December 2025 – Rules

For Filing with CSI and JCARR

Rule 4729:2-2-07 - Successful completion of the Test of English as a Foreign Language, Internet-based Test. (AMEND)

Successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) shall be the following minimum scores or higher:

(A) Writing: **twenty-two** ~~**twenty-four**~~;

(B) Speaking: **twenty-five** ~~**twenty-six**~~;

(C) Listening: **twenty-two** ~~**twenty-one**~~; and

(D) Reading: **twenty-one** ~~**twenty-two**~~.

Rule 4729:1-2-04 - Successful completion of the Test of English as a Foreign Language, Internet-based Test. (AMEND)

Successful completion of the "Test of English as a Foreign Language, Internet-based test" (TOEFL iBT) shall be the following minimum scores or higher:

(A) Writing: **twenty-two** ~~**twenty-four**~~;

(B) Speaking: **twenty-five** ~~**twenty-six**~~;

(C) Listening: **twenty-two** ~~**twenty-one**~~; and

(D) Reading: **twenty-one** ~~**twenty-two**~~.

Rule 4729:1-3-04 | Dispensing of ~~naloxone~~ overdose reversal drugs by pharmacists. (AMEND)

(A) A pharmacist may dispense ~~**naloxone**~~ **an overdose reversal drugs as defined in rule 4729-8-02 of the Administrative Code** without a prescription to either of the following in accordance with a 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**~~ **individual** in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(B) A ~~**physician**~~ **prescriber-**established protocol for the dispensing of ~~**naloxone**~~ **an overdose reversal drug** 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**~~ **the overdose reversal drug being dispensed**.

(2) Indications for use of ~~**naloxone**~~ **an overdose reversal drug** as rescue therapy, including criteria for identifying persons eligible to receive ~~**naloxone**~~ **an overdose reversal drug** under the protocol.

(3) Precautions and contraindications concerning dispensing ~~**naloxone**~~ **an overdose reversal drug**.

(4) ~~**Naloxone products**~~ **The overdose reversal drugs** 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.

(5) Any patient instructions **or training requirements.** ~~**in addition to the patient training specified in this rule and rule 4729:2-3-04 of the Administrative Code.**~~

(C) A pharmacist who dispenses ~~**naloxone**~~ **an overdose reversal drug** pursuant to this rule shall**:**

(1) Instruct the individual to whom ~~**naloxone**~~ **an overdose reversal drug** is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering ~~**naloxone**~~ **an overdose reversal drug; and**

(2) Offer to counsel the patient in accordance with rule 4729:5-5-09 of the Administrative Code.

(D) All overdose reversal drugs dispensed pursuant to this rule shall be in packaging that contains the manufacturer's instructions for use.

~~**(D) Except as provided in paragraph (E) this rule, a pharmacist or a pharmacist's designee that is appropriately trained shall provide in-person training, unless the in-person training requirement is waived by the board, and written educational materials to the individual to whom naloxone is dispensed that includes all 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 the naloxone dispensed;**~~

~~**(6) Procedures for administering the naloxone dispensed;**~~

~~**(7) Proper storage and expiration of the naloxone dispensed; and**~~

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

~~**(E) Patient training as required by paragraph (D) of this rule is not required if the patient has previously received training and all the following apply:**~~

~~**(1) The patient is offered training and refuses;**~~

~~**(2) The pharmacist or pharmacist designee has documentation confirming training pursuant to this rule has been provided within the previous twelve months;**~~

~~**(3) A pharmacist who dispenses naloxone pursuant to this rule shall still 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.**~~

~~**(F) 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 4729:5-5-09 of the Administrative Code if the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.**~~

~~**(G) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense naloxone pursuant to this rule are trained on the use of naloxone and can meet the training requirements listed in paragraphs (C) and (D) of this rule.**~~

~~**(H) A terminal distributor of dangerous drugs shall ensure that all pharmacist designees are trained on the use of naloxone and can meet the training requirements listed in paragraph (D) of this rule.**~~

(**E** ~~**I**~~) A pharmacist may document on a prescription form the dispensing of ~~**naloxone**~~ **an overdose reversal drug** by the pharmacist or a pharmacy intern supervised by the pharmacist. The form may be assigned a number for record-keeping purposes.

(**F** ~~**J**~~) All ~~**physician**~~ **prescriber**-established protocols must be signed and dated by the ~~**physician**~~ **prescriber** prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a ~~**physician**~~ **prescriber** on a biennial basis.

(1) A ~~**physician**~~ **prescriber** may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector or employee of the state board of pharmacy.

(**G** ~~**K**~~) Any pharmacy that dispenses ~~**naloxone**~~ **overdose reversal drugs** pursuant to section ~~**4729.44**~~ **3715.502** of the Revised Code shall notify the board, in a manner determined by the board, within thirty days of establishing a protocol. A pharmacy that no longer dispenses ~~**naloxone**~~ **overdose reversal drugs** pursuant to section ~~**4729.44**~~ **3715.502** of the Revised Code shall notify the board, in a manner determined by the board, within thirty days of discontinuation.

(1) Except in the event of a drug shortage, a pharmacy submitting notification of ~~**naloxone**~~ **overdose reversal drug** dispensing shall ensure ~~**naloxone**~~ **such drugs** ~~**is**~~ **are** made available in accordance with this rule.

(2) A pharmacy that has submitted notification of ~~**naloxone**~~ **overdose reversal drug** dispensing shall provide initial training to all new employees and annual training to existing employees on the availability of ~~**naloxone**~~ **overdose reversal drugs** ~~**dispensing**~~ pursuant to a protocol. Employees requiring training in accordance with this paragraph shall include: pharmacists, pharmacy interns, certified pharmacy technicians, registered pharmacy technicians, pharmacy technician trainees, and support personnel, as defined in rule 4729:3-1-01 of the Administrative Code, that have direct contact with the public. Training documentation records shall be maintained for a period of three years and shall be made readily retrievable.

(**H** ~~**L**~~) Paragraph (**G** ~~**K**~~) of this rule does not apply to institutional pharmacies that provide ~~**naloxone**~~ **overdose reversal drugs** to inpatients or patients upon discharge.

(I) As used in this rule, "prescriber" means any of the following:

(1) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery;

(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a current, valid license issued under Chapter 4723. of the Revised Code to practice nursing as an advanced practice registered nurse;

(3) A physician assistant who holds a license to practice as a physician assistant issued under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority; or

(4) A certified mental health assistant licensed under Chapter 4772. of the Revised Code who has been granted physician-delegated prescriptive authority by the physician supervising the certified mental health assistant.

(J) Nothing in this rule shall prohibit the sale or distribution of an overdose reversal drug by pharmacy personnel in accordance with section 3715.50 of the Revised Code.

Rule 4729:1-3-06 | Dispensing of epinephrine ~~autoinjectors~~ by pharmacists. (AMEND)

(A) A pharmacist may dispense ~~**an**~~ epinephrine**, which shall be an epinephrine autoinjector or any other formulation authorized pursuant to Chapter 4729. of the Revised Code,** ~~**autoinjector**~~ without a prescription to either of the following in accordance with a protocol specified in paragraph (B) of this rule:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs; or

(2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code.

(B) A physician-established protocol for the dispensing of epinephrine ~~**autoinjectors**~~ by a pharmacist or pharmacy intern under the direct supervision of a pharmacist shall include, but is not limited to, the following:

(1) Indications for use of epinephrine ~~**autoinjectors**~~, including criteria for identifying persons eligible to receive an autoinjector under the protocol.

(2) Precautions and contraindications related to the dispensing of epinephrine ~~**autoinjectors**~~.

(3) Epinephrine ~~**autoinjectors**~~ **formulations** authorized to be dispensed, including all the following information:

(a) Name of product;

(b) Dose;

(c) Quantity to be dispensed; and

(d) Directions for use.

(4) Any patient instructions in addition to the training specified in this rule and rule 4729:2-3-06 of the Administrative Code.

(C)

(1) A pharmacist who dispenses ~~**an**~~ epinephrine ~~**autoinjector**~~ pursuant to this rule shall instruct the individual to whom the epinephrine ~~**autoinjector**~~ is dispensed, either verbally or in writing, to summon emergency services as soon as practicable either before or after administering epinephrine.

(2) A pharmacist who dispenses ~~**an**~~ epinephrine ~~**autoinjector**~~ to an individual identified in paragraph (A) of this rule shall provide notification of the dispensing to the individual's primary care provider, if known, or to the prescriber who issued the individual the initial prescription for ~~**an**~~ epinephrine ~~**autoinjector**~~. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication;

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(D) When a pharmacist dispenses ~~**an**~~ epinephrine ~~**autoinjector**~~ pursuant to this rule, the pharmacist, or pharmacy intern under the direct supervision of a pharmacist, shall provide to the person receiving the ~~**device**~~ **medication** instruction on the proper method of administering epinephrine ~~**with the device**~~.

(E) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense epinephrine ~~**autoinjectors**~~ pursuant to this rule are trained on the use of epinephrine and can meet the training requirements listed in paragraphs (C) and (D) of this rule.

(F) A pharmacist may document the dispensing of ~~**an**~~ epinephrine ~~**autoinjector**~~ by the pharmacist or pharmacy intern under the direct supervision of the pharmacist on a prescription form. The form may be assigned a number for record-keeping purposes.

(G) This rule does not affect the authority of a pharmacist to:

(1) Dispense a new prescription or refill for epinephrine; or

(2) Contact a prescriber to obtain a new oral prescription for ~~**an**~~ epinephrine ~~**autoinjector**~~ in accordance with the applicable provisions of division 4729:5 of the Administrative Code.

(H) All physician-established protocols must be signed and dated by the physician prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a physician on a biennial basis.

(1) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(2) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector**,** or employee of the state board of pharmacy.

(I) As used in this rule:

(1) "Epinephrine" means an epinephrine autoinjector or any other formulation authorized pursuant to Chapter 4729. of the Revised Code.

(2) "Pharmacy affiliated with the pharmacist" as used in paragraph (A)(1) of this rule means the pharmacy that dispensed the epinephrine autoinjector or another pharmacy under common ownership of the pharmacy that dispensed the epinephrine autoinjector.

Rule 4729:1-3-07 | Dispensing nicotine replacement therapy by pharmacists. (AMEND)

(A) As used in this rule: ~~,~~

(**1)** "Nicotine replacement therapy" means a drug, including a dangerous drug, that delivers small doses of nicotine to an individual for the purpose of aiding in tobacco cessation or smoking cessation including for the cessation of alternative nicotine delivery systems, such as e-cigarettes.

(2) "Prescriber" means any of the following:

(a) Physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery; or

(b) Certified nurse-midwife, clinical nurse specialist, or certified nurse practitioner licensed under Chapter 4723. of the Revised Code.

(B) A pharmacist may dispense nicotine replacement therapy to individuals who are eighteen years old or older and seeking to quit using tobacco-containing products in accordance with paragraph (C) of this rule.

(C) For a pharmacist to be authorized to dispense nicotine replacement therapy under this rule, the pharmacist shall do both of the following:

(1) Successfully complete a course on nicotine replacement therapy that is taught by a provider that is accredited by the accreditation council for pharmacy education, or another provider approved by the state board of pharmacy, and that meets requirements established in paragraph (H) of this rule; and

(2) Practice in accordance with a ~~**physician**~~ **prescriber**-authorized protocol that meets the requirements of paragraph (D) of this rule.

(D) All of the following apply with respect to the protocol required by this rule:

(1) The protocol shall be established by a **prescriber defined in paragraph (A) of this rule.** ~~**physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.**~~

(2) The protocol shall specify a definitive set of treatment guidelines and the locations at which a pharmacist may dispense nicotine replacement therapy under this rule.

(3) The protocol shall specify the types of nicotine replacement therapy that may be dispensed.

(4) The protocol shall include provisions for implementation of the following requirements:

(a) Use by the pharmacist of a screening procedure, recommended by the United States centers for disease control and prevention or another organization approved by the board, to determine if an individual is a good candidate to receive nicotine replacement therapy dispensed as authorized by this rule;

(b) A requirement that the pharmacist refer high-risk individuals, as defined in the protocol, or individuals with contraindications to a primary care provider or, as appropriate, to another type of provider;

(c) A requirement that the pharmacist develop and implement a follow-up care plan in accordance with paragraph (D)(5) of this rule, including a recommendation by the pharmacist that the individual seek additional assistance with behavior change, including assistance from the Ohio tobacco quit line made available by the department of health.

(5) A follow-up care plan shall include all the following:

(a) A recommendation that the individual notify their provider that they have initiated a quit attempt;

(b) A plan to deal with the psychological aspects of tobacco addiction, including information regarding how to seek services from the Ohio tobacco quit line;

(c) A plan for how to deal with possible side effects;

(d) Instructions regarding how, when, and how many times to refill the medication;

(e) Follow-up with patient should occur within a clinically appropriate length of time after the initiation of the nicotine replacement therapy as deemed appropriate by the pharmacist;

(f) How and when to stop using nicotine replacement therapy;

(g) Instructions to seek assistance from the pharmacist or provider before continuing to use the medication if a relapse occurs and tobacco use is reinitiated;

(h) If a patient returns to the pharmacy to report a relapse, the follow-up care plan should include efforts to identify smoking cues and triggers and decide upon alternative coping strategies before a follow-up attempt to quit tobacco;

(i) If dual therapy is indicated for the patient, instructions to seek assistance from a prescribing provider to add prescription-only smoking cessation medication to the pharmacist-initiated nicotine replacement therapy.

(6) All **~~physician~~ prescriber**-established protocols must be signed and dated by the **~~physician~~ prescriber** prior to implementation and maintained by the terminal distributor of dangerous drugs. The protocols shall be renewed by a **~~physician~~ prescriber** on a biennial basis.

(a) A **~~physician~~ prescriber** may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.

(b) Each location licensed as a terminal distributor of dangerous drugs shall maintain a copy of the protocol on-site for inspection by an agent, inspector, or employee of the state board of pharmacy.

(E)

(1) Documentation related to screening, dispensing, and follow-up care plans shall be maintained in the records of the terminal distributor of dangerous drugs where the pharmacist practices for at least three years. Dispensing of nicotine replacement therapy may be documented on a prescription form, and the form may be assigned a number for recordkeeping purposes.

(2) Not later than seventy-two hours after a screening is conducted under this rule and the patient has been identified as a candidate for smoking cessation therapy, the pharmacist shall provide notice to the individual's primary care provider, if known, or to the individual if the primary care provider is unknown. The notice shall include results of the screening, and if applicable, the dispensing record and follow-up care plan. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication; or

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(3) A copy of the documentation identified in paragraph (E)(1) of this rule shall also be provided to the individual or the individual's primary care provider on request.

(F) This rule does not affect the authority of a pharmacist to do any of the following:

(1) Fill or refill prescriptions for nicotine replacement therapy;

(2) Sell nicotine replacement therapy that does not require a prescription.

(G) A provider who is not accredited by the accreditation council for pharmacy education may petition the board for approval of a course in accordance with division (C) of section 4729.284 of the Revised Code. The board shall develop and post a petition application on its website providing the criteria for approval.

(H) No pharmacist shall do either of the following:

(1) Dispense nicotine replacement therapy in accordance with a protocol unless the requirements of paragraph (C) of this rule have been met;

(2) Delegate to any person the pharmacist's authority to engage in or supervise the dispensing of nicotine replacement therapy.

(I) A terminal distributor of dangerous drugs shall ensure that all pharmacists that dispense nicotine replacement therapy pursuant to this rule have completed the requirements set forth in paragraph (C) of this rule.

(J) A terminal distributor of dangerous drugs dispensing nicotine replacement therapy in accordance with this rule shall also comply with the applicable record keeping provisions of Chapter 4729:5-5, 4729:5-8, or 4729:5-9 of the Administrative Code.

Rule 4729:1-6-01 | Definitions - consult agreements. (AMEND)

(A) "Certified nurse practitioner," "certified nurse-midwife," "clinical nurse specialist," and "standard care arrangement" have the same meanings as in section 4723.01 of the Revised Code.

(B) "Collaborating physician" means a physician who has entered into a standard care arrangement with a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

(C) "Communication between a pharmacist and practitioner acting under a consult agreement," as used in division (D)(6) of section 4729.39 of the Revised Code, means any of the following:

(1) Electronic mail that confirms delivery;

(2) Interoperable electronic medical records system;

(3) Facsimile that confirms delivery;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Documented verbal communication; or

(7) Any other method of documented notification as outlined in the consult agreement between the pharmacist and practitioner.

(D) "Comorbid disease," as used in division (D)(3)(a) of section 4729.39 of the Revised Code, means an additional disease that co-occurs with a primary disease. A comorbid disease may be related to or occur independently of the primary disease.

(E)

(1) "Communicated" as used in division (D)(4) of section 4729.39 of the Revised Code, means consent shall be obtained from each individual patient participating in a consult agreement. With the exception of inpatient management of patient care at an institutional facility,

consent shall be obtained prior to a pharmacist managing a patient's drug therapy and shall communicate all of the following:

(a) A pharmacist may be utilized in the management of the patient's care; and

(b) The patient's or an individual authorized to act on behalf of a patient's right to elect to participate in and withdraw from the consult agreement.

(2) Consent as required in paragraph (E)(1) of this rule may be obtained as a part of the patient's initial consent to treatment.

(F) "Consult agreement" means an agreement that has been entered into pursuant to section 4729.39 of the Revised Code.

(G) “Collaborating pharmacist” means a pharmacist managing a patient's drug therapy pursuant to a consult agreement.

(**H** ~~**G**~~) "Institutional facility" has the same meaning as defined in ~~**agency 4729**~~ **chapter 4729:5-9** of the Administrative Code.

~~**(H) "Managing pharmacist" means a pharmacist managing a patient's drug therapy pursuant to a consult agreement.**~~

(I) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(J) "Physician assistant" means an individual who is licensed to practice as a physician assistant under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority.

(K)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) **~~A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.~~** **A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier.**

(L) "Practitioner" means any of the following:

(1) Physician;

(2) Physician assistant;

(3) Clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner.

(M) "Primary disease," as used in division (D)(3)(a) of section 4729.39 of the Revised Code, means a disease that arises spontaneously and is not associated with or caused by a previous disease, injury, or event, but that may lead to a comorbid disease.

(N) "OARRS report" means a report of information related to a specific person generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(O) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the board.

(P) "Supervising physician" means a physician who has entered into a supervision agreement with a physician assistant under section 4730.19 of the Revised Code.

(Q) "Training and experience related to the particular diagnosis for which drug therapy is prescribed," as used in division (C)(3) of section 4729.39 of the Revised Code, means an Ohio licensed pharmacist whose license is in good standing and who meets the training and experience criteria specified in paragraph (A)(1)(k) of rule 4729:1-6-02 of the Administrative Code.

(R) "Written notice," as used in division (D)(2)(b) of section 4729.39 of the Revised Code, means one of the following methods that is capable of confirming delivery of the required written notice:

(1) Electronic mail;

(2) Interoperable electronic medical records system;

(3) Facsimile;

(4) Electronic prescribing system;

(5) Electronic pharmacy record system;

(6) Any other method in writing that provides notice in a timely manner; or

(7) Any other method of notification as outlined in the consult agreement that might reasonably be expected to allow for the confirmed transmission of the written notification required.

Rule 4729:1-6-02 | Consult agreements. (AMEND)

(A) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

(a) Identification of the practitioner(s) and pharmacist(s) authorized to enter into the agreement. This may include:

(i) Individual names of practitioners and pharmacists;

(ii) Practitioner or pharmacist practice groups; or

(iii) Identification based on institutional credentialing or privileging.

(b) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.

(c) A description of the drugs or drug categories managed as part of the agreement.

(d) A description of the procedures **(i.e., processes)**, decision criteria, and plan the **collaborating ~~managing~~** pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a **collaborating ~~managing~~** pharmacist is allowed to perform under a consult agreement.

(e) A description of the types of tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the **collaborating ~~managing~~** pharmacist**. Tests may only be ordered and evaluated if the tests relate specifically to the management of a patient's drug therapy. ~~as long as the tests relate to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated to manage the diagnoses and diseases under the agreement.~~**

(f) A description of how the **collaborating ~~managing~~** pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification.

(g) A description of how communication between a **collaborating ~~managing~~** pharmacist and practitioner acting under a consult agreement shall take place at regular intervals specified by the practitioner who authorized the agreement. The agreement may include a requirement that a **collaborating ~~managing~~** pharmacist send a consult report to each consulting practitioner.

(h) A provision that allows a practitioner to override a decision made by the **collaborating ~~managing~~** pharmacist when appropriate.

(i) A quality assurance mechanism to ensure that **collaborating ~~managing~~** pharmacists only act within the scope authorized by the consult agreement.

(j) A description of a continuous quality improvement (CQI) program used to evaluate the effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.

(k) The training and experience criteria for **collaborating ~~managing~~** pharmacists. The criteria may include privileging or credentialing, board certification, continuing education**,** or any other training requirements. The agreement shall include a process to verify that the **collaborating ~~managing~~** pharmacists meet the specified criteria.

(l) An effective date and expiration date.

(2) Institutional **facilities as defined in Chapter 4729:5-9 of the Administrative Code** or **~~ambulatory~~** outpatient facilities **owned and operated by institutional facilities** may implement a consult agreement and meet the requirements of paragraphs (A)(1)(b) to (A)(1)(e) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and made readily retrievable.

(3) The agreement shall be signed by the primary practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or

(b) A **collaborating ~~managing~~** pharmacist licensed pursuant to Chapter 4729. of the Revised Code.

(4) All amendments to a consult agreement shall be signed and dated by the primary practitioner, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to rule 4729:5-2-01 of the Administrative Code; or

(b) A **collaborating ~~managing~~** pharmacist licensed pursuant to Chapter 4729. of the Revised Code.

(5) A consult agreement shall be valid for a period not to exceed two years.

(6) Only Ohio licensed practitioners and Ohio licensed pharmacists **physically located in the United States** may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(B) Record keeping. As required by section 4729.39 of the Revised Code, a **collaborating ~~managing~~** pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records and are subject to the confidentiality requirements of rule 4729:5-3-05 of the Administrative Code.

(C) Managing drug therapy.

(1) For the purpose of implementing any actions related to the management of drug therapy listed in division (D)(1) of section 4729.39 of the Revised Code, the **collaborating ~~managing~~**

pharmacist may be authorized as one or both of the following, as specified in the consult agreement:

(a) A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile**,** or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement.

(i) For all outpatient prescriptions issued, the pharmacist shall comply with rules 4729:5-5-15 and 4729:5-5-05 of the Administrative Code.

(ii) For all inpatient prescriptions or orders issued at an institutional facility, the pharmacist shall comply with the requirements of ~~**agency 4729**~~ **chapter 4729:5-9** of the Administrative Code.

(b) With respect to non-controlled dangerous drugs only, an agent of the consulting practitioner(s). As an agent of the consulting practitioner(s), a pharmacist is authorized to issue a drug order, on behalf of the consulting practitioner(s), in writing, orally, by a manually signed drug order sent via facsimile**,** or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. A pharmacist issuing a prescription as an agent of a practitioner shall comply with all the following:

(i) For all outpatient prescriptions, the pharmacist shall comply with rules 4729:5-5-15 and 4729:5-5-05 of the Administrative Code.

(ii) For all inpatient prescriptions or orders issued at an institutional facility, the pharmacist shall comply with the prescription requirements of ~~**agency 4729**~~ **chapter 4729:5-9** of the Administrative Code.

(iii) Except as provided in paragraphs (C)(1)(b)(v) and (C)(1)(b)(vi) of this rule, the prescription shall include the required information of the consulting practitioner(s).

(iv) The prescription shall also include the name of the **collaborating** ~~**managing**~~ pharmacist acting as the agent of the consulting practitioner.

(v) The telephone number where the **collaborating ~~managing~~** pharmacist can be personally contacted during normal business hours. The telephone number may be in addition to or in place of the telephone number required by rule 4729:5-5-15 of the Administrative Code.

(vi) Pursuant to the consult agreement, all required positive identification (including a manual signature) on a prescription shall be of the **collaborating ~~managing~~** pharmacist on behalf of the consulting practitioner(s).

(2) If the **collaborating ~~managing~~** pharmacist is not the dispensing pharmacist or the person administering the dosage ordered, a copy of the consult agreement or privileging documentation shall be made available to the dispensing pharmacist or the person administering the dosage ordered if it is requested in order to prove the right of the **collaborating ~~managing~~** pharmacist to act in this manner.

(3) A **collaborating ~~managing~~** pharmacist shall request and review an OARRS report covering at least a one-year time period prior to any of the following:

(a) Adding a controlled substance drug **or a drug containing gabapentin** to a patient's drug therapy; or

(b) Adjusting a**ny of the following for a** controlled substance drug**~~'s~~ or a drug containing gabapentin:** strength, dose, dosage form, frequency of administration, or route of administration.

(4) Except as provided in paragraph (C)(5) of this rule, a **collaborating ~~managing~~** pharmacist shall not delegate drug therapy management to anyone other than another authorized pharmacist practicing under the consult agreement.

(5) A **collaborating ~~managing~~** pharmacist may delegate the administration of a drug to a licensed healthcare professional in accordance with their applicable scope of practice pursuant to the **collaborating ~~managing~~** pharmacist's order.

(6) A **collaborating ~~managing~~** pharmacist authorized to prescribe controlled substances pursuant to paragraph (C)(1)(a) of this rule shall comply with all the following:

(a) Maintain a valid controlled substance prescriber registration issued by the state board of pharmacy by submitting an application and a valid consult agreement, in a manner determined by the board, authorizing the pharmacist to prescribe controlled substances.

(i) A pharmacist shall be required to renew their controlled substance prescriber registration in accordance with a renewal schedule adopted by the board. A controlled substance prescriber registration shall be deemed void if a pharmacist does not renew their registration in accordance with the renewal schedule adopted by the board.

(ii) A pharmacist shall be required to notify the board, in a manner determined by the board, if they are no longer authorized to prescribe controlled substances pursuant to a consult agreement. Notification shall occur within five business days. A controlled substance prescriber registration shall be deemed void if the pharmacist no longer has a valid consult agreement authorizing the prescribing of a controlled substance. Failure to obtain or maintain a valid controlled substance prescriber registration prohibits a pharmacist from prescribing controlled substances.

(iii) A pharmacist applying for a controlled substance registration shall be an Ohio licensed pharmacist in good standing. The pharmacist shall not be the subject of any current board disciplinary action or have a restricted license. In determining whether to grant a registration, the board may consider any previous disciplinary action.

(iv) The board may deny a registration if the applicant fails to meet any of the required qualifications or if the board finds that issuing a controlled substance registration presents a danger to public safety.

(b) Subject to approval by the United States drug enforcement administration (D.E.A.), prescribe utilizing a valid **mid-level** D.E.A. registration**.~~, which includes either:~~**

~~(i) Obtaining and maintaining a valid registration with the D.E.A.; or~~

~~(ii) If authorized by federal law or regulation, a pharmacist who is employed as a staff prescriber of a hospital pursuant to a consult agreement who is not individually registered under the provisions of the controlled substances act and, therefore, does not possess a D.E.A. registration, may administer, dispense, and prescribe controlled~~

~~**substances, as specified in a consult agreement, under the registration of the hospital. A hospital that authorizes a pharmacist to dispense or prescribe under its registration shall assign a specific internal code number for each managing pharmacist so authorized.**~~

(c) ~~**Unless a pharmacist utilizes a hospital's D.E.A. registration,**~~ **F**ailure to obtain or maintain a valid D.E.A. registration shall prohibit a **collaborating** ~~**managing**~~ pharmacist from prescribing controlled substances.

(d) A **collaborating** pharmacist that obtains a valid registration with the D.E.A. pursuant to paragraph (C)(6)(b)~~**(i)**~~ of this rule shall:

(i) Submit the pharmacist's registration information, in a manner determined by the board, within thirty days of issuance.

(ii) Submit any changes to a pharmacist's registration, in a manner determined by the board, within thirty days of any change to the registration.

(7) A prescription, to be valid, must be issued for a legitimate medical purpose by a pharmacist authorized pursuant to a consult agreement. The responsibility for the proper prescribing is upon the **collaborating** ~~**managing**~~ pharmacist, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be considered a violation of this rule and may be subject to disciplinary action in accordance with Chapter 4729. of the Revised Code or any rule promulgated thereunder.

(D) Therapy management by formulary. The requirements of this chapter and section 4729.39 of the Revised Code do not apply within an institutional facility when the pharmacists are following the requirements of a formulary system that was developed pursuant to section 4729.381 of the Revised Code.

(E) Review of consult agreements. Upon the request of the state board of pharmacy, a pharmacist shall immediately provide a consult agreement and any relating policies or

documentation pursuant to this rule and division (D)(3) of section 4729.39 of the Revised Code. The state board of pharmacy may prohibit the execution of a consult agreement if the board finds any of the following:

(1) The agreement does not meet the requirements set forth in section 4729.39 of the Revised Code or this chapter of the Administrative Code; or

(2) The agreement, if executed, would present a danger to patient safety.

Rule 4729:1-6-03 | Standards for managing drug therapy. (AMEND)

(A) A **collaborating ~~managing~~** pharmacist shall prescribe in accordance with a valid prescriber-patient relationship. This includes, but is not limited to, the following:

(1) Reviewing a thorough history of the patient;

(2) Except as provided in paragraphs (F) and (G)(2) of this rule, conducting an initial consultation with the patient via in-person meeting, video conference, or by telephone **in accordance with all state and federal laws, rules, and regulations**;

(3) Ordering tests **that are related to the drug therapy being managed** and evaluation of test results in accordance with section 4729.39 of the Revised Code;

(4) Prescribing medication in accordance this division of the Administrative Code, ruling out the existence of any recognized contraindications;

(5) Consulting with the **~~authorizing~~** practitioner **or practitioners ~~on~~ who authorized** the consult agreement when necessary; and

(6) Documenting these steps in the patient's medical record.

(B) The pharmacist's prescriptive authority shall not exceed what is specified in the consult agreement.

(C) A **collaborating ~~managing~~** pharmacist shall comply with the same requirements for the prescribing dangerous drugs pursuant to Chapter 4731 of the Administrative Code.

(D) A pharmacist**~~, as part of an opioid treatment program licensed by the state,~~** may administer controlled substance narcotics pursuant to a consult agreement in accordance with this division of the Administrative Code for the maintenance or detoxification treatment of **~~opioid addiction~~ opioid-use disorder**.

(E) Except as provided in paragraphs (F) and (G)(1) of this rule, a **collaborating ~~managing~~** pharmacist shall, at a minimum, conduct a follow-up consultation with the patient on an annual basis. The review shall be conducted via in-person meeting, video conference**,** or by telephone and shall be documented in the patient's medical record.

(F) Paragraphs (A)(2) and (E) of this rule do not apply to the inpatient management **of** a patient's drug therapy pursuant to a consult agreement in an institutional facility.

(G) A hospital, clinic**,** or other healthcare facility that utilizes **collaborating ~~managing~~** pharmacists for the purposes of authorizing prescriptions that were originally issued by a consulting practitioner shall comply with the following:

(1)

(a) A **collaborating ~~managing~~** pharmacist, consulting practitioner, or agent of the consulting practitioner shall, at a minimum, conduct a follow-up consultation with the patient on an annual basis. The review shall be conducted via in-person meeting, video conference**,** or by telephone and shall be documented in the patient's medical record.

(b) The required follow-up consultation with patients pursuant to paragraph (G)(1)(a) of this rule does not apply if the patient, or an individual authorized to act on behalf of a patient, elects to opt-out of the follow-up consultation.

(2) The initial consultation requirement by a **collaborating ~~managing~~** pharmacist is not required if the **collaborating ~~managing~~** pharmacist is only engaged in the authorization of prescriptions.

(3) In addition to the communication requirements in paragraph (C) of rule 4729:1-6-01 of the Administrative Code, the hospital, clinic**,** or healthcare facility shall:

(a) Obtain patient consent specifically authorizing the use of **collaborating ~~managing~~** pharmacists to authorize prescriptions pursuant to a consult agreement.

(b) Provide contact information, either electronically or in writing, of the person or persons at the hospital, clinic**,** or other healthcare facility who are responsible for answering questions regarding the patient's drug therapy.

(4) Notwithstanding any other provision of the Administrative Code, all prescriptions authorized pursuant to this paragraph shall include the name of the **collaborating ~~managing~~** pharmacist authorizing the prescription and the telephone number where the **collaborating ~~managing~~** pharmacist can be personally contacted during normal business hours.

(5) **Collaborating ~~managing~~** pharmacists authorizing prescription refills in accordance with this paragraph shall utilize an electronic health records system that complies with the following:

(a) The system shall provide **collaborating ~~managing~~** pharmacists and consulting practitioner with real-time access to the patient's complete medical record maintained by the consulting practitioner, including patient lab results and prescriber and pharmacist notes.

(b) The electronic health records system shall have the capability to allow communication between **collaborating ~~managing~~** pharmacists and consulting practitioner.

(6) The consult agreement shall include an algorithm that is specific to refill authorizations. The algorithm must include, but is not limited to, the following decision criteria for **collaborating ~~managing~~** pharmacists to follow when conducting prescription refill authorizations:

(a) Required lab results;

(b) Any restrictions or limitations; and

(c) The maximum amount of time between prescriber visits a refill may be authorized based upon prevailing standards of care.

(H) Consult agreements shall not be utilized for the following:

(1) Administration of intravenous dangerous drugs; and

(2) The performance of cosmetic procedures, such as the injection of botulinum toxin or dermal fillers.

Rule 4729:2-3-04 | Dispensing of ~~naloxone~~ overdose reversal drugs by pharmacy interns. (AMEND)

(A) A pharmacy intern under the direct supervision of a pharmacist may dispense ~~**naloxone**~~ **an overdose reversal drugs as defined in rule 4729-8-02 of the Administrative Code** without a prescription to either of the following in accordance with an approved protocol specified in paragraph (B) of rule 4729:1-3-04 of the Administrative Code:

(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**~~ **individual** in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(B) A pharmacy intern under the direct supervision of a pharmacist who dispenses ~~**naloxone**~~ **an overdose reversal drug** pursuant to this rule shall**:**

(1) Instruct the individual to whom ~~**naloxone**~~ **the overdose reversal drug** is dispensed verbally or in writing to summon emergency services as soon as practicable either before or after administering ~~**naloxone**~~ **an overdose reversal drug; and**

(2) Offer to counsel the patient in accordance with rule 4729:5-5-09 of the Administrative Code.

(C) All overdose reversal drugs dispensed pursuant to this rule shall be in packaging that contains the manufacturer's instructions for use.

(D) Nothing in this rule shall prohibit the sale or distribution of an overdose reversal drug by pharmacy personnel in accordance with section 3715.50 of the Revised Code.

~~**(C) Except as provided in paragraph (D) this rule, a pharmacy intern shall provide in-person training, unless the in-person requirement is waived by the board, and written educational materials to the individual to whom naloxone is dispensed that includes all 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 the naloxone dispensed;**~~

~~**(6) Procedures for administering the naloxone dispensed;**~~

~~**(7) Proper storage and expiration of the naloxone dispensed; and**~~

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

~~**(D) Patient training as required by paragraph (C) of this rule is not required if the patient has previously received training and all the following apply:**~~

~~**(1) The patient is offered training and refuses;**~~

~~**(2) The pharmacy intern has documentation confirming training pursuant to this rule has been provided within the previous twelve months;**~~

~~**(3) A pharmacy intern under the direct supervision of a pharmacist who dispenses naloxone pursuant to this rule shall still 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.**~~

~~**(E) A terminal distributor of dangerous drugs shall ensure that all pharmacy interns that dispense naloxone pursuant to this rule are trained on the use of naloxone and can meet the training requirements listed in paragraphs (B) and (C) of this rule.**~~

Rule 4729:2-3-06 | Dispensing of epinephrine ~~autoinjectors~~ by pharmacy interns. (AMEND)

(A) A pharmacy intern under the direct supervision of a pharmacist may dispense epinephrine**, which shall be an epinephrine autoinjector or any other formulation authorized pursuant to Chapter 4729. of the Revised Code,** ~~**autoinjector**~~ without a prescription to either of the following in accordance with an approved protocol specified in paragraph (B) of rule 4729:1-3-06 of the Administrative Code:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs;

(2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code.

(B)

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

(2) A pharmacy intern who dispenses an epinephrine autoinjector to an individual identified in paragraph (A) of this rule shall provide notification of the dispensing to the individual's primary care provider, if known, or to the prescriber who issued the individual the initial prescription for an epinephrine ~~**autoinjector**~~. Notification shall be conducted using one of the following methods that is capable of confirming delivery of the required notification:

(a) Electronic mail;

(b) Interoperable electronic medical records system;

(c) Facsimile;

(d) Electronic prescribing system;

(e) Electronic pharmacy record system;

(f) Documented verbal communication;

(g) Any other method of notification that might reasonably be expected to allow for the confirmed transmission of the required notification.

(C) When a pharmacy intern dispenses ~~**an**~~ epinephrine ~~**autoinjector**~~ pursuant to this rule, the pharmacy intern shall provide to the person receiving the ~~**device**~~ **medication** instruction on the proper method of administering epinephrine ~~**with the device**~~.

(D) A terminal distributor of dangerous drugs shall ensure that all pharmacy interns that dispense epinephrine ~~**autoinjectors**~~ pursuant to this rule are trained on the use of epinephrine and can meet the training requirements listed in paragraphs (B) and (C) of this rule.

(E) This rule does not affect the authority of a pharmacy intern to contact a prescriber to obtain a new oral prescription for ~~**an**~~ epinephrine ~~**autoinjector**~~ in accordance with the applicable provisions of division 4729:5 of the Administrative Code.

(F) As used in this rule:

(1) "Epinephrine" means an epinephrine autoinjector or any other formulation authorized pursuant to Chapter 4729. of the Revised Code.

(2) "Pharmacy affiliated with the pharmacist" as used in paragraph (A)(1) of this rule means the pharmacy that dispensed the epinephrine autoinjector or another pharmacy under common ownership of the pharmacy that dispensed the epinephrine autoinjector.

Rule 4729:5-3-12 | Protocols and pre-printed orders for medication administration. (AMEND)

(A) A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs pursuant to a protocol. As used in this rule, "protocol" **or "standing order"** means a definitive set of written treatment guidelines with orders for drugs and their specified dosages for administration to individuals under the following circumstances:

(1) The provision of medical services to individuals in an emergency situation when the services of a prescriber authorized by the ~~revised code~~ **Revised Code** to prescribe dangerous drugs as part of their professional practice are not immediately available. An emergency situation may manifest itself by acute symptoms of sufficient severity that an authorized individual providing medical services under this paragraph could reasonably expect the absence of immediate medical attention to result in placing the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Examples of emergency situations includes cases such as heart attacks, severe burns, extravasation, overdoses, cyanide poisonings, electrocutions, or severe asthmatic attacks;

(2) The administration of biologicals or vaccines to individuals for the purpose of preventing diseases;

(3) The administration of vitamin K for prevention of vitamin K deficient bleeding in newborns;

(4) The administration of erythromycin for prevention of ophthalmia neonatorum; ~~and~~

(5) The administration of influenza antiviral treatment and chemoprophylaxis to residents and health care personnel at an institutional facility, as defined in ~~agency 4729~~ **Chapter 4729:5-9** of the Administrative Code, according to current guidance issued by the United States center for disease control and prevention**;**

(6) The administration of contrast and radiopharmaceuticals by radiographers and nuclear medicine technologists in accordance with Chapter 4773. of the Revised Code; and

(7) The administration of glucose to newborns for the management of hypoglycemia.

(B) A protocol described in paragraph (A) of this rule shall:

(1) Include a description of the intended recipients to whom the drugs are to be administered; drug name and strength; instructions of how to administer the drug, dosage, and frequency; signature of a prescriber or some other form of positive identification of the prescriber as defined in ~~**agency 4729**~~ **rule 4729:5-1-02** of the Administrative Code; and date of signature **or other form of positive identification used**;

(2) Be administered by an individual authorized by law to administer the drugs;

(3) Be made readily retrievable;

(4) Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care; and

(5) Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of authorization or reauthorization following any modification or amendment.

(C) A terminal distributor of dangerous drugs may distribute or dispense dangerous drugs for administration pursuant to a pre-printed order. As used in this rule, "pre-printed order" means a patient specific and dose specific order for the administration of a specific drug or drugs prescribed by a licensed health care professional authorized to prescribe drugs. The prescriber must complete an assessment and make a diagnosis prior to initiating a pre-printed order in accordance with the prescriber's scope of practice. The pre-printed order may only be initiated upon the order of a prescriber authorized by law to prescribe the drugs listed in the pre-printed orders. The drugs shall be administered by an individual authorized by law to administer the drugs.

(D) A pre-printed order described in paragraph (C) of this rule shall:

(1) Include the name of the patient; drug name and strength; specific instructions of how to administer the drug, dosage, and frequency; instructions of any patient specified dosage range based on objective measures such as calculations and patient physiologic data;

signature of the prescriber or some other form of positive identification of the prescriber as defined in ~~**agency 4729**~~ **rule 4729:5-1-02** of the Administrative Code; and date of signature;

(2) Apply only to those drugs for which the therapeutic dose is significantly lower than the dose expected to cause detrimental adverse effects;

(3) Can be performed without requiring the exercise of medical judgment;

(4) Will lead to results that are reasonably predictable and safe;

(5) Can be performed safely by the individual authorized to administer the drugs and without the need for repeated medical assessments;

(6) Be maintained by the terminal distributor of dangerous drugs for a period of three years from the date of initiation. A pre-printed order which becomes a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph;

(7) Be made readily retrievable;

(8) If performed improperly, would not present a danger of immediate and serious harm to the patient; and

(9) Be reviewed as necessary to ensure patient safety and practice in accordance with acceptable and prevailing standards of care.

(E) Nothing in this rule shall be construed to otherwise prohibit the dispensing or administration of dangerous drugs pursuant to a protocol that is specifically authorized in the Revised Code or agency 4729 of the Administrative Code.

(F) For purposes of this rule, a terminal distributor of dangerous drugs may distribute or dispense dangerous drugs for administration to animals pursuant to a protocol in accordance with the provisions of paragraphs (A) and (B) of this rule or a pre-printed order in accordance with the provisions of paragraphs (C) and (D) of this rule.

Rule 4729:5-3-14 | General security requirements. (AMENDMENT)

(A) All terminal distributors of dangerous drugs shall provide effective controls and procedures to:

(1) Deter and detect the theft and diversion of dangerous drugs; and

(2) Ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to 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.

(B) Substantial compliance with the standards set forth in this division of the Administrative Code may be deemed sufficient by the state board of pharmacy after evaluation of the overall security system and needs of the licensee or applicant. In evaluating the overall security system of a licensee or applicant, the state board of pharmacy may consider any of the following factors, as deemed relevant, for compliance with security requirements:

(1) The type of activity conducted;

(2) Type and form of dangerous drugs handled;

(3) Quantity of dangerous drugs handled;

(4) Location of the premises and the relationship such location bears on security needs;

(5) Type of building construction comprising the facility and the general characteristics of the building or buildings;

(6) Type of vaults, safes, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;

(7) Type of closures on vaults, safes, and secure enclosures;

(8) Adequacy of key control systems and/or combination lock control systems;

(9) Adequacy of electronic detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;

(10) Extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;

(11) Adequacy of supervision over authorized employees having access to areas containing dangerous drugs;

(12) Procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel; and

(13) Adequacy of the licensee's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of dangerous drugs in its operation.

(C) When physical security controls become inadequate as a result of a significant increase in the quantity of dangerous drugs in the possession of the licensee during normal business operation, the physical security controls shall be expanded and extended accordingly.

(D) Any applicant seeking to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in this division of the Administrative Code may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the state board of pharmacy.

(E) No pharmacy engaged in the dispensing of dangerous drugs shall operate out of a residence or personal dwelling.

Rule 4729:5-3-15 | Use of hospital and other institution D.E.A. registrations. (AMEND)

~~**(A) As used in this rule, "hospital or other institution" has the same meaning as in Part 1301 of the Code of Federal Regulations.**~~

(~~**B**~~ **A**) A prescriber who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, personally furnish, or prescribe controlled substances under the "Drug Enforcement Administration" (D.E.A.) registration of the hospital **or other institution in accordance with 21 CFR Part 1301.22 (March 24, 1997)**.

(~~**C**~~ **B**) A person pursuing an approved training program within the jurisdiction of the hospital or other institution and authorized to write prescriptions pursuant to paragraph (B) of rule 4729:5-1-02 of the Administrative Code may administer, personally furnish, or prescribe controlled substances under the registration of the hospital or other institution. Persons pursuing such approved training programs may function in sites outside the physical confines of the hospital or other institution only if such sites are part of the training program and the persons are under the employment and jurisdiction of the hospital or other institution administering the approved program. While functioning in the outside sites, such persons may continue to use the internal code assigned by the hospital or other institution administering the approved program, upon mutual agreement of the hospital or other institution and the outside site.

(~~**D**~~ **C**) The administering, personally furnishing, or prescribing must be done in the usual course of the person's professional practice and only within the scope of the person's employment in the hospital or other institution.

(~~**E**~~ **D**) Each person so authorized must be assigned a specific internal code number by the hospital or other institution 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~~,~~ **;** shall be preceded by a hyphen~~,~~ **;** and no more than ten characters in length, excluding the hyphen. A current list of the internal codes and the corresponding individual prescribers must be kept by the hospital or other institution 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.

A current list of internal codes and the corresponding individual prescribers shall be filed with the state board of pharmacy, in a manner and format determined by the board. Additions, deletions**,** or changes to the list must be submitted to the state board of pharmacy within ten business days of any such addition, deletion**,** or change.

(~~F~~ **E**) A pharmacist practicing under a consult agreement, as authorized in section 4729.39 of the Revised Code, shall not prescribe controlled substances under the registration of the hospital or other institution.

Rule 4729:5-3-16 | Returned drugs. (AMEND)

(A) No drug that has been dispensed pursuant to a prescription or personally furnished by a prescriber and has left the physical premises of the terminal distributor of dangerous drugs shall be returned to the terminal distributor or dispensed or personally furnished again, except as follows:

(1) Drugs dispensed for inpatients, as defined in ~~**agency 4729**~~ **Chapter 4729:5-9** of the Administrative Code, or personally furnished to inpatients provided that:

(a) The drugs are packaged in unopened, single-dose or tamper-evident containers; and

(b) The drugs have not been in the possession of the ultimate user.

(2) Drugs dispensed for inpatients, as defined in ~~**agency 4729**~~ **Chapter 4729:5-9** of the Administrative Code, in accordance with rule 4729:5-9-02.11 of the Administrative Code.

(3) Drugs dispensed for outpatients in accordance with rules 4729:5-5-22**,** ~~**and**~~ 4729:5-5-18**, and 4729:5-3-24** of the Administrative Code.

(4) Drugs dispensed for patients, which have not been dispensed or personally furnished directly to the ultimate user, that require further manipulation prior to administration.

(5) Drugs donated to a drug repository program in accordance with Chapter 4729:5-10 of the Administrative Code.

(6) Drugs returned for destruction or disposal in accordance with division 4729:10 of the Administrative Code and rule 4729:5-5-14 of the Administrative Code.

(7) Hazardous drugs for destruction or disposal in accordance with all applicable federal, state, and local laws, rules, and regulations.

(8) Drugs dispensed in error (e.g., drug dispensed to wrong patient, incorrect drug dispensed, etc.) for destruction or disposal in accordance with all applicable federal, state, and local laws, rules, and regulations.

(B) As used in this rule, "hazardous drug" means any drug listed on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code.

(C) Except as provided in section 4729.43 of the Revised Code, nothing in this rule prohibits a terminal distributor of dangerous drugs from administering a dangerous drug that was dispensed or personally furnished directly to a patient or patient's caregiver.

Rule 4729:5-5-03 | Filing and storage of prescriptions. (NO CHANGE)

All original outpatient prescriptions shall be filed in the following manner:

(A) Prescriptions for schedule II controlled substances shall be maintained in a separate prescription file for schedule II prescriptions.

(B) Prescriptions for schedule III, IV, and V controlled substances shall be maintained in a separate prescription file for schedule III, IV, and V prescriptions.

(C) Prescriptions for non-controlled substances shall be maintained in a separate prescription file for non-controlled prescriptions.

(D) Prescriptions containing multiple drug orders shall be filed in the most restrictive file.

(E) All non-controlled hard copy prescriptions, including facsimiles, maintained pursuant to this rule may be electronically maintained, provided that the system creates and maintains electronic records in accordance with the following:

(1) All hard copy prescriptions for non-controlled dangerous drugs may be electronically filed and then destroyed after one hundred and eighty days from the date of creation or receipt. Disposal of the hard copy shall use a secure method of destruction to ensure privacy and confidentiality of the contents.

(2) All hard copy prescriptions electronically filed in accordance with this rule shall be scanned front and back in full color (i.e., retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user. Prior to scanning, the written or faxed prescription shall be clearly notated to indicate it has been received by the pharmacy in a manner that does not destroy any of the original information contained on the prescription but prevents the unauthorized duplication of the prescription.

(3) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted.

(4) The electronic form shows the exact and legible image of the original hard copy prescription.

(5) All hard copy prescriptions filed electronically in accordance with this rule shall be deemed the original prescription.

(F) All electronically transmitted prescriptions, including faxed prescriptions received in an electronic format, shall be electronically stored and maintained in accordance with this rule.

(G) All electronic systems used to maintain prescription images or data shall:

(1) Contain security features to prevent unauthorized access to the records; and

(2) Contain daily back-up functionality to protect against loss of records.

(H) All prescription records stored in accordance with this rule shall be uniformly maintained for a period of three years.

(I) An outpatient pharmacy shall ensure that original prescriptions are properly filed in compliance with this rule and rule 4729:5-5-13 of the Administrative Code.

Rule 4729:5-5-05 | Prescription format requirements. (AMEND)

(A) Except as provided in paragraph (E) of this rule, 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 4729:5-5-15 of the Administrative Code.

(2) If handwritten, typewritten, or computer-generated hard copy, there are no more than three non-controlled 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; **and**

(b) There is only one prescription order selected per form.

(B) Except as provided in paragraph (E) of this rule, 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 4729:5-5-15 of the Administrative Code.

(2) The prescription contains only one prescription order per prescription form, whether handwritten, typewritten, computer-generated hard copy, 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 described in rule 4729:5-1-02 of the Administrative Code may not be dispensed unless the prescription is issued in accordance with this rule and complies with the requirements for drug enforcement administration (D.E.A.) registration numbers for hospital and other institution employed prescribers pursuant to ~~**agency 4729**~~ **4729:5-3-15** of the Administrative Code.

(D) A prescription for a controlled substance issued by a staff prescriber of a hospital or other institution may not be dispensed unless the prescription is issued in accordance with this rule and complies with either:

(1) The requirements for D.E.A. registration numbers for hospital or other institution employed prescribers pursuant to ~~**agency 4729**~~ **4729:5-3-15** of the Administrative Code; or

(2) Includes the prescriber's D.E.A. registration number.

(E) For purposes of preprinted outpatient prescription forms for hospice care programs, 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 the form.

(2) Preprinted forms shall not contain prescription orders for schedule II controlled substances. Schedule II controlled substances 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 controlled substances.

(7) All schedule II controlled substance prescriptions shall comply with 21 C.F.R. 1306.11 (~~**3/31/2010**~~ **March 31, 2010**).

Rule 4729:5-5-07 | Patient profiles. (AMEND)

All outpatient pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from the pharmacy.

(A) All patient profile systems shall maintain, at a minimum, the following data:

(1) The patient's data record, which shall contain all the following information:

(a) Full name of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals.

(b) Residential address, including the physical street address and telephone number of the patient or owner.

(c) Patient's date of birth.

(d) Patient's gender.

(e) A list of current patient-specific data consisting of at least the following, if made known to the pharmacist or agent of the pharmacist:

(i) Drug related allergies;

(ii) Previous drug reactions;

(iii) History of or active chronic conditions or disease states; and

(iv) Other drugs, including nonprescription drugs, devices, and nutritional supplements used on a routine basis.

(f) The pharmacist's comments relevant to the patient's drug therapy, including any other necessary information unique to the specific patient or drug.

(2) The patient's drug therapy record, which shall contain the following information for all prescriptions dispensed by the pharmacy within the last twelve months:

(a) The original prescription number.

(b) Date of issuance of the original prescription by the prescriber.

(c) Full name and address of the prescriber, including the physical address of the prescriber's practice location.

(d) The prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription.

(e) Directions for use.

(f) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed.

(g) The strength, dosage form, and quantity of the drug or device dispensed.

(h) The prescriber's federal drug enforcement administration registration number, if applicable.

(i) The total number of refills authorized by the prescriber.

(j) The date of dispensing.

(k) The refill history of the prescription, including all the following:

(i) The prescription number;

(ii) The brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed;

(iii) The date(s) of dispensing; and

(iv) The quantity dispensed.

(B) A pharmacist or an agent of the pharmacist shall make a reasonable effort to obtain a patient's medical history necessary to conduct a prospective drug utilization review. An agent of the pharmacist described in this paragraph shall be limited to the following persons: a pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(C) The patient profile shall be maintained for a period of not less than one year from the date of the last entry in the profile record. This record may be a hard copy or maintained as a part of computerized system.

Rule 4729:5-5-08 | Prospective-Drug utilization review. (AMEND)

(A) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying the following:

(1) Over-utilization or under-utilization;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment; and

(9) Food-nutritional supplements-drug interactions.

(B) Upon identifying any issue listed in paragraph (A) of this rule, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include, but shall not be limited to, the following:

(1) Requesting and reviewing an OARRS report or another state's prescription drug monitoring report;

(2) Consulting with the prescriber; or

(3) Counseling the patient.

(C) Prospective drug utilization review shall be performed using predetermined standards consistent with, but not limited to, any of the following:

(1) Peer-reviewed medical literature (i.e., scientific, medical, and pharmaceutical publications in which original manuscripts are rejected or published only after having been critically reviewed by unbiased independent experts);

(2) American hospital formulary service drug information; and

(3) United States pharmacopeia drug information.

(D) Prior to dispensing an outpatient prescription for a controlled substance dangerous drug or a drug containing gabapentin, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period in any of the following circumstances:

(1) A patient adds a new or different controlled substance dangerous drug or a drug containing gabapentin to the patient's therapy that was not previously included;

(2) An OARRS report has not been reviewed for that patient during the preceding twelve months, as indicated in the patient profile;

(3) A prescriber is located outside the usual pharmacy geographic area;

(4) A patient is from outside the usual pharmacy geographic area;

(5) A pharmacist has reason to believe the patient has received prescriptions for controlled substance dangerous drugs or a drug containing gabapentin from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location;

(6) Patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a controlled substance dangerous drug, or an unfamiliar patient requesting a reportable drug by specific name, street name, color, or identifying marks.

(E) In the event an OARRS report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to reviewing a report.

(F) A pharmacist may use a delegate licensed or registered in accordance with Chapter 4729. of the Revised Code to request an OARRS report.

(G) Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the

legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

Rule 4729:5-5-09 | Patient counseling. (NO CHANGE)

(A) A pharmacist or the pharmacist's designee shall verbally offer to provide the service of counseling pursuant to paragraph (B) of this rule to a patient or caregiver whenever any prescription, new or refill, is dispensed. A pharmacist or pharmacy intern under the personal supervision of a pharmacist 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. If the patient or caregiver is not physically present, the offer to counsel shall be made by telephone or in writing on a separate document accompanying the dispensed drug or incorporated as part of documentation, in a conspicuous manner, that is included with the dispensed drug. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population.

(B) In the event a patient or caregiver accepts an offer to counsel or requests counseling, a pharmacist~~,~~ or a pharmacy intern under the personal supervision of a pharmacist~~,~~ shall counsel the patient or caregiver. Such counseling may include, but is not limited to, the following:

(1) The name and description of the drug;

(2) The dosage form, dose, strength, frequency, route of administration, and duration of drug therapy;

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

(4) Special directions and precautions for preparation, administration, handling, storage, disposal, and use by the patient;

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

(6) Techniques for self-monitoring drug therapy;

(7) Proper storage and disposal;

(8) Prescription refill information;

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

(10) The pharmacist's comments relevant to the patient's drug therapy, including other necessary information unique to the patient or drug.

(C) Other forms of information may be used when appropriate to supplement the counseling by the pharmacist or intern. Examples of forms that may be used include, but are not limited to, drug product information leaflets, pictograph labels, and video programs.

(D) Notwithstanding any other rule of agency 4729 of the Administrative Code, "personal supervision," as used in paragraph (B) of this rule, means that a pharmacist is on the premises at all times and is aware of all counseling activities performed by the pharmacy intern. A pharmacist who has accepted responsibility for the supervision and training of a pharmacy intern is responsible for all acts performed by the pharmacy intern working under the pharmacist's supervision.

Rule 4729:5-5-10 | Manner of processing a prescription. (AMEND)

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

(B) A pharmacist dispensing an outpatient prescription shall comply with the requirements of this chapter, including, but not limited to, the following:

(1) Ensure that patient information is profiled pursuant to rule 4729:5-5-07 of the Administrative Code;

(2) Perform prospective drug utilization review pursuant to rule 4729:5-5-08 of the Administrative Code; and

(3) Ensure that the drug is labeled pursuant to rule 4729:5-5-06 of the Administrative Code.

(C) Prescriptions:

(1) The front of hard copy prescriptions for controlled substance dangerous drugs shall be clearly notated to indicate receipt by the pharmacy in a manner that does not destroy any of the original information contained on the prescription but prevents the unauthorized duplication of the prescription.

(2) When a pharmacist dispenses a drug pursuant to an original prescription, the pharmacist must record the date of such dispensing and the pharmacist's positive identification.

(3) When a pharmacist dispenses a drug pursuant to an authorized refill of a prescription, the pharmacist must record the date of such dispensing and the pharmacist's positive identification.

(D) Oral prescriptions:

(1) A pharmacist shall make a record of the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for ensuring the validity of the source of the oral prescription.

(2) Upon receiving a prescription from a recording device or voice mail service, a pharmacist shall transcribe the information. The pharmacist must document on the original prescription the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent. The pharmacist is responsible for ensuring the validity of the prescription removed from the recording device or voice mail service.

(3) A licensed pharmacy intern may receive telephone prescriptions and remove prescriptions from a recording device or voice mail service if the pharmacist on duty who is personally supervising the activity of the intern determines that the intern is competent to perform this function.

(a) The intern shall immediately transcribe the prescription, document the full name of the prescriber and, if transmitted by the prescriber's agent, the full name of the agent and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the intern and the pharmacist on duty shall be recorded to identify the responsibility for the receipt of the oral order.

(b) The pharmacist on duty is responsible for the accuracy of the prescription.

(c) The pharmacist on duty must be immediately available to answer questions or discuss the prescription with the prescriber or the prescriber's agent.

(4) A certified pharmacy technician may receive telephone prescriptions and remove prescriptions from a recording device or voice mail service for non-controlled drugs in accordance with rule 4729:3-3-04 of the Administrative Code.

(E) Facsimile prescriptions:

A facsimile shall only be valid as a prescription if a pharmacy retains a printed copy of a facsimile prescription or an electronic copy of the facsimile prescription in accordance with

rule 4729:5-5-03 of the Administrative Code. The facsimile prescription shall comply with the requirements of rule 4729:5-3-11 of the Administrative Code.

(F) Electronic prescriptions:

(1) A pharmacy receiving electronic prescriptions directly into its computer system shall ensure original prescription information received from the prescriber is maintained in accordance with rule 4729:5-5-03 of the Administrative Code.

(2) A pharmacy computer system receiving electronic prescriptions shall:

(a) Comply with the applicable provisions of 21 C.F.R. 1311 (**August 28, 2025**); and

(b) Have the capability to receive an ICD-10-CM medical diagnosis code for all controlled substance prescriptions pursuant to rule 4729:5-5-15 of the Administrative Code.

(G) Except as provided for in section 4729.46 of the Revised Code, a pharmacist shall not dispense a dangerous drug for the first time beyond six months from the date of issuance of a prescription.

(H) The quantity prescribed shall be considered the quantity dispensed, unless the quantity dispensed meets any of the following:

(1) If the dispensed prescription is less than the quantity prescribed, the pharmacist shall note the quantity dispensed on the original prescription or within a computerized recordkeeping system.

(2) If the quantity dispensed on a prescription is greater than the quantity prescribed, the pharmacist shall record on the original prescription or within a computerized recordkeeping system the name of the authorizing prescriber, the full name of the agent of the prescriber, if applicable, the quantity authorized to be dispensed, and the date that the authorization was obtained.

(3) A prescription dispensed in accordance with section 4729.40 of the Revised Code. The pharmacist shall note the quantity dispensed on the original prescription or within a computerized recordkeeping system.

(I) Where a prescription is written using a generic name, or where the pharmacist dispenses an equivalent drug product pursuant to the provisions of sections 4729.38 and 4729.381 of the Revised Code, the brand name or drug name and name of the manufacturer or distributor of the drug or the national drug code (NDC) number of the drug dispensed must be recorded in the record of dispensing by the pharmacist.

(J)

(1) A prescription issued by a prescriber who experiences a change of status, as defined in paragraph (J)(2) of this rule, that precludes a continued prescriber-patient relationship may be dispensed by a pharmacist in accordance with the following:

(a) In the exercise of the pharmacist's professional judgment:

(i) The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient; or

(ii) Failure to dispense the drug to the patient could result in harm to the health of the patient.

(b) The prescription was issued prior to the prescriber's change of status, as defined in paragraph (J)(2) of this rule, and in accordance with all applicable provisions of state and federal laws, rules, and regulations.

(c) For a non-controlled substance prescription, a pharmacist may dispense up to a thirty-day supply as provided in the prescription or, if the standard unit of dispensing for the drug exceeds a thirty-day supply, the amount of the drug dispensed shall not exceed the standard unit of dispensing. The pharmacist shall exercise professional judgment in determining the amount of the drug to be dispensed.

(d) For a controlled substance prescription, a pharmacist may dispense up to a seventy-two-hour supply as provided in the prescription. The pharmacist shall exercise professional judgment in determining the amount of the drug to be dispensed.

(2) A change of status includes, but is not limited to, the following: death, incapacity, suspension, surrender or revocation of the prescriber's license or registration, or permanent relocation.

(3) A prescription for a dangerous drug dispensed in accordance with paragraph (J)(1) of this rule is considered void after the initial dispensing and may not be dispensed again. Following the initial dispensing of the drug, a pharmacist shall utilize a manual or electronic method for invalidating the prescription to prevent further dispensing.

(K) A valid prescription for a schedule II controlled substance may be partially dispensed by a pharmacist in compliance with 21 CFR 1306.13 (July 21, 2023).

Rule 4729:5-5-11 | Prescription transfers. (NEW) (RESCIND CURRENT)

(A) An outpatient pharmacy may transfer prescriptions in accordance with the following:

(1) Prescriptions may only be transferred between pharmacists, except as follows:

(a) Pharmacy interns may transfer non-controlled prescriptions in accordance with paragraph (H) of this rule; and

(b) Certified pharmacy technicians may transfer non-controlled prescriptions in accordance with rule 4729:3-3-04 of the Administrative Code.

(2) Transfers of controlled substance prescriptions shall be communicated directly between two pharmacists in accordance with all applicable federal regulations.

(B) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(C) Transfers are subject to the following requirements:

(1) The transferring pharmacist, pharmacy intern, or certified technician shall do the following:

(a) Write the word “VOID” on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.

(b) Record on the reverse of the invalidated prescription the name, address, name of the pharmacist, pharmacy intern, or certified technician receiving the prescription information, and, if applicable, the DEA registration number of the pharmacy to which it was transferred; for electronic prescriptions, such information must be added to the prescription record.

(c) Record the date of the transfer and the name of the pharmacist, pharmacy intern, or certified pharmacy technician transferring the information.

(d) Ensure copies of controlled substance prescriptions may only be transferred if the prescription record in the system is invalidated to prevent further dispensing at the original pharmacy.

(2) For paper prescriptions and prescriptions received orally and reduced to writing, the pharmacist, pharmacy intern, or certified pharmacy technician receiving the transferred prescription information must write the word “transfer” on the face of the transferred prescription and reduce to writing all information required to be on a prescription pursuant to rule 4729:5-5-15 of the Administrative Code and include:

(a) Date of issuance of original prescription;

(b) Original number of refills authorized on original prescription.

(c) Date of original dispensing.

(d) Number of valid refills remaining and date(s) and locations of previous refill(s).

(e) Pharmacy's name, address, DEA registration number if transferring a controlled substance, and the serial prescription number from which the prescription information was transferred.

(f) The full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(g) Pharmacy's name, address, DEA registration number if transferring a controlled substance, and the serial prescription number from which the prescription was originally filled.

(3) For electronic prescriptions being transferred electronically, the transferring pharmacist, pharmacy intern, or certified pharmacy technician shall provide the receiving pharmacist, pharmacy intern, or certified pharmacy technician with the following information in addition to the original electronic prescription data as required by rule 4729:5-5-15 of the Administrative Code:

(a) The date of the original dispensing.

(b) The number of refills remaining and the date(s) and locations of previous refills.

(c) The transferring pharmacy's name, address, DEA registration number if transferring a controlled substance, and prescription number for each dispensing.

(d) The full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(e) The name, address, DEA registration number if transferring a controlled substance, and prescription number from the pharmacy that originally filled the prescription, if different.

(f) The contents of the prescription shall not be altered during transfer between pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(D) A prescription may be transferred by the use of a facsimile machine. A facsimile shall be considered a copy of the prescription if it meets the requirements of paragraph (C)(1) and (C)(2) of this rule, including invalidation of the original prescription. Facsimile copies must be recorded in writing pursuant to section 4729.37 of the Revised Code or stored in such a manner that will allow retention of the prescription record for three years from the date of the last transaction.

(E) Information on a prescription is the property of the patient and is intended to authorize the dispensing of a specific amount of medication for use by the patient.

(1) If the pharmacy is not able to provide the medication when needed by the patient pursuant to an authorized refill, the pharmacy shall, upon the request of the patient or patient's caregiver, transfer the prescription information to a pharmacy designated by the patient.

(2) Unless otherwise prohibited by law, no pharmacy shall refuse to transfer information about a prescription to another pharmacy when requested by the patient**, ~~or~~** patient's caregiver**, or pharmacy acting upon the request of the patient or patient's caregiver**.

Prescription information shall be transferred in accordance with this rule as soon as possible ~~to~~, but no later than three business days, **to** ensure that the patient's drug therapy is not interrupted.

(3) A prescription may only be transferred upon the request or consent of the patient or patient's caregiver.

(F) The transfer for initial dispensing of an electronic prescription for a controlled substance in Schedule II-V is permissible between pharmacies, upon request from the patient, on a one-time basis only. If the transferred prescription is for a controlled substance in Schedule III, IV, or V and includes authorized refills, the refills are transferred with the initial prescription to the pharmacy receiving the transfer.

(G) The transfer of an electronic prescription between pharmacies for the purpose of initial dispensing is subject to the following requirements:

(1) The prescription must be transferred from one pharmacy to another pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription for a controlled substance to another form (*e.g.,* facsimile) for transmission.

(2) The contents of the prescription shall not be altered during transfer between pharmacies. Any change to the content during transfer, including truncation or removal of data, will render the electronic prescription invalid.

(3) For controlled substances, the transfer must be communicated directly between two licensed pharmacists.

(4) The transferring pharmacist, pharmacy intern, or certified pharmacy technician must add the following to the electronic prescription records maintained by the transferring pharmacy:

(a) Information that the prescription has been transferred.

(b) The name, address, the name of the pharmacist, pharmacy intern, or certified pharmacy technician receiving the prescription information, and, if transferring a controlled substance, the DEA registration number of the pharmacy to which the prescription was transferred.

(5) The receiving pharmacist, pharmacy intern, or certified pharmacy technician shall do the following:

(a) Add the word “transfer” to the electronic prescription record at the receiving pharmacy.

(b) Annotate the prescription record with the name, address, and, if receiving a controlled substance, the DEA registration number of the pharmacy from which the prescription was transferred.

(c) Record the full name of the transferring pharmacist or, if transferred by a pharmacy intern or certified pharmacy technician, the full name of the transferring pharmacy intern or certified pharmacy technician and the pharmacist on duty who is supervising the activity of the intern or technician.

(c) Record the date of the transfer and the name of the pharmacist, pharmacy intern, or certified pharmacy technician receiving the prescription information.

(6) In lieu of manual data entry, the transferring or receiving pharmacy's prescription processing software may, if capable, capture the information required, as outlined in this paragraph, from the electronic prescription and automatically populate the corresponding data fields to document the transfer of an electronic controlled substance prescription between pharmacies. The transferring or receiving pharmacist, as applicable, must ensure that the populated information is complete and accurate.

(F) Transfer of prescription information between two pharmacies which are accessing the same real time, online database pursuant to the operation of a licensed central fill pharmacy shall not be considered a prescription transfer and is not subject to the requirements of this rule.

(G) Records documenting the transfer prescriptions shall be maintained for three years from the date of transfer or receipt, in a readily retrievable manner, by both the pharmacy transferring the prescription and the pharmacy receiving the prescription.

(H) A licensed pharmacy intern may transfer and receive transfers for non-controlled prescriptions in accordance with the following:

(1) The pharmacist on duty who is supervising the activity of the intern determines if the intern is competent to engage in such activities.

(2) The pharmacist on duty who is supervising the activity of the intern is responsible for the accuracy of a prescription transfer that is sent or received by the intern.

(3) The pharmacist on duty must be immediately available to answer questions or discuss the prescription transfer that is sent or received by the intern.

(4) The pharmacist or intern receiving a prescription transfer from an intern must document the full names of the intern and the intern's supervising pharmacist who transferred the prescription.

(5) The intern receiving a prescription transfer shall immediately transcribe the prescription and shall review the prescription with the pharmacist on duty. Prior to dispensing, positive identification of the intern and the supervising pharmacist on duty shall be recorded to identify who is responsible for the receipt of the transfer.

(6) The pharmacist or intern transferring a prescription to an intern must document the full names of the receiving intern and the pharmacist on duty.

(7) The intern shall not transfer or receive a transfer for a controlled substance prescription.

(8) The intern and the pharmacist on duty shall comply with all the requirements of this rule.

Rule 4729:5-5-12 | Partial dispensing of schedule II of controlled substances. (RESCIND CURRENT RULE)

Rule 4729:5-5-13 | Serial numbering of prescriptions. (NO CHANGE)

All outpatient prescriptions must be serially numbered when entered into a computer system or when dispensed under a manual system.

(A) The serial number must appear on the original prescription.

(B) There must be a complete accounting of all numbers used in the serial numbering system.

(C) All prescriptions that cannot be refilled, either because of the dispensing of all refills or the length of time since issuance, shall be assigned a new serial number upon an authorization for additional dispensing by a prescriber or prescriber's agent.

Rule 4729:5-5-16 | Pharmacist modifications to a prescription. (AMEND)

(A) For a schedule II controlled substance prescription:

(1) A pharmacist shall not make changes to the drug prescribed, except for substitution permitted by law, the prescriber's signature, or the patient's name.

(2) Any other modification, except for substitution permitted by law, may only be made after consultation with and agreement of the prescriber.

(B) For a schedule III-V controlled substance prescription:

(1) Except as provided for in paragraph (D) of this rule, a pharmacist shall not make changes to the drug prescribed, except for substitution permitted by law, the prescriber's signature, or the patient's name.

(2) Any other modification, except for substitution permitted by law, may only be made after consultation with and agreement of the prescriber or the prescriber's agent.

(C) For a non-controlled substance dangerous drug prescription:

(1) Except as provided for in paragraphs (D) and (E) of this rule, a pharmacist shall not make changes to the drug prescribed, except for substitution permitted by law, the prescriber's signature, or the patient's name.

(2) Any other modification, except for substitution permitted by law or in accordance with paragraph (E) of this rule, may only be made after consultation with and agreement of the prescriber or the prescriber's agent.

(D) Except for a schedule II controlled substance prescription, a pharmacist may correct a patient's name on a prescription after consultation with and agreement of the prescriber or the prescriber's agent.

(E) For a non-controlled substance prescription, a pharmacist may change the dosage form, drug strength, drug quantity, and directions for use without consultation with and agreement of the prescriber or agent of the prescriber in accordance with the following:

(1) The drug selected must be the same drug indicated on the prescription;

(2) The drug selected must have the same frequency and duration of therapy as the drug indicated on the prescription;

(3) The prescription is for a human patient;

(4) No modifications shall be made pursuant to this paragraph if "dispense as written" or another phrase or indicator having a similar meaning is indicated on the prescription;

(5) The pharmacist who selects the drug to be dispensed pursuant to this paragraph shall assume the same responsibility for selecting the dispensed drug as would be incurred in filling a prescription for a drug using the prescribed form; and

(6) The pharmacist shall not substitute between long-acting and short-acting forms of the drug.

(F) A pharmacist may dispense a quantity of a drug in a manner that varies from the prescription in accordance with ~~**paragraph (H) of**~~ rule 4729:5-5-10 of the Administrative Code ~~**or rule 4729:5-5-12 of the Administrative Code**~~ and all applicable federal and state laws, rules, and regulations.

(G) Pursuant to section 4729.391 of the Revised Code, a pharmacist may modify a drug's prescription to also include a drug delivery device, if the pharmacist determines that the device is necessary for the drug's administration.

(**H** ~~**G**~~) All consultations and corresponding changes performed in accordance with this rule shall be noted by the pharmacist on the prescription or in the patient's profile and shall be communicated to the patient or patient's caregiver.

Rule 4729:5-5-17 | Drugs repackaged or relabeled by a pharmacy. (NO CHANGE)

(A) As used in this rule, "repackaging" means the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.

(B) The following rule applies to dangerous drugs repackaged by an outpatient pharmacy. The rule does not apply to any of the following:

(1) Repackaging drug products for use in animals;

(2) Repackaging non-dangerous drug products;

(3) Radiopharmaceuticals as defined in Chapter 4729:5-6 of the Administrative Code;

(4) Repackaging conducted by outsourcing facilities or repackagers licensed in accordance with section 4729.52 of the Revised Code;

(5) Removing a drug product from the original container at the point of care (e.g., patient's bedside) for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient (e.g., drawing up a syringe to administer directly to the patient);

(6) Upon receipt of a valid patient-specific prescription or medication order, a licensed pharmacy removing from one container the quantity of non-sterile drug products (e.g., oral dosage forms) necessary to fill the prescription and placing it in a different container to dispense directly to the patient; and

(7) Investigational new drugs being studied under an investigational new drug application.

(C) Drugs repackaged by an outpatient pharmacy shall comply with the following:

(1) "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities" guidance issued by the United States food and drug administration (January 2017) and any other subsequent repackaging guidance issued by the food and drug administration that is approved by the board;

(2) For sterile compounded drug preparations, United States pharmacopeia chapter <797> as referenced in rule 4729:7-1-01 of the Administrative Code.

(D) Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following:

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

(2) National drug code or universal product code, if applicable, which may be embedded in a bar code or quick response (QR) code on the label;

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

(4) Pharmacy control number;

(5) The beyond-use date of the repackaged drug in accordance with the guidance listed in paragraph (C) of this rule.

(E) All drugs dispensed for outpatient use shall also be labeled in accordance with rule 4729:5-5-06 of the Administrative Code.

(F) A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept in a readily retrievable manner for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include the following:

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

(2) National drug code or universal product code, if applicable, which may be embedded in a bar code or quick response (QR) code on the label;

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

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

(5) Pharmacy control number;

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

(7) The pharmacy's beyond-use date in accordance with the guidance listed in paragraph (C) of this rule;

(8) The positive identification of the individual responsible for the repackaging of the drug; and

(9) The positive identification of the pharmacist conducting the final verification of the repackaged drug to confirm the accuracy of the drug and conformity to the requirements of this rule prior to dispensing or distribution.

(G) A pharmacy that uses supplemental labels that contain a bar code or QR code for the purpose of identifying a repackaged drug shall capture the positive identification of the pharmacist responsible for the following:

(1) Association of the bar code to the drug product; and

(2) Association of the label to the drug product.

Rule 4729:5-5-22 | Return to stock in an outpatient pharmacy. (AMEND)

(A) As used in this rule:

(1) "Pharmacy delivery agent" means an employee of the pharmacy, United States postal service, or common or contract carrier who delivers dangerous drugs that have been dispensed.

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

(B) An outpatient pharmacy may return dangerous drugs to stock shelves that have been dispensed, but have never left the pharmacy (i.e., never picked up by a patient or caregiver) or the control of a pharmacy delivery agent (i.e., never delivered to a patient or caregiver), if the pharmacy complies with all of the following:

(1) The pharmacy has the capability to place the expiration date, as required by this rule, on the prescription label.

(2) The expiration date on the label shall not exceed the expiration date on the manufacturer's container or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If multiple manufacturer containers are used, the expiration date shall not exceed the expiration date on the manufacturer's container that will expire first or one year from the date the drug was originally dispensed and placed in the prescription vial, whichever date is earlier. If the prescription container is the manufacturer's original sealed packaging, the expiration date is the expiration date listed on the packaging.

(3) The dangerous drug products returned to stock shelves shall be maintained in the container in which they were filled and shall maintain their original prescription label containing the original expiration date assigned. The label on the container shall not be removed, altered, or replaced with another label or have any other label added, except as follows:

(a) Adding to or modifying the existing label, if the drug name, dose, and original expiration date are maintained.

(b) Adding a new label over the existing label on the container **or relabeling the container**. In this instance, the drug shall be verified by a pharmacist or an electronic verification system following the application of the new label. The new label shall include the expiration date assigned on the original label.

(c) A prescription label may be removed if the prescription container is the manufacturer's original sealed packaging and the removal of the label does not remove or otherwise cause to make unreadable the expiration date and lot number on the manufacturer's packaging.

(4) The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.

(5) When dispensing a dangerous drug that was previously returned to stock to another patient, a new container shall be used or, in the case of unit dose or unit of use products, all previous patient information shall be removed.

(6) Drugs returned to stock shelves shall be stored in accordance with rule 4729:5-5-02 of the Administrative Code. The pharmacy shall develop and implement a policy to ensure that drugs are maintained by pharmacy delivery agents within temperatures as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(7) In the case of recalls, any drugs returned to stock shelves containing the drug affected by the recall shall be removed from the shelves immediately, unless the lot number can be determined.

(8) A dangerous drug that leaves the prescription department of the pharmacy in the custody of a pharmacy delivery agent may only be returned to stock shelves if the drug meets either of the following prior to initially leaving the prescription department:

(a) Each dangerous drug prescription is dispensed in a tamper evident container or package prior to leaving the pharmacy; or

(b) The dangerous drug prescription is dispensed in the manufacturer's original tamper evident packaging.

(9) A dangerous drug that is dispensed and shows any signs of tampering or adulteration shall not be returned to stock shelves.

(C) A pharmacy may also return drugs to stock shelves if the drugs were dispensed to a terminal distributor of dangerous drugs that is under the same common ownership and control as the pharmacy in accordance with 4729:5-3-24 of the Administrative Code. All drugs returned to stock shelves in accordance with this paragraph shall comply with the requirements of this rule.

(**D** ~~C~~) A dangerous drug that exceeds its assigned expiration date, as described in paragraph (B) of this rule, shall be removed from the area for the storage of drugs used for dispensing and administration in accordance with rule 4729:5-3-06 of the Administrative Code.

(**E** ~~D~~) Non-controlled drugs dispensed by a government entity and delivered for outpatients to a psychiatric outpatient facility or to any service provider licensed as a terminal distributor of dangerous drugs may be returned to stock if all the following apply:

(1) The drugs are packaged in unopened, single-dose or tamper-evident containers; and

(2) The drugs have not been in the possession of the ultimate user.

(**F** ~~E~~) This rule does not apply to drugs dispensed for inpatients pursuant to ~~**agency 4729**~~ **Chapter 4729:5-9** of the Administrative Code. Drugs dispensed for inpatients may be returned to stock in accordance with the applicable provisions of ~~**agency 4729**~~ **Chapter 4729:5-9** of the Administrative Code.

(**G** ~~H~~) A pharmacy may transfer dangerous drugs that are returned to stock shelves that meet the requirements of this rule to another pharmacy if the transfer is conducted in accordance with paragraph (E) of rule 4729:5-3-09 of the Administrative Code.

Rule 4729:5-5-23 | Security, control, and storage of dangerous drugs in an outpatient pharmacy. (AMEND)

(A) The following applies to an outpatient pharmacy licensed as a terminal distributor of dangerous drugs:

(1) Except as provided in paragraph (A)(6) of this rule, a pharmacist shall provide supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, **and** all records relating to the distribution of dangerous drugs, except where the board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code, at all times in order to deter and detect theft or diversion.

(2) The pharmacy shall be separated from the merchandising or public areas.

(3) The pharmacist or pharmacists on duty:

(a) Shall be physically present at the licensed location and responsible for the security of the pharmacy and supervision of pharmacy personnel.

(b) If the pharmacy is located within a store or business, shall ensure that all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacists on duty or secured in a designated area in accordance with paragraph (A)(6)(i) of this rule.

(4) No person, other than a licensed pharmacist, may enter the pharmacy unless the person is on business directly concerning the operation, maintenance, or repair of the pharmacy and a pharmacist employed by the pharmacy is physically present at the same time.

(5) All schedule II controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe and shall not be dispersed through the stock of dangerous drugs. The cabinet or safe shall remain locked and secured when not in use. Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs.

(6) Whenever a pharmacist cannot meet the supervision requirements in paragraph (A)(3)(a) of this rule, security of the pharmacy must be provided in accordance with the following:

(a) The pharmacy must be secured by either:

(i) A physical barrier (i.e.**,** barricade) with suitable locks approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

(ii) An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis **(i.e., twice per year)**. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation. This notification requirement does not apply if a pharmacy also utilizes an approved physical barrier in accordance with paragraph (A)(6)(a)(i) of this rule.

(b) Except as provided in paragraph (A)(6)(i) of this rule, the pharmacy must contain all dangerous drugs, hypodermics, and D.E.A. controlled substance order forms and every other item or product that requires the supervision or sale by a pharmacist.

(c) Only a licensed pharmacist may have access to keys or other methods of gaining access to the pharmacy.

(i) Keys to the pharmacy that are not in the possession of a licensed pharmacist that are maintained on-site shall be secured to prevent unauthorized access.

(ii) All combinations or access codes, including alarm codes, shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(d) All records relating to the distribution of dangerous drugs must be maintained in the pharmacy, except as follows:

(i) The board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code; or

(ii) Any designated area outside the pharmacy used to store records that complies with paragraph (A)(6)(i) of this rule.

(e) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the pharmacy.

(f) Only a pharmacist may have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist.

(g) No prescription, dangerous drug, hypodermic, nor any other item or product that requires the supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the pharmacy is closed.

(h) 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.

(i) Any designated area outside the pharmacy 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, hypodermics, and 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 this chapter of the Administrative Code, and every other item or product that requires the supervision or sale by a pharmacist shall meet the following requirements:

(i) The designated area shall be secured by an approved physical barrier with suitable locks to detect unauthorized entry. Except for extraordinary circumstances beyond the pharmacy's

control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

(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 supervision by a pharmacist.

(iv) No controlled substances may be stored outside of the pharmacy, except as authorized under division 4729:10 of the Administrative Code.

(j) If an outpatient pharmacy provides services by means of a drive-through facility, the drive-through facility shall be constructed and maintained in a manner, and with materials, that secures the premises of the pharmacy from unauthorized access.

(B) Refrigerators and freezers used for the storage of dangerous drugs shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations **(i.e., shall be logged every day even if the facility is closed to the public)**; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs. **A terminal distributor may keep unopened bottled water in the refrigerator to help maintain consistent temperatures.**

(C) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.

Rule 4729:5-5-24 | Drug inventory records and other record keeping provisions. (AMEND)

(A) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received~~,~~ **;** the name and address of the seller~~,~~ **;** the name and address of the recipient~~,~~ **;** ~~**and**~~ the date of receipt**; and a transaction statement if required in accordance with Section 582 of the Food, Drug, and Cosmetic (FD&C) Act (October 1, 2025)**.

(B) Temperature logs maintained in accordance with paragraph (B) of rule 4729:5-5-23 of the Administrative Code shall include either:

(1) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(2) For automated systems that provide temperature monitoring, either of the following:

(a) A report that provides, at a minimum, the date and time of observation and the temperature recorded; or

(b) A report that provides temperature excursions, if any, and the date, time, temperature recorded, and length of the noted excursion.

(C) Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed~~,~~ **;** the date of disposal~~,~~ **;** the method of disposal~~,~~ **;** and the positive identification of the licensed or registered health care professional that performed the disposal.

(D) Records of controlled substance drug disposal shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal, one of whom shall be a pharmacist.

(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient, records shall also include the positive identification of two licensed or registered healthcare professionals conducting and witnessing the disposal.

(E) Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold~~,~~ **;** the address of the location where the drugs were transferred or sold~~;~~ **and** the date of transfer or sale**; and a transaction statement if required in accordance with Section 582 of the Food, Drug, and Cosmetic (FD&C) Act (October 1, 2025).**

(F) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;

(3) Contains security features to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.

(G) All records maintained in accordance with this chapter shall be readily retrievable and uniformly maintained for a period of three years.

(H)

(1) Except as provided for in paragraph (H)(2) of this rule, all records maintained in accordance with this chapter shall be maintained on-site.

(2) An outpatient pharmacy located in this state intending to maintain records at a location other than the location licensed by the state board of pharmacy shall send a request in a manner determined by the board. The board will provide written or electronic notification to the outpatient pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained at the licensed location. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(I) All records required in accordance with this chapter shall comply with the following:

(1) Be maintained under appropriate supervision and control to restrict unauthorized access, including security features to prevent unauthorized access to computerized records; and

(2) All computerized records shall contain daily back-up functionality to protect against record loss.

(J) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.

Rule 4729:3-3-01 | Pharmacy Technician Trainees. (AMEND)

(A) A pharmacy technician trainee shall wear a name tag or badge which contains the designation "Pharmacy Technician Trainee." The required designation may be added to an existing name tag or badge. The name tag or badge and the required designation shall contain lettering of a legible size.

(B) A pharmacy technician trainee may, under the direct supervision of a pharmacist, engage in the following activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment:

(1) Accepting new written, faxed or electronic prescription orders from a prescriber or a prescriber's agent but shall not include verbal orders;

(2) Entering information into and retrieving information from a database or patient profile;

(3) Preparing and affixing labels;

(4) Stocking dangerous drugs and retrieving those drugs from inventory;

(5) Counting and pouring dangerous drugs into containers;

(6) Placing dangerous drugs into containers prior to dispensing by a pharmacist;

(7) Non-sterile drug compounding following the completion of site-specific training pursuant to rule 4729:3-3-02 of the Administrative Code;

(8) Sterile drug compounding following the completion of a site-specific training pursuant to rule 4729:3-3-02 of the Administrative Code;

(9) Packaging and selling a dangerous drug to a patient or patient representative; ~~**and**~~

(10) Sending or receiving electronic prescriptions between pharmacies accessing the same prescription records in a centralized database or pharmacy computers linked in any other manner~~**;**~~ **and**

(11) Stocking automated drug storage systems, floor stock, and crash carts at a location licensed as a terminal distributor of dangerous drugs if either of the following applies:

(a) The terminal distributor utilizes barcode administration for restocking the drugs and develops and implements a quality assurance program to ensure the accuracy of the personnel stocking the dangerous drugs; or

(b) For restocking automated drug storage systems only: a pharmacist verifies the final dispensing of a dangerous drug removed from the automated drug storage system.

(C) A pharmacist is not permitted to supervise more than three pharmacy technician trainees engaging in the activities pursuant to paragraph (B) of this rule at any time, unless otherwise approved by the board.

(D) The number of pharmacy technician trainees supervised by a pharmacist does not limit the number of pharmacy interns that can be supervised by a pharmacist in accordance with rule 4729:2-1-01 of the Administrative Code.

Rule 4729:5-3-13 | Temporary removal of dangerous drugs from a licensed location. (AMEND)

No licensed terminal distributor of dangerous drugs shall engage in the sale or other distribution of dangerous drugs at retail or maintain possession, custody, or control of dangerous drugs for any purpose at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor, except as follows:

(A) A licensed health professional authorized to prescribe drugs may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(B) A person authorized to personally furnish or dispense ~~**naloxone**~~ **an overdose reversal drug** in accordance with ~~**a physician**~~ **an** approved protocol. The ~~**naloxone**~~ **overdose reversal drug(s)** shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The authorized person shall maintain direct supervision and control over the ~~**naloxone**~~ **overdose reversal drug(s)** removed from the terminal distributor. If direct supervision is not provided, the ~~**naloxone**~~ **overdose reversal drug(s)** shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or

distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(C) A licensed health care professional, in accordance with their applicable scope of practice, who provides immunizations or any other non-controlled substance dangerous drugs that may be administered in accordance with a protocol or valid prescriber's order may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(D) An emergency medical service (EMS) organization providing emergency medical services and in accordance with Chapter 4729:5-14 of the Administrative Code.

(E) A veterinarian licensed pursuant to Chapter 4741. of the Revised Code may maintain a supply of dangerous drugs obtained from a licensed terminal distributor of dangerous drugs at another location in order to treat current or prospective patients.

(1) A veterinarian shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(2) Any drugs maintained pursuant to this paragraph are subject to inspection by a board of pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss

reporting, disposal, and inventory requirements of division 4729:5 of the Administrative Code. Records shall be maintained by the terminal distributor of dangerous drugs in accordance with Chapter 4729:5-20 of the Administrative Code.

(3) The responsible person on the terminal distributor of dangerous drugs license from which the drugs are obtained shall be responsible for compliance with the requirements of this paragraph.

(4) A veterinarian maintaining dangerous drugs in accordance with this rule shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs.

(5) The terminal distributor of dangerous drugs shall also maintain the following records for controlled substance dangerous drugs removed from the terminal distributor of dangerous drugs that are stored off-site for more than twenty-four hours: name, strength, dosage form, and quantity of the controlled substance dangerous drugs, the positive identification of the veterinarian who removed the drugs, and the address of the location where the drugs are maintained. Corresponding records shall also be maintained for any controlled substances returned to the terminal distributor's inventory of dangerous drugs from the off-site location.

(6) All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return.

(7) Failure by a veterinarian to exercise supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code or adequate safeguards as required in division (C) of section 4729.55 of the Revised Code shall be deemed a violation of this rule.

(F) A person licensed or certified under Chapter 4765. of the Revised Code may maintain a supply of medical oxygen and/or ~~**naloxone**~~ **overdose reversal drug(s)** obtained from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients in the event of an emergency. The medical oxygen and/or ~~**naloxone**~~ **overdose reversal drug(s)** shall be maintained for an amount of time as determined by written authorization from the licensee's medical director. Medical oxygen and ~~**naloxone**~~ **overdose**

reversal drug(s) shall only be administered in accordance with the licensee's protocol or valid prescriber order. The individuals authorized by ~~to~~ this paragraph shall maintain personal supervision and control over the medical oxygen and/or ~~naloxone~~ **overdose reversal drug(s)** removed from the terminal distributor. If personal supervision is not provided, the medical oxygen and/or ~~naloxone~~ **overdose reversal drug(s)** shall be ~~physically secured in a manner to prevent unauthorized access and shall be~~ stored at temperatures and conditions which will ensure the integrity of the medical oxygen and/or ~~naloxone~~ **overdose reversal drug(s)**prior to its use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(G) A certified officer, as defined in section 4729.533 of the Revised Code, may maintain a supply of dangerous drugs, as authorized in rule 4729:5-15-05 of the Administrative Code, obtained from a licensed terminal distributor of dangerous drugs with a chemical capture classification at another location in order to engage in chemical capture.

(1) A certified officer shall maintain direct supervision and control over the dangerous drugs, equipment, and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs, equipment, and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(2) Any drugs maintained pursuant to this paragraph are subject to inspection by a board of pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss reporting, disposal, and inventory requirements of division 4729:5 of the Administrative Code.

(3) Records shall be maintained by the terminal distributor of dangerous drugs in accordance with Chapter 4729:5-15 of the Administrative Code. The responsible person on the terminal distributor of dangerous drugs license from which the drugs are obtained shall be responsible for compliance with the requirements of this paragraph.

(4) A certified officer maintaining dangerous drugs in accordance with this rule shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs.

(5) The terminal distributor of dangerous drugs shall also maintain the following records for controlled substance dangerous drugs removed from the terminal distributor of dangerous drugs that are stored off-site: name, strength, dosage form, and quantity of the controlled substance dangerous drugs, the positive identification of the certified officer who removed the drugs, and the address of the location where the drugs are maintained. Corresponding records shall also be maintained for any controlled substances returned to the terminal distributor's inventory of dangerous drugs from the off-site location.

(6) All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return.

(7) Failure by a certified officer to exercise supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code or adequate safeguards as required in division (C) of section 4729.55 of the Revised Code shall be deemed a violation of this rule.

(H) An opioid treatment program operating a mobile opioid treatment program in accordance with rule 4729:5-21-05 of the Administrative Code.

(I) An anesthesiologist licensed in accordance with Chapter 4731. of the Revised Code or a dental anesthesiologist that possesses a general anesthesia permit issued under Chapter 4715. of the Revised Code or has obtained provisional general anesthesia privileges in accordance with Chapter 4715. of the Administrative Code, may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within five days (one hundred and twenty hours). The anesthesiologist or dental anesthesiologist shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to

prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(**J**) As used in this rule, "direct supervision" means an individual authorized pursuant to this rule is in the immediate area and within visual range of dangerous drugs and/or hypodermics to deter and detect diversion.

Rule 4729:6-3-02 | Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents. (AMEND)

(A) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the administrative code 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 licensed location:

(1) The state board of pharmacy, by telephone or other method determined by the board, 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 (~~**9/9/2014**~~ **June 22, 2023**);

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

(B) The theft or significant loss of controlled substances by a licensee shall be reported by using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within ~~**thirty**~~ **forty-five** days following the discovery of such theft or significant loss.

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

(2) A request for a waiver of the ~~**thirty**~~ **forty-five**-day limit must be requested in a manner determined by the board.

(C) The theft or significant loss of non-controlled dangerous drugs shall be reported by a licensee to the state board of pharmacy, in a manner determined by the board, within ~~**thirty**~~ **forty-five** days following the discovery of such theft or significant loss of non-controlled dangerous drugs. The report shall be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.

(1) An exemption may be obtained upon sufficient cause if the form cannot be filed within ~~**thirty**~~ **forty-five** days.

(2) A request for a waiver of the ~~**thirty**~~ **forty-five**-day limit must be requested in a manner determined by the board.

(D) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of 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.

(E) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.16 (~~**9/9/2014**~~ **September 30, 2019**) of the theft or loss of DEA form 222.

Rule 4729:5-3-02 | Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents. (AMEND)

(A) A terminal 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 licensed location:

(1) The state board of pharmacy, by telephone or other method determined by the board, 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 (~~**9/9/2014**~~ **June 22, 2023**);

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

(B) The theft or significant loss of controlled substances shall be reported by a licensee using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within ~~**thirty**~~ **forty-five** days following the discovery of such theft or significant loss.

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

(2) A request for a waiver of the ~~**thirty**~~ **forty-five**-day limit must be requested in a manner determined by the board.

(C) The theft or significant loss of non-controlled dangerous drugs shall be reported to the state board of pharmacy, in a manner determined by the board, by the licensee within ~~**thirty**~~ **forty-five** days following the discovery of such theft or significant loss of non-controlled dangerous drugs. The report shall be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.

(1) An exemption may be obtained upon sufficient cause if the form cannot be filed within ~~**thirty**~~ **forty-five** days.

(2) A request for a waiver of the ~~**thirty**~~ **forty-five**-day limit must be requested in a manner determined by the board.

(D) A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of 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.

(E) A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.16 (~~**9/9/2014**~~ **September 30, 2019**) of the theft or loss of any DEA form 222.

Rule 4729:5-4-02 | Duty to Report. (AMEND)

(A) As used in this rule:

(1) "Dishonesty" means any action by a licensee, registrant or applicant to include, but is not limited to, making any statement that deceives, misrepresents or misleads, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in the practice of pharmacy or in the operation or conduct of a pharmacy.

(2) "Dispensing error" or "error in dispensing" has the same meaning as rule 4729:5-3-22 of the Administrative Code.

(3) "Reckless behavior" means a person who acts recklessly or who is reckless. A person acts recklessly when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that the person's conduct is likely to cause a certain result or is likely to be of a certain nature. A person is reckless with respect to circumstances when, with heedless indifference to the consequences, the person disregards a substantial and unjustifiable risk that such circumstances are likely to exist.

(4) "Unprofessional conduct" means conduct that is detrimental to the best interests of the public, including conduct that endangers the health, safety or welfare of a patient or client. Such conduct shall include, but not be limited to, the following acts: coercion, intimidation, harassment, sexual harassment, improper use of private health information, threats, degradation of character, indecent or obscene conduct, and theft.

(B) A pharmacy licensed as a terminal distributor of dangerous drugs shall be required to report, from direct observation or objective evidence, the following to the board in accordance with paragraph (C) of this rule:

(1) Any error in dispensing when the error is the result of reckless behavior.

(2) Any error in dispensing where the error results in any of the following per the "National Coordinating Council for Medication Error Reporting and Prevention Medication Error Index (Revised 2/20/2001)":

(a) Category G: an error occurred that resulted in permanent patient harm.

(b) Category H: an error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest).

(c) Category I: an error occurred that resulted in patient death.

(3) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on an error or errors in dispensing.

(4) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on engaging in unprofessional conduct, dishonesty, or reckless behavior.

(5) The termination or resignation of employment of any individual licensed or registered by the board that was based, in whole or in part, on conduct indicating an individual licensed or registered by the board is practicing pharmacy while physically or mentally impaired by alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.

(6) The receipt of a prescription or medication order where a pharmacist refuses to dispense the prescription or medication order on the basis that it is or is suspected to be fraudulent.

(7) The receipt of an illegitimate product as defined in 21 U.S.C. 360eee (November 27, 2013) and the United States food and drug administration guidance: "definitions of suspect product and illegitimate product for verification obligations under the drug supply chain security act guidance for industry" (March 2023).

(C) Reporting required in accordance with this rule shall be made by mail, using the board's online complaint form (available on the board's website: www.pharmacy.ohio.gov), or telephone and shall include the following information:

(1) For violations listed in paragraphs (B)(1) through (B)(5) of this rule:

(a) The name of the ~~**employer**~~ **pharmacy** and the **pharmacy's** ~~**employer's**~~ terminal distributor license number;

(b) If applicable, the full name and license or registration number of the licensee or registrant for which a report is being made;

(c) If applicable, an explanation of the error in dispensing that occurred, including details regarding any patient harm;

(d) If applicable, an explanation of the circumstances that resulted in the individual's termination or resignation from employment; and

(e) The date(s) of and place(s) of occurrence(s), if known.

(2) For violations listed in paragraphs (B)(6) of this rule:

(a) The name of the pharmacy and the pharmacy's terminal distributor license number;

(b) A description of the prescription or order that is or is suspected to be fraudulent;

(c) Name and address of the issuing prescriber; and

(d) The date the prescription or order was received.

(3) For violations listed in paragraph (B)(7) of this rule, the pharmacy shall submit a copy of the required form FDA 3911 (May 2023).

(D) All reports submitted in accordance with this rule shall protect the confidentiality of patients. The Board may request additional information, including patient information, as part of an investigation conducted in accordance with Chapter 4729. of the Revised Code.

(E) All required reporting shall be submitted to the board no later than:

(1) For an error in dispensing pursuant to paragraphs (B)(1) to (B)(3) of this rule, ten days from the date the quality assurance program review in accordance with rule 4729:5-3-22 of the Administrative Code was completed; and

(2) For the termination or resignation of an employee pursuant to paragraphs (B)(4) and (B)(5) of this rule, ten days from the date the individual is terminated or resigns from employment.

(3) For the receipt of a fraudulent or suspected fraudulent prescription or medication order, ten days from the date the pharmacist refused to dispense the prescription or medication order.

(4) For the receipt of an illegitimate product, twenty-four hours from the date the product is determined, in coordination with the manufacturer, to be illegitimate.

(F) Notwithstanding any provision of agency 4729 of the Administrative Code, a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee shall not be required to make a report to the board pursuant to the applicable duty to report rules in divisions 4729:1, 4729:2, and 4729:3 of the Administrative Code if the licensee or registrant is employed by or under contract with a pharmacy licensed as a terminal distributor of dangerous drugs and the terminal distributor submits a report in accordance with this rule.

(G) In accordance with section 4729.23 of the Revised Code, information submitted to the board in accordance with this rule shall be deemed confidential, is not a public record, and is not subject to discovery in any civil action.

Rule 4729:11-1-01 | Definitions - home medical equipment.

As used in this division:

(A) "24/7 coverage" means that facilities that provide HME services must have a telephone number that is operational twenty-four hours a day, seven days a week that clients can call to seek assistance. The telephone line may be an answering service that is monitored on a regular basis by the HME provider and should also alert clients to contact 911 in an emergency.

(B) "Abandoned application" means an application submitted for licensure or registration where an applicant fails to complete all application requirements within thirty days after being notified of the incomplete application 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 an application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the licensure or registration requirements in effect at the time of reapplication.

An application shall not be deemed abandoned if the application is subject to any of the following:

(1) An administrative proceeding; or

(2) If there is discipline pending against the applicant.

(C) "Accrediting body" means an agency recognized by the board under rule 4729:11-2-04 of the Administrative Code.

(D) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section 3719.011 of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or drugs, or the individual's use or abuse of alcohol or drugs endangers the health, safety, or welfare of the individual or others.

(E) "Board" means the state board of pharmacy.

(F) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(G) "Certificate of registration" or "registration" means a person holding a valid certificate of registration issued under Chapter 4752. of the Revised Code.

(H) "Client" or "patient" means a person who receives HME services from a HME services provider.

(I) "CMS" means the centers for medicare and medicaid services.

(J) "Contact hour" means a period of sixty minutes with a minimum of fifty minutes of instruction. For credit hours earned on an academic quarter system, one credit hour is equivalent to ten contact hours. For credit hours earned on an academic trimester system, one credit hour is equivalent to twelve contact hours. For credit hours earned on an academic semester system, one credit hour is equivalent to fifteen contact hours.

(K) "Disciplinary action" means any of the following by a federal agency or licensing agency of any state or jurisdiction, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement:

(1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration or certification;

(2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action;

(3) An administrative fine or monetary penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand, or probation;

(4) An action to reprimand or place the license, registration, or certification holder on probation;

(5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation, or surrender;

(6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;

(7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation;

(8) The surrender of a license or other relinquishment, registration or certification in lieu of a formal sanction against a person's license, registration or certificate, whether permanent or temporary;

(9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license in the future.

(10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.

(L) "Disqualifying offense" has the same meaning as defined in rule 4729-3-01 of the Administrative Code.

(M) "Expired certificate of registration" means the holder of a certificate of registration under Chapter 4752. of the Revised Code has failed to fulfill all requirements of certificate renewal and has failed to request that the board place the certificate into inactive status.

(N) "Expired license" means the holder of a license under Chapter 4752. of the Revised Code has failed to fulfill all requirements of licensure renewal and has failed to request that the board place the license into inactive status.

(O) "Home medical equipment" or "HME" has the same meaning as defined in section 4752.01 of the Revised Code. Pursuant to division (B)(3) of that section, HME shall also include the following equipment:

(1) Hospital grade pulse oximeters pursuant to a prescription issued by a prescriber;

(2) Home photo therapy (bili lights or blankets);

(3) Individually sized or customized accessories that are an integral part of equipment defined in this paragraph and paragraphs (U) and (EE) of this rule;

(4) Transcutaneous electronic nerve stimulators (TENS), excluding devices labeled by the federal food and drug administration for over-the-counter use and are identified with the federal food and drug administration product code "NUH.OTC TENS";

(5) Drop foot stimulators;

(6) Bone growth stimulators;

(7) Vision restoration therapy devices;

(8) In-home patient lifts;

(9) Life-sustaining equipment as defined in paragraph (U) of this rule; and

(10) Technologically sophisticated medical equipment as defined in paragraph (EE) of this rule.

(P) "Home medical equipment services" or "HME services" has the same meaning as defined in section 4752.01 of the Revised Code.

(Q) "Home medical equipment services provider" or "HME services provider" has the same meaning as defined in section 4752.01 of the Revised Code.

(R) "Inactive status" means the status of a license or registration issued under Chapter 4752. of the Revised Code of a facility that has made a request, in a manner determined by the board, that the board place the license or registration into inactive status. A facility with an inactive license does not hold a current, valid license or certificate of registration under Chapter 4752. of the Revised Code.

(S) "In-service education" means that a continuing education program is offered by a HME service provider organization and not an approved peer review organization.

(T) "Joint commission on accreditation of healthcare organizations," as used in section 4752.12 of the Revised Code, means "the joint commission" or its predecessor organization.

(U) "Life sustaining equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following:

(1) Ventilators;

(2) Oxygen concentrators;

(3) Oxygen liquid systems;

(4) Oxygen compressed gas systems;

(5) Non-invasive ventilator system (e.g. bi-level, iron lungs, rocking beds, diaphragmatic pacers, etc.);

(6) Any other life sustaining equipment as determined by the board.

(V) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions. It also includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

(W) "Place on probation" means to take action against a license or registration for a period of time determined by the board which imposes conditions or other requirements, or suspends or otherwise restricts some or all of the activities in which the licensee or registrant may engage.

(X) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(Y) "Refuse to grant or renew" means to deny original or continued licensure or registration for a period of at least twenty-four months. After twenty-four months, or such period of time

as the individual board order may require, a person licensed or registered by the board or a person seeking to attain such status by licensure or registration, and whose license or registration the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such status by licensure or registration, whose license the state board of pharmacy has refused to grant or renew must meet all requirements established by the board in rule and as may be set forth in the person's board order.

(Z) "Registered" and "licensed" mean that a person has met the initial qualifications for a certificate of registration (registered) or license (licensed) with the state board of pharmacy under Chapter 4752. of the Revised Code and rules adopted thereunder and have complied with renewal procedures, including payment of applicable fees.

(AA) "Revoke" means to take action against a license or registration rendering such license or registration void and such license or registration shall not be reissued. Revoke is an action that is permanent against the licensee or registrant.

(BB) "Staff" means employees or their representatives of a licensee or registrant.

(CC) "Suspend" means to take action against a license or certificate of registration rendering such license or registration without force and effect for a period of time as determined by the state board of pharmacy.

(DD) "Summary suspension" means to take immediate action against a license or registration without a prior hearing rendering such license or registration without force and effect for a period of time as indicated in section 4752.09 of the Revised Code. The board may suspend a license or registration issued pursuant to Chapter 4752. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(EE) "Technologically sophisticated medical equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following:

(1) Oxygen conservation devices;

(2) CPAP (continuous positive airway pressure) devices;

(3) High frequency chest wall oscillators (vests);

(4) Intrapulmonary percussive ventilation (IPV) devices;

(5) Intermittent positive pressure breathing (IPPB) devices;

(6) Cough-assist mechanical in-exsuffaltor;

(7) Apnea monitors;

(8) Percussors for chest physiotherapy;

(9) Suction machines;

(10) Feeding pumps;

(11) Infusion pumps;

(12) Continuous passive motion (CPM) devices;

(13) Custom seating or positioning systems;

(14) Custom rehab equipment (e.g. standers and gait trainers);

(15) Vacuum assisted wound closure devices;

(16) Electric wheelchairs and custom scooters;

(17) Auto-titrating airway devices; ~~**and**~~

(18) Wearable cardioverter defibrillators; and

(~~**18**~~ **19**) Any other technologically sophisticated medical equipment as determined by the board.

4729:3-5-01 **Continuing education – definitions.**

As used in Chapter 4729:3-5 of the Administrative Code.

(A) "A.C.P.E." means the accreditation council for pharmacy education.

(B) "Continuing education unit" or "C.E.U." means ten contact hours of participation in an organized continuing pharmacy education experience presented by an approved provider.

(C) "Continuing pharmacy education" or "continuing education", as required in section 4729.12 of the Revised Code, means post-registration pharmacy education undertaken to maintain professional competency to practice as a pharmacy technician, improve professional skills, and preserve uniform qualifications for continuing the practice of the profession for the purpose of protecting public health and welfare. Continuing pharmacy education may be obtained from any of the following providers:

(1) A pharmacy jurisprudence program pursuant to paragraph (~~D~~E) of this rule;

(2) An approved in-state provider of volunteer healthcare services in accordance with section 4745.04 of the Revised Code and ~~agency 4729~~Chapter 4729-6 of the Administrative Code;

(3) An A.C.P.E. accredited continuing education provider.

(D) "One-third of a licensee's continuing education requirement" as used in division (C) of section 4745.04 of the Revised Code and paragraph (C) of rule 4729:3-5-02 of the Administrative Code, means the total number of required C.E.U.s for licensure renewal divided by three and rounded down to the nearest whole number.

(E) "Pharmacy jurisprudence" means continuing education the includes any of the following:

(1) An A.C.P.E. law program as identified by A.C.P.E numbering convention "03";

(2) A board of pharmacy approved continuing education program provided by an in-state approved jurisprudence provider pursuant to ~~agency 4729~~Chapter 4729-6 of the Administrative Code that pertains to current or recent changes to laws, rules, and regulations relating to the practice of pharmacy; or

(3) A program presented by the state board of pharmacy that pertains to current or recent changes to laws, rules, and regulations relating to the practice of pharmacy.

(F) "Patient or medication safety" means an A.C.P.E. continuing education program identified by the A.C.P.E. numbering convention "05" that ~~deals with~~pertains to the prevention of healthcare errors and the elimination or mitigation of patient injury caused by healthcare errors.

(G) "Veteran" means anyone who is serving or has served under honorable conditions in any component of the armed forces, including the national guard and reserve.

~~(13)~~(14) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.

~~(14)~~(15) For a controlled substance:

(a) Indicate the drug enforcement administration registration number of the prescriber pursuant to 21 CFR 1306.05 (3/31/2010).

(b) Except for veterinarians licensed pursuant to Chapter 4741. of the Revised Code, indicate either:

(i) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance is being used to treat. The code shall, at a minimum, include the first four alphanumeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5).

(ii) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the Code on Dental Procedures and Nomenclature (CDT Code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription.

~~(15)~~(16) Except for veterinarians licensed under Chapter 4741. of the Revised Code, for all controlled substances and products containing gabapentin: indicate the prescriber's intended days' supply of the prescription.

~~(16)~~(17) For a managing pharmacist acting as an agent of a physician pursuant to section 4729.39 of the Revised Code and Chapter 4729:1-6 of the Administrative Code, the prescription shall include the full name of the managing pharmacist.

~~(17)~~(18) Be issued in compliance with all applicable federal and Ohio laws, rules, and regulations.

(C) Failure of a prescription to contain the requirements set forth in paragraphs (B)(~~14~~15)(b) and (B)(~~15~~16) of this rule or of the pharmacist to obtain the information set forth in paragraphs (B)(~~14~~15)(b) and (B)(~~15~~16) of this rule shall not render the prescription, if dispensed in good faith, to be invalid.