employment in the hospital(s) or institution(s). Approved internship and residency programs are those accredited by the "Accreditation Council for Graduate Medical Education (ACGME)" or the "American Osteopathic Association (AOA)". Approved clinical fellowships are those at institutions which have a residency program in the same or a related clinical field which is accredited by the ACGME or the AOA.
- (C) A nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for drugs in the course of their professional practice in a state, as defined in division (G) of section 1.59 of the Revised Code, other than Ohio is authorized to write prescriptions in that state for drugs to be dispensed in the state of Ohio.
- (D) An advanced practice nurse approved pursuant to section 4723.48 of the Revised Code may prescribe those drugs which have been approved by the committee on prescriptive governance for advanced practice nurses and pursuant to the standard care agreement for that advanced practice nurse.
- (E) A physician assistant approved pursuant to section 4730.44 of the Revised Code may prescribe those drugs approved in rule by the medical board and pursuant to the physician supervisory plan for that physician assistant.

**4729-5-27 Record keeping.**

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

- (A) There must be positive identification of the pharmacist or pharmacists responsible for performing all activities relating to the practice of pharmacy including, but not limited to:
  - (1) Prescription information entered into the record keeping system;
  - (2) Prospective drug utilization review;
  - (3) Dispensing;
  - (4) Patient counseling;
  - (5) Administering adult immunizations;
  - (6) Prescription information reduced to writing from an order received by telephone, facsimile, or recording device.
- (B) Records of dispensing must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber.

- (C) All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours.
- (D) All prescriptions or other records relating to the practice of pharmacy, which are required to be kept for three years according to section 4729.37 of the Revised Code, may be microfilmed or placed on electronic, magnetic media. The microfilm or electronic, magnetic media used for this purpose must comply with the "International Standards Organization" standards of quality approved for permanent records. Such records are subject to all other paragraphs of this rule.
- (E) Any pharmacy intending to maintain records relating to the practice of pharmacy at a location other than the place licensed with the state board of pharmacy must first send written notification to the state board of pharmacy ~~by mail or facsimile~~. 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 office will send written notification of the approval or ~~disapproval~~ denial of the request. ~~Only after receiving the notice of the board's approval may the records be placed in the new location. A copy of the board's approval shall be maintained with other records relating to the practice of pharmacy. Any such alternate location shall be secured and accessible only to representatives of the terminal distributor of dangerous drugs.~~
- (F) Alternate record keeping systems include, but are not limited to, the following:
- (1) A system that utilizes the original hard copy prescription to document the initial dispensing of a prescription, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system would require the manual signature or initials of a pharmacist on a hard copy record as indicated in paragraph (I) of this rule.
  - (2) A computerized system that documents the positive identification of the pharmacist responsible for the practice of pharmacy. If this method is used, it must be approved by the board and provide a daily backup.
  - (3) Any record keeping system approved by the board.
- (G) All computerized record keeping systems must be capable of providing immediate retrieval (via CRT display and hard copy printout or other mutually agreeable transfer medium) of patient profile information for all prescriptions filled within the previous twelve months and retrieval within three working days, excluding weekends and holidays, of all prescriptions dispensed within the previous three years. This information shall include at least, but is not limited to, the following data:
- (1) The original prescription number;
  - (2) Date of issuance of the original prescription order by the prescriber;
  - (3) Date of dispensing by the pharmacist;
  - (4) Full name and address of the patient;
  - (5) Full name and address of the prescriber;
  - (6) Directions for use;
  - (7) The name, strength, dosage form, and quantity of the drug prescribed;
  - (8) The quantity dispensed if different from the quantity prescribed;

- (9) If utilizing a board approved system pursuant to paragraph (F)(2) of this rule, there must be positive identification documented within the system of the pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code, and the pharmacist responsible for dispensing;
  - (10) The total number of refills authorized by the prescriber;
  - (11) The refill history of the prescription as defined in paragraph (H) of this rule.
- (H) The refill history of the prescription must include, but is not limited to:
- (1) The prescription number;
  - (2) The name and strength of the drug dispensed;
  - (3) The date of refill;
  - (4) The quantity dispensed;
  - (5) If utilizing a board approved system pursuant to paragraph (F)(2) of this rule, there must be positive identification documented within the system of the pharmacist responsible for prospective drug utilization review as defined in rule 4729-5-20 of the Administrative Code and the pharmacist responsible for dispensing for each refill;
  - (6) The total number of refills dispensed to date for that prescription order.
- (I) Hard copy documentation as required pursuant to paragraph (F)(1) of this rule must be provided by each individual pharmacist who makes use of such system by one of the following methods:
- (1) A hard copy printout of each day's prescription refill data that shall include, at a minimum, the following data:
    - (a) Date of dispensing;
    - (b) Prescription number;
    - (c) Patient name;
    - (d) Name, strength (if applicable), and quantity of drug;
    - (e) Identification of pharmacy and pharmacist;
    - (f) Identification of controlled substances.

This printout must be verified, dated, and signed by each individual pharmacist who dispensed a prescription that day. The pharmacist must verify that the data on the printout is complete and correct and sign a statement to that effect on the document as he/she would sign a check or legal document (e.g., J. H. Smith or Jane H. Smith). These documents must be maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing. If the printout is prepared at a location other than that where the drug was dispensed, the printout must be provided to the licensed location within three working days, excluding holidays and weekends, of the date on which the drugs were dispensed. Such printouts must be verified and signed by each pharmacist who dispensed drugs within twenty-four hours of the date the printout is received;

- (2) A tamper evident log book in which shall be entered, at a minimum, the date of dispensing and prescription number. The dispensing pharmacist must manually record his/her name or initials on each log book entry at the time of dispensing each refill; or
- (3) Each individual pharmacist involved in dispensing drugs must enter into a tamper evident log book, at a minimum, the following data for each prescription refilled:
  - (a) Date of dispensing;
  - (b) Prescription number;
  - (c) Patient name;
  - (d) Name, strength (if applicable), and quantity of drug;
  - (e) Identification of the pharmacist;
  - (f) Identification of controlled substances.

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

(J) ~~Any computerized record keeping system must have the capability of producing a printout by any data field which the user pharmacy is responsible for maintaining pursuant to federal and state laws and their implementing regulations and rules within three working days of a request being submitted by an individual authorized by law to access such records.~~ In addition to the immediate retrieval and production of patient profile information required by paragraph (G) of this rule, a pharmacy that utilizes a computerized record keeping system must be able to:

- (1) Produce:
  - (a) An electronic record in a character-delimited or fixed-width ASCII text file or other mutually acceptable format that contains any requested data fields the user pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations; and
  - (b) A hardcopy printout sorted by any requested data fields that the user pharmacy is responsible for maintaining pursuant to all federal and state laws, rules, and regulations.
- (2) Provide, within three working days of a request by an individual authorized by law to access such records, any requested:
  - (a) Printout; or
  - (b) Electronic record and a definition file describing the file layout and column width, if applicable.

(K) In the event that the computerized record keeping system experiences down time, a record of all refills dispensed during such time must be recorded on the back of the original prescription. The refill information must be entered into the computerized record keeping system as soon as it is available for use. During the time the computerized record keeping system is not available, prescriptions may be refilled only if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.

- (L) A pharmacy purging a computerized record keeping system of prescription records must develop a method of record keeping capable of providing retrieval (via CRT display, hard copy printout, or other mutually agreeable transfer medium) within three working days, excluding holidays and weekends, of prescription order information for all prescriptions filled or refilled within the previous three years. This information shall include, at a minimum, the following data:
- (1) Pharmacy name and address;
  - (2) Original prescription number;
  - (3) Date of issuance of the original prescription order by the prescriber;
  - (4) Date of original dispensing by the pharmacist;
  - (5) Full name and address of the patient;
  - (6) Full name and address of the prescriber;
  - (7) Directions for use;
  - (8) Name, strength, dosage form, and quantity of the drug prescribed;
  - (9) Quantity dispensed if different from the quantity prescribed;
  - (10) Total number of refills authorized by the prescriber;
  - (11) Total number of refills dispensed to date for that prescription order;
  - (12) Date of each refill;
  - (13) Name or initials of each individual dispensing pharmacist.
- (M) A log must be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited to, the following:
- (1) Date and time of change;
  - (2) Changes made;
  - (3) Pharmacist making the change.
- (N) Prescriptions entered into a computer system but not dispensed must meet all of the following conditions:
- (1) The complete prescription information must be entered in the computer system;
  - (2) The information must appear in the patient's profile;
  - (3) There is positive identification, in the computer system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system; and
  - (4) The original prescription is filed according to rule 4729-5-09 of the Administrative Code.
- (O) Records shall be maintained for three years on all ~~adult~~ immunizations administered pursuant to section 4729.41 of the Revised Code and must include at least the following information:

- (1) Full name and address of the patient;
  - (2) Patient's date of birth or age;
  - (3) Patient's gender;
  - (4) Patient's applicable allergy information;
  - (5) Date of administration ~~by the pharmacist~~;
  - (6) Name, strength, and dose of the ~~adult~~ immunization administered;
  - (7) Lot number and expiration date of the immunization;
  - (8) Route of administration;
  - (9) Location of the injection site;
  - (10) Positive identification of the administering pharmacist or the administering pharmacy intern and supervising pharmacist;
  - (11) ~~Documentation~~ Positive identification of the patient, parent, or legal guardian of the patient who gives informed consent to administer an immunization.
- (P) A pharmacist or pharmacy intern under the direct supervision of a pharmacist who administers ~~adult immunizations~~ an immunization pursuant to section 4729.41 of the Revised Code shall maintain and immediately make available, upon the request of the state board of pharmacy, the following records:
- (1) Documentation of the successful completion of a board approved course in the administration of ~~adult~~ immunizations;
  - (2) Documentation of current certification to perform basic life support procedures pursuant to division (B)(2) of section 4729.41 of the Revised Code.

**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 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.
  - (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) 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.

**4729-5-36 Course requirements in the administration of ~~adult~~ immunizations.**

- (A) A course in the administration of ~~adult~~ immunizations developed pursuant to division (B)(1) of section 4729.41 of the revised code shall meet at least the following requirements:
- (1) The instructor shall be a licensed health care professional and have the appropriate education and experience to teach a course in the administration of ~~adult~~ immunizations.
  - (2) The content must meet the standards established for such courses by the centers for disease control and prevention in the public health service of the united states department of health and human services.
  - (3) The course must be a minimum of five hours in length and include at least the following:
    - (a) A review of immunology that includes a discussion of the body's immune system reaction to the immunizations.
    - (b) A review of each ~~immunization~~ medication listed in division (A) of section 4729.41 of the revised code that includes the following:
      - (i) Disease states associated with the immunization;
      - (ii) Type or nature of activity of the immunization;
      - (iii) Appropriate administration schedules;
      - (iv) Appropriate routes of administration;
      - (v) Appropriate injection sites;
      - (vi) Appropriate dosages;
      - (vii) Appropriate monitoring and treatment of the patient for adverse reactions;
      - (viii) Appropriate patient populations;
      - (ix) Precautions and contraindications;
      - (x) Proper storage requirements for the immunization.
    - (c) A review of sterile technique in injectable dosage preparation and administration.
    - (d) A minimum of one hour of instruction and physical participation in administration techniques.
    - (e) A review of the proper disposal procedures for contaminated needles and immunizations.
    - (f) A review of the proper procedures for accidental needle sticks.
  - (4) The course must provide a method to evaluate the successful mastery of the content.

- (B) All courses in ~~adult~~ immunizations must be submitted to the state board of pharmacy for approval. The courses may be reviewed with the state medical board and the board of nursing, as appropriate. Any subsequent revisions to the course, after the initial approval, must be submitted to the state board of pharmacy for approval.

**4729-5-37 Protocols for the administration of ~~adult~~ immunizations.**

- (A) To be considered an approved protocol pursuant to division (B)(3) of section 4729.41 of the revised code, the physician-established protocol for the administration of ~~adult~~ immunizations must include at least the following:
  - (1) For each ~~immunization~~ medication listed in division (A) of section 4729.41 of the revised code:
    - (a) Name and strength;
    - (b) Precautions and contraindications;
    - (c) Intended audience or patient population;
    - (d) Appropriate dosage;
    - (e) Appropriate administration schedules;
    - (f) Appropriate routes of administration;
    - (g) Appropriate injection sites.
  - (2) The length of time the pharmacist or pharmacy intern under the direct supervision of a pharmacist must observe an individual for adverse effects, which shall be based on appropriate standards of care established by the physician. The location of the observation shall be in the general vicinity of the administering pharmacist or pharmacy intern to allow for on-going evaluation.
  - (3) A method to address emergency situations including, but not limited to, adverse reactions, anaphylactic reactions, and accidental needle sticks.
  - (4) A method to notify an individual's physician or the applicable board of health within thirty days after administering ~~an immunization~~ a medication, except for influenza immunizations administered to individuals eighteen years of age and older.
  - (5) The locations that a pharmacist or pharmacy intern under the direct supervision of a pharmacist may engage in the administration of immunizations.
- (B) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the administering pharmacist. The pharmacist must renew the protocol annually with the physician.
- (C) Upon the request of the state board of pharmacy, a pharmacist shall immediately provide the protocols for ~~adult~~ immunizations pursuant to division (B)(3) of section 4729.41 of the revised code. The state board of pharmacy, after review, may approve the protocol or return it to the pharmacist for revision without approval. If a protocol has been returned for revision without approval, it may not be implemented until the board has approved it. The state

board of pharmacy may review the protocols with the state medical board and the board of nursing, as appropriate.

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

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

- (A) In a pharmacy.
  - (1) Personal supervision by a pharmacist of the dangerous drugs at all times to deter and detect theft or diversion; except,
    - (2) Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:
      - (a) The prescription department or stock of dangerous drugs must be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time the pharmacist is not present. Such a barrier, before being put into use, must be approved by the state board of pharmacy.
      - (b) The prescription department must contain all dangerous drugs, exempt narcotics, hypodermics, poisons, and every other item or product that requires the personal supervision or sale by a pharmacist.
      - (c) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the prescription department.
      - (d) Except as provided in rule 4729-17-03 of the Administrative Code, only a pharmacist may have access to the prescription department or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, exempt narcotics, hypodermics, poisons, and any other item or product that requires the personal supervision or sale by a pharmacist.
      - (e) No prescription, dangerous drug, exempt narcotic, hypodermic, nor any other item or product that requires the personal supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the prescription department is closed.
      - (f) New or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.
      - (g) Notice to the public of operating hours of the prescription department must be posted.
  - (3) Areas designated for the dispensing, compounding, and storage of dangerous drugs shall meet the security requirements in rule 4729-9-05 of the Administrative Code.

No person may be within the physical confines of the area designated for the dispensing, compounding, and storage of dangerous drugs unless under the personal supervision of a pharmacist.

- (B) In other terminal distributors of dangerous drugs, including but not limited to, emergency medical services pursuant to division (C) of section 4729.54 of the Revised Code, first-aid departments pursuant to rule 4729-9-04 of the Administrative Code, approved laboratories pursuant to paragraph (A) of rule 4729-13-01 of the Administrative Code, and animal shelters pursuant to paragraph (A) of rule 4729-14-01 of the Administrative Code, dangerous drugs must be stored in an area secured by either a physical barrier with suitable locks and/or an electronic barrier to deter and detect unauthorized access.
- (C) A pharmacist, prescriber, or responsible person for a terminal distributor of dangerous drugs license pursuant to paragraph (C) of rule 4729-13-01 or paragraph (C) of rule 4729-14-01 of the Administrative Code who has signed as being responsible for a terminal distributor of dangerous drugs license is responsible to monitor for suspicious orders, unusual usage, or questionable disposition of dangerous drugs.
- (D) 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 use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board.

#### **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, or used. 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.
- (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) All records of receipt, distribution, administering, dispensing, inventory, or using controlled substances shall be kept for a period of three years at the place where the controlled substances are located. Any ~~prescriber or~~ terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send ~~notification~~ a written request to the state board of pharmacy; ~~if not contested by the board within sixty days, it will stand as approved.~~ 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.

**4729-9-22 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. 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 drugs, other than controlled substances, administered, dispensed, or used which become a permanent part of the patient's medical record shall be deemed to meet the requirements of paragraph (B) of this rule.
- (D) All records of receipt, distribution, administering, dispensing, selling, destroying, or using dangerous drugs shall be kept for a period of three years at the place where the dangerous drugs are located. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send notification a written request to the state board of pharmacy ~~by certified mail, return receipt requested, if not contested by the board within sixty days, it will stand as approved.~~ 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 ~~request with the return receipt~~ 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.

**4729-10-01 Definitions.**

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

- (A) "Nonresident pharmacy" means any pharmacy, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into Ohio;
- (B) "Nonresident terminal distributor of dangerous drugs" means any person, as defined in section 4729.01 of the Revised Code, located outside of Ohio that ships, mails, or delivers in any manner, dangerous drugs at retail into Ohio;
- (C) "Pharmacist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice pharmacy in the state where he/she is practicing.

- ~~(D)~~ "Dentist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice dentistry in the state where he is practicing.
- ~~(E)~~ "Optometrist," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice optometry in the state where he is practicing.
- ~~(F)~~ "Physician," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice medicine in the state where he is practicing.
- ~~(G)~~ "Veterinarian," as used in division (B)(2) of section 4729.55 of the Revised Code, means an individual who holds a current license to practice veterinary medicine in the state where he is practicing.
- (D) "Licensed health professional authorized to prescribe drugs" or "prescriber" as used in division (B) of section 4729.55 means an individual who is authorized by law to prescribe drugs or dangerous drugs in the state where the individual is practicing.
- ~~(H)~~(E) "Dangerous drug" has the same meaning as given that term in section 4729.01 of the Revised Code.

**4729-10-02 Licensure.**

Each nonresident terminal distributor of dangerous drugs that sells dangerous drugs at retail in the state of Ohio shall obtain a terminal distributor of dangerous drugs license pursuant to sections 4729.54 and 4729.55 of the Revised Code and Chapter 4729-10 of the Administrative Code.

- (A) Conditions of licensure. The nonresident terminal distributor of dangerous drugs shall provide the following information relative to the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code:
  - (1) Full name, address, and telephone number of the person who desires to be licensed as a nonresident terminal distributor of dangerous drugs.
    - (a) If incorporated, the application for licensure must include copies of the incorporation papers; and names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the stock.
    - (b) If a proprietorship, the application for licensure must include the name, address, date of birth, and social security number of the owner(s).
    - (c) If a partnership, the application for licensure must include the names, addresses, dates of birth, and social security numbers of the partners.
    - (d) If the entity applying for a license is a private investment group, the application for licensure must include the names, addresses, dates of birth, and social security numbers of the investors.
  - (2) Certification from the appropriate licensing authority that the applicant maintains at all times a valid, unexpired license, permit, or registration to properly carry on the

- business of a distributor of dangerous drugs in the state in which the facility is located and from where dangerous drugs are being sold at retail to residents in Ohio. The certification(s) must include licenses, permits, or registrations required to cover the categories of dangerous drugs which the nonresident terminal distributor of dangerous drugs will be selling at retail to persons in the state of Ohio (i.e., controlled substance drug products as well as noncontrolled substance drug products).
- (3) A copy of the most recent inspection report, any warning notices, notice of deficiency reports, or any other related reports issued by the regulatory licensing agency and drug law enforcement agencies of the state in which it is located or any federal agencies regulating and enforcing laws governing the legal distribution of drugs.
  - (4) A narrative description of the type of business the nonresident terminal distributor of dangerous drugs will ~~be carrying on~~ conduct within the category of licensure requested. The description shall include the type of professional services that will be provided in accordance with federal and state laws governing the legal distribution of drugs and professional pharmacy practice.
  - (5) If the nonresident terminal distributor is a pharmacy, the application shall be accompanied by:
    - (a) The name and license number of the responsible pharmacist (pharmacist-in-charge).
    - (b) Certification from the appropriate licensing authority that the responsible pharmacist's license is current and in good standing.
    - (c) The telephone number where the responsible pharmacist may be reached during normal business hours.
    - (d) A list of all pharmacists employed by the pharmacy who are dispensing dangerous drugs pursuant to prescriptions to residents of this state. The list shall include each pharmacist's license number and the date that the license will expire.
    - (e) A description of the following:
      - (i) Normal delivery protocols and times;
      - (ii) Any special packaging or procedures used in delivering temperature-sensitive drug products;
      - (iii) The procedure to be followed if the patient's prescription drug is not available at the nonresident pharmacy, or if delivery will be delayed beyond the normal delivery time;
      - (iv) The procedure to be followed upon receipt of a prescription for an acute illness that assures the patient the opportunity to obtain the medication immediately.
      - (v) The procedure to be followed that will ensure that the patient's medication therapy is not interrupted when the nonresident pharmacy has been

advised by the patient or patient’s caregiver that the patient’s prescription medication has not been received within the normal delivery time.

- (6) Nonresident terminal distributors of dangerous drugs where the responsible person is a ~~dentist, optometrist, physician, or veterinarian~~ prescriber shall submit the following information with their application:
  - (a) The name and license number of the responsible ~~dentist, optometrist, physician, or veterinarian~~ prescriber.
  - (b) Certification from the appropriate licensing authority that the responsible person’s license is current and in good standing.
  - (c) The telephone number where the responsible ~~dentist, optometrist, physician, or veterinarian~~ prescriber may be reached during normal business hours.
  - (d) A list of all ~~dentists, optometrists, physicians, or veterinarians~~ prescribers employed by the nonresident terminal distributor who are selling dangerous drugs at retail to residents of this state. The list shall include the license numbers and the date that the licenses to practice will expire.

**4729-10-03 Compliance.**

Each nonresident terminal distributor of dangerous drugs shall:

- (A) Maintain, in readily retrievable form, records of all dangerous drugs sold at retail to persons in Ohio.
- (B) Comply with all the statutory and regulatory requirements of the state of Ohio for controlled substances, including those that are different from federal law, unless such compliance would cause the nonresident terminal distributor of dangerous drugs to violate the statutory or regulatory requirements of the state in which it is located.
- (C) Supply upon request and in a timely manner all information needed by the board of pharmacy to carry out its responsibilities as a licensing, regulatory, and drug law enforcement agency of the state of Ohio.
- (D) Supply upon request and in a timely manner all information needed by the board of pharmacy and any local, state, or federal agency to carry out its responsibilities in enforcing the federal and state laws governing the distribution of drugs in the state of Ohio.
- (E) ~~Supply upon request and in a timely manner all information needed by the board of pharmacy to carry out its responsibilities in licensing and regulating professional practice in the state of Ohio.~~
- (F) If the nonresident terminal distributor is a pharmacy, there must be an offer to counsel the patient issued with every prescription filled. The offer shall be made by telephone or in writing on a separate document and shall accompany the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy’s primary patient population. The pharmacy shall have sufficient telephone service to provide reasonable access to incoming callers.

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

- (A) An eligible sample drug shall only be distributed directly to a charitable pharmacy by a:
  - (1) Manufacturer;
  - (2) Manufacturer's representative;
  - ~~(2)~~(3) Wholesale distributor of dangerous drugs acting on behalf of a manufacturer; or
  - ~~(3)~~(4) Prescriber practicing in a location that is licensed as a terminal distributor of dangerous drugs.
  
- (B) If a sample drug is furnished by a prescriber:
  - (1) A record must be created by the prescriber documenting the sample drug transfer. The record shall contain the:
    - (a) Name and address of the supplying prescriber;
    - (b) Name, strength, and quantity of the sample drug supplied;
    - (c) Date of the sample drug transfer;
    - (d) Name and address of the charitable pharmacy receiving the sample drug.
  - (2) ~~A copy of the original record issued by the manufacturer or the wholesale distributor documenting the transfer of the sample drug to the prescriber must be furnished to the charitable pharmacy upon receiving a sample drug.~~
  - ~~(3)~~ A copy of all required records documenting the transfer of a sample drug must be kept by the prescriber and the charitable pharmacy for a minimum of three years and be stored in a readily retrievable manner.
  - ~~(4)~~(3) The prescriber shall not transfer a sample drug to a charitable pharmacy unless the sample drug was received directly from a manufacturer, a manufacturer's representative, or by a wholesaler acting on behalf of a manufacturer and meets the eligibility requirements pursuant to rule 4729-36-05 of the Administrative Code.
  - ~~(5)~~(4) The sample drug must not have any physical signs of tampering.
  - ~~(6)~~(5) The sample drug packaging must not have any physical signs of tampering.

**4729-37-03 Entities required to submit information.**

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

- (A) All pharmacies located outside this state and licensed as a terminal distributor of dangerous drugs ~~that dispense~~ shall report all drugs identified in rule 4729-37-02 of the Administrative Code that are dispensed to outpatients residing in this state.

(B) All pharmacies located within this state and licensed as a terminal distributor of dangerous drugs shall report all drugs identified in rule 4729-37-02 of the Administrative Code that are dispensed to all outpatients.

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

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

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

**4729-37-04 Information required for submission.**

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

- (1) Pharmacy drug enforcement administration registration number;
- (2) Pharmacy name;
- (3) Pharmacy address;
- (4) Pharmacy telephone number;
- (5) Patient full name;
- (6) Patient address;
- (7) Patient telephone number;
- (8) Patient date of birth;
- (9) Patient gender;
- (10) Prescriber's drug enforcement administration registration number;
- (11) Date prescription was issued by the prescriber;
- (12) Date the prescription was dispensed by the pharmacy;
- (13) Indication of whether the prescription dispensed is new or a refill;

- (14) Number of the refill being dispensed;
  - (15) National drug code of the actual drug dispensed;
  - (16) Quantity of drug dispensed;
  - (17) Number of days' supply of drug dispensed;
  - (18) Serial or prescription number assigned to the prescription order;
  - (19) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial pharmacy benefit manager (PBM) insurance, major medical, or workers' compensation.
- (B) Wholesalers and pharmacies pursuant to paragraphs ~~(B)~~ and (C) and (D) of rule 4729-37-03 of the Administrative Code that sell drugs identified in rule 4729-37-02 of the Administrative Code at wholesale must report the following information to the board of pharmacy in the following sequence:
- (1) Wholesaler or pharmacy drug enforcement administration registration number;
  - (2) Purchaser's drug enforcement administration registration number;
  - (3) National drug code number of the actual drug sold;
  - (4) Quantity of the drug sold;
  - (5) Date of sale.

**4729-37-06 Electronic format required for the transmission of wholesale drugs.**

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

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

- (A) All drug dispensing ~~and wholesale drug sale~~ information required to be submitted to the board of pharmacy pursuant to rules 4729-37-02 and 4729-37-04 of the Administrative Code must be submitted twice a month as follows:
- (1) During the first through the fifth day of each month; and
  - (2) During the fifteenth through the twentieth day of each month-; and

- ~~(B)~~ (3) ~~Information~~ The information reported to the board of pharmacy shall be consecutive and inclusive from the last date and time information was submitted and shall be reported no later than twenty-one days after the date of the dispensing ~~or wholesale sale~~.
- (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.