3/12/19

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New

4729:5-3-14: Provides general security requirements for terminal distributors of dangerous drugs.

4729:5-5-23: Provides security, control and storage requirements for dangerous drugs maintained by an outpatient pharmacy.

4729:5-3-13: Authorizes the temporary removal of dangerous drugs from a licensed location.

4729:5-5-24: Provides the requirements for the drug inventory records at an outpatient pharmacy.

Rescind:

4729-9-05: Provides general security requirements for licensees and authorizes the temporary removal of dangerous drugs from a licensed location.

Comments on the proposed rules will be accepted until close of business on **March 28, 2019**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

In addition, please copy your comments to: **CSIPublicComments@governor.ohio.gov**

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Security, Temporary Removal of Drugs and Outpatient Pharmacy Records

Rule Number(s):

New:

- 4729:5-3-14; 4729:5-5-23; 4729:5-3-13; 4729:5-5-24

Rescinds:

- 4729-9-05

Date: 3/12/2019

Rule Type:

New	5-Year Review
Amended	**Rescinded**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

New

- 4729:5-3-14: Provides general security requirements for terminal distributors of dangerous drugs.
- 4729:5-5-23: Provides security, control and storage requirements for dangerous drugs maintained by an outpatient pharmacy.
- 4729:5-3-13: Authorizes the temporary removal of dangerous drugs from a licensed location.
- 4729:5-5-24: Provides the requirements for the drug inventory records at an outpatient pharmacy.

Rescind:

- 4729-9-05: Provides general security requirements for licensees and authorizes the temporary removal of dangerous drugs from a licensed location.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

The rules do not implement a federal requirement.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

This rule exceeds federal requirements because licensure and regulation of terminal distributors is reserved for state authorities and is required pursuant to Chapter 4729. of the Revised Code.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

Section 4729.26 of the Ohio Revised Code authorizes the Board to adopt rules governing the practice of pharmacy and the storage of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture,

distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

Without these regulations, the Board would not be able to provide uniform standards for:

- Drug security requirements for all terminal distributors of dangerous drugs and outpatient pharmacies;
- The temporary removal of dangerous drugs from a licensed location; and
- Maintaining drug inventory records at an outpatient pharmacy.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The success of these regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rule.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

This rule package posted to the Board's website for public comment and disseminated to the Board's external stakeholder list. Prior to filing with CSI, the rule was reviewed and approved by the Board of Pharmacy.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Stakeholders recommended the following changes that were adopted by the Board:

- Removal of panic alarm requirement for outpatient pharmacies;
- Removal of double-sided scan requirement for paper records;
- Provide greater flexibility in regard to temperature monitoring standards; and
- Modify veterinarian requirements for the removal of drugs from a licensed site.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not used to develop or review this rule.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

As the regulations are essential to protecting the public's safety by ensuring uniform security and recordkeeping standards for dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did put forth a performance-based regulation for this rule package, specifically as it relates to policies for responding to temperature excursions at an outpatient pharmacy in order to ensure drug integrity.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The rule package impacts the following:

- Ohio terminal distributors of dangerous drugs.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Violation of these rules may result in administrative licensure discipline for a terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

- 4729:5-3-14: Provides general security requirements for terminal distributors of dangerous drugs. This rule may require expanded security measures in the event physical security controls become inadequate as a result of a significant increase in the quantity of dangerous drugs in the possession of the licensee. This language mirrors current DEA language and rule 4729-9-05. The Board did remove an existing provision in 4729-9-05 that require notification to the Board of new facilities used to store dangerous drugs.
- 4729:5-5-23: Provides security, control and storage requirements for dangerous drugs maintained by an outpatient pharmacy. This rule does require the implementation of both a physical barrier and alarm system to deter and detect the diversion of dangerous drugs from a pharmacy. This may result in costs for pharmacies that only have an alarm system or a physical barrier. Additionally, pharmacies will be required to record daily temperature logs and implement a system to detect temperature excursions. This will add to overall compliance costs. A search conducted by the Board found automated temperature monitoring products available for around $100. Further, the rule will no longer permit outpatient pharmacies to disperse controlled substances among non-controlled substance stock. Therefore, outpatient pharmacies may have to obtain additional cabinets or safes for the storage of controlled substances. This change is an attempt to reduce employee pilferage.
- 4729:5-3-13: Authorizes the temporary removal of dangerous drugs from a licensed location. A veterinarian that seeks to store drugs off-site for more than 24-hours may incur additional costs to ensure drugs are maintained at the proper

temperature and are stored securely. In addition, the veterinarian will be required to obtain a one-time approval to store drugs off-site. The process for submitting a request for approval is estimated to be approximately 15-20 minutes.

- 4729:5-5-24: Provides the requirements for the drug inventory records at an outpatient pharmacy. Outpatient pharmacies may experience increased compliance costs to maintain records in accordance with this rule. However, it should be noted that the recordkeeping requirements are similar, apart from the maintenance of temperature logs, to the current requirements in OAC 4729-9-22 and 4729-9-14.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Board determined that the regulatory intent justifies the impact on business because without the regulations the Board would not be able to provide ensuring uniform security and recordkeeping standards for dangerous drugs for terminal distributors of dangerous drugs.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

This rule does not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure to not meet and maintain standards is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

18. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729:5-3-14 – General security requirements. New. (Rescind 4729-9-05)

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

(1) Deter and detect 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;

(13) Availability of local police protection or of the licensee's or applicant's security personnel, and;

(14) 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.

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

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

(1) Except as provided in paragraph (A)(7) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted 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 must be separated from the merchandising or public areas.

(3) The pharmacist on duty:

(a) Is responsible for securing the pharmacy at all times when the pharmacist is not personally present in the pharmacy, except when the pharmacist is in the immediate area and can observe and exercise control over the pharmacy.

(b) If the pharmacy is located within a store or business, shall ensure that all dangerous drugs, controlled substances, exempt narcotics, poisons 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 on duty or secured in a designated area in accordance with paragraph (A)(7)(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 in the pharmacy is physically present at the same time.

(5) A pharmacy shall maintain on its premises an alarm system capable of detecting unauthorized access when the pharmacy is closed.

(6) All schedule II controlled substance dangerous drugs shall be stored in a separate, secured, 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.

(7) Whenever personal supervision of the pharmacy is not provided by a pharmacist, physical security of the pharmacy must be provided according to the following requirements:

(a) The pharmacy must be secured by a physical barrier (i.e. barricade) with suitable locks when a pharmacist is not present. Such a barrier must be approved within seventy-two hours of installation by an agent, officer or inspector of the board.

(b) Except as provided in paragraph (A)(7)(i) of this rule, the pharmacy must contain all dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms and every other item or product that requires the personal 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 a 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)(7)(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, exempt narcotics, hypodermics, poisons, and any other item or product that requires the personal supervision or sale by a pharmacist.

(g) No prescription, dangerous drug, exempt narcotic, hypodermic, nor any other item or product that requires the personal supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the 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, exempt narcotics, hypodermics, poisons, records relating to the

distribution of dangerous drugs except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to this chapter of the Administrative Code, and every other item or product that requires the personal supervision or sale by a pharmacist shall meet the following requirements:

(i) The designated area shall be secured by a physical barrier with suitable locks to detect unauthorized entry. Such a barrier must be approved within seventy-two hours of installation by an agent, officer or inspector of the board.

(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 personal supervision by a pharmacist.

(iv) No controlled substances may be stored outside of the pharmacy.

(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.

(C) Refrigerators and freezers used for the storage of dangerous drugs and devices at an institutional facility shall comply with the following:

(1) Maintain temperature logs with, at a minimum, daily observations to ensure proper refrigeration and freezer temperatures are maintained.

(2) Temperature control systems must be able to notify the responsible person or the responsible person's designee of temperature excursions.

(3) 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.

(4) 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.

(D) 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.

4729:5-3-13 – Temporary Removal of Dangerous Drugs from a Licensed Location (New)

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 in accordance with a physician approved protocol. The naloxone 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 removed from the terminal distributor. If direct supervision is not provided, the naloxone 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 that cannot be treated at the location licensed as a terminal distributor of dangerous drugs. Prior to the storage of dangerous drugs at an off-site location, the responsible person on the terminal distributor of dangerous drugs shall obtain approval, in manner determined by the board, from the board's executive director or the director's designee. Approval shall be granted upon the demonstrated need that the drugs are necessary to treat patients at a location other than a terminal distributor of dangerous drugs and the veterinarian is unable to comply with paragraph (A) of this rule. The approval shall remain in effect indefinitely unless the veterinarian seeks to store drugs at another location, the veterinarian is no longer employed by the terminal distributor of dangerous drugs, or if rescinded by the board. 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. 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, 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. 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. 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.

(F) A person licensed or certified under Chapter 4765. of the Revised Code may maintain a supply of medical oxygen 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 shall be maintained for an amount of time as determined by written authorization from the licensee's medical director. Medical oxygen 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 removed from the terminal distributor. If personal supervision is not provided, the medical oxygen 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 prior to its use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(G) 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 the dangerous drug(s) to deter and detect diversion.

4729:5-5-24 – Drug inventory records at an outpatient pharmacy. (New)

(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.

(B) Temperature logs maintained in accordance with paragraph (C) 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, a report that provides, at a minimum, the date and time of observation and the temperature recorded.

(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, the positive identification of the licensed 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.

(E) Records of transfer, including sales conducted in accordance with rule 4729:5-3-09 of the Administrative Code, shall contain the name, strength, dosage form, and quantity of the dangerous drug transferred, the name and address of the location where the drugs were transferred, the name and address of the pharmacy conducting the transfer, and the date of transfer.

(F) All records maintained in accordance with this chapter rule be readily retrievable and shall be kept for a period of three years at the place where the dangerous drugs are located.

(G) An outpatient pharmacy located in this state intending to maintain records pursuant to this chapter at an alternate location must first send a written request to the state board of pharmacy. The request shall contain the outpatient pharmacy's name and license number and the name and address of the alternate location. The state board of pharmacy will send written notification to the outpatient pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to representatives or contractors of the terminal distributor of dangerous drugs.

(H) 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) All paper records maintained electronically 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;

(2) A record or entry in a record, once created, shall be unalterable but may be added to or annotated as necessary if the identification of the individual that made the addition or annotation to the record or entry is captured by the recordkeeping system and complies with the requirements of this rule;

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

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

(I) All records required in accordance with this rule shall be maintained under appropriate supervision and control to restrict unauthorized access.