5/7/2018

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

- 4729:5-19-01- Definition section for clinics and prescriber offices rule chapter.
- 4729:5-19-02- Establishes the requirements for a prescriber who personally furnishes dangerous drugs.
- 4729:5-19-03- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs
- 4729:5-19-04- Provides the requirements for record keeping for a clinic or prescriber office.

Comments on the proposed rules will be accepted until close of business on **May 25, 2018**. 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: Clinics and Prescriber Offices

Rule Number(s):

New

- 4729:5-19-01
- 4729:5-19-02
- 4729:5-19-03
- 4729:5-19-04

Date: 5/7/2018

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Amended	Rescinded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

- 4729:5-19-01- Definition section for clinics and prescriber offices rule chapter.

- 4729:5-19-02- Establishes the requirements for a prescriber who personally furnishes dangerous drugs.
- 4729:5-19-03- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs
- 4729:5-19-04- Provides the requirements for record keeping for a clinic or prescriber office.

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?

These 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 package exceeds federal requirements because the regulation of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the State of Ohio Board of Pharmacy.

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 of Pharmacy to adopt rules governing the distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules for the administration and enforcement of Chapter 3719. of the Revised Code in order to prescribe the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, prescribe, or administer controlled substances.

Without these regulations, the Board of Pharmacy would not be able to ensure the licensure and safe operation of clinics and prescriber offices.

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

The success of the 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 rules.

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 was distributed for initial public comment by posting the rule package to the Board's proposed rules website.

Prior to filing with CSI, the rules were 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?**

The Board received the following comments during the initial comment process:

- The Board should not regulate prescriber offices (8 Commenters).
    - Note: The Ohio Revised Code gives the Board the authority to regulate the distribution of dangerous drugs in prescriber offices.
- The OSMA supported efforts to restrict the use of positive identification to controlled substances.
- The OVMA requested that the definitions section specifically exempt veterinarians from the definition of a clinic or prescriber office.
- Remove specific references to physicians in the personal furnishing rule (1 Commenter).
    - Note: The specific reference to physicians is required by law.

The Board made the following change to the rule package:

- 4729:5-19-01: Exempted veterinarians from the definition of a clinic or prescriber and all physician references in the rule draft comes directly from the statute.

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 package.

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 standards for the distribution of 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 not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform practice standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

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 quarterly webinars from the Director of Policy 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:

- Clinics licensed as terminal distributors of dangerous drugs; and
- Prescribers.

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.

New

- 4729:5-19-01- Definition section for clinics and prescriber offices rule chapter. This should not have an adverse impact as it is a definitional.
- 4729:5-19-02- Establishes the requirements for a prescriber who personally furnishes dangerous drugs. The labeling, final check requirements by a prescriber and the counseling provisions of this rule may result in an increase in the overall time necessary to personally furnish a medication to a patient.
- 4729:5-19-03- Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs. The expected adverse impact associated with this rule are the costs of investing in a lockable cabinet or other secure storage area to store dangerous drugs and hypodermics, performing monthly checks if drugs are refrigerated or frozen and ensuring that multiple use vials are appropriately labeled to ensure they are not expired or adulterated.
- 4729:5-19-04- Provides the requirements for record keeping for a clinic or prescriber office. There may be an overall increase in administrative costs associated with complying with the rule.

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

The Board believes that the regulatory intent justifies the impact on business because the regulations are intended to protect and promote public safety. The rules ensure uniform regulations protect the health and safety of patients.

Regulatory Flexibility

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

This rule package 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 regulations are 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 of a standard of care in the distribution of dangerous drugs 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.

4729:5-19-01 – Clinics and Prescriber Offices – Definitions.

As used in Chapter 4729:5-19 of the Administrative Code:

(A) “Clinic” or “Prescriber Office” means a facility licensed as a terminal distributor of dangerous drugs in accordance with 4729.51 of the Revised Code where a licensed prescriber serves as the responsible person on the license and drugs are possessed on-site for administration or personally furnishing. The facility shall comply with all requirements set forth in this chapter. A clinic or prescriber office does not include a veterinary clinic as defined in rule 4729:5-20-01 of the Administrative Code.

(B) "Direct supervision" or "personal supervision" means licensed prescriber shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs.

(C) “Dosage unit” means any of the following:

(1) A single pill, capsule, ampule, tablet;

(2) In the case of a liquid solution, one (1) milliliter;

(3) In the case of a cream, lotion or gel, one (1) gram; or

(4) Any other form of administration available as a single unit.

(D) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(E) "Personally furnish" or “personally furnishing” means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting.

(F)

(1) "Positive identification" means a method of identifying a person that does not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as 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 available on request to those individuals authorized
by law to review such records; 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.

(G) “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.

(H) "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.

(I) “Sample” means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer.

(K) "Tamper-evident" means a package, storage container or other physical barrier is sealed or secured in such a way that access to the drugs or hypodermics stored within is not possible without leaving visible proof that such access has been attempted or made.

4729:5-19-02 – Personally furnishing dangerous drugs.

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

(1) The name and address of the prescriber.

(2) The name of the patient for whom the drug is intended.

(3) Name and strength of the dangerous drug.

(4) Directions for use.

(5) Date furnished.

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

(B) A prescriber who personally furnishes a dangerous drug labeled as a sample and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide written documentation accompanying the sample including the following:

(1) Name of the prescriber.

(2) Name of the patient.

(3) Directions for use.

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

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

(1) Methadone personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07 (9/1/2015);

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

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

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

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

(E) A prescriber may designate a health care professional acting within the scope of the professional's practice and, under the direct supervision of the prescriber, to prepare and package a dangerous drug that will be personally furnished by the prescriber.

(F) A prescriber shall perform the final check of the dangerous drug (i.e. the final association of a drug with a patient) prior to personally furnishing. The final check shall be documented using positive identification.

(G) Counseling.

(1) A prescriber or the prescriber's designee shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (G)(2) of this rule to the owner or caregiver whenever any dangerous drug is personally furnished. A prescriber shall not be required to counsel an owner or caregiver when the owner or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.

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

(a) The name and description of the drug;

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

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

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

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

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage;

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

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

(H) Provision of dangerous drugs.

(1) A prescriber may delegate an individual or individuals to distribute dangerous drugs personally furnished by a prescriber if all the following apply:

(a) A prescriber authorized to personally furnish dangerous drugs provides direct supervision;

(b) Counseling is offered in accordance with paragraph (G) of this rule;

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

(d) The drugs are sealed in a tamper-evident manner.

(2) Paragraph (H)(1)(a) of this rule does not apply if a non-controlled dangerous is provided to the patient by a licensed health care professional, acting within the scope of the professional's practice, and a prescriber authorized to personally furnish dangerous drugs is available for counseling by means of electronic communication during normal hours of operation.

(I) No prescriber may personally furnish to a patient to whom there is no valid prescriber patient relationship, pursuant to applicable state and federal laws, regulations, and rules.

(J) Personally furnishing naloxone.

(1) Except as provided in paragraph (J)(3) of this rule, an authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with section 4731.941 of the Revised Code, shall do all of the following:

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

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

(c) Keep and maintain all records in accordance with this chapter.

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

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

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

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

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

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

(L) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personal furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

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

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

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

(N) A prescriber personally furnishing controlled substances and dangerous drugs containing gabapentin shall comply with all drug database reporting requirements pursuant to Chapter 4729. of the Revised Code and all rules adopted thereunder.

4729:5-19-03 – Security, control and storage of dangerous drugs.

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

(B) Controlled substance dangerous drugs, dangerous drugs containing propofol and gabapentin, uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms, and poisons must be stored in an area or areas secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet, to deter and detect unauthorized access.

(1) Only a prescriber shall have possession of the keys or access codes to the secure area or areas specified in paragraph (B) of this rule. Any additional keys shall be maintained in a secure place that is inaccessible to unauthorized persons.

(2) A licensed health care professional, acting within the scope of the professional's practice may have access to controlled substances, dangerous drugs containing propofol and gabapentin, and poisons only under the direct supervision of a prescriber.

(3) Only a prescriber shall have access to uncompleted prescription blank(s) used for writing a prescription.

(4) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms only under the direct supervision of a prescriber.

(5) Only prescribers may have unsupervised access to controlled substance dangerous drugs.

(C) Non-controlled dangerous drugs shall be secured in a tamper-evident manner to deter and detect unauthorized access.

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

(E) All records relating to the administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access.

(F) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will 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 monthly temperature logs to ensure proper refrigeration temperatures at 36º to 46ºF (2º to 8ºC) and freezer temperatures at 14º to -13ºF (-25º to -10ºC) are maintained at all times;

(2) If a temperature excursion occurs, all affected inventory must be temporarily removed from active inventory and not administered or personally furnished until a documented evaluation of product integrity is completed; and

(3) The responsible person shall develop and monitor a policy that no food or beverage products are permitted to be stored in the refrigerators or freezers.

(G) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or the beyond-use date shall be maintained in a separate record. 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.

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

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

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

4729:5-19-04 – Record Keeping.

(A) A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed or transferred.

(B) The acts of prescribing, administering, and disposal of controlled substance dangerous drugs shall be documented with positive identification.

(C) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the persons from whom received and the date of receipt.

(D) Temperature logs maintained in accordance with paragraph (F) of rule 4729:5-19-03 shall include the date of observation, the full name or the initials of the individual performing the check, and the temperature recorded.

(E) Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drug were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver.

(F) Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the identification of the health care professional administering the drug, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered and the date of administration.

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

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

(3) Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph.

(G) Records of dangerous drug disposal, 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 identification of the licensed health care professional that performed the disposal.

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

(I) Records of transfer 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 address of the location where the drugs were transferred and the date of transfer.

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

(1) A terminal distributor intending to maintain records, described in this rule, at a location other than the place 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 representatives or contractors of the terminal distributor of dangerous drugs.

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

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

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