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FULL TEXT SHOWING CHANGESUNDERLINED = Add New LanguageLINED THROUGH = ~~Remove~~ Old Language**4729-5-16 LABELING OF DRUGS DISPENSED ON PRESCRIPTION**

- (A) No drug may be dispensed on prescription unless a label is affixed to the container in which such drug is dispensed and such label includes:
- (1) The name and address of the pharmacy as it appears on the terminal distributor of dangerous drugs license unless it is filled pursuant to a board-approved central filling operation, in which case the label shall bear the name and address of the originating pharmacy as it appears on the terminal distributor of dangerous drugs license;
 - (2) The full name of the patient for whom the drug is prescribed; or, if the patient is an animal, the full name of the owner and identification of the animal;
 - (3) The full name of the prescriber;
 - (4) Directions for use of the drug;
 - (5) The date of dispensing;
 - (6) Any cautions which may be required by federal or state law;
 - (7) The serial number of the prescription;
 - (8) The proprietary name, if any, or the generic name and the name of the distributor of the drug dispensed; and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission in writing in the case of a written prescription, or verbally in the case of an orally transmitted prescription;
 - (9) The quantity of drug dispensed;
 - (10) If filled as part of a board-approved central filling operation, an identification of the pharmacy providing the drugs for the dispensing operation.
- (B) The term "affix" means the prescription label must be attached or fastened to the container.
- (C) At least the prescription number and the name of the patient must be placed on all prescription containers too small to bear a complete prescription label and dispensed in a container bearing a complete prescription label. The label bearing only the prescription number and the name of the patient does not need to be applied to any product whose function would be impaired by such a label. In all cases, a complete prescription label meeting the requirements of paragraph (A) of this rule must be applied to the container in which such product is dispensed.
- (D) This rule does not apply to drugs which are dispensed for use by inpatients of an institutional facility whereby the drug is not in the possession of the ultimate user prior to administration. Such drugs shall be labeled in accordance with rule 4729-17-10 of the Administrative Code.

4729-5-21 MANNER OF PROCESSING 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) A pharmacist when dispensing a prescription must:
- (1) Ensure that patient information is profiled pursuant to rule 4729-5-18 of the Administrative Code;
 - (2) Perform prospective drug utilization review pursuant to rule 4729-5-20 of the Administrative Code;
 - (3) Ensure that the drug is labeled pursuant to rule 4729-5-16 of the Administrative Code;
 - (4) Ensure that a patient is given an offer to counsel pursuant to rule 4729-5-22 of the Administrative Code;
 - (5) Ensure that a prescription is filed pursuant to rule 4729-5-09 of the Administrative Code.
- (C) Prescriptions:
- (1) A pharmacist may receive a signed hard copy prescription, an oral prescription, a facsimile of a signed prescription, or a prescription sent using a board approved electronic prescription transmission system. The pharmacist shall follow the prescription record keeping processes noted in paragraphs (C), (D), (E), and (F) of this rule for each of these types of prescriptions received unless utilizing an alternate record keeping system pursuant to rule 4729-5-27 of the Administrative Code that has been approved by the board.
 - (2) When a pharmacist dispenses a drug pursuant to an original prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or, if approved by the state board of pharmacy, enter his/her positive identification into the computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code. If an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, the record of dispensing must also be recorded in the alternate record keeping system.
 - (3) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, he/she must record the date of such dispensing and either manually record his/her name or initials on the original prescription or enter such information in an alternate record keeping system or, if approved by the state board of pharmacy, enter his/her positive identification into a computerized record keeping system pursuant to rule 4729-5-27 of the Administrative Code.

(D) Oral prescriptions:

- (1) The pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, on the original prescription and, if used, on the alternate system of record keeping. The pharmacist is responsible for assuring the validity of the source of the oral prescription.
- (2) Upon receiving a prescription from a recording device, the pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for assuring the validity of the prescription removed from the recorder.
- (3) A licensed pharmacy intern may receive telephone prescriptions and remove prescriptions from a recording device if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to perform this function.
 - (a) The intern shall immediately reduce the prescription to writing, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent, and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the oral order.
 - (b) The supervising pharmacist on duty is responsible for the accuracy of the prescription.
 - (c) The supervising pharmacist on duty must be immediately available to answer questions or discuss the prescription with the caller.

(E) Facsimile prescriptions:

- (1) A facsimile shall only be valid as a prescription if a system is in place that will allow the pharmacist to maintain the facsimile as a part of the prescription record including the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent as well as identification of the origin of the facsimile.
- (2) The pharmacist must record the prescription in writing pursuant to section 4729.37 of the Revised Code or store the facsimile copy in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(F) Electronic prescriptions:

- (1) Electronic prescriptions may be received by a pharmacy if the electronic prescription transmission system has been approved by the state board of pharmacy.
- (2) A pharmacy desiring to receive electronic prescriptions directly into its computer system must obtain approval from the state board of pharmacy. The original prescription information received from the prescriber must be saved and a hardcopy prescription must be printed to document the dispensing. The hardcopy prescription must be filed serially in the prescription file pursuant to rule 4729-5-09 of the Administrative Code.

- (G) A pharmacist may not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription.

- (H) The quantity dispensed shall be considered the quantity prescribed unless the quantity dispensed on a:
- (1) New prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription. If the quantity dispensed on a new prescription is greater than the quantity prescribed, the pharmacist shall also record on the original prescription the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.
 - (2) Refill prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription or enter the quantity dispensed on an alternate record pursuant to paragraph (F) of rule 4729-5-27 of the Administrative Code. If the quantity dispensed on a refill prescription is greater than the quantity prescribed, the pharmacist shall also record the name of the authorizing prescriber, the full name of the agent of the prescriber if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.
- (I) Where a prescription is written using a generic name, or where the pharmacist dispenses an equivalent drug product pursuant to the provisions of sections 4729.38 and 4729.381 of the Revised Code, the brand name or drug name and name of the manufacturer or distributor of the drug or the national drug code (NDC) number of the drug dispensed must be recorded on the record of dispensing by the pharmacist.
- (J) A pharmacist who modifies a patient's drug therapy pursuant to a consult agreement and is:
- (1) Also responsible for the dispensing of the drug to the patient must include on the drug order the name of the physician who originally prescribed the drug, sign the pharmacist's full name, and be in compliance with this rule in the same manner as the prescriber.
 - (2) Not responsible for the dispensing of the drug to the patient may transmit the order to a pharmacy by acting as an agent of the physician. Such pharmacist must personally transmit the order verbally or by facsimile to another pharmacist and be in compliance with this rule.

4729-5-24 PRESCRIPTION COPY

- (A) A pharmacist may transfer a copy of a prescription; a pharmacist may refill a copy of a prescription; such actions must be in accordance with the following:
- (1) Copies of prescriptions shall be transferred only between pharmacists except as provided in paragraph (G) of this rule; copies of prescriptions for controlled substances pursuant to sections 3719.41, 3719.43, and 3719.44 of the Revised Code shall be communicated directly between two pharmacists and shall be transferred only one time. However, pharmacies electronically sharing a real time, online database may transfer a controlled substance prescription up to the maximum number of refills permitted by law and the prescriber's authorization pursuant to paragraph (A)(4) of this rule.
 - (2) The copy transferred shall be an exact duplicate of the original prescription except that it shall also include:

- (a) Serial prescription number assigned to the prescription;
 - (b) Name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy transferring the copy;
 - (c) Date of issuance of the prescription;
 - (d) Date of original dispensing of the prescription;
 - (e) Original number of refills;
 - (f) Date of last refill;
 - (g) Number of valid refills remaining; and
 - (h) The full name of the transferring pharmacist.
- (3) Copies transferred for nonrefillable prescriptions shall be marked on the face of the prescription or orally noted by the transferring pharmacist "For Information Purposes Only" and are not valid prescriptions for the dispensing of drugs.
- (4) The pharmacist transferring a copy of a prescription must:
- (a) Cancel the original prescription by writing the word "void" on the face of the prescription in such a way as to avoid destroying any of the original information contained on the prescription;
 - (b) Record on the reverse side of the original written prescription:
 - (i) ~~Date~~ The date of transfer;
 - (ii) His/her signature; and
 - (iii) ~~When transferring an oral prescription, the~~ The name and address (and "D.E.A." number for controlled substance prescriptions) of the pharmacy receiving the prescription, and the full name of the pharmacist at the receiving pharmacy the prescription.
 - (c) Except, if an alternate record keeping system is being used pursuant to rule 4729-5-27 of the Administrative Code, copies of prescriptions may be transferred by a pharmacist if the prescription record in the system is invalidated to prevent further dispensing at the original site. The prescription record in the system must contain the date of transfer, full name of pharmacist making transfer, full name of pharmacist receiving the prescription, and the name and address of the pharmacy receiving the copy. Also, original written prescriptions for controlled substances must be canceled as required in paragraphs (A)(4)(a) and (A)(4)(b) of this rule.
- (5) The pharmacist receiving a copy of a prescription must:
- (a) Exercise reasonable diligence to determine validity of the copy;
 - (b) Reduce an oral prescription to writing by recording all of the information transferred (must include all information required in paragraph (A)(2) of this rule) and write the word "transfer" on the face of the prescription;

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

- (G) A licensed pharmacy intern may send or receive copies of prescriptions pursuant to the following:
- (1) The pharmacist on duty who is supervising the activity of the intern will determine if the intern is competent to send or receive a prescription copy.
 - (2) The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription copy that is sent or received by an intern.
 - (3) The supervising pharmacist must be immediately available to answer questions or discuss the prescription copy that is sent or received by an intern.
 - (4) The intern may not send or receive a prescription copy for a controlled substance.
 - (5) The pharmacist or intern receiving a prescription copy from an intern must document the full names of the sending intern and his/her supervising pharmacist. The receiving intern shall immediately reduce the prescription copy to writing and shall review the prescription with the supervising pharmacist. Prior to dispensing, positive identification of the intern and the supervising pharmacist shall be made on the prescription to identify the responsibility for the receipt of the copy.
 - (6) The pharmacist or intern sending a prescription copy to an intern must document the full names of the receiving intern and his/her supervising pharmacist. There must be documented positive identification of the sending intern and his/her supervising pharmacist who authorized the transfer of the prescription copy.
 - (7) The approved intern and the supervising pharmacist must meet all the requirements of this rule.

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. 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 denial of the request. 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) 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 immunizations administered pursuant to section 4729.41 of the Revised Code and rule 4729-5-38 of the Administrative 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
 - (6) Name, strength, and dose of the immunization administered;
 - (7) Lot number and expiration date of the immunization;
 - (8) Route of administration;
 - (10) Positive identification of the administering pharmacist or the administering pharmacy intern and supervising pharmacist;
 - (11) Positive identification, 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 an immunization pursuant to section 4729.41 of the Revised Code and rule 4729-5-38 of the Administrative 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 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 residential 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.
 - (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.

4729-11-07 STANDARD PHARMACEUTICAL REFERENCES

All editions, with cumulative changes, if any, of the following reference works are recognized and approved by the state board of pharmacy:

- (A) "Drug Facts and Comparisons";
- (B) "Martindale: The Extra Pharmacopoeia";
- (C) "Remington's Pharmaceutical Sciences";
- (D) "United States Dispensatory";
- (E) "United States Pharmacopeia/National Formulary" ("USP/NF");
- ~~(F) "United States Pharmacopeia Dispensing Information" ("USP DI");~~
- ~~(EG) "American Hospital Formulary Service Drug Information" ("AHFS Drug Information").~~

4729-15-01 DEFINITIONS

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

- ~~(A) "Nuclear pharmacy" is a pharmacy where prescriptions for radiopharmaceuticals are filled or where radiopharmaceuticals are compounded or dispensed by a pharmacist licensed by the proper authorities to receive, possess, and use such drugs. A nuclear pharmacy shall be licensed by the United States "Nuclear Regulatory Commission" or the appropriate state nuclear regulatory agencies, other appropriate state agencies, and by the state board of pharmacy.~~
- ~~(B) "Radiopharmaceutical," a dangerous drug as defined in division (D) of section 4729.01 of the Revised Code, shall include any article that exhibits spontaneous decay or disintegration of an~~

~~unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such article.~~

~~(C) "Nuclear pharmacist" shall be a licensed pharmacist holding a current identification card in the state of Ohio, and meets the following standards:~~

~~(1) Be certified as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or~~

~~(2) Meet minimal standards of training for an "authorized user" of radioactive material or for an "authorized nuclear pharmacist (ANP)" designation by the proper nuclear regulatory agency, the United States Nuclear Regulatory Commission, or the appropriate state agency including:~~

~~(a) Have received a minimum of two hundred contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy or a program approved by the nuclear regulatory commission, with emphasis in the following areas:~~

~~(i) Radiation physics and instrumentation (eighty-five hours);~~

~~(ii) Radiation protection (forty-five hours);~~

~~(iii) Mathematics of radioactivity (twenty hours);~~

~~(iv) Radiation biology (twenty hours);~~

~~(v) Radiopharmaceutical chemistry (thirty hours).~~

~~(b) Attain a minimum of five hundred hours of clinical nuclear pharmacy training under the supervision of a pharmacist trained in nuclear pharmacy and who is an "authorized user" or an "authorized nuclear pharmacist" as defined by the nuclear regulatory commission.~~

~~(D) "Class 100 environment" has the same meaning as in rule 4729-19-01 of the Administrative Code.~~

~~(E) "Class 100,000 environment" means an atmospheric environment that contains no more than 100,000 particles of 0.5 microns in diameter or larger per cubic foot of air according to "Federal Standard 209E". A class 100,000 environment is equivalent to ISO class 8.~~

(A) "Class 100 environment" means an atmospheric environment that contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air according to "Federal Standard 209E". A class 100 environment is equivalent to ISO class 5.

(B) "Class 100,000 environment" means an atmospheric environment that contains no more than one hundred thousand particles of 0.5 microns in diameter or larger per cubic foot of air according to "Federal Standard 209E". A class 100,000 environment is equivalent to ISO class 8.

(C) "Nuclear pharmacist" shall be a licensed pharmacist holding a current identification card in the state of Ohio, and meets the following standards:

(1) Be certified as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or

(2) Meet minimal standards of training for an "authorized user" of radioactive material or for an "authorized nuclear pharmacist (ANP)" designation by the proper nuclear regulatory agency, the United States nuclear regulatory commission, or the appropriate state agency including:

(a) Have received a minimum of two hundred contact hours of didactic instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an accredited college of pharmacy or a program approved by the nuclear regulatory commission, with emphasis in the following areas:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics of radioactivity;

(iv) Radiation biology;

(v) Radiopharmaceutical chemistry.

(b) Attain a minimum of five hundred hours of clinical nuclear pharmacy training under the supervision of a pharmacist trained in nuclear pharmacy and who is an "authorized user" or an "authorized nuclear pharmacist" as defined by the nuclear regulatory commission.

(D) "Nuclear pharmacy" is a pharmacy where prescriptions for radiopharmaceuticals are filled or where radiopharmaceuticals are compounded or dispensed by a pharmacist licensed by the proper authorities to receive, possess, and use such drugs. A nuclear pharmacy shall be licensed by the United States nuclear regulatory commission or the appropriate state nuclear regulatory agencies, other appropriate state agencies, and by the state board of pharmacy.

(E) "Radiopharmaceutical," a dangerous drug as defined in division (F) of section 4729.01 of the Revised Code, shall include any article that exhibits spontaneous decay or disintegration of an unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such article.

4729-15-03 MINIMUM STANDARDS FOR A NUCLEAR PHARMACY

(A) A nuclear pharmacy shall comply with all applicable local, state, and federal requirements. If a nuclear pharmacy compounds parenteral or sterile product prescriptions other than radiopharmaceuticals or biohazardous materials, the pharmacy shall also comply with rule 4729-19-04 of the Administrative Code.

(B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile radiopharmaceutical prescriptions. The policy and procedure manual shall include at a minimum:

(1) A quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education;

(2) Justification for the chosen beyond use dates of compounded products;

- (3) Proper handling, storage, and disposal of drugs, radiopharmaceuticals, and radioactive waste;
- (4) Proper handling, storage, and disposal of biohazardous materials, if applicable;
- (5) Handling of spills and exposure to radioactive and biohazardous materials;
- (6) Proper documentation and reporting of adverse events;
- (7) Procedures to resolve conflicts when sterile product preparation may interfere with radiation safety practices and equipment. These procedures should use the principle of as clean as reasonably achievable. ~~For example, class 100,000 conditions will be employed in the area where generator elution is performed with a terminal sterilization filter to obtain as reasonably achievable class 100 conditions.~~

The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy agent.

(C) Physical requirements

- (1) The facility shall have a designated area with access limited to authorized personnel for preparing sterile radiopharmaceutical products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood or other primary engineering control devices that provide a class 100 environment and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
- (2) The facility compounding radiopharmaceutical prescriptions shall have appropriate:
 - (a) ~~Environmental~~ Primary engineering control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; at a minimum, there shall be a physical barrier separating the area where biohazardous products such as human blood are prepared; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air. ~~Environmental control devices for handling biohazardous substances such as human blood, if applicable. At a minimum, there shall be a physical barrier separating the area where biohazardous products are prepared;~~
 - (b) Shielding of radioactive materials;
 - (c) Compounding devices and equipment;
 - (d) Storage conditions for drugs, radiopharmaceuticals, and biohazardous materials;
 - (e) Appropriate disposal containers for used needles, syringes, etc.
- (3) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

- (4) The compounding of sterile products shall be done within a class 100 environment except in an emergency situation when the product is required to meet the immediate needs of a patient whose health would otherwise be jeopardized.

(D) Delivery service

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to assure the proper labeling, environmental controls, integrity, and safety of all products transported.

(E) Disposal of radioactive and/or biohazardous waste

The responsible nuclear pharmacist shall ensure that all employees comply with all applicable local, state, and federal requirements to assure that there is a system for the disposal of radioactive and/or biohazardous waste in a manner so as not to endanger the public health.

(F) Health care professional counseling

When appropriate, a nuclear pharmacist shall be involved in discussing with each health care professional responsible for receiving, storing, and administering a radiopharmaceutical product, the following matters:

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

(G) Quality assurance

- (1) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, finished compounded drug products, and facilities.
- (2) At a minimum, there shall be written quality assurance programs developed that address:
 - (a) Adequate training and continuing competency monitoring of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training;
 - (b) Continued verification of compounding accuracy and including when possible physical inspection of end products;
 - (c) Continued verification of automated compounding devices;
 - (d) Continued verification that appropriate beyond use dates are being assigned to compounded products;
 - (e) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected. If bulk compounding of sterile

products is being performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine;

- (f) All clean rooms and laminar flow hoods shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operation efficiency shall be maintained for at least three years.

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 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 full 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 unless otherwise approved by the board of pharmacy.
 - (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 full 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.

4729-19-04 MINIMUM STANDARDS FOR COMPOUNDING PARENTERAL OR STERILE PRODUCT PRESCRIPTIONS

- (A) A compounding facility shall meet the minimum standards for institutional ~~facility~~ pharmacies pursuant to rule 4729-17-08 of the Administrative Code.
- (B) A policy and procedure manual shall be prepared and maintained regarding the compounding, dispensing, and delivery of sterile product prescriptions. The policy and procedure manual shall include at a minimum:
- (1) A quality assurance program for the purpose of monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education.
 - (2) Justification for the chosen beyond use dates of compounded products.
 - (3) Handling of cytotoxic waste, if applicable.

The policy and procedure manual shall be current and available for inspection and copying by a state board of pharmacy designated agent.

- (C) Physical requirements
- (1) The facility shall have a designated area with access limited to authorized personnel for preparing parenteral and sterile products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled area. It shall be used only for the preparations of these specialty products. It shall be of sufficient size to accommodate a laminar airflow hood or other primary engineering control devices that provide a class 100 environment and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.
 - (2) The facility compounding parenteral and sterile product prescriptions shall have:
 - (a) Appropriate ~~environmental~~ primary engineering control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; furthermore, these devices are to be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;
 - (b) Appropriate disposal containers for used needles, syringes, etc. and, if applicable, for cytotoxic waste from the preparation of chemotherapy agents;
 - (c) Appropriate environmental control including approved biohazard cabinetry when cytotoxic drug products are prepared;
 - (d) Infusion devices and equipment, if appropriate;
 - (e) Appropriate temperature controlled transport containers.

- (3) The facility shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.
- (4) The facility shall have sufficient current reference materials related to sterile products to meet the needs of the facility staff.
- (5) The compounding of sterile products shall be done within a class 100 environment except in an emergency situation when the product is required to treat the immediate needs of a patient whose health would otherwise be jeopardized.

(D) Delivery service

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

(E) Disposal of cytotoxic and/or hazardous waste

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

(F) Cytotoxic drugs

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

- (1) All cytotoxic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet or other appropriate Class II primary engineering control device. ~~Other products should not be compounded in this cabinet.~~
- (2) Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include at least gloves and gowns with tight cuffs.
- (3) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.
- (4) Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements.
- (5) Written procedures for handling both major and minor spills of cytotoxic agents shall be developed and shall be included in the policy and procedure manual.
- (6) Prepared doses of cytotoxic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(G) Patient training

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

- (1) Dosage form, dosage, route of administration, and duration of drug therapy;
- (2) Special directions and precautions for preparation and administration;

- (3) Proper storage; and
- (4) Stability or incompatibilities of the medication.

(H) Quality assurance

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

- (1) At a minimum, there shall be written quality assurance programs developed that address:
 - (a) Adequate training and continuing competency monitoring of all personnel in personal cleansing, proper attire, aseptic technique, proper clean room conduct, and clean room disinfecting procedures. Instructors shall have the appropriate knowledge and experience necessary to conduct the training;
 - (b) Continued verification of compounding accuracy including physical inspection of end products;
 - (c) Continued verification of automated compounding devices;
 - (d) Continued verification that appropriate beyond use dates are being assigned to compounded products;
 - (e) End product testing including, but not limited to, the appropriate sampling of products if microbial contamination is suspected. Additionally, if bulk compounding of parenteral or sterile products is being performed using nonsterile chemicals, extensive end product testing must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.
- (2) All clean rooms, ~~and~~ laminar flow hoods, and other primary engineering devices shall have environmental monitoring performed at least every six months to certify operational efficiency. There shall be a plan in place for immediate corrective action if operational efficiency is not certified. Records certifying operational efficiency shall be maintained for at least three years.

4729-22-01 LICENSURE

Each person, whether located within or outside this state, who sells oxygen in original packages labeled as required by the "federal Food, Drug, and Cosmetic Act" to persons residing in this state, shall obtain a limited category II terminal distributor of dangerous drugs license from the board of pharmacy pursuant to the provisions of sections 4729.54 and 4729.55 of the Revised Code, ~~and, if the A person who~~ is a nonresident and is selling medical oxygen at retail to Ohio residents from another state, must also comply with the requirements in Chapter 4729-10 of the Administrative Code. This requirement shall not apply to persons already licensed to purchase, possess, and sell unlimited category II dangerous drugs at retail.

4729-22-02 SECURITY, STORAGE, AND SALE

Medical oxygen may be sold only at retail to patients pursuant to an order from a ~~person authorized to prescribe oxygen~~ prescriber in the course of their professional practice. Medical oxygen may be sold at retail and must be maintained in accordance with Chapters 3715. and 4729. of the Revised Code; rules 4729-9-05, 4729-9-11, 4729-9-12, and Chapter 4729-21 of the Administrative Code; and the "Federal Food, Drug and Cosmetic Act".

4729-22-04 PRESCRIBER'S ORDER

Before making an initial sale of medical oxygen to a patient, the retail seller must have an order issued by a ~~person authorized to prescribe oxygen~~ prescriber in the course of the prescriber's professional practice. The order must include the full name and address of the patient, the positive identification of the prescriber, the manually printed, typewritten, or preprinted full name and address of the prescriber, the telephone number where the prescriber can be personally contacted during normal business hours, and documentation of need. This order must be renewed at least annually.