12/19/18

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

- 4729:5-3-12: Provides the requirements for protocols for medication administration via a protocol or standing order.
- 4729:5-5-22: Establishes the standards and procedures for return to stock in a pharmacy.
- 4729:5-16-01: Definition section for the approved laboratories rule chapter.
- 4729:5-16-02: Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs.
- 4729:5-16-03: Provides the requirements for record keeping for an approved laboratory.

Rescinds:

- Chapter 4729-13: Current requirements for approved laboratories chapter.
- 4729-5-01: Provides definition section for general chapter on pharmacists and pharmacies, including medication protocols.
- 4729-5-14: Provides the requirements for return to stock in a pharmacy.

Comments on the proposed rules will be accepted until close of business on **January 18, 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: **Approved Laboratories, Protocols, and Return to Stock**

Rule Number(s):

New:

- **4729:5-3-12**
- **4729:5-5-22**
- **4729:5-16-01**
- **4729:5-16-02**
- **4729:5-16-03**

Rescinds:

- **4729-5-01**
- **4729-5-14**
- **4729-13-01**
- **4729-13-02**
- **4729-13-03**
- **4729-13-04**
- **4729-13-05**

Date: **12/19/2018**

Rule Type:

New	5-Year Review
Amended	**Rescinded**

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

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

- 4729:5-3-12: Provides the requirements for protocols for medication administration via a protocol or standing order.
- 4729:5-5-22: Establishes the standards and procedures for return to stock in a pharmacy.
- 4729:5-16-01: Definition section for the approved laboratories rule chapter.
- 4729:5-16-02: Provides the requirements of the responsible person on the license which includes establishing standards for security, control and storage of dangerous drugs.
- 4729:5-16-03: Provides the requirements for record keeping for an approved laboratory.

Rescinds:

- Chapter 4729-13: Current requirements for approved laboratories chapter.
- 4729-5-01: Provides definition section for general chapter on pharmacists and pharmacies, including medication protocols.
- 4729-5-14: Provides the requirements for return to stock in a pharmacy.

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. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 3719.01, 4729.01, 4729.54, 4729.55, 4729.57.

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.**

These rules exceed federal requirements because the regulation of dangerous drugs is traditionally done at the state level. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy, including the licensure of facilities that store dangerous drugs and record keeping requirements, has been left to state boards. Additionally, ORC 3719. also requires the Board to develop standards for the operation of laboratories that possess controlled substances.

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.

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:

- Approved laboratories, including security and control of dangerous drugs and record keeping requirements;
- Implementation of medication protocols for drug administration; and
- The return of drugs to stock by pharmacies.

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 rule.

Development of the Regulation

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

Rule 4729:5-5-22 package was reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from several practice settings, is responsible for reviewing and approving all rules prior to their legislatively mandated five-year date.

Rule 4729:5-3-12 was disseminated to stakeholders for public comment by email as well as posted to the Board's website for public comment.

Chapter 4729:5-16 was disseminated to stakeholders for public comment by email as well as posted to the Board's website for public comment.

Prior to filing with CSI, the rule package 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?

For the approved laboratory rules, the Board received input from the Ohio State University and the Ohio Bureau of Criminal Identification and Investigation. Input received from stakeholders led to several modifications to the draft laboratory rules, including:

- Language permitting a responsible person to approve designees who may also provide supervision and control of drugs;
- The rule was amended to clarify that adulterated drugs do not be disposed in accordance with rule if conducting research on or working with adulterated drugs;
- Updated recordkeeping standards for the administration of drugs to research animals.

The Ohio Department of Health also provided feedback on rule 4729:5-3-12. As a result, a new category of protocol was added to the administration of preventive flu medications.

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 standards for the practice of pharmacy, administration of medications and the operation of laboratories, 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 procedures for licensure and the practice of pharmacy.

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 rule 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 rule package 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:

- Laboratories, pharmacies and other entities licensed as 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 this rule 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

- 4729:5-3-12: Provides the requirements for protocols for medication administration via a protocol or standing order. This rule will result in increased administrative costs to a licensee seeking to administer drugs via protocol. Such costs include the time it takes to establish and approve a protocol as well as requirement to review each protocol every two years.
- 4729:5-5-22: Establishes the standards and procedures for return to stock in a pharmacy. Allows a pharmacy to return dangerous drugs that have been dispensed, but not picked up by or delivered to patients and have never left the prescription department of the pharmacy or the control of the pharmacy delivery agent, to stock shelves. The regulation may require upgrades to pharmacy computer systems to ensure the proper expiration date is included on the prescription label. Furthermore, entities that add new labeling (which is optional) will be required to have pharmacists conduct additional checks of medications that are returned to stock. Depending on volume, this will require additional pharmacist hours to meet this requirement.
- 4729:5-16-01: Definition section for the approved laboratories rule chapter. This is a definitional section and should not have an adverse impact.
- 4729:5-16-02: 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 safe to store controlled substances. NOTE: The security requirements mirror federal regulations. Licensees with temperature-controlled drugs on-site will be required to perform daily temperature monitoring of refrigerators and freezers. A review by Board staff identified products on the market under $100 that automate the temperature monitoring process.

- 4729:5-16-03: Provides the requirements for record keeping for an approved laboratory. There may be an overall increase in administrative costs associated with complying with this rule. However, the feedback provided by stakeholders is intended to mitigate the regulatory burden, particularly research laboratories.

Rescinds:

- Chapter 4729-13: Current requirements for approved laboratories chapter.
- 4729-5-01: Provides definition section for general chapter on pharmacists and pharmacies, including medication protocols.
- 4729-5-14: Provides the requirements for return to stock in a pharmacy.

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 the regulations protect and promote public safety by:

- Implementing security and control of dangerous drugs at approved laboratories prevent diversion;
- Ensuring appropriate safeguards to protect the integrity of drugs that are returned to stock in a pharmacy; and
- Developing and implementing standards for drug administration via protocols to protect patient safety.

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 of a standard of care in the practice of pharmacy or

the administration or storage of prescription 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 and regulations.

4729:5-3-12 – Protocols for Medication Administration (Rescind 4729-5-01)

(A) A terminal distributor of dangerous drugs may administer dangerous drugs via a protocol or standing order pursuant to any of the following:

(1) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber. A protocol may be used only by licensed health care professionals when providing limited medical services to individuals in an emergency situation when the services of a prescriber are not immediately available;

(2) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber. A protocol may be used only by licensed health care professionals when administering biologicals or vaccines to individuals for the purpose of preventing diseases;

(3) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber. A protocol may be used only by licensed healthcare professionals when administering vitamin K for prevention of vitamin K deficient bleeding in newborns;

(4) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber. A protocol may be used only by licensed healthcare professionals when administering erythromycin for prevention of ophthalmia neonatorum;

(5) A definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized by a prescriber. A protocol may be used only by licensed healthcare professionals at an institutional facility, as defined in agency 4729 of the Administrative Code, when administering influenza antiviral treatment and chemoprophylaxis to residents and health care personnel according to current guidance issued by the United States center for disease control and prevention.

(6) A definitive set of written treatment guidelines that include patient specific and dose specific orders for the administration of a specific drug that have been authorized by a prescriber to be used when the services of that prescriber are not immediately available. The treatment guidelines shall meet all the following requirements:

(a) The drugs shall only be administered by an individual authorized by law to administer the drugs that are listed in the treatment guidelines.

(b) A prescriber must complete an assessment and make a diagnosis prior to ordering a set of treatment guidelines.

(c) The treatment guidelines:

(i) Can only be initiated upon the order of a prescriber, and the prescriber, utilizing positive identification, must create an order in the patient record to acknowledge and document an adjustment made pursuant to the treatment guidelines before another dose or frequency adjustment can be made;

(ii) Shall only apply to adjusting the dose or frequency of the administration of a specific drug that has been previously ordered by a prescriber;

(iii) Apply only to those drugs that may require calculations for specific dose and frequency adjustments which shall be based on objective measures;

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

(v) Do not apply to those drugs for which a dosage change selected within the usual normal dose range could cause detrimental adverse effects;

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

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

(viii) Can be performed safely without repeated medical assessments;

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

(B) A protocol shall:

(1) Be used only by individuals authorized by law to administer the drugs and to perform the procedures included in the protocol;

(2) Be made readily retrievable; and

(3) Comply with the provision of the "Joint Regulatory Statement - Use of Protocols to Initiate or Adjust Medications" attached as an appendix to this rule.

(C) A protocol listed in paragraphs (A)(1) to (A)(5) of this rule shall be reviewed, and updated as necessary, by the authorizing prescriber at least every two years.

(D) Upon the request of the state board of pharmacy, the responsible person shall provide a copy of a protocol for review within three business days. The state board of pharmacy may prohibit the execution of a protocol if any of the following applies:

(1) The protocol does not meet the requirements set forth in this rule;

(2) The protocol presents a danger to patient safety; or

(3) Upon the recommendation of the appropriate health care regulatory board.

(E) This rule does not prohibit the dispensing or administration of dangerous drugs pursuant to a protocol as authorized in the Revised Code or agency 4729 of the Administrative Code.

4729:5-5-22 Return to stock in a pharmacy.

(A) As used in this rule:

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

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

(B) A pharmacy may return dangerous drugs to stock shelves that have been dispensed, but not picked up by or delivered to patients and have never left the prescription department of the pharmacy or the control of the pharmacy delivery agent, if the pharmacy complies with all of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(E) This rule does not apply to drugs dispensed for inpatients pursuant to agency 4729 of the Administrative Code. Drugs dispensed for inpatients may be returned to stock in accordance with the applicable provisions of agency 4729 of the Administrative Code.

4729:5-16 – Approved Laboratories (Rescinds Chapter 4729-13)

4729:5-16-01 – Approved Laboratories – Definitions.

As used in Chapter 4729:5-16 of the Administrative Code:

(A) "Approved Laboratory" means any facility licensed as a terminal distributor of dangerous drugs in accordance with section 4729.54 of the Revised Code where dangerous drugs and controlled substances are possessed for scientific, clinical or instructional purposes. The facility shall comply with all requirements set forth in this chapter. An approved laboratory does not include a laboratory licensed under section 3796. of the Revised Code.

(B) “Anonymous sample,” means an unknown substance submitted to an approved laboratory for qualitative and or quantitative analysis.

(C) "Controlled substance" means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V.

(D) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(E) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-2-01 of the Administrative Code.

(F) ”Personal supervision" means licensed prescriber, pharmacist, responsible person, or the responsible person’s designee shall be physically present at the licensed location to deter and detect the diversion of dangerous drugs or controlled substances.

(G) "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. A prescriber at an approved laboratory who personally furnishes a dangerous drug or controlled substance shall comply with the requirements of rule 4729:5-19-02 of the Administrative Code.

(H)

(1) "Positive identification" means a method of laboratory personnel 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 prescribed, administered, or dispensed the dangerous drug or controlled substance. 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.

(I) "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 and controlled substances 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.

4729:5-16-02 – Security, control and storage of dangerous drugs.

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

(B) Except as provided in paragraph (H) of this rule, controlled substance dangerous drugs, dangerous drugs containing propofol and gabapentin, exempt narcotics and poisons shall be stored in securely locked, substantially constructed cabinet(s) or safe(s).

(1) The cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public, except 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 controlled substances, a prescriber or licensed health care professional shall provide for adequate observation of the area.

(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.

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than the responsible person or the responsible person's designee if not being used by the responsible person, responsible person's designee, or a laboratory employee or researcher in accordance with paragraph (B)(6)(a), (B)(6)(b) or (B)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom.

(5) During non-business hours, 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 (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule, only the responsible person or the responsible person's designee shall have possession of keys, combinations or access codes to the cabinet or safe specified in paragraph (B) of this rule.

(a) A prescriber may provide a laboratory employee or academic researcher with a temporary key for the purposes of accessing controlled substances, dangerous drugs and poisons listed paragraph (B) of this rule. An employee or researcher shall return the key provided in accordance with this rule to the responsible person or responsible person's designee or a secured location with restricted access (such as a lockbox) no later than the end of the employee's shift,

the end of the researcher's activity, or if there is no longer a responsible person or designee available to provide personal supervision.

(b) A responsible person or the person's designee may provide an employee or researcher with a key, combination or access code for the purposes of accessing controlled substances, dangerous drugs and poisons listed paragraph (B) of this rule, 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 the responsible person or the responsible person's designee;

(ii) The room is locked during non-business hours or when there is no longer a responsible person or responsible person's designee available to provide personal supervision.

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

(C) An employee or researcher of the approved laboratory may have access to controlled substances, dangerous drugs containing propofol, and poisons only under the personal supervision of a prescriber, pharmacist, approved laboratory's responsible person, or the responsible person's designee. A responsible person may have more than one designee. All designee's shall meet the requirements of the responsible person set forth in rule 4729:5-2-01 of the Administrative Code. A laboratory shall maintain a current list of all approved designees.

(D) Only a prescriber shall only have access to uncompleted prescription blank(s) used for writing a prescription. Uncompleted prescription blank(s) shall be secured when not in use.

(E) Personnel authorized by the responsible person may have access to D.E.A. controlled substance order forms under the personal supervision of the laboratory's responsible person. D.E.A. controlled substance order forms shall be secured when not in use.

(F) Controlled substances in the process of testing, use, or research shall be immediately returned to the required storage location upon completion of each such process.

(G) All standards and samples containing, or suspected of containing, a dangerous drug or controlled substance shall be treated as schedule I and II controlled substances.

(H) 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 750 pounds, it must be secured to the floor or wall in such a way that it cannot be readily removed.

(2) The cabinet or safe shall be placed in a designated drug storage area that is not accessible by the public, except 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 controlled substances, the responsible person or the responsible person's designee 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.

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

(6) During non-business hours, 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 the responsible person or the responsible person's designee shall have possession of the key, combination or access code to the safe or cabinet specified in this paragraph.

(I) When the laboratory is not in use by authorized personnel, non-controlled dangerous drugs and hypodermics shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially constructed cabinet/safe, locked room, or secured facility.

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

(K) All areas where dangerous drugs, controlled substances 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 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) Unless otherwise required by research, maintain temperature logs with a daily observation and entry 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 implement a policy that no food or beverage products are permitted to be stored in the refrigerators or freezers.

(L) Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code. This paragraph does not apply to drugs submitted to crime laboratories for analysis or laboratories conducting research using adulterated drugs.

(M) Approved laboratories shall comply with all state and federal laws, rules and regulations governing the use of controlled substances for the purpose of research or chemical analysis.

(N) Unless consumed as part of an analysis, disposal of controlled substance dangerous drugs shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code.

(O) Unless consumed as part of an analysis, disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code.

(P) Unless consumed as part of an analysis, disposal of controlled substances that are not dangerous drugs or any unused portion of a submitted anonymous sample for scientific analysis shall be conducted as follows:

(1) The method of disposal shall render the drug or substance non-retrievable as defined in rule 4729:5-3-01 of the Administrative Code.

(2) Disposal shall be conducted by any of the following:

(a) The responsible person or the responsible person’s designee and one other employee of the approved laboratory;

(b) Two employees of the approved laboratory designated by the responsible person; or

(c) A contracted waste disposal company in compliance with all federal, state and local laws, rules and regulations.

(3) Records for the disposal of the drug or substance shall contain the actual identification of the drug or substance, form, and quantity disposed, the date disposed, the method of disposal and the positive identification of the personnel who disposed of the drugs.

4729:5-16-03 – Record Keeping.

(A) An approved laboratory shall keep a record of all dangerous drugs and controlled substances received, administered, personally furnished, used (i.e. chemical analysis or research), disposed, destroyed or transferred.

(B) The acts of administering, using (i.e. chemical analysis or research) and destroying controlled substances shall be documented with positive identification.

(C) Records of receipt shall contain a description of the substance (if known, the name, strength, dosage form and quantity of the drug), name and address of the persons from whom the substance was received and the date of receipt.

(D) Except as provided in paragraph (E) of this rule, records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the identification of the person personally furnishing the drug, the name, address and date of birth of the person to whom or for whose use the dangerous drug were personally furnished, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver.

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

(F) Except as provided in paragraphs (G) and (H) of this rule, records of administration shall contain the name, strength, dosage form, and quantity of the drugs administered, the name and date of birth of the person to whom or for whose use the drugs were administered, the identification of the person administering the drug, and the date of administration.

(1) Records of non-controlled substances 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 substances 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 or protocol 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) Except as provided in paragraph (H) of this rule, records of administration for animal use shall contain the name, strength, dosage form, and quantity of the drugs administered, the name or identification number of the animal to whom or for whose use the drugs were administered, the identification of the person administering the drug, and the date of administration.

(1) Records of non-controlled substances 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 substances 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 or protocol 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.

(H) Records of administration for non-human research purposes shall contain the name of the drugs administered, the name or identifier of the animal, group of animals, or group of cells for whose use the drugs were administered, and the date of research protocol began. Administration to an animal or group of animals will be pursuant to an approved Institutional Animal Care and Use Committee (IACUC) protocol which outlines the name, strength, dosage form, quantity of the drug to be administered and a timeline for subsequent administration(s). Documentation within a lab notebook or research record of shall be deemed to meet the requirements of this paragraph.

(I) An approved laboratory conducting chemical analysis with dangerous drugs or controlled substances shall maintain records with the following information for each dangerous drug:

(1) The name of the drug.

(2) The form or forms received or manufactured (e.g., powder, granulation, tablet, capsule, or solution) and the concentration in such form (e.g., "C.P.," "U.S.P.," "N.F.," ten-milligram tablet, or ten-milligram concentration per milliliter).

(3) The total number of the forms received or manufactured (e.g., one hundred tablets, thirty one-milliliter vials), including the date and quantity of each receipt or manufacture, and the name, address, if any, of the person from whom received.

(4) The quantity utilized in any manner by the laboratory including the date and manner of utilization, and the name, address, of each person to whom provided for utilization.

(5) The identification of the person or persons conducting the chemical analysis.

(6) This paragraph does not apply to records relating to known or suspected controlled substances or dangerous drugs received as evidentiary material.

(J) An approved laboratory conducting research with dangerous drugs or controlled substances shall maintain records with the following information for each dangerous drug:

(1) The name of the drug.

(2) Each finished form (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., one-hundred-tablet bottle or five-milliliter vial).

(3) The number of commercial containers of each such finished form received from other persons including the date of and the number of containers in each receipt and the name, address, and registration numbers of the persons from whom the containers were received.

(4) The number of units or volume of such finished dosage form or commercial containers provided. The date and name and address of the person to whom it was provided. The date and name and address of the person utilizing or administering the drug and the quantity utilized on behalf of the researcher.

(5) The identification of the person or persons conducting the research.

(K) An approved laboratory conducting chemical analysis of anonymous samples of suspected controlled substances or dangerous drugs shall maintain records containing the following information, to the extent known and reasonably ascertainable by the person conducting the analysis:

(1) Date the sample received;

(2) Purported contents and actual identification;

(3) Quantity received;

(4) Form of sample (i.e., powder, liquid, tablets, etc.);

(5) Description of sample;

(6) Quantity utilized in analysis; and

(7) The identification of the individual conducting the analysis.

(L) Records of dangerous drug disposal, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of disposal, the identification of the person that performed the disposal.

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

(N) Records of the disposal of controlled substances that are not dangerous drugs or any unused portion of a submitted anonymous sample shall be maintained in accordance with paragraph (P) of rule 4729:5-16-02 of the Administrative Code.

(O) 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 or controlled substance transferred, the address of the location where the drugs were transferred and the date of transfer.

(P) Temperature logs maintained in accordance with paragraph (K) of rule 4729:5-16-03 shall include either:

(1) The date 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 of observation and the temperature recorded.

(Q) 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 or controlled substances 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 of the terminal distributor of dangerous drugs.

(R) 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 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 individual user names and passwords, to prevent unauthorized access to the records; and

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