



## **June 2026 – Rules and Resolutions**

### **Resolutions**

#### **1) Theft or Significant Loss Reporting\***

*To harmonize Ohio's theft or significant loss reporting with recently enacted federal regulations, the Board hereby extends the deadline for reporting theft or significant loss reports pursuant to paragraphs (B) of OAC 4729:5-3-02 and 4729:6-3-02 from thirty days following the discovery of such theft or significant loss to forty-five days from the discovery of such theft or significant loss.*

#### **2) Seneca County EMS Drug Sale**

*To minimize pharmaceutical waste and allow for the Seneca County EMS to move to a drug exchange model, the Ohio Board of Pharmacy hereby authorizes the Seneca County EMS (Lic. No. 020365100) to conduct a one-time occasional sale of dangerous drugs from inventory to the Tiffin Fire - Division of Ambulance Service (Lic. No. 020327650). As required by OAC 4729:5-14-04, records of transfer or sale will be maintained by the Seneca County EMS and records of receipt will be maintained by the Tiffin Fire - Division of Ambulance Service. Any one-time sale or distribution of controlled substances shall comply with [21 CFR 1307.11](#).*

**For Filing with JCARR**

**4729:5-5-04 Record keeping. (AMEND) ([Link to Rule Text](#))**

**Amendments for Approval:**

(O) A pharmacy that utilizes a computerized system to dispense dangerous drugs may use hardcopy records and manual signatures to capture positive identification for any of the following:

(1) Compounding and the dispensation of compounded drugs; **and**

(2) Ancillary services as defined in rule 4729:5-5-02.1 of the Administrative Code; **and**

**(3) Records maintained in accordance with rule 4729:5-3-17 of the Administrative Code.**

**4729:5-2-01 – Responsible person - terminal distributor. ([Link to Rule Text](#))**

**Amendments for Approval:**

(A)(2) Except as provided for in this paragraph **and rule 4729:5-18-02 of the Administrative Code**, a pharmacist shall not serve as the responsible person for more than one outpatient pharmacy. A pharmacist may serve as the responsible person for up to two outpatient pharmacies if the following requirements are met:

...

(A)(3) The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

...

(A)(7)(f) The requirements of paragraphs (A)(2)(b) through (A)(2)(**e f**) can be met.

...

(B)(2) Except as provided in paragraphs (B)(7) of this rule, a pharmacist may serve as the responsible person on no more two pharmacies, either outpatient or institutional, licensed as terminal distributors of dangerous drugs if both **locations pharmacies** are located on a campus, as defined in section 4729:5-1-01 of the Administrative Code, and the pharmacist is not currently on probation or is otherwise restricted from serving as the responsible person on multiple licenses pursuant to a settlement agreement or order of the board.

...

(B)(3)(a) The practice of the profession of pharmacy performed within the institutional pharmacy and, if applicable, **the institutional** facility, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of

the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

...

(B)(3)(c) In conjunction with the appropriate interdisciplinary committees, the development of written policies and procedures which are consistent with this division of the Administrative Code and other applicable federal and state laws, regulations, and rules governing the legal distribution of drugs, adherence to these policies and procedures in order to provide for the safe distribution of drugs in all areas of the institutional facility, and making readily retrievable a current copy of these written policies and procedures.

...

(C)(1)(d) Unless the licensee can demonstrate that such compliance would cause the non-resident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements, the terminal distributor of dangerous drugs and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy

...

(C)(2)(a) Only a pharmacist or prescriber may be the responsible person for a non-resident terminal distributor of dangerous drugs **that is not a pharmacy.**

...

(C)(2)(d) Unless the licensee can demonstrate that such compliance would cause the non-resident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements, the terminal distributor of dangerous drugs and all pharmacists and prescribers on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs.

...

(E)(1) Only the following may be the responsible person whose name appears on the terminal distributor of dangerous drugs license for an EMS organization:

(a) **A** physician licensed in accordance with Chapter 4731 of the Revised Code;

(b) **A** pharmacist licensed in accordance with Chapter 4729 of the Revised Code; or

(c) **An** advanced emergency medical technician or paramedic issued a certificate to practice in accordance with Chapter 4765 of the Revised Code.

...

(G)(1) A process to review and document **for** compliance with the following requirements:

...

(G)(3) For on-site, in-person visits conducted in accordance with paragraph (F)(3) of this rule, the pharmacist shall document the visit and such documentation shall be provided to the responsible person no later than three business days from **the date of** the visit.

...

(G)(4) All documentation required by this paragraph shall be maintained for three years from the date of visit. A copy of this documentation shall be maintained at, **or accessible by,** the terminal distributor of dangerous drugs where the visit **is was** conducted for immediate on-site inspection by an agent, officer, or inspector of the board.

...

(F) Except as otherwise provided in paragraphs (A), (B), (C), (D), and (E) of this rule, a responsible person of a terminal distributor of dangerous drugs shall comply with **any of the following: one or more of the following:**

...

(H)(5) A responsible person shall hold a valid Ohio license, registration, or certification ~~to~~ from an occupational licensing board as defined in section 4798.01 of the Revised Code. **This requirement does not apply to terminal distributors of dangerous drugs that do not require the responsible person to hold a professional license, registration, or certification in accordance with the resolution issued by the board in pursuant to paragraph (H)(7) of this rule.**

...

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

JCARR Comments on 4729:5-2-01 – Responsible person - terminal distributor. ([Link to Rule Text](#))

Organization	Comment	Draft Board Response
<p><b>Cleveland Clinic</b> <b>(Comment #1)</b></p>	<p>We suggest the Board amend the rule to require quarterly in-person visits of the terminal distributor by either certified pharmacy technicians or licensed pharmacists employed by the institutional facility, in accordance with paragraph G. Given that the pharmacy board already entrusts technicians with state inspections, it is both reasonable and efficient to allow certified or licensed pharmacy personnel to conduct these visits. This change would provide needed flexibility and improve timeliness, ensuring that audits are completed promptly by available, qualified personnel. Technicians have demonstrated their capability and reliability and permitting certified personnel to perform these duties would further strengthen oversight while supporting operational efficiency. Therefore, we suggest the language be amended as follows.</p> <p><i>For on-site, in-person visits conducted in accordance with paragraph (F)(3) of this rule, a licensed pharmacist <b>or certified pharmacy technician</b> shall document the visit and such documentation shall be provided to the responsible person no later</i></p>	<p>The Board did not authorize pharmacy technicians to conduct inspections of terminal distributors of dangerous drugs at this time.</p> <p>While technicians are trusted with certain tasks, they are not permitted to serve as the responsible person on a TDDD license.</p>

	<p><i>than three business days from the date of visit.</i></p>	
<p><b>Cleveland Clinic (Comment #2)</b></p>	<p>In today’s healthcare environment, much of the documentation and recordkeeping are conducted and securely stored electronically, offering increased efficiency and enhanced security compared to traditional paper methods. We urge the Board to amend the rule language to permit electronic or readily retrievable records, rather than requiring a paper copy. This change would align with modern practices and support a more streamlined audit process. We suggest the language be amended as follows.</p> <p><i>All documentation required by this paragraph shall be maintained for three years from the date of visit. A copy of this documentation shall be maintained, <b><u>or be readily available</u></b> at the terminal distributor of dangerous drugs where the visit was conducted for immediate on-site inspection by an agent, officer, or inspector of the board.</i></p>	<p>This comment was incorporated into the rule.</p>

**4729:5-3-25 – Electronic product verification. ([Link to Rule Text](#))**

**Amendments for Approval:**

(B) For a pharmacist to engage in electronic product verification, the pharmacist shall:

(4) ~~is~~ **Be** a current or contracted employee of the pharmacy operating the electronic verification system.

...

(C)(4) The images shall contain the following to ensure the pharmacist is able to appropriately verify the prescription prior to dispensing.

(a) A clear image of the prescription label affixed to the drug or device;

(b) The full quantity of the filled prescription;

(c) Except as provided in paragraph (C)(5) of this rule, the medication stock bottle or container and label of a drug that has been returned to stock in accordance with rule 4729:5-5-22 of the Administrative Code used to fill the prescription, if applicable; **and**

(d) Clear markings present on the drug being dispensed (e.g., tablets, capsules, etc.), if applicable; **and**

(e) A clear image of the following, if not otherwise captured or maintained in the pharmacy system:

(i) The drug's national drug code, as defined in 21 CFR 207.33 (April 1, 2026), or global trade item number; and

(ii) The drug's serial number, lot number, and expiration date.

## **For Filing with CSI & JCARR**

### **4729:5-3-11 – Transmission of outpatient prescriptions. (AMEND)**

(A) Oral transmission by a prescriber or a prescriber's agent of an original outpatient prescription authorized by a prescriber shall comply with the requirements of rule [4729:5-5-15](#) of the Administrative Code. For any oral outpatient prescription transmitted by an agent of a prescriber, the prescriber's agent must provide the agent's first and last name when transmitting the prescription. An oral prescription may be transmitted by a prescriber or prescriber's agent to a recording device or voice mail service.

(B) Original written outpatient prescriptions shall be authorized and signed by a prescriber, **using a manual, wet-ink signature, in the same manner as the prescriber would sign a check or legal document**, and may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy.

(1) The facsimile of the prescription must include the identification number of the facsimile machine **which that** is used to transmit the prescription, the full name of the prescriber, and, if applicable, the full name of the prescriber's agent transmitting the prescription to the pharmacy.

(2) The prescription must comply with the requirements of rule [4729:5-5-15](#) of the Administrative Code.

(3) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the location where it was issued for three years from the date of issuance. Following the successful transmission of the prescription, the word "VOID" or "FAXED" shall be written or stamped on the face of the original prescription in a manner that does not destroy any of the original information contained on the prescription.

(4) Outpatient prescriptions for schedule II controlled substances may be transmitted by facsimile in accordance with 21 C.F.R. 1306.11 (**~~5/1/2019~~ March 31, 2010**) and shall meet the facsimile requirements of this rule.

(C) Outpatient prescriptions may be transmitted by means of an electronic prescription transmission system that complies with the prescription requirements in rule [4729:5-5-15](#) of the Administrative Code.

(1) An outpatient prescription transmitted by means of an electronic prescription transmission system shall include the full name of the prescriber's agent transmitting the prescription.

(2) A controlled substance outpatient prescription shall only be transmitted by means of an electronic prescription transmission system if the system complies with 21 C.F.R. 1311 ~~(5/1/2019)~~**April 1, 2026**.

(3) Except as provided in paragraphs (C)(4) and (C)(5) of this rule, no prescriptions may be transmitted by means of an electronic prescription transmission system that converts the prescription into a **computer-generated or scanned fax or image** ~~computer-generated images, fax or scanned image~~.

**(4) A non-controlled prescription may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image if the transmission is conducted by means of a system that meets the prescription requirements of rule [4729:5-5-15](#) of the Administrative Code and either of the following apply:**

**(a) The prescription transmission system operates within a closed-system. A closed system includes any system whereby prescription information is transmitted directly between:**

**(i) Any division, subsidiary, parent or affiliated or related company under common ownership and control; or**

**(ii) One or more contracted entities. Contracted means having a written agreement (to include business associate agreements) between one or more prescribers and a pharmacy and shall not include a third-party intermediary unless otherwise approved by the board.**

**(b) The transmission of a prescription for compounded total parenteral nutrition for dispensation by a pharmacy.**

~~(4) A non-controlled prescription may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image if all the following apply:~~

~~(a) The transmission is conducted by means of a board-approved system that meets the prescription requirements of rule 4729:5-5-15 of the Administrative Code.~~

~~(b) The prescription transmission system operates within a closed system. A closed system includes any system whereby prescription information is transmitted directly between:~~

~~(i) Any division, subsidiary, parent, or affiliated or related company under common ownership and control; or~~

~~(ii) One or more contracted entities. Contracted means having a written agreement (to include business associate agreements) between one or more prescribers and a pharmacy and shall not include a third-party intermediary unless otherwise approved by the board.~~

(5) A non-controlled prescription may be converted into a computer-generated fax by a **board approved** third-party intermediary only if the conversion is necessitated by a temporary telecommunication outage of the third-party intermediary or receiving pharmacy. **Unless otherwise approved by the board, the telecommunications outage shall not last more than seventy-two continuous hours.**

**(D) Outpatient prescriptions shall not be transmitted via electronic mail (e-mail) and shall be transmitted in compliance with 45 CFR Part 160 (April 1, 2026) and 45 CFR Part 164 (April 1, 2026).**

**CSI Comments on OAC 4729:5-3-11 – Transmission of outpatient prescriptions**

<b>Organization</b>	<b>Comment</b>	<b>Draft Board Response</b>
<p><b>University Hospitals</b></p>	<p>University Hospitals (UH) appreciates the opportunity to provide comments on the proposed amendment to 4729:5 -3-11 - Transmission of outpatient prescriptions that is currently under BIA CSI review. We value the Board’s ongoing work to ensure safety in the distribution of dangerous drugs and appreciate the transparency and engagement throughout this process.</p> <p>Based on internal review and discussions with our outpatient and inpatient pharmacy and prescriber office and clinic leaders, UH offers the following comments, questions, and recommended modifications for clarification.</p> <p><b>Rule 4729:5-3-11</b> Transmission of outpatient prescriptions <i>(Documentation of orally transmitted prescriptions by a prescriber or prescriber’s agent)</i></p> <p>Pharmacy and prescriber office leaders expressed concern with the addition of “All oral prescriptions transmitted by a prescriber or prescriber’s agent shall be documented in the patient’s medical record by the issuing prescriber” in paragraph (A). The statement requires additional chart documentation without defining specific requirements.</p>	<p>To avoid confusion, this proposed provision was deleted from the rule.</p> <p>After additional review by staff, it was determined that this requirement is no longer necessary.</p>

	<p>UH respectfully requests clarification on the intent of the statement regarding “All oral prescriptions transmitted by a prescriber or <b>prescriber’s agent shall be documented in the patient’s medical record by the issuing prescriber</b>”:</p> <ul style="list-style-type: none"><li>• Does the provider documenting the intent to initiate medication therapy in the patient’s chart and/or in the medication history suffice?</li><li>• Are there positive identification requirements for issuing prescriber documentation?</li><li>• Does this requirement also apply to oral script clarification/modifications provided by a prescriber’s agent in consult with the prescriber?</li><li>• For protocols and pre-printed orders, will the issuing prescriber be required to provide additional documentation beyond the signed protocol and pre-printed orders in accordance with 4729:5-3-12?</li></ul> <p>Additional guidance would be helpful regarding what constitutes as “documenting” and whether there are positive ID requirements. If documentation is needed beyond notating a medication initiation in the medication history and/or note, this proposed amendment would create additional workload and duplicative efforts.</p>	
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	<p>Thank you again for the opportunity to provide comments. UH appreciates the Board's continued collaboration and commitment to supporting safe and effective pharmacy practice across Ohio.</p> <p>We look forward to ongoing partnership as these rules advance.</p>	
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**CSI Comments on 4729:5-4-01 – Disciplinary actions ([Link to Rule Text](#)).**

<b>Organization</b>	<b>Comment</b>	<b>Draft Board Response</b>
<p><b>Ohio Dermatological Association</b></p>	<p>The Ohio Dermatological Association (ODA) appreciates the opportunity to submit stakeholder comments during the current comment period on the Board’s proposed amendments to Rule 4729:5-4-01 governing disciplinary actions applicable to terminal distributors of dangerous drugs (TDDD). ODA previously submitted comments on an earlier iteration of this rule package during the initial stakeholder outreach period, in which we raised concerns about the scope and clarity of proposed changes to paragraph (B)(26).</p> <p>Following the submission of those comments, ODA had the opportunity to meet with Board staff to discuss our concerns in greater detail. We are grateful for that engagement and for the Board’s willingness to consider ODA’s perspective as part of its deliberative process.</p> <p>ODA understands that the Board has since revised the proposed language to clarify that the expanded disciplinary exposure in paragraph (B)(26) is directed at individuals whose relationship to the licensee’s operations involves ordering drugs or consulting as to what specific drugs to purchase. This revision meaningfully</p>	<p>The Board appreciates the opportunity to work with the Ohio Dermatological Association (ODA) to address their potential concerns with the initial draft of OAC 4729:5-4-01. Per the request of ODA, the Board will develop additional guidance prior to the implementation of the rule.</p>

addresses the core concern ODA raised in our earlier comments, namely, that the prior language appeared to sweep in individuals with no operational connection to drug handling, storage, or dispensing.

In light of these revisions, *ODA is neutral on the proposed amendments to Rule 4729:5-4-01* as currently drafted. We do not oppose the Board’s adoption of the rule as revised and we appreciate the collaborative process that produced the current language.

ODA continues to encourage the Board, as implementation proceeds, to consider providing additional interpretive guidance or compliance resources for physician-operated TDDD licensees regarding the practical application of the revised provision. Such guidance would assist our members in achieving compliance without uncertainty. ODA remains willing and ready to provide any feedback or requests for guidance as any particular compliance questions arise.

Thank you again for the opportunity to participate in this process and for the Board’s engagement with ODA on these issues. We look forward to continued dialogue.

**Rule 4729:5-4-01 | Disciplinary actions. (AMEND)**

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on an **applicant or** person licensed as a terminal distributor of dangerous drugs for any of the causes set forth in paragraph (B) of this rule:

- (1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license;
- (2) Reprimand or place the license holder on probation;
- (3) Impose a monetary penalty or forfeiture as set forth in section [4729.57](#) of the Revised Code.

(B) The board may impose the sanctions set forth in paragraph (A) of this rule for any of the following:

- (1) Making any false material statements in an application for a license or renewal of a license as a terminal distributor of dangerous drugs.
- (2) Violating any rule of the board.
- (3) Violating any provision of Chapter 4729. of the Revised Code.
- (4) Except as provided in section [4729.89](#) of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code.
- (5) Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code.
- (6) Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor.
- (7) Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section [4729.55](#) of the Revised Code.

(8) Except as provided in division (C) of section [4729.57](#) of the Revised Code:

(a) Waiving the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the services provided by a terminal distributor of dangerous drugs, would otherwise be required to pay for the services if the waiver is used as an enticement to a patient or group of patients to receive pharmacy services from that terminal distributor;

(b) Advertising that the terminal distributor will waive the payment of all or any part of a deductible or copayment that an individual, pursuant to a health insurance or health care policy, contract, or plan that covers the pharmaceutical services, would otherwise be required to pay for the services.

(9) Conviction of a felony.

(10) Violation of any restrictions placed by the state board of pharmacy on a license or violating any terms of a board order issued against the licensee **or settlement agreement with the board entered by the licensee.**

(11) Exclusion from participation in medicare or a state health care program.

(12) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(13) Being the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(14) Commission of an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.

(15) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(16) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(17) Is addicted to or abusing alcohol or drugs.

(18) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(19) Employs a responsible person that does not meet the requirements set forth in rule [4729:5-2-01](#) of the Administrative Code.

(20) The ownership of such entity has been transferred from a person whose license issued in accordance with Chapter 4729. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other professional licensing agency to a spouse, ~~or other~~ family member, **or previous employee or agent of the person whose license was revoked or disciplined.**

(21) The ownership of such facility has been transferred from **the real property owner or** a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other professional licensing agency to another who employs **or contracts with** the former owner or **the spouse, family member, or previous employee or agent of the person whose license was revoked or disciplined. who allows the former owner to be present within the physical confines of the location to be licensed.**

(22) Except as provided in Chapter 3719. of the Revised Code, dispensing a sample drug as defined in rule [4729:6-3-08](#) of the Administrative Code.

(23) The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others.

(24) The furnishing of false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of dangerous drugs from manufacturers, repackagers, third-party logistics providers, outsourcing facilities, wholesale distributors or other terminal distributors.

(25) Retaliating against or disciplining an employee for filing a complaint with a board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

- (a) Removing or suspending the employee from employment;
- (b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
- (c) Transferring or reassigning the employee;
- (d) Denying the employee a promotion that otherwise would have been received;
- (e) Reducing the employee in pay or position.

(26) Unless otherwise approved by the board, a terminal distributor knowingly: **employs or contracts with a person; has any agent, owner, partner, member, officer, director or manager of the applicant or person licensed as a terminal distributor of dangerous drugs; or if the applicant or licensee is a corporation or limited liability company, any shareholder directly or indirectly owning voting interests or membership interests in the corporation or limited liability company, with access to drug stock or any role in the purchasing, ordering, directing, or recommending of drug stock who: with access to drug stock who:**

- (a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.
- (b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

- (c) Has committed an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.
- (d) Has committed an act that constitutes a misdemeanor or felony drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.
- (e) Has been subject to any of the following:
  - (i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or
  - (ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.
- (f) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.
- (g) Is addicted to or abusing alcohol or drugs.
- (h) Has been excluded from participation in medicare or a state health care program.
- (i) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.
- (j) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
  - (i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or
  - (ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.
- (k) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the ~~employee's~~ individual's professional practice.

**(l) Has actively participated in the operation or ownership of an entity licensed by the board that has demonstrated a disregard for the laws or regulations of this state or any other state, including but not limited to, an entity that has been suspended, revoked, or disciplined by the board for violations of section 4729.51 of the Revised Code, the “Federal Food, Drug, and Cosmetic Act,” 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., 4729. of the Revised Code, or any rule of the board.**

**Rule 4729:6-4-01 | Disciplinary actions. (AMEND)**

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on **an applicant or** person licensed as a distributor of dangerous drugs for any of the causes set forth in paragraph (B) of this rule:

- (1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license;
- (2) Reprimand or place the license holder on probation;
- (3) Impose a monetary penalty or forfeiture as set forth in section [4729.56](#) of the Revised Code.

(B) The board may impose the sanctions set forth in paragraph (A) of this rule for any of the following:

- (1) Making any false material statements in an application for licensure or licensure renewal under section [4729.52](#) of the Revised Code.
- (2) Violating any federal, state, or local drug law; any provision of Chapter 2925., 3715., 3719., or 4729. of the Revised Code; or any rule of the board.
- (3) A conviction of a felony.
- (4) Commission of an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.
- (5) Failing to satisfy the qualifications for licensure under section [4729.53](#) of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the license is granted or renewed.
- (6) Falsely or fraudulently promoting to the public a drug that is a controlled substance included in schedule I, II, III, IV, or V, except that nothing in this rule prohibits a drug distributor from furnishing information concerning a controlled substance to a health care provider or licensed terminal distributor.

**~~(7) Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), United States Code Title 21 (10/22/2017). Violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C. 301.;~~**

(8) Failing to comply with the requirements of rule [4729:6-3-05](#) of the Administrative Code.

(9) Conducting the sale of a suspicious order without conducting an independent analysis prior to completing a sale to determine whether the reported drugs are likely to be diverted from legitimate channels in accordance with rule [4729:6-3-05](#) of the Administrative Code.

(10) Commission of a crime of moral turpitude as defined in section [4776.10](#) of the Revised Code.

(11) Violation of any restrictions placed by the state board of pharmacy on a license or violating any terms of a board order issued against the licensee **or settlement agreement with the board entered by the licensee.**

(12) Exclusion from participation in Medicare or a state health care program.

(13) Being denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(14) Being the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or

(b) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(15) Has been subject to any of the following:

(a) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(b) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(16) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(17) Is addicted to or abusing alcohol or drugs.

(18) Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice.

(19) Employs a responsible person that does not meet the requirements set forth in rule [4729:6-2-01](#) of the Administrative Code.

(20) Retaliating against or disciplining an employee for filing a complaint with a board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:

(a) Removing or suspending the employee from employment;

(b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;

(c) Transferring or reassigning the employee;

(d) Denying the employee a promotion that otherwise would have been received;

(e) Reducing the employee in pay or position.

(21) The method used by the drug distributor to store, possess or distribute dangerous drugs poses serious harm to others.

(22) The ownership of such entity has been transferred from a person whose license issued in accordance with Chapter 4729. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to a spouse, ~~or other~~ family member, **or previous employee or agent of the person whose license was revoked or disciplined.**

(23) The ownership of such facility has been transferred from a licensee whose license has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to another who employs **or contracts with** the former owner **or the spouse, family member, or previous employee or agent of the person whose license was revoked or disciplined, or who allows the former owner to be present within the physical confines of the location to be licensed.**

(24) Unless otherwise approved by the board, a distributor knowingly: employs **or contracts with** a person; **has any agent, owner, partner, member, officer, director or manager of the applicant or person licensed as a distributor of dangerous drugs; or if the applicant or licensee is a corporation or limited liability company, any shareholder directly or indirectly owning voting interests or membership interests in the corporation or limited liability company, with access to drug stock or any role in the purchasing, ordering, directing, or recommending of drug stock who: with access to drug stock who:**

(a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(c) Has committed an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed.

(d) Has committed an act that constitutes a misdemeanor or felony drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed.

(e) Has been subject to any of the following:

(i) A finding by a court of the person's eligibility for intervention in lieu of conviction; or

(ii) A finding by a court of the person's eligibility for treatment or intervention in lieu of conviction in another jurisdiction.

(f) Has been granted entry into a diversion program, deferred prosecution program, or the equivalent thereof.

(g) Is addicted to or abusing alcohol or drugs.

(h) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.

(i) Has been excluded from participation in medicare or a state health care program.

(j) Has been denied a license or registration by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.

(k) Has been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license or registration; or

(ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, securing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.

(l) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the ~~employee's~~ individual's professional practice.

**(m) Has actively participated in the operation or ownership of an entity licensed by the board that has demonstrated a disregard for the laws or regulations of this state or any other state, including but not limited to, an entity that has been suspended, revoked, or disciplined by the board for violations of section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., 4729. of the Revised Code, or any rule of the board.**

**4729:5-15-01 – Animal shelters, dog wardens, and wild animal rehabilitation facilities - definitions. (AMEND)**

As used in Chapter 4729:5-15 of the Administrative Code:

(A) "Animal shelter" means a facility licensed as terminal distributor of dangerous drugs in accordance with section [4729.531](#) of the Revised Code or section [4729.54](#) of the Revised Code.

An animal shelter shall be operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code and shall comply with all requirements set forth in this chapter.

(1) An animal shelter that does not have a licensed veterinarian serving as the responsible person shall obtain a limited license as terminal distributor of dangerous drugs in accordance with section [4729.531](#) of the Revised Code.

(2) An animal shelter shall ensure that all agents and employees who perform euthanasia, other than registered veterinary technicians or licensed veterinarians, shall successfully complete a euthanasia technician certification course described in section [4729.532](#) of the Revised Code.

(3) An animal shelter shall comply with the initial licensure and renewal requirements set forth in rule [4729:5-2-02](#) of the Administrative Code.

(4) The board may suspend, revoke, restrict, limit, or refuse to grant or renew any license issued to an animal shelter in accordance with rule [4729:5-4-01](#) of the Administrative Code.

(B) "Certified officer" means an individual who meets the requirements established under section [4729.534](#) of the Revised Code.

(C) "Chemical capture" means using an anesthetic drug or sedative on a companion animal to do any of the following:

(1) Immobilize and capture;

(2) Attempt to immobilize and capture; or

(3) Attempt to immobilize or capture.

(D) "Chemical capture classification" means an authorization for a facility licensed as a terminal distributor of dangerous drugs in accordance with section [4729.532](#) of the Revised Code to purchase, possess, and administer a combination of drugs for chemical capture.

(E) "Companion animal" has the same meaning as in section [959.131](#) of the Revised Code.

(F) "Controlled substance" has the same meaning as in section [3719.01](#) of the Revised Code.

(G) "County dog warden" means a dog warden or deputy dog warden appointed or employed under section [955.12](#) of the Revised Code.

(1) A county dog warden shall ensure that all agents and employees who perform euthanasia, other than registered veterinary technicians or licensed veterinarians, shall successfully complete a euthanasia technician certification course described in section [4729.532](#) of the Revised Code.

(2) A county dog warden shall comply with the initial licensure and renewal requirements set forth in rule [4729:5-2-02](#) of the Administrative Code.

(3) The board may suspend, revoke, restrict, limit, or refuse to grant or renew any license issued to a county dog warden in accordance with rule [4729:5-4-01](#) of the Administrative Code.

(H) "Dangerous drug" has the same meaning as in section [4729.01](#) of the Revised Code.

(I) "Euthanasia" has the same meaning as in paragraph (A) of rule [901:12-1-01](#) of the Administrative Code.

(J) "Euthanasia technician" is an individual that has successfully completed a euthanasia certification course, the curriculum of which has been approved by the veterinary medical licensing board pursuant to section [4729.532](#) of the Revised Code, and is in possession of a certificate which documents the successful completion of the certification course. For the purposes of this chapter, a euthanasia technician is considered a certified health care professional.

(K) "Personal supervision" means the person specified in rule shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

(L) "Personally furnish" or "personally furnishing" means the distribution of dangerous drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting. For the purposes of this chapter, the prescriber shall be a veterinarian. A veterinarian at an animal shelter who personally furnishes a dangerous drug shall comply with the requirements of rule [4729:5-20-02](#) of the Administrative Code.

(M)

(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.**

(N) "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.

(O) "Registered veterinary technician" has the same meaning as in section [4741.01](#) of the Revised Code.

(P) "Responsible person" has the same meaning as defined in rule [4729:5-2-01](#) of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section [4729.55](#) of the Revised Code, adequate safeguards as required in division (C) of section [4729.55](#) of the Revised Code, security and control of dangerous drugs, and maintaining all drug records otherwise required.

(Q) "Veterinarian" means an individual licensed by the state of Ohio to practice veterinary medicine pursuant to Chapter 4741. of the Revised Code.

**(R) "Wild animal rehabilitation facility" or "WARF" means a facility that holds a permit issued by the chief of the division of wildlife for rehabilitation purposes in accordance with section [1533.08](#) of the Revised Code or rules adopted by the chief.**

**(1) A WARF shall ensure that all agents and employees who perform euthanasia, other than registered veterinary technicians or licensed veterinarians, shall successfully complete a euthanasia technician certification course described in section [4729.532](#) of the Revised Code.**

**(2) A WARF shall comply with the initial licensure and renewal requirements set forth in rule [4729:5-2-02](#) of the Administrative Code.**

**(3) The board may suspend, revoke, restrict, limit, or refuse to grant or renew any license issued to a WARF in accordance with rule [4729:5-4-01](#) of the Administrative Code.**

**4729:5-15-02 – Security and control of dangerous drugs. (AMEND)**

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs.

(B) Controlled substance dangerous drugs used to perform euthanasia or chemical capture shall be stored in a securely locked, substantially constructed cabinet or safe.

(1) The cabinet or safe shall be placed in an area that is not readily accessible to the public. The public does not include volunteers of the animal shelter, **county dog warden, or WARF.**

(2) The cabinet or safe shall remain locked and secured when not in use.

(3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian, registered veterinary technician, responsible person, euthanasia technician, certified officer, dog warden, or executive director of the shelter **or WARF.** All locks shall be kept in good working order with keys removed therefrom.

(5) When not staffed by shelter, **county dog warden, or WARF** personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(6) Only a veterinarian, registered veterinary technician, euthanasia technician, executive director of the shelter **or WARF,** certified officer, dog warden, or the licensee's responsible person shall be able to access the cabinet or safe.

(C) Except as provided in paragraph (E) of this rule, controlled substance dangerous drugs that are not used to perform euthanasia or chemical capture shall be stored in a securely locked, substantially constructed cabinet or safe.

(1) The cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public. The public does not include volunteers of the animal shelter, **county dog warden, or WARF.**

(2) The cabinet or safe shall remain locked and secured when not in use.

(3) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian if not being used by a veterinarian or a veterinary technician in accordance with paragraph (C)(6)(a), (C)(6)(b), or (C)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom.

(5) When not staffed by shelter, **county dog warden, or WARF** personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(6) Except as provided in paragraph (C)(6)(a), (C)(6)(b), or (C)(6)(c) of this rule, only a veterinarian shall be able to access the cabinet or safe.

(a) A veterinarian may provide a veterinary technician with a temporary key for the purposes of accessing the cabinet or safe. A veterinary technician shall return the key provided in accordance with this paragraph to the veterinarian or a secured location with restricted access (such as a lockbox) no later than the end of the technician's shift or if there is no longer a veterinarian available to provide personal supervision.

(b) A veterinarian may provide a veterinary technician with a key, combination, or access code for the purposes of accessing the cabinet or safe, if all the following conditions apply:

(i) The cabinet or safe is maintained in a room secured by a physical barrier with suitable locks that can only be unlocked by a veterinarian;

(ii) The room is locked when not staffed by personnel or when there is no longer a veterinarian available to provide personal supervision.

(c) Any other method approved by the board's executive director or the director's designee that provides effective controls and procedures to guard against theft and diversion.

(D) Except as provided in paragraphs (B) and (E) of this rule, a registered veterinary technician may have access to controlled substances only under the personal supervision of a veterinarian.

(E) Employees or volunteers of an animal shelter, **WARF**, or county dog warden that are designated by the responsible person or the shelter **or WARF's** executive director may have unsupervised access to controlled substances only under the following conditions:

(1) The drugs have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal.

(2) The drugs must be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, safe, or room. Access to the cabinet, safe, or room shall be limited to designated staff. The cabinet or safe must be separate from those required in paragraphs (B), (C), and (I) of this rule.

(a) The cabinet or safe shall be placed in an area that is not readily accessible to the public. The public does not include volunteers of the animal shelter, **county dog warden, or WARF. or county dog warden.**

(b) The cabinet, safe, or room shall remain locked and secured when not in use.

(c) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than designated staff. All locks shall be kept in good working order with keys removed therefrom.

(d) When not staffed by shelter, **county dog warden, or WARF** personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(3) A record of drug administration shall be maintained in accordance with paragraph (E) of rule [4729:5-15-03](#) of the Administrative Code.

(4) The responsible person shall report the theft or significant loss of drugs maintained pursuant to this paragraph in accordance with rule [4729:5-3-02](#) of the Administrative Code.

(5) The responsible person, ~~or~~ shelter's executive director, **or WARF's executive director** shall maintain a current list of all designated employees or volunteers for immediate inspection by an agent, officer, ~~or~~ inspector of the board.

(F) Non-controlled dangerous drugs that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration may be administered by an animal shelter, **WARF**, or county dog warden employee or volunteer.

(G) Only a veterinarian shall have access to uncompleted prescription blanks used for writing a prescription. Uncompleted prescription blanks shall be secured when not in use.

(H)

(1) For an animal shelter or county dog warden that is licensed in accordance with section [4729.54](#) of the Revised Code: personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of a veterinarian. D.E.A. controlled substance order forms shall be secured when not in use.

(2) For an animal shelter, **WARF**, or county dog warden that is licensed in accordance with section [4729.531](#) of the Revised Code: personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the personal supervision of the responsible person. D.E.A. controlled substance order forms shall be secured when not in use.

(I) Thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine shall be stored in a separate safe or steel cabinet equivalent to a U.S. government class V security container from all other controlled substances.

(1) There is no minimum size or weight requirement, but if the cabinet or safe weighs less than seven hundred fifty pounds, it must be secured to the floor or wall in such a way that it cannot be readily removed.

(2) Except as provided for in this paragraph, the cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, patients, business guests, or visitors to be present in or pass through areas containing the cabinet or safe, a veterinarian or veterinary technician shall provide for adequate observation of the area.

(3) The cabinet or safe shall remain locked and secured when not in use.

(4) In the case of a combination lock or access code, the combination or access code shall be changed upon termination of employment of an employee having knowledge of the combination or access code.

(5) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian if not being used by a veterinarian. All locks shall be kept in good working order with keys removed therefrom.

(6) When not staffed by personnel, the cabinet or safe shall be maintained in an area secured by a physical barrier with suitable locks, which may include a locked room or secure facility.

(7) Only a veterinarian shall be able to access the safe or cabinet.

(J) When not staffed by personnel, hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections. Members of the public do not include volunteers of the animal shelter, **WARF**, or county dog warden.

(K) When not staffed by personnel, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, locked room, or secured facility. During normal business hours, non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs. Members of the public do not include volunteers of the animal shelter, **WARF**, or county dog warden.

(L) In the event of a change of ownership of an animal, an employee or volunteer may transfer dangerous drugs that have been personally furnished by a veterinarian or dispensed by a pharmacy for direct administration to an animal to the animal's new owner or caregiver. The transfer of controlled substances shall be documented in accordance with paragraph (I) of rule [4729:5-15-03](#) of the Administrative Code.

(M) All records relating to the receipt, administration, distribution, personal furnishing, and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict access by those who neither work for, or volunteer at, the animal shelter, **WARF**, or county dog warden.

(N) All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices 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; 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 drugs.

(O) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a date opened. Multiple-dose vials shall be examined prior to use for evidence of

physical or chemical contamination. Vials that have any of the following characteristics shall be deemed adulterated:

(1) Contain particulate matter, precipitates, turbidity, or discoloration;

(2) Mislabeled; or

(3) Noticeable coring (damage to the rubber stopper).

(P) Adulterated drugs, including expired drugs, shall be stored in accordance with rule [4729:5-3-06](#) of the Administrative Code.

(Q) Disposal of controlled substances shall be conducted in accordance with rule [4729:5-3-01](#) of the Administrative Code.

(R) Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule [4729:5-3-06](#) of the Administrative Code.

**4729:5-15-03 – Record keeping. (AMEND)**

(A) An animal shelter, **WARF**, or county dog warden shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold, or transferred.

(B) 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. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement.

(C) Records of temperature control monitoring described in paragraph (N) of rule [4729:5-15-02](#) of the Administrative Code shall include any of the following:

(1) For temperature logs, either:

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

(b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded.

(2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion.

(D) Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished; the name or identification of the animal; name and address of the animal's owner or caregiver if the owner or caregiver is not the animal shelter, **WARF, or county dog warden**; the date the drug is personally furnished; and, if applicable, the date the drug is received by the animal's owner or caregiver. A veterinarian shall be required to document the final association of a controlled substances dangerous drug with a patient using positive identification.

(E)

(1) Records of administration or use shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered; the name or identification of the animal to whom or for whose use the dangerous drugs were administered; and the date of administration. For controlled substance dangerous drugs, the administration record shall also include the positive identification of the person administering the drug.

(2) Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(3) Orders for the administration of controlled substances shall be documented using positive identification. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(4) Paragraph (E)(3) of this rule does not apply in any of the following instances:

(a) Administration of dangerous drugs authorized under Chapter 4729. of the Revised Code to perform euthanasia by means of lethal injection by a veterinarian, registered veterinary technician, or euthanasia technician;

(b) Administration of dangerous drugs pursuant to paragraph (E) of rule [4729:5-15-02](#) of the Administrative Code; and

(c) Administration of approved drugs for chemical capture pursuant to rule [4729:5-15-05](#) of the Administrative Code.

(F) Records of disposal of dangerous drugs 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 identification of the person that performed the disposal.

(G) 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, including drugs maintained in accordance with paragraph (E) of rule [4729:5-15-02](#) of the Administrative Code, is performed on-site, records shall also include the positive identification of two persons conducting and

witnessing the disposal, one of whom shall be the responsible person or a veterinarian, **county dog warden**, registered veterinary technician, or certified euthanasia technician.

(2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient or controlled substances maintained in accordance with paragraph (E) of rule [4729:5-15-02](#) of the Administrative Code, records shall also include the positive identification of two persons conducting and witnessing the disposal, one of whom shall be the responsible person or a veterinarian, **county dog warden**, registered veterinary technician, or certified euthanasia technician.

(H) Records of transfer or sale conducted in accordance with chapter 4729. of the Revised Code and rule [4729:5-3-09](#) of the Administrative Code shall contain the name, strength, dosage form, ~~expiration date~~, 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.

(I) Records of controlled substances transferred in accordance with paragraph (L) of rule [4729:5-15-02](#) of the Administrative Code shall contain the name, strength, dosage form, and quantity of the dangerous drugs transferred; the name or identification of the animal; name and address of the animal's owner or caregiver if the owner or caregiver is not the animal shelter, **WARF, or county dog warden**; the positive identification of the ~~animal shelter~~ **animal shelter** employee or volunteer transferring the drug; the date the drug is transferred; and the date the drug is received by the animal's owner or caregiver.

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

(K) In addition to the inventory requirements set forth in rule [4729:5-3-07](#) of the Administrative Code, the responsible person for an animal shelter, **WARF, or county dog warden** that maintains controlled substance dangerous drugs used to perform euthanasia listed in paragraph (B) of rule [4729:5-15-04](#) of the Administrative Code shall be responsible for completing a monthly inventory, in accordance with rule [4729:5-3-07](#) of the Administrative Code, of those drugs to deter and detect diversion.

(L) An animal shelter, **WARF**, or county dog warden licensed as a limited category II or limited category III terminal distributor of dangerous drugs may only possess dangerous drugs that are on the drug list submitted to the board pursuant to section [4729.54](#) of Revised Code and only at locations licensed by the state board of pharmacy. The responsible person may modify the drugs that may be possessed and administered by the limited facility by submitting a new drug list to the state board of pharmacy in a manner determined by the board.

(M) All records maintained in accordance with this rule and rule [4729:5-15-02](#) of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years.

(1) A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(N) All records maintained pursuant to this rule and rule [4729:5-15-02](#) of the Administrative Code 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 shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;

(3) Contains security features, such as unique user names and passwords, to prevent unauthorized access; and

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

**4729:5-15-04 – Drugs approved for euthanasia. (AMEND)**

(A) Pursuant to section [4729.532](#) of the Revised Code, except for a licensed veterinarian or registered veterinary technician, no agent or employee of an animal shelter, **no agent or employee of a wild animal rehabilitation facility**, and no county dog warden or agent or employee of a county dog warden shall perform euthanasia by means of lethal injection on an animal by use of any substance other than a substance in a manufactured dosage form that the state veterinary medical licensing board has approved under chapter 4741. of the Administrative Code.

(B) Before euthanasia, a euthanasia technician may administer a solution of one or more of the following drugs exclusively for the purpose of inducing anesthesia, sedation, or unconsciousness prior to euthanasia:

- (1) Ketamine;
- (2) Tiletamine and zolazepam; and
- (3) Xylazine.

**4729:5-15-05 – Chemical capture classification. (AMEND)**

(A) Upon application of an animal shelter or county dog warden that holds a limited license issued under section [4729.531](#) of the Revised Code, the state board of pharmacy may grant a chemical capture classification to the limited license. The classification permits the holder to purchase, possess, and administer a combination of drugs for chemical capture. Unless otherwise approved by the board, no such classification shall authorize or permit the distribution of these drugs to any person other than the originating wholesale distributor of the drugs.

(1) To qualify for a chemical capture classification under this rule, an applicant shall appoint or employ a certified officer.

(2) An animal shelter or county dog warden shall comply with the initial licensure and renewal requirements set forth in rule [4729:5-2-02](#) of the Administrative Code. As part of this licensing process, the animal shelter or county dog warden shall provide a list of drugs, signed by the responsible person, that will be used for chemical capture.

(3) A certified officer may use any of the following drugs for use as part of the chemical capture process:

(a) Ketamine;

(b) Xylazine;

(c) Tiletamine and zolazepam;

(d) Yohimbine;

(e) Tolazoline; and

(f) Atipamezole.

(B) All areas where drugs and devices used for chemical capture are stored shall comply with the security and storage requirements of rule [4729:5-15-02](#) of the Administrative Code and rule [4729:5-3-13](#) of the Administrative Code.

(C) All drugs used for chemical capture shall comply with the following:

(1) Record\_keeping requirements of rule [4729:5-15-03](#) of the Administrative Code; and

(2) Drug disposal requirements of rule [4729:5-15-02](#) of the Administrative Code.

(D) The animal shelter or dog warden shall develop and implement a drug dosing protocol for all drugs and equipment used in chemical capture.

(1) The protocol shall be reviewed and signed by a veterinarian licensed under Chapter 4741. of the Revised Code.

(2) The protocol shall include the following: drug, dose, concentration, approved uses for drug delivery, approved equipment for use, circumstances for use, contraindications, any known common complications/side effects, and weight ranges with corresponding volume of drug to be administered.

(3) A documented review of the protocol shall be conducted by a veterinarian licensed under Chapter 4741. of the Revised Code at least once every five years.

(E) All equipment used in chemical capture shall:

(1) Be secured to prevent unauthorized access by individuals who are not certified officers;

(2) Maintained and used in accordance with the manufacturer's instructions and the protocol established in accordance with paragraph (D) of this rule.

(3) Be disposed of in accordance with the manufacturer's instructions.

(F) An animal shelter or dog warden with a chemical capture classification shall develop and implement policies and procedures that incorporate the following based upon nationally recognized standards for chemical capture:

(1) Determining when chemical capture is appropriate. Such policies and procedures shall make all reasonable efforts to ensure animal safety, certified officer safety, and the safety of the public.

(2) The care of a companion animal immediately upon capture. Certified officers engaged in chemical capture must have a written animal handling and post capture protocol which includes:

- (a) The procedure for removing the dart from a captured animal;
  - (b) First aid for the animal, with particular reference to the dart wound and potential emergencies (including: hyperthermia, hypothermia, shock, bloat, respiratory distress, and cardiac arrest); and
  - (c) Appropriate location and handling for the animal during recovery from the capture event.
- (G) A terminal distributor of dangerous drugs with a chemical capture classification shall maintain records for every certified officer that has completed training in accordance **with** section [4729.534](#) of the Revised Code. Such documentation shall be made readily retrievable and shall be maintained for one year from the date the certified officer is no longer employed by or affiliated with the terminal distributor of dangerous drugs.
- (H) A wild animal rehabilitation facility or WARF is not eligible for a terminal distributor of dangerous drugs with a chemical capture classification.**