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STATE OF OHIO BOARD OF PHARMACY

New and Updated Rules – Q1 and Q2 of 2016

Updated 7-6-2016

The Board has adopted a number of rule changes in the first and second quarter of 2016. To assist licensees in maintaining compliance with these requirements, a complete list of the changes along with implementation dates can be found on the next page. Some highlights include the following:

- Changes to the Board's Responsible Person (RP) rule (OAC 4729-5-11) including new requirements for wholesalers and reduction in the notification time when there is a change of RP.
- Personal furnishing requirements for prescribers licensed as terminal distributors of dangerous drugs (OAC 4729-5-17).
- A new central fill pharmacy rule (OAC 4729-5-28).
- Updates to the security and control requirements for terminal distributors of dangerous drugs (OAC 4729-9-11).

NOTE: Rule implementation dates vary. A copy of the rule text is included in this document.

4729-3-03 Application for registration as a pharmacy intern. *(Amended Effective 9.1.2016)*

4729-5-04 Violations as evidence for denial of a pharmacist or intern license. *(Amended Effective 4.28.2016)*

4729-5-11 Responsible person. *(Amended Effective 9.1.2016)*

4729-5-13 Prescription format. *(Amended Effective 9.1.2016)*

4729-5-14 Prescription format for a hospice outpatient. *(Rescinded Effective 9.1.2016)*
NOTE: Rule text amended into 4729-5-13.

4729-5-17 Personally furnishing dangerous drugs. *(Amended Effective 8.15.2016)*

4729-5-28 Central fill pharmacies. *(New Effective 8.15.2016)*

4729-5-39 Dispensing of naloxone. *(Amended Effective 6.6.2016)*

4729-9-01 Definitions. *(Amended Effective 4.28.2016)*

4729-9-10 Occasional sale. *(Amended Effective 6.30.2016)*

4729-9-11 Security and control of dangerous drugs. *(Amended Effective 8.15.2016)*

4729-9-15 Report of theft or loss of dangerous drugs, controlled substances, and drug documents. *(Amended Effective 4.28.2016)*

4729-9-16 Minimum requirements for wholesalers. *(Amended Effective 4.28.2016)*

4729-9-21 Drugs compounded in a pharmacy. *(Rescinded Effective 4.28.2016)*
NOTE: See rule 4729-16-03.

4729-11-02 Schedule I controlled substances. *(Amended Effective 6.26.2016)*

4729-11-07 Standard pharmaceutical references. *(Amended Effective 6.6.2016)*

4729-13-06 Responsible person for approved laboratories. *(Rescinded Effective 9.1.2016)*
NOTE: All responsible person requirements are now listed in 4729-5-11.

4729-14-06 Responsible person for an approved animal shelter. *(Rescinded Effective 9.1.2016)*
NOTE: All responsible person requirements are now listed in 4729-5-11.

4729-17-01 Definitions; institutional facility. *(Amended Effective 4.28.2016)*

4729-17-02 Responsible person for an institutional pharmacy. *(Amended Effective 9.1.2016)*

4729-17-03 Security and control of drugs in an institutional facility. *(Amended Effective 9.1.2016)*

4729-17-04 Records; institutional pharmacy. *(Amended Effective 9.1.2016)*

4729-17-08 Minimum standards for an institutional pharmacy. *(Amended Effective 9.1.2016)*

4729-17-09 Drug orders for patients of an institutional facility. *(Amended Effective 9.1.2016)*

4729-17-10 Labeling of prescriptions for patients of an institutional facility. *(Amended Effective 9.1.2016)*

4729-17-11 Labeling of prescriptions for outpatients. *(Rescinded Effective 9.1.2016)*
NOTE: Rule text amended into 4729-17-10.

4729-17-13 D.E.A. numbers for hospital employed prescribers. *(Amended Effective 10.1.2016)*

4729-33-02 Licensure. *(Amended Effective 4.10.2016)*

4729-3-03 **Application for registration as a pharmacy intern.**

(A) Every person desiring to register as a pharmacy intern for the purpose of obtaining the practical experience required for examination and registration as a pharmacist shall submit the following to the state board of pharmacy:

(1) A completed application form ~~(form #0100 version 09/12)~~ as provided by the board, which can be accessed by visiting http://www.pharmacy.ohio.gov;

(2) A head and shoulders photograph taken within the previous six months;

(3) Fee;

(4) Documentation, ~~as determined by the state board of pharmacy~~ in a manner prescribed by the board, that the applicant has in fact successfully completed a minimum of sixty semester or ninety quarter hours of college work; and

(5) ~~A certificate of enrollment~~Documentation, in a manner prescribed by the board, from a school of pharmacy certifying that the person is enrolled in a school of pharmacy and has begun taking professional classes directly related to the practice of pharmacy; or

(6) All items listed in paragraphs (A)(1) to (A)(3) of this rule and:

(a) Certification of having obtained a first professional degree in pharmacy from a program that has been recognized and approved by the state board of pharmacy; or

(b) Certification of having established educational equivalency by obtaining a "Foreign Pharmacy Graduate Examination Commission (FPGEC)" certificate, and evidence of successful completion of the "Test of Spoken English as a Foreign Language, Internet-based test" (TOEFL iBT) pursuant to rule 4729-5-34 of the Administrative Code.

(B) The state board of pharmacy may register an applicant as a pharmacy intern as soon as the state board of pharmacy receives all the required items set forth in paragraphs (A)(1) to (A)(5) or paragraph (A)(6) of this rule.

(C) The state board of pharmacy may, pursuant to rule 4729-5-04 of the Administrative Code, deny the issuance of a certificate of registration or an identification card to practice as a pharmacy intern.

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4729-5-04 **Violations as evidence for denial of a pharmacist or intern license.**

The board of pharmacy may consider as evidence of a person not meeting the requirements provided in division (B) of section 4729.08, division (B) of section 4729.09, and sections 4729.11 and 4729.12 of the Revised Code, and may discipline or deny a person admission to the licensure examination, or may deny the issuance of a ~~certificate of registration or an identification card~~license to practice pharmacy as a pharmacist or a licenese to practice as a pharmacy intern in Ohio if such person:

(A) ~~Has been convicted of a felony;~~Violated any state or federal law or rule regardless of the jurisdiction in which the acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration;

(B) ~~Has been convicted of violating any state or federal pharmacy or drug law;~~Violated, conspired to violate, attempted to violate, or aided and abetted in the violation of any of the provisions of Chapters 4729., 3715., 3719. and 2925. of the Revised Code, or any rule adopted by the board under those provisions;

(C) ~~Is not of good moral character and habits;~~Committed acts that constitute moral turpitude as defined in section 4776.10 of the Revised Code or gross immorality;

(D) Is addicted to or abusing ~~liquor~~ alcohol, ~~or~~ drugs or other chemical substances or impaired physically or mentally to such a degree as to render the pharmacist or pharmacy intern unfit to practice pharmacy;

(E) Has been disciplined by the Ohio state board of pharmacy pursuant to section 4729.16 of the Revised Code; ~~or~~

(F) Has been disciplined by any professional licensing board~~.~~;

(G) Has permitted anyone other than a pharmacist or pharmacy intern to practice pharmacy;

(H) Has knowingly lent the pharmacist's or pharmacy intern's name to an illegal practitioner of pharmacy or has a professional connection with an illegal practitioner of pharmacy;

(I) Has divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home;

(J) Has violated the terms of a consult agreement entered into pursuant to section 4729.39

of the Revised Code;

(K) Has committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under chapter 4729 of the Revised Code;

(L) Failed to conform to prevailing standards of care of similar pharmacists or pharmacy interns under same or similar circumstances, whether or not actual injury to a patient is established; or

(M) Violated any restrictions placed by the board on a license or violated any terms of a board order issued against the licensee.

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4729-5-11 **Responsible person.**

(A) For a pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Only a pharmacist may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for a pharmacy as defined in division (A) of section 4729.01 of the Revised Code. A pharmacist shall be the responsible person for no more than one such pharmacy unless granted permission in accordance with paragraph (E) of this rule. ~~except with written permission from the state board of pharmacy. A written request shall be submitted outlining the circumstances requiring a pharmacist to be responsible for more than one pharmacy and the period of time during which the circumstances will exist. A pharmacist shall not be designated the responsible person for a pharmacy unless he/she will be physically present in the pharmacy a sufficient amount of time to provide supervision and control.~~

(2) The responsible person shall be responsible for the practice of the profession of pharmacy, including but not limited to ~~"~~supervision and control~~"~~ of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, ~~"~~adequate safeguards~~"~~ as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs as required in rule 4729-9-11 of the Administrative Code and maintaining all drug records otherwise required.

(3) The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of drugs and the practice of pharmacy.

(B) For locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revised Code:

(1) Only a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery may be the responsible person whose name appears on the category III terminal distributor of dangerous drugs with a pain management classification license as defined in section 4729.552 of the Revised Code. A physician shall be the responsible person for no more than one such location unless granted permission in accordance with paragraph (E) of this rule~~except with written permission from the state board of pharmacy. A written request shall be submitted outlining the circumstances requiring a physician to be responsible for more than one location and the period of time during which the circumstances will exist~~. A physician shall not be designated the responsible person for a location licensed as a category III terminal distributor of dangerous drugs with a pain management classification unless he/she will be

physically present at the location for a sufficient amount of time to provide supervision.

(2) All employees of the facility, including the responsible person, shall submit to a criminal records check in accordance with section 4776.02 of the Revised Code.

(3) The responsible person for locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revised Code must meet one of the following requirements:

(a) Hold current subspecialty certification in pain management by the American board of medical specialties, or hold a current certificate of added qualification in pain management by the American osteopathic association bureau of osteopathic specialists; or

(b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists; or

(c) Hold current board certification by the American board of pain medicine; or

(d) Hold current board certification by the American board of interventional pain physicians; or

(e) Hold current board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American board of medical specialties or hold current primary certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology by the American osteopathic association bureau of osteopathic specialists.

(4) No responsible person for locations licensed as a category III terminal distributor of dangerous drugs with a pain management classification under section 4729.552 of the Revised Code shall:

(a) Have ever been denied a license to prescribe, dispense, personally furnish,

administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, personally furnishing, diverting, supplying or selling a controlled substance or other dangerous drug.

(b) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, personally furnishing, diverting, administering, supplying, or selling a controlled substance or other dangerous drug.

(c) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescribers inappropriate prescribing, dispensing, diverting, administering, personally furnishing, diverting, supplying or selling a controlled substance or other dangerous drug.

(5) The person to whom the category III terminal distributor of dangerous drugs license with a pain management classification has been issued, the responsible person and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules regulating the operation of a pain management clinic and prescribing of controlled substances.

(C) For all locations licensed as a terminal distributor of dangerous drugs:

(1) A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times.

~~(2) The responsible person whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.~~

~~(3)~~(2) When there is a change of responsible person, the state board of pharmacy shall be notified ~~by the new responsible person~~ within ~~thirty~~ ten days of the effective date of the appointment of the new responsible person ~~on a board approved form. This notice to the state board of pharmacy shall be sent by regular mail or by verified facsimile transmission.~~in a manner prescribed by the board. For an animal shelter licensed as a terminal distributor of dangerous drugs, the notification shall include a notarized drug list prepared pursuant to paragraph (D) of rule 4729-14-03 of the Administrative Code.

~~(4)~~(3) A complete inventory, pursuant to federal regulations and rule 4729-9-14 of the Administrative Code, shall be taken of the controlled substances on hand with the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.

~~(5)~~(4) The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are ~~is~~ responsible for compliance with all state and federal laws, regulations, and rules regulating the distribution of dangerous drugs.

(5) A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site.

(6) The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs as required in rule 4729-9-11 of the Administrative Code and maintaining all records relating to the distribution dangerous drugs.

(7) The board of pharmacy shall issue a resolution providing the credential types required for the responsible person of each classification of terminal distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for that classification type. The resolution shall be updated as necessary and available on the board's web site, www.pharmacy.ohio.gov.

(D) For all locations licensed as a wholesale distributor of dangerous drugs:

(1) A location licensed as a wholesale distributor of dangerous drugs must have a responsible person at all times.

(2) When there is a change of responsible person, the state board of pharmacy shall be notified by the new responsible person within ten days of the effective date of the appointment of the new responsible person in a manner prescribed by the board.

(3) A responsible person shall not be designated the responsible person for more than one location licensed as a wholesale distributor of dangerous drugs unless granted permission in accordance with paragraph (E) of this rule.

(4) A complete inventory pursuant to section 1304.11 of the code of federal

regulations (9/1/2015) shall be taken of the controlled substances on site by the new responsible person on the effective date of the change of responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the wholesale distributor of dangerous drugs.

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

(6) The board of pharmacy shall issue a resolution providing the credential types or qualifications required for the responsible person of each classification of wholesale distributor of dangerous drugs license. Only individuals that meet the credentials specified may be the responsible person for that classification type. The resolution shall be updated as necessary and available on the board's web site, www.pharmacy.ohio.gov.

(E) Written requests for being a responsible person at more than one location must be submitted to the state board of pharmacy in a manner prescribed by the board. The executive director or designee shall have the authority to temporarily approve or deny a request for being a responsible person at more than one location for a period not to exceed 60 days. The full Board will review requests the executive director or designee has temporarily approved at the next scheduled Board meeting. A terminal or wholesale distributor of dangerous drugs whose request has been denied either by the executive director, the executive director's designee or the board will be provided with a written explanation of denial and allowed one opportunity to resubmit its request to address the identified concerns. If the Board approves a request for being a responsible person at more than one location, the request will be good for a period of up to one year, unless otherwise indicated by the board.

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

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

(A) Except as provided in paragraph (F) of this rule, ~~No~~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) Except as provided in paragraph (F) of this rule, no~~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.

(F) (F) For purposes of preprinted prescription forms for hospice care program outpatients, the following conditions apply:

(1) Preprinted prescription forms may contain multiple orders on one form and the prescriber may select as many drug orders as necessary. Additional prescriptions may be manually added to this sheet.

(2) Preprinted forms may not contain prescription orders for schedule II drugs. Schedule II drugs may be manually added to the preprinted forms and signed by the prescriber.

(3) The prescriber shall indicate on each preprinted form the drug orders authorized on the form by either:

(a) Manually indicating the total drug orders authorized on the form; or

(b) Manually initialing each drug order.

(4) All written drug orders must be signed by the prescriber.

(5) All signed prescriptions may be faxed from the prescriber or the hospice location to the pharmacy.

(6) At the direction of the prescriber, verbal drug orders may be transmitted to the pharmacy by the prescriber's agent, including a hospice nurse, except for schedule II drug orders.

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TO BE RESCINDED

4729-5-14 **Prescription format for a hospice outpatient.**

For purposes of preprinted prescription forms for hospice outpatients, the following conditions apply:

(A) Preprinted prescription forms may contain multiple orders on one form and the prescriber may select as many drug orders as necessary. Additional prescriptions may be manually added to this sheet.

(B) Preprinted forms may not contain prescription orders for schedule II drugs. Schedule II drugs may be manually added to the preprinted forms and signed by the prescriber.

(C) The prescriber shall indicate on each preprinted form the drug orders authorized on the form by either:

(1) Manually indicating the total drug orders authorized on the form; or

(2) Manually initialing each drug order.

(D) All written drug orders must be signed by the prescriber.

(E) All signed prescriptions may be faxed from the prescriber or the hospice location to the pharmacy.

(F) At the direction of the prescriber, verbal drug orders may be transmitted to the pharmacy by the prescriber's agent, including a hospice nurse, except for schedule II drug orders.

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

(A) Whenever a prescriber personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, the prescriber shall affix to the container a label showing:

(1) The name and address of the prescriber.

(2) The name of the patient for whom the drug is intended. If the patient is an animal, the name of the owner and identification of the animal.

(3) Name and strength of the dangerous drug.

(4) Directions for use.

(5) Date furnished.

(6) If a compounded drug product, the statement "Compounded Drug Product" or other similar statement shall also be displayed prominently on the label.

(B) Whenever a prescriber personally furnishes a dangerous drug, labeled as a sample pursuant to section 3719.81 of the Revised Code and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide, in written format, the following:

(1) Name of the prescriber.

(2) Name of the patient. If the patient is an animal, the name of the owner and identification of the animal.

(3) Directions for use.

(C) For controlled substances, personally furnishing quantities are limited to a seventy-two hour supply and in any thirty day period the personally furnishing quantities supplied to all patients shall not exceed two thousand five hundred dosage units pursuant to section 4729.291 of the Revised Code.

(D) None of the following shall be counted in determining whether the amounts specified in paragraph (C) of this rule have been exceeded:

(1) Methadone personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21

C.F.R. 1306.07 (9/1/2015);

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program that possesses a terminal distributor of dangerous drugs license issued under section 4729.54 of the Revised Code, is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11 (9/1/2015), and meets either of the following criteria:

(a) Buprenorphine and methadone are personally furnished by physicians treating patients participating in the program.

(b) Buprenorphine, but not methadone, is personally furnished by physicians treating patients participating in the program, the program is accredited by a national accrediting organization approved by the substance abuse and mental health services administration, the service of personally furnishing buprenorphine has, notwithstanding section 5119.371 of the Revised Code, been certified by the department of mental health and addiction services under section 5119.36 of the Revised Code, and the program maintains in the record of a patient to whom buprenorphine has been administered or personally furnished a copy of the physician's signed and dated written order for that act.

(c) Controlled substances personally furnished to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

~~(1) Methadone provided to patients for the purpose of treating drug addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07 (6/23/2005);~~

~~(2) Buprenorphine provided to patients for the purpose of treating drug addiction, if the prescriber is exempt from separate registration with the United States drug enforcement administration pursuant to 21 C.F.R. 1301.28 (5/22/2008);~~

~~(3) Controlled substances provided to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.~~

(E) Paragraph (C) of this rule does not apply to a prescriber who is a veterinarian.

(F) A prescriber may designate a health care professional acting within the scope of the professional's practice and, under the supervision of the prescriber, to prepare and

package a dangerous drug that will be personally furnished by the prescriber.

(G) A prescriber shall perform the final check of the dangerous drug prior to personally furnishing. The final check shall be documented using positive identification pursuant to rule 4729-5-01 of the Administrative Code.

(H) Counseling.

(1) A prescriber or the prescriber's designee shall personally offer to provide the service of counseling pursuant to paragraph (H)(2) of this rule to the patient or caregiver whenever any dangerous drug is personally furnished. A prescriber shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. In this situation, when counseling is refused, the prescriber or the prescriber's designee shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver, unless the prescriber is a veterinarian.

(2) Prescriber counseling may include, but is not limited to, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) The intended use of the drug and the expected action;

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage;

(h) Action to be taken in the event of a missed dose; and

(i) The prescriber's comments relevant to the individual's drug therapy, including other necessary information unique to the specific patient or drug.

(I) Distribution of Dangerous Drugs.

(1) A prescriber may delegate an individual or individuals to distribute dangerous

drugs personally furnished by a prescriber if all of the following apply:

(a) A prescriber authorized to personally furnish dangerous drugs provides on-site supervision;

(b) The designated individual offers counseling to the patient or caregiver to be provided by the on-site prescriber in accordance with paragraph (H) of this rule; and

(c) This task may be delegated in accordance with applicable state laws and rules.

(2) Paragraphs (I)(1)(a) and (b) of this rule do not apply in any of the following:

(a) The drug is provided to the patient by a health care professional, acting within the scope of the professional's practice, and the drug provided is either:

(i) Methadone for the purpose of treating drug dependence or addiction; or

(ii) Buprenorphine for the purpose of treating drug dependence or addiction as part of an opioid treatment program that is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11 (9/1/2015).

(b) The dangerous drug is being provided to a patient by a licensed Ohio pharmacist.

(c) The dangerous drug is being provided in accordance with paragraph (K) of this rule.

(d) A non-controlled dangerous drug is provided to the patient by a health care professional, acting within the scope of the professional's practice, and a prescriber authorized to personally furnish dangerous drugs is available for counseling by means of electronic communication during normal hours of operation.

(J) No prescriber may personally furnish to a patient to whom there is no valid prescriber patient relationship, pursuant to applicable state and federal laws, regulations, and rules. This may include a requirement for a documented patient encounter.

(K) Personally Furnishing Naloxone.

(1) Except as provided in paragraph (K)(3) of this rule, an authorized individual

personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with section 4731.941 of the revised code, shall do all of the following:

(a) Prepare, package and appropriately label the naloxone.

(b) Conduct the final check of the naloxone prior to personally furnishing on behalf of the prescriber.

(c) Keep and maintain all records in accordance with rule 4729-9-22 of the Administrative Code.

(d) Conduct patient counseling, including training on the use of naloxone, as specified in the physician protocol.

(2) An authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with section 4731.941 of the revised code may personally furnish the drug to themselves in order to assist an individual who there is reason to believe is experiencing an opioid-related overdose if all of the following conditions are met:

(a) The authorized individual complies with the protocol established by the authorizing physician, including having completed the training required by the protocol.

(b) The authorized individual has received training instructing them to summon emergency services as soon as practicable either before or after administering naloxone.

(c) Such practice is authorized in the physician approved protocol.

(3) An authorized individual personally furnishing naloxone pursuant to paragraph K(2) of this rule shall not be required to comply with the paragraphs (K)(1)(a), (K)(1)(b) or (K)(1)(d) of this rule.

(L) Records of drugs personally furnished shall be kept in accordance with rules 4729-9-22 and 4729-9-14 of the Administrative Code.

(M) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729-5-10 of the Administrative Code is the property of that patient and is not considered personal furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729-5-10 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(N) Paragraph (M) does not prohibit a prescriber from charging a patient for any of the following:

(1) the cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) the cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber.

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4729-5-28 **Central fill pharmacies.**

(A) As used in this rule:

(1) "Central fill pharmacy" means a pharmacy or central filling operation licensed as a terminal distributor of dangerous drugs acting as an agent of or under contract with an originating pharmacy to fill or refill a prescription. A central fill pharmacy may also be the originating pharmacy pursuant to paragraph (L) of this rule.

(2) "Originating pharmacy" means a pharmacy licensed as a terminal distributor of dangerous drugs that uses a central fill pharmacy to fill or refill a prescription order and pursuant to paragraph (O) of rule 4729-5-01 of the Administrative Code.

(B) An originating pharmacy may outsource prescription filling or refilling to a central fill pharmacy provided the pharmacies have the same owner or the pharmacies have entered into a written contract or agreement. The contract or agreement shall outline the services to be provided and the responsibilities and accountability of each pharmacy to comply with federal and state laws, rules and regulations.

(C) A central fill pharmacy and originating pharmacy shall comply with all applicable federal laws and regulations, including those specified in Federal Register Citation 68 FR 37405 (July 24, 2003.)

(D) The originating and central fill pharmacies must have access to common electronic files as part of a real time, online database or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.

(E) An originating pharmacy using a central fill pharmacy is responsible for maintaining records of the processing of all prescriptions entered into its information system including prescriptions filled or refilled at a central fill pharmacy. The pharmacist at the originating pharmacy must comply with the minimum required information for a patient profile pursuant to rule 4729-5-18 of the Administration Code prior to sending a prescription to the central fill pharmacy. The information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the originating pharmacy's prescriptions.

(F) The prescription label of a centrally filled prescription shall display the name and address of the originating pharmacy, pursuant to paragraphs (A)(1) and (A)(10) of rule 4729-5-16 of the Administrative Code. The label shall also display the name of the central fill pharmacy.

(G) The serial number used by the central fill pharmacy shall be the same as the originating pharmacy if in accordance with paragraph (D) of rule 4729-5-19 of the Administrative Code.

(H) Unless the central fill pharmacy operates pursuant to paragraph (L) of this rule, the originating pharmacy shall designate staff members to be responsible for signing for the receipt of prescriptions delivered from the central fill pharmacy. The receipt must be maintained as part of the prescription records.

(I) All central fill pharmacies providing central prescription filling processing services to pharmacies in Ohio shall be licensed as a terminal distributor of dangerous drugs.

(J) The originating pharmacy and central fill pharmacy shall maintain a policy and procedure manual, which shall be available for inspection by a state board of pharmacy designated agent. The manual shall include all of the following:

(1) Outline the responsibilities of each of the pharmacies;

(2) Include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies participating in the central fill prescription filling; and

(3) Include policies and procedures for:

(a) Protection of the confidentiality and integrity of patient information;

(b) Maintenance of appropriate records to identify the method(s) of positive identification used, as defined in paragraph (N) of rule 4729-5-01 of the Administrative Code, and specific activity(ies) of each pharmacist who performed any processing;

(c) Compliance with federal and state laws, rules and regulations;

(d) Operation of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and

(e) Annual review of the written policies and procedures and documentation of such review.

(K) No medication shall be returned to the central fill pharmacy by the originating pharmacy. This paragraph does not apply if a central fill pharmacy operates in accordance with paragraph (L) of this rule and the dangerous drugs have not left the custody of the central fill pharmacy.

(L) A central fill pharmacy may dispense a prescription directly to a patient pursuant to the following requirements:

(1) A drug utilization review is conducted pursuant to a written contract or agreement in accordance with rule 4729-5-20 of the Administrative Code and is appropriately documented by a pharmacist using positive identification as defined in rule 4729-5-01 of the administrative code;

(2) Patient counseling is provided pursuant to a written contract or agreement in accordance with rule 4729-5-22 of the Administrative Code;

(3) The dispensing software shall utilize positive identification as defined in rule 4729-5-01 of the administrative code to distinguish between the practice of pharmacy conducted at the central fill pharmacy, the originating pharmacy and any contracted location;

(4) The dispensing is conducted in accordance with all applicable state and federal laws, regulations and rules.

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4729-5-39 **Dispensing of naloxone.**

(A) A pharmacist or pharmacy intern under the direct supervision of a pharmacist may dispense naloxone without a prescription to either of the following in accordance with an approved protocol specified in paragraph (B) of this rule:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose~~; or~~.

~~(3) A peace officer as defined in section 2921.51 of the Revised Code.~~

(B) To be considered an approved protocol pursuant to section 4729.44 of the Revised Code, the physician-established protocol for the dispensing of naloxone by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

(1) A description of the clinical pharmacology of naloxone.

(2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol.

(3) Precautions and contraindications concerning dispensing naloxone.

(4) Assessment and follow-up actions by the pharmacist or pharmacy intern.

(5) Naloxone products authorized to be dispensed, including all of the following information:

(a) Name of product;

(b) Dose;

(c) Route of administration and required delivery device; and

(d) Directions for use.

(6) Any patient instructions in addition to the counseling specified in paragraphs (C) and (D) of this rule.

(C) A pharmacist or pharmacy intern under the direct supervision of a pharmacist who dispenses naloxone pursuant to this rule shall instruct the individual to whom naloxone is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering naloxone.

(D) A pharmacist, ~~or~~ pharmacy intern under the direct supervision of a pharmacist, or a pharmacist's designee that is appropriately trained shall personally provide ~~the service of verbal counseling~~ in-person training and written educational materials to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed, including, but not limited to, all of the following:

(1) Risk factors of opioid overdose;

(2) Strategies to prevent opioid overdose;

(3) Signs of opioid overdose;

(4) Steps in responding to an overdose;

(5) Information on naloxone;

(6) Procedures for administering naloxone;

(7) Proper storage and expiration of naloxone product dispensed; and

(8) Information on where to obtain a referral for substance abuse treatment.

(E) If training conducted pursuant to paragraph (D) of this rule is offered by a pharmacist's designee, the pharmacist shall not be required to counsel a patient or caregiver pursuant to rule 4729-5-22 of the administrative code if the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. In this situation, when counseling is refused, the pharmacist or their designee shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver.

~~(E)~~(F) The pharmacy's responsible person shall ensure that all pharmacists and pharmacy interns that dispense naloxone pursuant to this rule are appropriately trained on the use of naloxone and can meet the ~~counseling~~ training requirements listed in paragraphs (C) and (D) of this rule.

(G) The terminal distributor and the pharmacy's responsible person shall ensure that all

pharmacist designees are appropriately trained on the use of naloxone and can meet the training requirements listed in paragraph (D) of this rule.

~~(F)~~(H) A pharmacist may document the dispensing of naloxone by the pharmacist or a pharmacy intern supervised by the pharmacist on a prescription form. The form may be assigned a number for record-keeping purposes.

(I) Paragraph (L) of this rule does not apply to institutional pharmacies that provide naloxone to inpatients or patients upon discharge.

(J) A licensed terminal distributor of dangerous drugs may make occasional sales of naloxone at wholesale pursuant to rule 4729-9-10 of the Administrative Code to a state or local law enforcement agency if the terminal distributor is any of the following:

(1) A pharmacy;

(2) A board of health of a city or general health district;

(3) An authority having the duties of a board of health under section 3709.05 of the Revised Code; or

(4) A health department operated by such a board or authority.

~~(G)~~(K) All physician-established protocols shall be signed and dated by the physician prior to implementation and maintained by the pharmacy's responsible person. The protocol shall be made readily available to the dispensing pharmacist or pharmacy intern under the direct supervision of a pharmacist. ~~The pharmacy's responsible person shall renew the protocol annually with the physician.~~

~~(H)~~(L) Any pharmacy that dispenses naloxone pursuant to this rule, shall notify the board, in a manner prescribed by the board, within thirty days of establishing an approved protocol. A pharmacy that no longer dispenses naloxone pursuant to this rule shall notify the board, in a manner prescribed by the board, within thirty days of discontinuation.

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4729-9-01 **Definitions.**

(A) "Dangerous drug," as defined in section 4729.01 of the Revised Code, means any drug or drug product whose commercial package bears a label containing the symbol "Rx only", the legend "Caution: Federal Law Prohibits Dispensing Without Prescription" or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Licensed Veterinarian", or any similar restrictive statement.

(B) "Adulterated drug" means a ~~A~~ dangerous drug ~~is adulterated if~~ that is beyond the expiration date as stated by the manufacturer, packer, or distributor in its labeling or if it is not stored or dispensed according to the requirement of the federal act as indicated in the product labeling. This does not apply to expired drugs that are donated pursuant to sections 3715.88 to 3715.92 of the Revised Code. A compounded dangerous drug is considered adulterated if it exceeds:

(1) The beyond use date as indicated in United States pharmacopeia chapters <795> and <797>, USP 38 - NF 33, or any official supplement thereto (9/10/2015); or

(2) The beyond use date if prepared strictly in accordance with manufacturers' product labeling as specified in that labeling or from appropriate literature sources or direct testing.

(C) "Psychiatric outpatient facility" means a facility where psychiatric evaluation and treatment is provided on an outpatient basis.

(D) As used in Chapters 3719. and 4729. of the Revised Code, "registered" and "licensed" mean that an individual or facility has met the initial qualifications for registration and licensure with the state board of pharmacy and, if they are still actively practicing pharmacy or distributing drugs, have complied with annual renewal procedures, including payment of applicable fees.

(E) "Revoke", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license rendering such license void and such license may not be reissued. "Revoke" is an action that is permanent against the license and licensee.

(F) "Suspend", as used in Chapters 3719. and 4729. of the Revised Code, means to take action against a license rendering such license without force and effect for a period of time as determined by the state board of pharmacy. The board may require that an individual whose license has been suspended may not be employed by or work in a facility licensed by the state board of pharmacy to possess or distribute dangerous drugs during such period of suspension.

(G) "Summary suspension", as used in Chapter 3719. and 4729. of the Revised Code, means to take immediate action against a license, registration or identification card

without a prior hearing rendering such license without force and effect for a period of time as indicated in sections 3719.031, 3719.121 or 4729.571 of the Revised Code. The board may suspend a license, registration or identification card issued pursuant to Chapters 3719. and 4729. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

~~(G)~~(H) "Place on probation", as used in Chapter 4729. of the Revised Code, means to take action against a license suspending some or all of the sanctions imposed by the board against that license. The terms of the probation shall state the period of time covered by the probation and may include other conditions as determined by the state board of pharmacy.

~~(H)~~(I) "Refuse to grant or renew", as used in Chapter 4729. of the Revised Code, means to deny original or continued licensure for a period of at least twelve months. After twelve months or such period of time as the individual board order may require, a pharmacist, a pharmacy intern, a terminal distributor of dangerous drugs, a wholesale distributor of dangerous drugs, a wholesaler of controlled substances, a manufacturer of controlled substances, or an individual or facility who desires to attain such status by licensure, and whose license the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A pharmacist, or an individual who desires to attain such status by licensure, whose license the state board of pharmacy has refused to grant or renew must meet any requirements established by the board or must pass any examination required by the board.

~~(I)~~(J) "Campus", as used to describe a type of terminal distributor of dangerous drugs license issued pursuant to division (E) of section 4729.51 of the Revised Code, means an establishment or place consisting of multiple buildings where dangerous drugs are stored that are located on a contiguous plot of land. All such buildings and stocks of dangerous drugs shall be under common ownership and control.

~~(J)~~(K) "Certified diabetes educator", as used in Chapters 3719. and 4729. of the Revised Code, means a person who has been certified to conduct diabetes education by the "National Certification Board for Diabetes Educators (NCBDE)".

(L) "Abandoned application" means an application for a terminal or wholesale distributor of dangerous drugs where the applicant fails to complete all application requirements within 30 days after being notified by the board. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by Board staff. If the application is abandoned, the applicant shall be required to reapply for licensure, submit the required fee and comply with the licensing requirements in effect at the time of reapplication.

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4729-9-10 **Occasional sale.**

The term "occasional sale" as used in section 4729.51 of the Revised Code means a wholesale sale of a drug by a pharmacist who is a terminal distributor of dangerous drugs or is employed by a terminal distributor of dangerous drugs and the buyer shall be any of the following: wholesale distributor of dangerous drugs, ~~a~~ terminal distributor of dangerous drugs, ~~or a~~ prescriber as defined in section 4729.01 of the Revised Code, or any entity exempted from licensure as a terminal distributor of dangerous drugs pursuant to section 4729.51 of the Revised Code.~~.~~

The total value of all dangerous drugs distributed by the terminal distributor of dangerous drugs pursuant to this rule shall not exceed five per cent of the total value of dangerous drugs purchased by the terminal distributor of dangerous drugs during the same calendar year. In addition, the total amount of controlled substances sold pursuant to this rule shall not exceed the allowable amount as specified in 21 C.F.R. 1307.11 (3/16/2016).

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

The limits set forth in this rule do not apply to terminal distributors of dangerous drugs that conduct occasional sales of naloxone at wholesale to a state or local law enforcement agency.

The limits set forth in this rule do not apply to pharmacies that conduct occasional sales of naloxone at wholesale.

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

A pharmacist, prescriber, ~~or~~and responsible person pursuant to rule 4729-5-11 ~~paragraph (F) of rule 4729-13-01 or paragraph (H) 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~~ ensure 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) Except as provided in paragraph (A)(2) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the Board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, at all times in order to deter and detect theft or diversion;

~~(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, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs except where the Board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, 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) If a pharmacy utilizes a board approved delivery system that securely stores and releases a dispensed prescription drug to a patient the pharmacy must be open for business and a pharmacist must be physically present and available for consultation, unless otherwise authorized by the board.

(h) Any designated area outside the prescription department at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, exempt narcotics, hypodermics, poisons, records relating to the distribution of dangerous drugs except where the Board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, and every other item or product that requires the personal supervision or sale by a pharmacist shall meet the following requirements:

(i) The designated area shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect unauthorized entry. Such a barrier, before being put into use, must be approved by the state board of pharmacy.

(ii) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy.

(iii) Authorized personnel may have access if there is on-site supervision by a pharmacist.

(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 4729-9-03 of the Administrative Code, approved laboratories pursuant to paragraph (D) 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, shall comply with all of the following: ~~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.~~

(1) Dangerous drugs, exempt narcotics, uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms, hypodermics and poisons must be stored in an area secured by either a physical barrier with suitable locks, which may include a substantially constructed cabinet, and/or an electronic barrier to deter and detect unauthorized access;

(2) All records relating to the dispensing, distribution, personal furnishing and sale of dangerous drugs shall be maintained on-site under appropriate supervision and control to restrict unauthorized access.

(3) Paragraph (B)(1) of this rule does not apply to hypodermics at veterinary facilities if all of the following conditions are met:

(a) During non-business hours, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, and/or an electronic barrier to deter and detect unauthorized access;

(b) During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections.

(C) A pharmacist, prescriber, or responsible person for a terminal distributor of dangerous drugs license pursuant to rule 4729-5-11 ~~paragraph (F) of rule 4729-13-01 or paragraph (H) of rule 4729-14-01 of the~~ 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 dangerous 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 ~~insure~~ 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. Records relating to the distribution of dangerous drugs shall be maintained in a secure manner that ensures the integrity of the information.

(E) Only individuals authorized under state laws or rules shall have unsupervised access to dangerous drugs.

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

(A) Each prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs:

(1) The state board of pharmacy, by telephone immediately upon discovery of the theft or significant loss;

(2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76(b) (1/21/2016);

(3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

(B) Controlled substance thefts must also be reported by using the federal DEA report form whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them. A copy of the federal form regarding such theft or loss shall be filed with the state board of pharmacy within thirty days following the discovery of such theft or loss.

(1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.

(2) A request for a waiver of the thirty-day limit must be requested in writing.

(C) Each prescriber, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs immediately upon discovery of any theft or loss of:

(1) Uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed, shall notify the state board of pharmacy and law enforcement authorities.

(2) Official written order form(s) as defined in division (Q) of section 3719.01 of the Revised Code shall notify the state board of pharmacy and law enforcement authorities, and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.12(b) (1/21/2016).

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4729-9-16 **Minimum requirements for wholesalers.**

The following minimum requirements shall apply to all persons distributing dangerous drugs at wholesale in Ohio:

(A) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a wholesale distributor of dangerous drugs:

(1) The name, full business address (not a post office box), and telephone number;

(2) All trade or business names used by the licensee, any trade or business names under which licensee was previously or is presently licensed;

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs;

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency);

(5) The full name(s) of the owner and/or operator of the licensee, including:

(a) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity;

(b) If a partnership, the full name of each partner, and the name of the partnership;

(c) If a corporation, the full name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, the corporation number, and a copy of the corporation papers;

(d) If a government agency, the name of the agency, and the full name of each officer and director of the agency.

(6) If the entity making application for a wholesale distributor of dangerous drugs license is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to distribute dangerous drugs in that state and the experience the licensing authority has had with the entity. This information will be used as part of the consideration in licensing the entity by

the Ohio state board of pharmacy. The Ohio board will respond to inquiries of a similar nature from other states about licensees in Ohio.

(7) Pursuant to division (A)(1) of section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license will not be issued until the owner(s), ~~or if incorporated~~ the officers~~,~~ (if incorporated) or agency directors (if a government agency) of the wholesale operation submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. ~~Additionally, a criminal records check is required every time there is a change in officers.~~ If there is a change in officers, owners or agency directors, all new officers, owners or agency directors shall submit to a criminal records check. The criminal records check shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The owner(s) or officers may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or if located outside of Ohio they may submit ink fingerprint impressions as instructed on a form provided by the board.

(B) Prior to the end of the licensing period, a renewal application requesting such information as the state board of pharmacy may require will be sent to the address of record to the attention of the responsible person. Such renewal application form shall be completed and returned with the applicable fee on or before the established deadline.

(C) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored no longer than two years pursuant to rule 4729-9-17 of the Administrative Code;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(D) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(1) Access from outside the premises shall be kept to a minimum and be well controlled.

(2) The outside perimeter of the premises shall be well lighted.

(3) Entry into areas where dangerous drugs are held shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are held shall be equipped with a state board of pharmacy approved alarm system to detect unauthorized entry after hours.

(5) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of dangerous drugs.

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all stored drugs.

(F) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or dangerous drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents;

(2) Each outgoing shipment shall be carefully inspected for identity of the dangerous drug products and to ensure that there is no delivery of dangerous drugs that have been damaged in storage or held under improper conditions;

(3) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all incoming and outgoing dangerous drugs.

(G) All returned, damaged, and outdated, dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to their supplier.

(2) Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, identify, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (H) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(H) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs.

(1) These records shall include but not be limited to the following information:

(a) The source of the drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The identity and quantity of the drugs received and distributed or disposed of.

(c) The dates of receipt and distribution of the drugs.

(d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized by division (B) of section 4729.51 of the Revised Code.

(e) A system of procedures shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse.

(i) The wholesaler shall inform the state board of pharmacy of suspicious orders for drugs, as described in paragraph (H)(1)(e) of this rule, when discovered. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

(ii) Reports, generated by the system as described in paragraph (H)(1)(e) of this rule, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

(2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials for a period of three years following disposition of the drugs.

(3) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized state board of pharmacy designated agents, federal, state, or local law enforcement agency officials.

(b) Wholesalers intending to maintain records, described in this rule, at a location other than the place licensed by the state board of pharmacy must first send notification to the board.

(I) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility

in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(4) A procedure to ensure that any outdated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated dangerous drugs. This documentation shall be maintained for three years after disposition of the outdated drugs.

(J) Wholesale distributors of dangerous drugs shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. A wholesale distributor of dangerous drugs shall have a responsible person pursuant to rule 4729-5-11 of the Administrative Code.~~When there is a change in the designated contact person to whom communications with the state board of pharmacy may be directed, the board shall be notified of the new contact person within thirty days on a board approved form. This notice to the board shall be sent by certified mail, return receipt requested, or by verified facsimile transmission.~~

(K) Personnel employed in the wholesale distribution of dangerous drugs shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

(L) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Wholesale drug distributors shall permit properly identified and authorized state board of pharmacy designated agents, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Any entity making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.

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

(N) The state board of pharmacy shall be notified of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the registrant being used or implemented.

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TO BE RESCINDED

4729-9-21 **Drugs compounded in a pharmacy.**

(A) In order to compound prescriptions, a pharmacy shall meet the minimum standards for a pharmacy pursuant to rule 4729-9-02 of the Administrative Code.

(B) Parenteral and sterile product prescriptions shall be compounded in accordance with Chapter 4729-19 and/or Chapter 4729-15 of the Administrative Code.

(C) For all compounded prescriptions, the pharmacist shall:

(1) Comply with the "United States Pharmacopeial Convention Chapter 795" when compounding non-sterile drug products;

(2) Comply with the "United States Pharmacopeial Convention Chapter 797" when compounding sterile compounded drug products;

(3) Comply with section 503A of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

(4) Inspect and approve the compounding process;

(5) Perform the final check of the finished product.

(D) For all compounded prescriptions, the pharmacist shall be responsible for:

(1) All compounding records;

(2) The proper maintenance, cleanliness, and use of all equipment used in compounding.

(E) Personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

(F) A prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(G) A compounded prescription that is dispensed to a patient must be labeled according

to rule 4729-5-16 of the Administrative Code.

(H) Labels for a compounded prescription that is prepared in anticipation of a prescription drug order shall contain, but not be limited to, the following:

(1) The name, strength, and quantity of each drug used in the compounded prescription;

(2) The identification of the repackager by name or by the final seven digits of its terminal distributor of dangerous drugs license number;

(3) Pharmacy control number;

(4) The pharmacy's expiration date or beyond use date.

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4729-11-02 **Schedule I controlled substances.**

(A) The state board of pharmacy hereby schedules the following synthetic cannabinoid compounds as schedule I controlled substance hallucinogens:

(1) PB-22 (chemical name: quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate) ~~shall be a schedule I controlled substance~~;

(2) 5-Fluoro-PB-22 (chemical name: quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate) ~~shall be a schedule I controlled substance~~.

(B) Except as otherwise provided in section 3719.41 of the Revised Code, any compound that meets at least three of the following pharmacophore requirements to bind at the CB1 and CB2 receptors, as identified by a report from an established forensic laboratory, is a schedule I controlled substance hallucinogen:

(1) A chemical scaffold consisting of substituted or non-substituted ring structures that facilitate binding of required elements (such as: indole compounds, indazoles, benzimidazoles or other ring types);

(2) Alkyl or aryl side chain off the chemical scaffold providing hydrophobic interaction with the CB1 and CB2 receptors;

(3) Carbonyl or ester or equivalent for hydrogen bonding;

(4) Cyclohexane, naphthalene ring, substituted butanamide or equivalent for steric requirements for CB1 and CB2 receptor binding.

(C) Except as otherwise provided in section 3719.41 of the Revised Code, any compound that contains the structural requirements of the cathinone pharmacophore, as identified by a report from an established forensic laboratory, is a schedule I controlled substance.

(D) Except as otherwise provided in section 3719.41 of the Revised Code, any compound that meets the following fentanyl pharmacophore requirements to bind at the mu receptor, as identified by a report from an established forensic laboratory, is a schedule I controlled substance opiate:

(1) A chemical scaffold consisting of: ~~a five, six or seven member ring structure containing a nitrogen, whether or not further substituted;~~

(a) a five, six or seven member ring structure containing a nitrogen, whether

or not further substituted; and

(b) An attached nitrogen to the ring, whether or not that nitrogen is enclosed in a ring structure, including an attached aromatic ring or other lipophilic group to that nitrogen;

~~(2) An attached nitrogen to the ring, whether or not that nitrogen is enclosed in a ring structure, including an attached aromatic ring or other lipophilic group to that nitrogen;~~

~~(3)~~(2) A polar functional group attached to the chemical scaffold, including but not limited to, a hydroxyl, ketone, amide or ester;

~~(4)~~(3) An alkyl or aryl substitution off the ring nitrogen of the chemical scaffold; and

~~(5)~~(4) The compound has not been approved for medical use by the United States food and drug administration.

(E) 6-monoacetylmorphine (6-MAM) is a schedule I controlled substance opium derivative.

(F) 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (U-47700) is a schedule I controlled substance opium derivative.

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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) "American Hospital Formulary Service Drug Information" ("AHFS Drug Information").~~:~~

(G) A controlled substance reference table compiled by the state board of pharmacy using any of the reference works listed in this rule. This table shall be made available on the board's web site.

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TO BE RESCINDED

4729-13-06 **Responsible person for approved laboratories.**

(A) The responsible person whose name appears on the terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.

(B) The responsible person is responsible for maintaining adequate supervision and control over the dangerous drugs and controlled substances acquired, utilized, destroyed, or administered by the approved laboratory and maintaining all records required by this chapter and federal law to be kept at the establishment or place described in the license.

(C) If there is a change in the responsible person, the board of pharmacy shall be notified within thirty days thereof of the date of change and the name of the new responsible person.

(1) This notice to the board of pharmacy shall be made by completing, signing, and returning the form supplied by the board by regular mail or by verified facsimile transmission.

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

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TO BE RESCINDED

4729-14-06 **Responsible person for an approved animal shelter.**

(A) An individual shall be the responsible person for no more than one such location except with written permission from the board. A written request shall be submitted outlining the circumstances requiring an individual to be responsible for more than one location and the period of time during which the circumstances will exist. An individual shall not be designated the responsible person for a location unless that person shall be physically present in the facility a sufficient amount of time to provide supervision and control.

(B) The responsible person whose name appears on the limited terminal distributor of dangerous drugs license shall sign the license and shall maintain the license in a readily available place in the principal location of the business.

(C) The responsible person is responsible for maintaining adequate supervision and control over the dangerous drugs acquired, utilized, or administered by the approved animal shelter and is responsible for maintaining all required records.

(D) If there is a change in the responsible person, the board of pharmacy shall be notified within thirty days thereof of the date of change and the name of the new responsible person.

(1) This notice to the board of pharmacy shall be made by completing, signing, and returning the form supplied by the board by regular mail or by verified facsimile transmission.

(2) Included with this notice to the board shall be a notarized drug list prepared pursuant to paragraph (D) of rule 4729-14-03 of the Administrative Code.

(3) A complete inventory of the controlled substances on hand shall be taken, pursuant to federal regulations, with the new responsible person. The new responsible person shall be responsible for completing and maintaining this inventory record at the site of the terminal distributor of dangerous drugs.

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4729-17-01 **Definitions; institutional facility.**

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

(A) "Institutional facility" means a hospital as defined in section 3727.01 of the Revised Code, or a facility licensed by the Ohio state board of pharmacy and the Ohio department of health, the Ohio department of rehabilitation and correction, ~~or~~ the Ohio department of developmental disabilities, or the Ohio department of mental health and addiction services at which medical care is provided on site and a medical record documenting episodes of care, including medications ordered and administered, is maintained, including but not limited to:

(1) Convalescent homes;

(2) Developmental facilities;

(3) Long term care facilities;

(4) Nursing homes;

(5) Psychiatric facilities;

(6) Rehabilitation facilities;

(7) Developmental disability facilities~~.~~;

(8) Level III sub-acute detoxification facilities.

(B) "Inpatient" means any person who receives drugs for use while within the institutional facility.

(C) "Inpatient prescription" means a written, electronic, or oral order for a drug to be dispensed for use in treating an inpatient.

(D) "Dispensing of a drug pursuant to an inpatient prescription" means the professional review by a pharmacist required to place a specific drug in final association with the name of a particular inpatient pursuant to the lawful order of a prescriber. In the case of an automated drug delivery system meeting the requirements of rule 4729-5-35 of the Administrative Code, the final association with the name of a particular inpatient will be deemed to have occurred when the pharmacist has given final approval to the patient specific order in the system.

(E) "Contingency drugs" are those drugs which may be required to meet the therapeutic

needs of inpatients when a licensed pharmacist is not available and personally in full and actual charge of the institutional pharmacy.

(F) "Emergency drugs" are those drugs which are required to meet the immediate therapeutic needs of inpatients in order to sustain life in an emergency crisis.

(G) "Outpatient" means any person who receives drugs for use outside of the institutional facility.

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

(I) "Positive identification" has the same meaning as paragraph (N) of rule 4729-5-01 of the Administrative Code except that a specific hospital having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for, but not limited to, the prescribing and administration of a drug if approved by the board of pharmacy.

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

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

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

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

(d) An ongoing quality assurance program is in place to ensure that paragraphs (I)(1)(a) to (I)(1)(c) of this rule are being fulfilled and reviewed; and

(e) Appropriate policies and procedures are in place to address all of the items in paragraphs (I)(1)(a) to (I)(1)(d) of this rule.

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

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

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

(c) Waste of a controlled substance.

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

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

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4729-17-02 **Responsible person for an institutional pharmacy.**

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

(A) The institutional pharmacy director or designated pharmacist shall be the pharmacist-in-charge pursuant to section 4729.27 of the Revised Code, the responsible person pursuant to rule 4729-5-11 of the Administrative Code, and the pharmacist responsible for maintaining supervision and control over the possession and custody of all dangerous drugs acquired by the institutional facility pursuant to division (B) of section 4729.55 of the Revised Code.

(B) A pharmacist shall be the responsible person for no more than one pharmacy except with written permission from the state board of pharmacy unless granted permission in accordance with paragraph (E) of rule 4729-5-11 of the Administrative Code. ~~A written request shall be submitted outlining the circumstances requiring a pharmacist to be responsible for more than one pharmacy and the period of time during which the circumstances will exist. A pharmacist shall not be designated the responsible person for a pharmacy unless he/she will be physically present in the pharmacy a sufficient amount of time to provide supervision and control.~~

~~(C) The terminal distributor of dangerous drugs license issued to the institutional facility shall be signed by the responsible person and maintained in a readily available place in the pharmacy.~~

~~(D)~~(C) The responsible person shall:

(1) Be responsible for the practice of pharmacy performed within the institution;

(2) Develop, implement, supervise, and coordinate all services provided by the pharmacy;

(3) In conjunction with the appropriate interdisciplinary committees, be responsible for the development of written policies and procedures which are consistent with this chapter of the Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs, ~~assure~~ ensure adherence to these policies and procedures in order to provide for the safe and efficient distribution of drugs in all areas of the institution, and make available a current copy of these written policies and procedures for inspection and/or copying by an employee of the state board of pharmacy;

(4) Be responsible for the security and control of all drugs within the institution;

(5) Be responsible for the maintenance of all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs.

(D) Any change of the responsible person shall be done in accordance with rule 4729-5-11 of the Administrative Code.

~~(E) An institutional pharmacy director or designated pharmacist, who becomes the responsible person shall:~~

~~(1) File a written notice to the state board of pharmacy by regular mail, or by verified facsimile transmission within thirty days. This notice shall include:~~

~~(a) The name, address, and dangerous drug distributor license number(s) of the institutional pharmacy;~~

~~(b) His/her name and pharmacist registration identification number; and~~

~~(c) The date on which he/she became the responsible person.~~

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

~~(a) The original copy of the inventory shall be maintained in the pharmacy with all other required controlled substance records;~~

~~(b) This inventory shall serve as the inventory of controlled substances for which the new or acting responsible person is responsible.~~

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

(A) In the absence of a licensed pharmacist, drugs ordered by a prescriber for patient treatment may be obtained in the following manner:

(1) Where a licensed pharmacist is not present twenty-four hours-a-day, drugs for patient treatment may be made available to licensed health care professionals authorized pursuant to the Revised Code to administer drugs in the course of their professional practice by the use of contingency drug supplies pursuant to the provisions of paragraph (A)(2) of this rule. A licensed pharmacist shall be available for emergencies when the institutional pharmacy is closed.

(2) Contingency drugs shall be used only in the absence of a licensed pharmacist, and shall be stored in a locked cabinet(s) or other enclosure(s) constructed and located outside of the institutional pharmacy. The storage area must be sufficiently secure to deny access, without obvious damage, to unauthorized persons. The responsible person shall:

(a) Designate those who may obtain access to the drug supply;

(b) Determine, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included in the contingency drug supply;

(c) Ensure that such drugs are properly labeled and packaged in sufficient quantities to provide drug therapy during the period when the institutional pharmacy is not open;

(d) Provide controls adequate to prevent diversion of the drugs, and institute record keeping procedures to account adequately for the drugs when used and the positive identification of the person who obtained the drugs from the drug supply;

(e) Provide procedures for the inspection of the contingency drug inventory to ~~assure~~ ensure proper utilization and replacement of the drug supply.

(3) For a pharmacy located on the premises of the institutional facility, when a drug is not available from the contingency drug supply and such drug is required to treat the immediate needs of an inpatient or outpatient whose health would otherwise be jeopardized, such drug may be obtained from the institutional pharmacy pursuant to written policies and procedures implemented by the responsible person.

(a) The policies and procedures shall:

(i) Identify the personnel authorized to access the pharmacy and the conditions under which access may be gained to the pharmacy;

(ii) Ensure a minimum of two employees of the institution, one of whom shall be a health care professional licensed pursuant to Chapter 4723. (Nursing Practice Act) or 4731. (Medical Practice Act) of the Revised Code and authorized by such chapter to administer drugs in the course of their professional practice, to accompany each other when accessing the pharmacy;

(iii) Provide a written record documenting emergency access to the pharmacy. Such record shall include the names, titles, and positive identification of all institutional personnel accessing the pharmacy, date and time of access, the name and quantity of drugs obtained, the name of the patient, and the name of the ordering prescriber.

(b) The written record of each access to the institutional pharmacy when it is closed and a pharmacist is not present shall be filed, within twenty-four hours, with the responsible person and maintained in the pharmacy for three years.

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

(1) Provide for a limited quantity of dangerous drugs to be maintained at any one location;

(2) Provide for the proper storage and labeling of all such drugs;

(3) Provide for storage in a secure area. If dangerous drugs cannot be stored in a secure area, they shall be stored in a container which is sealed with a tamper-evident seal that must be broken to gain access to the drugs;

(4) Provide for notification of the responsible person, or designated pharmacist, when the dangerous drug supply has been accessed and/or drugs used;

(5) Provide for replacement of the drugs used, and the dangerous drug supply to be

re-sealed;

(6) Provide for inspection of the dangerous drug supply, on a regular basis, to detect unauthorized use of such drugs and which drugs have exceeded their expiration or beyond use date;

(7) Provide adequate record keeping procedures to document the disposition of drugs from the supply.

(C) Security

(1) All areas occupied by an institutional pharmacy shall be capable of being secured by key, or other effective mechanism, so as to prevent access by unauthorized personnel.

(2) In the absence of a licensed pharmacist, all areas occupied by an institutional pharmacy shall be secured so as to prevent access by unauthorized personnel.

(3) The responsible person shall develop and implement policies and procedures which will detect and deter the diversion and/or adulteration of drugs.

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4729-17-04 **Records; institutional pharmacy.**

All drug records shall be maintained for a period of three years pursuant to section 4729.37 of the Revised Code. All drug records must be readily retrievable within three working days, excluding holidays and weekends, of all drug transactions within the previous three years. Electronic drug record keeping systems, computerized record keeping systems, or subsequent storage of such records, must be readily retrievable via ~~CRT~~ digital display, hard copy printout, or other mutually agreeable transfer medium. If an electronic drug record keeping system is being utilized as defined in paragraph (H) of rule 4729-17-01 of the Administrative Code the method(s) of achieving positive identification must be approved by the state board of pharmacy prior to implementation pursuant to paragraph (I) of rule 4729-17-01 of the Administrative Code. The responsible person shall be responsible for maintaining the following records:

(A) A record of all drugs purchased, the quantity received, and the name, address, and wholesale distributor registration number of the person from whom the drugs were purchased.

(B) All drug orders and records relating to the practice of pharmacy.

(1) Records of drugs dispensed shall include, but are not limited to:

(a) The name, strength, and quantity of drugs dispensed;

(b) The date of dispensing;

(c) The name of the inpatient to whom, or for whose use, the drug was dispensed; and

(d) Positive identification of all pharmacists involved in the dispensing.

(2) All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:

(a) The name of the inpatient to whom, or for whose benefit, the activity was performed;

(b) The practice of pharmacy activity performed;

(c) The results of the activity, if applicable; and

(d) Positive identification of all pharmacists involved in the activity,

identifying the function performed by each pharmacist.

(3) Records of drugs dispensed for outpatients shall be maintained pursuant to rule 4729-5-27 of the Administrative Code.

(C) A record of all drugs compounded or repackaged for use only within the institution, which shall include at least the following:

(1) Name of drug, strength, quantity, and dosage form;

(2) Manufacturer's or distributor's control number;

(3) Manufacturer's or distributor's name, if a generic drug is used;

(4) Pharmacy control number;

(5) Manufacturer's or distributor's expiration date;

(6) The pharmacy's expiration date or beyond-use date;

(7) Positive identification of the pharmacist responsible for the compounding or repackaging of the drug.

(D) A record of the distribution of dangerous drugs to other areas of the institution for administration or use as described in paragraph (B) of rule 4729-17-03 of the Administrative Code, which shall include at least the following:

(1) The name, strength, dosage form, and amount of drug distributed;

(2) The area receiving the drug;

(3) The date distributed;

(4) Positive identification of the individual receiving the drug if it is a controlled substance;

(5) The area of the institution receiving the dangerous drug shall make a record of all such drugs administered to patients. Such records shall include at least the following:

(a) Name of the patient;

(b) Name, dosage form, and strength when applicable of the drug;

(c) Date and time the drug was administered;

(d) Quantity administered;

(e) Positive identification of the personnel administering the drug.

(E) A log that must be maintained of all changes made to a drug record in an electronic drug record keeping system or a computerized record keeping system after a drug transaction has been made. Such log may be accessible for review, but shall be protected from being altered in any way. The log must contain at least, but is not limited, to the following:

(1) Date and time of change;

(2) Changes made;

(3) Person making the change.

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4729-17-08 **Minimum standards for an institutional pharmacy.**

(A) ~~Library~~Resources

(1) All pharmacists working in a pharmacy must be able to access all current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio;

(2) The pharmacy shall ~~carry and utilize~~have access to the references necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws, rules and regulations; and

(3) Telephone number of a poison control center.

(B) Drug inventory, fixtures, and space

(1) The inventory of drugs and equipment shall be commensurate with the scope of pharmacy services provided, and housed in suitable, well-lighted and well-ventilated room(s), in a clean and sanitary area.

(2) All areas where drugs are stored shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing or administration as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(3) All areas where drugs are stored shall provide adequate physical security to deter and detect their diversion and/or adulteration.

(C) Personnel

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

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4729-17-09 **Drug orders for patients of an institutional facility.**

(A) Drugs shall be dispensed by a pharmacist for inpatients pursuant to an original patient specific order issued by a prescriber.

(1) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of an electronic drug record keeping system may be considered an original order for the dispensing of drugs. Access to such system for entering and transmitting original orders shall be restricted to licensed health care professionals using positive identification. If the licensed health care professional entering the order into the system is not the prescriber, there shall be a system in place requiring the positive identification of the prescriber for each order within a reasonable period of time which shall be available in a readily retrievable fashion.

~~(1)~~(2) Oral orders issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacist by personnel authorized by, and in accordance with, written policies and procedures of the facility. Such orders shall be recorded by the pharmacist, noting the full name(s) of the authorized personnel transmitting the order. Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility.

~~(2)~~(3) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of a facsimile machine to facsimile machine transfer shall be transmitted by personnel authorized by, and in accordance with, written policies and procedures of the facility. The pharmacist receiving the facsimile shall have in place written policies and procedures allowing only authorized personnel access to the drug order facsimile. The pharmacist shall maintain the facsimile showing the origin of the order as a part of the drug order record. This facsimile must be maintained if it is the only record showing the pharmacist responsible for dispensing the drug.

~~(3) Drug orders for inpatients of an institutional facility transmitted to a pharmacist by use of an electronic drug record keeping system may be considered an original order for the dispensing of drugs. Access to such system for entering and transmitting original orders shall be restricted to licensed health care professionals using positive identification. If the licensed health care professional entering the order into the system is not the prescriber, there shall be a system in place requiring the positive identification of the prescriber for each order within a reasonable period of time which shall be available in a readily retrievable fashion.~~

(B) All orders for drugs for inpatients shall include, but are not limited to, at least the

following:

(1) Name of patient;

(2) Name, strength, and dosage form of drug;

(3) Directions for use, including route of administration;

(4) Date prescribed; and

(5) Prescriber's positive identification.

(C) Drugs shall be dispensed for outpatients pursuant to an original order of a prescriber. All orders for the dispensing of drugs to outpatients shall, at a minimum, conform to rule 4729-5-30 of the Administrative Code, shall be labeled in accordance with rule 4729-5-16 of the Administrative Code, and the records shall be maintained in accordance with rule 4729-5-27 of the Administrative Code.

(D) An original signed prescription for a schedule II controlled substance prepared in accordance with federal and state requirements and issued for a resident in a long term care facility may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be received and maintained pursuant to rules 4729-5-21 and 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at either the prescriber's office or the long term care facility.

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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.

(D) All drugs dispensed for use by outpatients of an institutional facility shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code except as noted in paragraph (A) of rule 4729-17-10 of the Administrative Code.

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TO BE RESCINDED

4729-17-11 **Labeling of prescriptions for outpatients.**

All drugs dispensed for use by outpatients of an institutional facility shall be labeled in accordance with paragraphs (A), (B), and (C) of rule 4729-5-16 of the Administrative Code except as noted in paragraph (A) of rule 4729-17-10 of the Administrative Code.

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

(A) A person authorized to write prescriptions pursuant to rule 4729-5-15 of the Administrative Code who is employed as a staff prescriber of a hospital, is not individually registered under the provisions of the controlled substances act and, therefore, does not possess a "Drug Enforcement Administration" (D.E.A.) number, may administer, dispense, and prescribe controlled substances under the registration of the hospital.

(B) A person pursuing an approved training program within the jurisdiction of the hospital and authorized to write prescriptions pursuant to paragraph (B) of rule 4729-5-15 of the Administrative Code may administer, dispense, or prescribe controlled substances under the registration of the hospital. Persons pursuing such approved training programs may function in sites outside the physical confines of the hospital only if such sites are part of the training program and the persons are under the employment and jurisdiction of the hospital administering the approved program. While functioning in the outside sites, such persons may continue to use the internal code assigned by the hospital administering the approved program, upon mutual agreement of the hospital and the outside site.

(C) The administering, dispensing, or prescribing must be done in the usual course of his/her professional practice and only within the scope of his/her employment.

(D) Each person so authorized must be assigned a specific internal code number by the hospital which will be used as a suffix to the hospital D.E.A. registration number. Such internal code number shall consist of numbers, letters, or a combination thereof, ~~and~~ shall be preceded by a hyphen, and no more than 10 characters in length, excluding the hyphen. A list of the internal codes and the corresponding individual prescribers must be kept by the hospital and made available at all times to other registrants, state board of pharmacy designated agents, investigators of the state medical board, and federal, state, county, or municipal law enforcement agencies for verification. An initial list of internal codes and the corresponding individual prescribers must be electronically submitted to the state board of pharmacy, in a format prescribed by the board, within 30 days of the effective date of this rule. Additions, deletions or changes to the list must be submitted to the state board of pharmacy within five business days of any such addition, deletion or change.

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4729-33-02 **Licensure.**

(A) Any emergency medical service (EMS) organization that desires to stock dangerous drugs shall apply for and maintain a license as a terminal distributor of dangerous drugs. The one location that serves as the main station will be deemed the headquarters location. Any other locations associated with this headquarters where dangerous drugs will be stored will be licensed as "satellites". Only the headquarters location will be charged a license fee or renewal license fee.

(B) Each location, headquarters and satellites, must be licensed as a limited terminal distributor of dangerous drugs and must maintain a current terminal distributor of dangerous drugs license and drug addendum.

(C) An application for licensure must include all of the following:

(1) A completed application;

(2) A compilation of all protocols involving dangerous drugs that have been signed by the medical director and notarized;

(3) A list of drugs referenced in the protocols to be stocked by the EMS organization, signed by the medical director and notarized;

(4) A list of personnel employed, including volunteers, by the EMS organization who may access and administer dangerous drugs, which includes the name of the individual, level of certification, their certification number, and expiration date;

(5) A list of any and all formal written mutual aid agreements with other EMS organizations;

(6) The fee for the appropriate category of licensure.

(D) Each location, headquarters and satellite, may only possess those dangerous drugs that are on the drug list submitted to the board pursuant to paragraph (C)(3) of this rule ~~listed on the drug addendum~~ and only at locations licensed by the board of pharmacy.

(1) A medical director may modify the drugs that can be possessed and administered by an emergency medical service organization by submitting a new ~~add dangerous drugs to the~~ drug list ~~by submitting revised, signed and notarized protocols and list of medications, and the addendum update fee~~in a manner prescribed by the board.

(2) (2) A modification to the drug list shall require an update to the EMS organization's protocols. The updated protocols shall be maintained and readily retrievable upon inspection at the location licensed by the board and are not required to be submitted with the updated drug list as described in paragraph (D)(1) of this rule.

~~(2) A medical director may delete dangerous drugs from the drug list by submitting a letter listing the drugs to be deleted.~~

(E) A new application and fee is required prior to any change of location, addition of a satellite location, change of category, name change, or change of ownership. ~~These changes may be made during the annual renewal period with no additional fee other than the renewal fee.~~The new application and required fee shall be submitted within 30 days of any change in the ownership, business or trade name, category, or address.

(F) The responsible person shall comply with rule 4729-5-11 of the Administrative Code.~~provide supervision and control of all locations where dangerous drugs are stored. The responsible person must be a physician licensed pursuant to Chapter 4731. of the Revised Code or a pharmacist licensed pursuant to Chapter 4729. of the Revised Code.~~

~~(1) To change the responsible person, the new responsible person must complete and return a notification of change of responsible person form within thirty days by regular mail or verified facsimile transmission.~~

~~(2)~~(G) To change the medical director of an EMS organization, the new medical director ~~must~~ shall submit notification, in a manner prescribed by the board, to the board within five business days of the change. ~~a signed and notarized letter stating that he/she is accepting responsibility for the EMS organization.~~The notification shall indicate whether or not the medical director approves of the current protocol and drug list. If the new medical director makes any changes the drug list, they shall comply with the requirements in paragraph (D) of this rule. If the new medical director makes any changes to the protocols, they shall comply with paragraph (J) of this rule.

~~(a) If the new medical director approves of the current protocol and drug list, a signed and notarized letter must be submitted stating the current protocols and drug list on file have been reviewed and are approved by the medical director for use by this EMS organization, or~~

~~(b) If the new medical director desires to change the protocols or drug list, the medical director must submit the revised, signed, and notarized protocols and drug list, and the addendum update fee.~~

~~(G)~~(H) Any changes in the list of dangerous drugs referenced in an EMS organization's protocol shall ~~protocols that involve dangerous drugs must~~ be submitted to the state board of pharmacy prior to the implementation of the protocols involved. ~~The state board of pharmacy may discuss such protocols with the state board of emergency medical, fire and transportation services, state medical board, or other governmental agencies as needed to assure their validity.~~

~~(H)~~(I) Any change of personnel shall be updated ~~requires a letter from the organization~~ within thirty days of the change listing the type of change (addition, update, or deletion), names of the personnel involved, level of certification, their certification number, and expiration date. Personnel lists shall be maintained by the EMS organization and shall be readily retrievable upon inspection by the Board.

(J) An EMS organization shall maintain a current copy of their protocols at their licensed location. Protocols shall be readily retrievable upon inspection by the Board.

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