4/9/2019

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

- 4729:5-9-01 – Definitions for institutional facilities. Requires separate licensure for outpatient pharmacies residing on the campus of an institutional facility.
- 4729:5-9-02 – Provides the minimum standards for an institutional pharmacy.
- 4729:5-9-03 – Provides the security and control requirements for dangerous drugs in an institutional facility, including an institutional pharmacy.
- 4729:5-9-04 – Provides the record keeping requirements for institutional facilities, including institutional pharmacies.
- 4729:5-9-05 – Provides the requirements for institutional point of care locations.
- 4729:5-9-06 – Permits the temporary absence of a pharmacist from an institutional pharmacy.
- 4729:5-9-07 – Provides the requirements for maintaining patient profiles at institutional pharmacies.
- 4729:5-9-08 – Provides the requirements for pharmacists to conduct inpatient drug utilization reviews.
- 4729:5-9-09 – Provides the requirements for drug orders, outpatient prescriptions and personally furnishing dangerous drugs in an institutional facility and/or institutional pharmacy.
- 4729:5-9-10 – Provides the requirements for the labeling of dangerous drugs for use within an institutional facility.
- 4729:5-9-11 – Provides the requirements for the operation of hospital self-service employee prescription kiosks.
- 4729:5-9-12 – Permits a prescriber of a hospital to utilize the hospital's DEA registration for the purpose of issuing controlled substance prescriptions.
- 4729:5-9-13 – Provides standards for the return of drugs within an institutional facility.

- 4729:5-9-14 – Authorizes the dispensing of drugs in med paks.
- 4729:5-9-15 – Provides the requirements for the repackaging and relabeling of drugs by an intuitional pharmacy.

Rescinds:

- 4729-17-01 – Provides definitions for institutional facilities.
- 4729-17-02 – Provides requirements for responsible person for an institutional pharmacy.
- 4729-17-03 – Provides the security and control requirements for dangerous drugs in an institutional facility, including an institutional pharmacy.
- 4729-17-04 – Provides the record keeping requirements for institutional facilities, including institutional pharmacies.
- 4729-17-05 – Provides the controlled substance record keeping requirements for institutional facilities, including institutional pharmacies.
- 4729-17-06 – Provides the requirements for institutional point of care locations.
- 4729-17-07 – Permits the temporary absence of a pharmacist from an institutional pharmacy.
- 4729-17-08 – Provides the minimum standards for an institutional pharmacy.
- 4729-17-09 – Provides the requirement for drug orders for patients of an institutional facility.
- 4729-17-10 – Provides the requirements for the labeling of dangerous drugs for use within an institutional facility.
- 4729-17-11 – Provides the requirements for the operation of hospital self-service employee prescription kiosks.
- 4729-17-13 – Permits a prescriber of a hospital to utilize the hospital's DEA registration for the purpose of issuing controlled substance prescriptions.

Comments on the proposed rules will be accepted until close of business on **May 14, 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: Institutional Facilities

Rule Number(s):

New:

- **4729:5-9-01**
- **4729:5-9-02**
- **4729:5-9-03**
- **4729:5-9-04**
- **4729:5-9-05**
- **4729:5-9-06**
- **4729:5-9-07**
- **4729:5-9-08**
- **4729:5-9-09**
- **4729:5-9-10**
- **4729:5-9-11**
- **4729:5-9-12**
- **4729:5-9-13**
- **4729:5-9-14**
- **4729:5-9-15**

Rescinds:

- **4729-17-01**
- **4729-17-02**
- **4729-17-03**

- **4729-17-04**
- **4729-17-05**
- **4729-17-06**
- **4729-17-07**
- **4729-17-08**
- **4729-17-09**
- **4729-17-10**
- **4729-17-11**
- **4729-17-13**

Date: 4/9/2019

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.**
   - 4729:5-9-01 – Definitions for institutional facilities. Requires separate licensure for outpatient pharmacies residing on the campus of an institutional facility.
   - 4729:5-9-02 – Provides the minimum standards for an institutional pharmacy.
   - 4729:5-9-03 – Provides the security and control requirements for dangerous drugs in an institutional facility, including an institutional pharmacy.
   - 4729:5-9-04 – Provides the record keeping requirements for institutional facilities, including institutional pharmacies.

- 4729:5-9-05 – Provides the requirements for institutional point of care locations.
- 4729:5-9-06 – Permits the temporary absence of a pharmacist from an institutional pharmacy.
- 4729:5-9-07 – Provides the requirements for maintaining patient profiles at institutional pharmacies.
- 4729:5-9-08 – Provides the requirements for pharmacists to conduct inpatient drug utilization reviews.
- 4729:5-9-09 – Provides the requirements for drug orders, outpatient prescriptions and personally furnishing dangerous drugs in an institutional facility and/or institutional pharmacy.
- 4729:5-9-10 – Provides the requirements for the labeling of dangerous drugs for use within an institutional facility.
- 4729:5-9-11 – Provides the requirements for the operation of hospital self-service employee prescription kiosks.
- 4729:5-9-12 – Permits a prescriber of a hospital to utilize the hospital's DEA registration for the purpose of issuing controlled substance prescriptions.
- 4729:5-9-13 – Provides standards for the return of drugs within an institutional facility.
- 4729:5-9-14 – Authorizes the dispensing of drugs in med paks.
- 4729:5-9-15 – Provides the requirements for the repackaging and relabeling of drugs by an intuitional pharmacy.

Rescinds:

- 4729-17-01 – Provides definitions for institutional facilities.
- 4729-17-02 – Provides requirements for responsible person for an institutional pharmacy.
- 4729-17-03 – Provides the security and control requirements for dangerous drugs in an institutional facility, including an institutional pharmacy.
- 4729-17-04 – Provides the record keeping requirements for institutional facilities, including institutional pharmacies.
- 4729-17-05 – Provides the controlled substance record keeping requirements for institutional facilities, including institutional pharmacies.

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- 4729-17-10 – Provides the requirements for the labeling of dangerous drugs for use within an institutional facility.
- 4729-17-11 – Provides the requirements for the operation of hospital self-service employee prescription kiosks.
- 4729-17-13 – Permits a prescriber of a hospital to utilize the hospital's DEA registration for the purpose of issuing controlled substance prescriptions.

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.

These rules exceed federal requirements because the regulation of the practice of pharmacy has traditionally been done at the state level. Per Ohio law, the Board regulates all aspects of pharmacy practice and the distribution of dangerous drugs.

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 practice of pharmacy and distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of pharmacy to adopt rules governing controlled substances.

These rules are necessary to ensure uniform standards for the recordkeeping, storage and distribution of dangerous drugs at institutional facilities and 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 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 reviewed by the Board's Rules Review Committee. The Committee, composed of pharmacists from a number of practice settings (including institutional facilities), is responsible for reviewing and approving all rules prior to their legislatively mandated five-year date.

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 proposed rules, the Committee made the following recommendations that were incorporated into the rule package:

- 4729:5-9-01: The addition of free-standing emergency departments to the definition of institutional facility.
- 4729:5-9-01: The addition of the definition of readily retrievable to the definitions section.
- 4729:5-9-03: The electronic timeout for automated medication systems was extended.

- 4729:5-9-03: Hypodermics were removed from general security requirements and, instead, the rule requires an institutional facility/pharmacy develop a policy to prevent unauthorized access.
- 4729:5-9-08: Clarified that, except as required in policy, drugs under the control of a prescriber are not subject to prospective drug reviews by a pharmacist.

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 safe distribution of dangerous drugs by institutional facilities/pharmacies, 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.***

In several instances, the rule package does allow institutional facilities and pharmacies to develop and implement policies to achieve required outcomes. Examples include: safe storage of hypodermics, temperature excursion response and pharmacist review of override medications.

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 institutional facilities and pharmacies licensed as terminal distributors of dangerous drugs. Institutional facilities and pharmacies are defined in proposed rule 4729:5-9-01.

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

- 4729:5-9-01 – Definitions for institutional facilities. Requires separate licensure for outpatient pharmacies residing on the campus of an institutional facility. Depending on the type of drugs dispensed by the outpatient pharmacy, the cost of obtaining a separate license is either $320 or $440 every two years.
- 4729:5-9-02 – Provides the minimum standards for an institutional pharmacy. The rule requires access to specific references. Most of the references are available online at no-cost. However, the required compounding references are proprietary and cost $850 to

access. It should be noted that meeting such standards set forth in the compounding references is required for accreditation so most institutional pharmacies conducting drug compounding already have access to these references.

- 4729:5-9-03 – Provides the security and control requirements for dangerous drugs in an institutional facility, including an institutional pharmacy. Costs associated with this rule include the cost of securing controlled substances, administrative costs to develop and implement policies for the review of medications removed from automated medication systems, implementing a physical or electronic barrier to secure an institutional pharmacy, and maintaining systems capable of temperature control monitoring.

- 4729:5-9-04 – Provides the record keeping requirements for institutional facilities, including institutional pharmacies. This rule requires record keeping systems to incorporate positive identification (NOTE: this is a current requirement). The cost of implementing positive identification can range given that it can be accomplished using simple methods (i.e. a paper record with a hard copy signature) to more technologically sophisticated methods (i.e. biometric scans). In general, this rule presents an overall administrative burden to maintain all records relating to the administration, dispensing and distribution of dangerous drugs within an institutional facility/pharmacy.

- 4729:5-9-05 – Provides the requirements for institutional point of care locations. The cost of implementing a point of care location is the requirement to secure all drugs in a substantially constructed cabinet or safe. This includes the use of an automated medication system.

- 4729:5-9-06 – Permits the temporary absence of a pharmacist from an institutional pharmacy. This rule is optional. Those choosing to implement the requirement of this rule will experience increased administrative costs to develop and implement the required policies and procedures.

- 4729:5-9-07 – Provides the requirements for maintaining patient profiles at institutional pharmacies. While pharmacies are already required to maintain patient profiles, an institutional pharmacy may have to make additional investments in software upgrades to capture the information required by the rule.

- 4729:5-9-08 – Provides the requirements for pharmacists to conduct inpatient drug utilization reviews. Requires pharmacists to conduct prospective and retrospective drug utilization reviews. The costs of retrospective reviews will vary based upon the policies implemented by the institutional facility.

- 4729:5-9-09 – Provides the requirements for drug orders, outpatient prescriptions and personally furnishing dangerous drugs in an institutional facility and/or institutional pharmacy. This rule may result in increased costs as all outpatient prescriptions must be

dispensed in accordance with the applicable outpatient provisions in Chapter 4792:5 of the Administrative Code.

- 4729:5-9-10 – Provides the requirements for the labeling of dangerous drugs for use within an institutional facility. This rule may result in increased administrative and information technology costs to capture the positive identification of individuals associating a barcode to a drug product and a label to a drug product.
- 4729:5-9-11 – Provides the requirements for the operation of hospital self-service employee prescription kiosks. Those that choose to install a kiosk will have to ensure the kiosk has the proper security requirements, including video cameras. Furthermore, it requires any kiosk not on a hospital campus to be separately licensed as a terminal distributor of dangerous drugs. The cost of the license ranges from $160 to $220 per year based upon the type of drugs contained in the kiosk.
- 4729:5-9-12 – Permits a prescriber of a hospital to utilize the hospital's DEA registration for the purpose of issuing controlled substance prescriptions. The cost of this rule is the submission of internal prescriber codes to the Board of Pharmacy.
- 4729:5-9-13 – Provides standards for the return of drugs within an institutional facility. The cost of this rule is the wastage of drugs that do not meet the requirements of the rule and cannot be returned to stock.
- 4729:5-9-14 – Authorizes the dispensing of drugs in med paks. The adverse impact of this rule is the administrative burden and information technology costs that may be associated with the labeling requirements for med paks.
- 4729:5-9-15 – Provides the requirements for the repackaging and relabeling of drugs by an intuitional pharmacy. This rule may result in increased administrative and information technology costs to capture the recordkeeping requirements, including the positive identification of individuals associating a barcode to a drug product and a label to a drug product.

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 ensuring uniform standards for the distribution of drugs by institutional facilities/pharmacies. It is in the public's interest to ensure that proper safeguards are implemented to prevent the diversion of drugs and maintain accountability for the care provided by pharmacists working in an institutional facility.

Regulatory Flexibility

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

The rules do 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 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 and regulations.

4729:5-9 Institutional facility.

4729:5-9-01 Definitions.

As used in Chapter 4729:5-9 of the Administrative Code:

(A) "Institutional facility" means a hospital as defined in section 3727.01 of the Revised Code, or a facility licensed or registered by the state board of pharmacy and the Ohio department of health, the Ohio department of rehabilitation and correction, the Ohio department of developmental disabilities, or the Ohio department of mental health and addiction services at which medical care is provided on site and a medical record documenting episodes of care, including dangerous drugs ordered and administered, is maintained. An institutional facility shall comply with all applicable provisions of this chapter and may also include any of the following facilities:

(1) Freestanding inpatient rehabilitation facility or inpatient rehabilitation facility as defined in rule 3701-83-25 of the Administrative Code;

(2) Ambulatory surgical facility as defined in rule 3701-83-15 of the Administrative Code;

(3) Nursing home licensed under Chapter 3721. of the Revised Code, skilled nursing facility that meets the requirements for participation in medicare, or nursing facility that meets the requirements for participation in medicaid;

(4) Inpatient psychiatric service provider as defined in rule 5122-14-01 of the Administrative Code;

(5) Facility that provides twenty-four-hour medically supervised detoxification services (level III) that is certified by the Ohio department of mental health and addiction services;

(6) State or local correctional facility, as defined in section 5163.45 of the Revised Code;

(7) Freestanding emergency department;

(8) Any other facility as determined by the board.

(B) “Institutional pharmacy” means a pharmacy that primarily provides inpatient pharmacy services to an institutional facility in accordance with this chapter. An institutional pharmacy shall comply with all applicable provisions of this chapter.

(C) "Audit trail" means all materials and documents required for the entire processing of a prescription, which shall be sufficient to document or reconstruct the origin of the prescription order, and authorization of subsequent modifications of that order.

(D) “Automated medication system” means a mechanical system that performs operations or activities, other than compounding or administration, related to the storage, packaging, or dispensing of drugs, and collects, controls, and maintains transaction information and records.

(E) "Contingency drugs" are dangerous drugs which may be required to meet the therapeutic needs of patients when a licensed pharmacist is not available and personally in full and actual charge of the institutional pharmacy.

(F) "Dispense” means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug. In the case of an automated drug delivery system meeting the requirements of agency 4729 of the Administrative Code, the final association of a drug to a patient will be deemed to have occurred when the pharmacist has given final approval to the patient specific order in the system.

(G) "Electronic drug record keeping system" means a system of storing drug records electronically and capturing positive identification.

(H) "Inpatient" means any person who receives drugs for use while within an institutional facility.

(I) "Inpatient prescription" or “medication order” means a written, electronic, or oral order for a drug to be dispensed or administered for use in treating an inpatient.

(J) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-1-02 of the Administrative Code but shall be limited to a prescriber practicing within the prescriber's applicable scope of practice.

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

(L) "Outpatient" means any person who receives drugs for use outside of an institutional facility.

(M) "Outpatient institutional pharmacy" means a pharmacy located within or on the campus of an institutional facility that provides outpatient pharmacy services which is physically separate from, and not contiguous to, the area in which inpatient pharmacy services are provided. An outpatient institutional pharmacy shall have a separate terminal distributor of dangerous drugs license in addition to the license for the institutional facility. An outpatient institutional pharmacy shall comply with the requirements of chapter 4729:5-5 of the Administrative Code. An inpatient pharmacy that also provides outpatient pharmacy services shall comply with the applicable provisions of this chapter, including rule 4729:5-9-09 of the Administrative Code.

(N) “Override medication” means a dangerous drug that may be removed from an automated medication system prior to pharmacist review in accordance with 4729:5-9-08 of the

Administrative Code because the institutional facility's interdisciplinary committee has determined that the clinical status of the patient would be compromised by delay.

(O) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional activities.

(P) "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 an institutional facility.

(Q) "Pharmacist" means an individual who holds a current pharmacist license under Chapter 4729. of the Revised Code.

(R) "Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.

(S)

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

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

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

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

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

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

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

(T) "Point of care location" means a location within an institutional facility that stores dangerous drugs and all the following apply:

(1) The point of care location is licensed as a terminal distributor of dangerous drugs;

(2) The dangerous drugs are not owned by the institutional facility where the point of care location is located;

(3) The dangerous drugs stored are owned by another institutional facility licensed as a terminal distributor of dangerous drugs; and

(4) The location may be used for the administration, personally furnishing, or dispensing of dangerous drugs, including controlled substances.

(U) "Practice of pharmacy" is as defined in division (B) of section 4729.01 of the Revised Code.

(V) “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.

(W) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

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

4729:5-9-02 Minimum standards for an institutional pharmacy.

(A) Library

(1) All pharmacists working in an institutional pharmacy must be able to access all current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio, including internet access to the following:

(a) The board's website;

(b) LAWriter® Ohio Laws and Rules (http://codes.ohio.gov);

(c) The code of laws of the United States of America (variously abbreviated to Code of Laws of the United States, United States Code, U.S. Code, U.S.C., or USC);

(d) The code of federal regulations; and

(e) If engaged in the compounding of dangerous drugs, all references listed in rule 4729:7-1-01 of the Administrative Code.

(2) The pharmacy shall have access to and utilize the references necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws, this shall include hard copy or internet access to appropriate pharmacy reference materials.

(3) All pharmacists working in a pharmacy shall have access to the telephone number of a poison control center.

(B) Equipment

The pharmacy shall carry and utilize the equipment necessary to conduct a pharmacy in a manner that is in the best interest of the patients served and to comply with all state and federal laws.

(C) Stock of drugs

The stock of drugs shall include such chemicals, drugs, and preparations sufficient to compound and prepare all types of prescriptions offered by the pharmacy.

(D) Space and fixtures

(1) All areas where drugs, equipment and devices are stored and prepared shall be dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to their dispensing or administering as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(2) All storage areas shall provide adequate security for all dangerous drugs in accordance with the requirements of this chapter.

(E) Personnel

(1) The pharmacy shall be appropriately staffed to operate in a safe and effective manner pursuant to section 4729.55 of the Revised Code.

(2) An employee of a pharmacy that may have contact with patients or the public must be identified by a name tag that includes the employee's job title.

4729:5-9-03 Security, storage and control of dangerous drugs in an institutional facility.

(A) In the absence of a licensed pharmacist, drugs ordered by a prescriber for patient treatment may be obtained in the following manner:

(1) Where a licensed pharmacist is not continuously present, drugs for patient treatment may be made available to licensed health care professionals authorized pursuant to the Revised Code to administer drugs in the course of the professional's practice by the use of contingency drug supplies pursuant to the provisions of this paragraph. A licensed pharmacist shall be made available for emergencies when the institutional pharmacy is closed.

(2) Contingency drugs shall be used only in the absence of a licensed pharmacist.

(3) Controlled substance dangerous drugs shall be stored in accordance with paragraphs (B) or (C) of this rule.

(4) Non-controlled dangerous drugs shall be stored in a secure area to deter and detect unauthorized access. If non-controlled dangerous drugs cannot be stored in a secure area, they shall be stored in a tamper-evident manner.

(5) With respect to contingency drugs, the responsible person shall:

(a) Designate those who may obtain access to the drug supply;

(b) Determine, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included in the contingency drug supply;

(c) Ensure that such drugs are properly labeled and packaged in sufficient quantities to provide drug therapy;

(d) Provide security controls to prevent diversion of the drugs, and institute record keeping procedures to account for the drugs when used and the positive identification of the person who obtained the drugs from the drug supply;

(e) Provide procedures for the inspection of the contingency drug inventory to ensure proper utilization and replacement of the drug supply; and

(f) Compliance with controlled substance requirements of paragraph (B) of this rule.

(6) For a pharmacy located on the premises of the institutional facility, when a dangerous drug is not available from the contingency drug supply and such drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drug may be obtained from the institutional pharmacy pursuant to written policies and procedures implemented by the responsible person.

(a) The policies and procedures shall:

(i) Identify the personnel authorized to access the pharmacy and the conditions under which access may be gained to the pharmacy;

(ii) Ensure a minimum of two employees of the institutional facility, one of whom shall be a health care professional licensed pursuant to Chapter 4723. (Nursing Practice Act) or a prescriber and authorized by such chapter to administer drugs in the course of the professional's practice, to accompany each other when accessing the pharmacy;

(iii) Provide a written record documenting emergency access to the pharmacy. Such record shall include the names, titles, and positive identification of all institutional personnel accessing the pharmacy, date and time of access, the name and quantity of drugs obtained, the name of the patient, and the name of the ordering prescriber.

(b) The written record of each access to the institutional pharmacy when it is closed and a pharmacist is not present shall be filed, within twenty-four hours, with the responsible person or responsible person's designee and maintained in the pharmacy for three years.

(B) All controlled substances maintained as stock in areas outside of the pharmacy shall meet the following requirements, unless stored in an automated medication system that meets the requirements of paragraph (C) of this rule:

(1) The drugs shall be a securely locked in a substantially constructed cabinet or safe to deter and detect unauthorized access.

(2) At every change of shift, a reconciliation shall be conducted by both the departing and incoming licensed health care professional responsible for the security of the drugs in the area in which they are stored and shall include the following:

(a) A physical count and reconciliation of the controlled substances and proof-of-use sheets or electronic records to ensure the accountability of all doses;

(b) An inspection of the packaging to ensure its integrity;

(c) The positive identification of the persons conducting the reconciliation; and

(d) The immediate reporting of any unresolved discrepancy to the appropriate personnel within the institution, including the responsible person or the responsible person's designee.

(3) All controlled substances shall be packaged in tamper-evident containers except multi-dose liquids and injectables where unit-of-use packaging is not available.

(4) Maintain a proof-of-use sheet or approved computerized recordkeeping system for each drug in accordance with paragraph (F) of rule 4729:5-9-04 of the Administrative Code.

(C) All controlled substances maintained as stock in areas outside of the pharmacy that are stored in an automated medication system shall comply with all the following requirements:

(1) The automated medication system shall be a securely locked and substantially constructed to deter and detect unauthorized access.

(2) The system shall document the positive identification of every person accessing the system and shall record the date and time of access;

(3) Shall maintain a recordkeeping system in accordance with paragraph (G) of rule 4729:5-9-04 of the Administrative Code.

(4) At least annually, the responsible person shall cause a reconciliation of the automated medication system to be conducted. The reconciliation shall include the following:

(a) A physical count and reconciliation of the controlled substances to ensure the accountability of all doses;

(b) An inspection of the packaging to ensure its integrity:

(c) The positive identification of the persons conducting the reconciliation; and

(d) The immediate reporting of any unresolved discrepancy to the appropriate personnel within the institution, including the responsible person or the responsible person's designee.

(5) Access to all controlled substances stored in automated medication systems shall be limited to one drug and strength at a time.

(6) Unless the system only allows access to one dose at a time, all controlled substances stored in automated medication systems shall be packaged in tamper-evident containers.

(D) All automated medication systems utilized by an institutional facility shall comply with the following:

(1) The compartment or area used to store drugs shall only remain open for a maximum of ninety seconds.

(2) Except as provided in paragraph (D)(3) of this rule, the computer program used to access all drugs within the automated medication system shall have an electronic timeout of ninety seconds of inactivity.

(3) For an automated medication system used exclusively for administering anesthesia drugs that is under the immediate supervision of a licensed healthcare provider, the computer program used to access all drugs within the automated medication system shall have an electronic timeout of thirty minutes of inactivity or less.

(4) The institutional facility shall develop and implement policies and procedures for all automated medication systems that include the following:

(a) Provide for a written or electronic record documenting access to the automated medication system to access override medications. Such record shall include the names, titles, and positive identification of all institutional personnel accessing override medications, date and time of access, the name and quantity of drugs obtained, and the name of the patient.

(b) Provide security controls to prevent diversion of the drugs, policies and procedures to track access to emergency override access keys;

(c) Provide procedures for the inspection of the systems to ensure proper utilization and replacement of the drug supply; and

(5) If override medications are utilized, the institutional facility shall develop and implement policies to review appropriate usage by a pharmacist;

(6) All policies and procedures required in accordance with paragraph (D)(4) and (D)(5) shall be maintained in a readily retrievable manner.

(E) Supplies of dangerous drugs may be maintained in patient care areas according to written policies and procedures developed and implemented by the responsible person. The policies and procedures shall comply with all the following:

(1) Provide for a limited quantity of dangerous drugs to be maintained at any one location;

(2) Provide for the proper storage and labeling of all such drugs;

(3) All controlled substances shall be secured in accordance with paragraph (B) or (C) of this rule.

(4) Non-controlled dangerous drugs shall be stored in a secure area to prevent unauthorized access. If non-controlled dangerous drugs cannot be stored in a secure area, they shall be stored in a tamper-evident manner;

(5) Provide for notification of the responsible person, or designated pharmacist, when the dangerous drug supply has been accessed and/or drugs used;

(6) Provide for replacement of the drug supply;

(7) Provide for inspection of the dangerous drug supply, on a regular basis, to detect unauthorized use of such drugs and which drugs have exceeded their expiration or beyond use date;

(8) Provide record keeping procedures to document the disposition of drugs from the supply in accordance with this chapter of the Administrative Code.

(F) An institutional pharmacy shall comply with all the following security measures:

(1) All areas occupied by an institutional pharmacy shall be capable of being secured by key, or other effective mechanism, to prevent access by unauthorized personnel.

(a) Except as provided in paragraph (A)(6) of this rule, only a licensed pharmacist may have access to keys, alarm codes, or other methods of gaining access to the pharmacy.

(b) 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.

(c) 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.

(2) Except as provided in rule 4729:5-9-06 of the Administrative Code, a pharmacist shall provide supervision of the dangerous drugs, exempt narcotics, D.E.A. controlled substance order forms, all 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 in accordance with this chapter, at all times in order to deter and detect theft or diversion.

(3) Except as provided in rule 4729:5-9-06 of the Administrative Code, in the absence of a licensed pharmacist, all areas occupied by an institutional pharmacy must be secured by either:

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

(b) An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation.

(4) Except as provided in paragraph (A)(6) of this rule, only a pharmacist may have access to an institutional pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, exempt narcotics, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist.

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

(6) Any designated area located outside an institutional 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, 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, and every other item or product that requires the supervision or sale by a pharmacist shall be secured by an approved physical barrier with suitable locks to detect unauthorized entry. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

(G) All controlled substances dispensed to inpatients in an institutional facility in quantities exceeding a seventy-two-hour supply shall be dispensed and maintained according to the following requirements:

(1) All controlled substances dispensed in quantities exceeding a seventy-two-hour supply shall be packaged in tamper-evident, unit-of-use containers except multi-dose liquids and injectables where unit-of-use packaging is not available;

(2) The drugs shall be stored in a securely locked, substantially constructed cabinet, including an automated medication system, or safe to deter and detect unauthorized access;

(3) A proof-of-use sheet or approved electronic recordkeeping system shall be maintained in accordance with paragraph (E) of rule 4729:5-9-04 of the Administrative Code.

(4) At every change of shift, a reconciliation shall be conducted by both the departing and incoming licensed health care professional responsible for the security of the drugs in the area in which they are stored and shall include at least the following:

(a) A physical count and reconciliation of the controlled substances and proof-of-use sheets or electronic records to ensure the accountability of all doses;

(b) An inspection of the packaging to ensure its integrity;

(c) The positive identification of the persons conducting the reconciliation; and

(d) The immediate reporting of any unresolved discrepancy to the appropriate personnel within the institution, including the responsible person or the responsible person's designee at the pharmacy responsible for the terminal distributor of dangerous drugs license.

(H) Refrigerators and freezers used for the storage of dangerous drugs 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 drugs.

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

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

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

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

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

(L) In accordance with section 3719.172 of the Revised Code, an institutional facility shall develop and implement policies to prevent hypodermics from theft or acquisition by any unauthorized person.

(M) The provisions of this rule do not apply to dangerous drugs that were dispensed to the patient prior to entering an institutional facility.

4729:5-9-04 Record Keeping.

(A) All records maintained in accordance with this chapter shall be uniformly maintained for a period of three years. Except as provided in paragraph (A)(3) of this rule, all records shall be made readily retrievable.

(1) Computerized drug record keeping systems or subsequent storage of such records, must be retrievable via digital display, hard copy printout, or other mutually agreeable transfer medium.

(2) If a computerized drug record keeping system is being utilized, the method(s) of achieving positive identification must be approved, in a manner determined by the board, prior to implementation or any subsequent modification.

(3) Record keeping systems shall provide immediate retrieval via digital display and hard copy printout or other mutually agreeable transfer medium of information for all prescriptions dispensed within the previous twelve months and shall provide in a manner that is readily retrievable information on all prescriptions dispensed beyond the previous twelve months but within the previous three years.

(4) All computerized record keeping systems shall be able to capture records edited by authorized personnel and maintain an audit trail as defined in rule 4729:5-9-01 of the Administrative Code.

(5) 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.

(6) All computerized record keeping systems, including systems used to store scanned paper records, shall have daily back-up functionality to protect against record loss and security features to prevent unauthorized access.

(B) All records maintained in accordance with this chapter shall be maintained at the place where the dangerous drugs are located.

(1) An institutional facility 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 facility’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 facility 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.

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

(C) At an institutional pharmacy:

(1) There shall be positive identification of the licensed or registered individuals responsible for performing the following activities authorized in Chapter 4729. of the Revised Code and agency 4729 of the Administrative Code:

(a) Prescription information entered into the record keeping system. This provision shall take effect one-year from the effective date of this rule.

(b) Verification by the pharmacist of the prescription information entered into the record keeping system.

(c) Drug utilization review in accordance with rule 4729:5-9-08 of the Administrative Code, which shall be captured as a standalone action or as part of either:

(i) The pharmacist verification of prescription information in paragraph (C)(1)(b) of this rule; or

(ii) The dispensing process in paragraph (C)(1)(d) of this rule.

(d) Dispensing.

(e) Compounding in accordance with chapter 4729:7-2 of the Administrative Code.

(f) Administering immunizations pursuant to section 4729.41 of the Revised Code.

(g) Administering other injectable drugs pursuant to section 4729.44 of the Revised Code.

(h) Prescription information transcribed from an order received by telephone or recording device.

(i) Any changes or annotations made to a prescription or order.

(2) Shall maintain the following records:

(a) All inpatient prescriptions issued in accordance with rule 4729:5-9-09 of the Administrative Code.

(b) Records of drugs dispensed shall including all the following:

(i) The name, strength, dosage form, and quantity of drugs dispensed;

(ii) The date of dispensing;

(iii) The name of the inpatient to whom, or for whose use, the drug was dispensed; and

(iv) The positive identification of the individuals involved in the dispensing process in accordance with paragraph (C)(1) of this rule.

(3) Shall maintain records of all drugs dispensed to outpatients pursuant to rule 4729:5-5-04 of the Administrative Code.

(4) Shall maintain records of all drugs repackaged pursuant to rule 4729:5-9-15 of the Administrative Code.

(5) Shall maintain records of all drugs compounded pursuant to Chapter 4729:7-2 of the Administrative Code.

(6) Shall maintain records for the distribution of dangerous drugs to other areas of the institutional facility for administration or use as described in rule 4729:5-9-03 of the Administrative Code, which shall include all the following:

(a) The name, strength, dosage form, and amount of drug distributed;

(b) The area receiving the drug;

(c) The date distributed; and

(d) For non-controlled drugs: The identification of the facility personnel receiving the drug or authorized personnel stocking the automated medication system.

(e) For controlled substance drugs: The positive identification of the facility personnel receiving the drug or authorized personnel stocking the automated medication system.

(D) The area of the institutional facility receiving the dangerous drug in accordance with paragraph (C)(6) of this rule shall make a record of all such drugs administered to patients. Such records shall include the following:

(a) Name of the patient;

(b) Name, dosage form, and strength when applicable of the drug;

(c) Date and time the drug was administered;

(d) Quantity administered;

(e) Positive identification of the personnel administering the drug.

(E) All controlled substances dispensed to inpatients in an institutional facility in quantities exceeding a seventy-two-hour supply shall maintain a proof-of-use sheet or approved electronic record keeping system for each drug that includes the following information:

(1) Patient name;

(2) Date and time of access;

(3) Drug name, strength, and quantity obtained and quantity remaining;

(4) The positive identification of the person administering the controlled substance drug;

(5) The disposal of an unused portion of a controlled substance conducted in accordance with paragraph (I) of rule 4729:5-9-03 of the Administrative Code.

(F) All controlled substances maintained as stock in areas outside of the pharmacy that are not stored in an automated medication system shall maintain a proof-of-use sheet or approved computerized recordkeeping system for each drug that includes the following information:

(1) Patient name;

(2) Date and time of access;

(3) Drug name, strength, and quantity obtained;

(4) The positive identification of the person administering the controlled substance drug; and

(5) The disposal of an unused portion of a controlled substance conducted in accordance with paragraph (I) of rule 4729:5-9-03 of the Administrative Code.

(G) All controlled substances maintained as stock in areas outside of the pharmacy that are stored in an automated medication system shall maintain a recordkeeping system that includes the following information:

(1) Patient name;

(2) Date and time of access;

(3) Drug name, strength, and quantity removed;

(4) The positive identification of the person removing the drug; and

(5) The disposal of an unused portion of a controlled substance conducted in accordance with paragraph (I) of rule 4729:5-9-03 of the Administrative Code.

(H) Records of personally furnishing shall contain the name, strength, dosage form, lot number 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.

(I) 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.

(J) Temperature logs maintained in accordance with paragraph (H) of rule 4729:5-9-03 of the Administrative Code 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, either of the following:

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

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

(K) 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.

(L) Records of controlled substance drug disposal shall comply with the requirements of rules 4729:5-3-01 and 4729:5-9-03 of the Administrative Code.

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

(N) Records of transfers to other terminal distributors of dangerous drugs, 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 address of the location where the drugs were transferred and the date of transfer.

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

4729:5-9-05 Institutional point of care location.

(A) "Point of care location" has the same meaning as in rule 4729:5-9-01 of the Administrative Code.

(B) Dangerous drugs maintained at a point of care location shall be a securely locked, substantially constructed cabinet, including an automated medication system, or safe to deter and detect unauthorized access.

(C) The responsible person for the point of care location shall be an employee of the institutional pharmacy that owns the drug stock and shall be responsible for all the following:

(1) Designating those who may obtain access to the drug stock;

(2) Determining, in conjunction with the appropriate interdisciplinary committees, the drugs that are to be included at the point of care location;

(3) Providing controls to prevent the diversion of the drug stock and instituting record keeping procedures to account for the drugs when used and the positive identification of the person who obtained the drugs from the drug stock;

(4) Provide procedures for the inspection of the point of care location to ensure proper utilization and replacement of the drug stock.

(D) If dangerous drugs that are controlled substances are stored at the point of care location, the owner of the drug stock shall either:

(1) Obtain a drug enforcement administration (DEA) registration for the point of care location; or

(2) Utilize the DEA registration of the institutional facility where the point of care location is located. The institutional facility where the point of care location is located shall be responsible for compliance with all federal and state laws and regulations relating to the possession and use of controlled substances.

(E) This rule does not apply to pharmacy-supplied contingency drugs in an institutional facility licensed as a terminal distributor of dangerous drugs.

(F) An institutional point of care location that contains controlled substances shall comply with the requirements of rules 4729:5-9-03 and 4729:5-9-04 of the Administrative Code.

4729:5-9-06 Temporary absence of a pharmacist in an institutional pharmacy.

(A) A pharmacist practicing within an institutional facility may temporarily leave the pharmacy to engage in the practice of pharmacy within the institutional facility without closing the pharmacy and removing staff from the pharmacy if the practicing pharmacist can ensure there are adequate security measures and policies to maintain the security of the drug stock in the pharmacist's absence.

(B) If in the professional judgment of the pharmacist, for reasons of security or otherwise, the pharmacist determines that the pharmacy should close during the pharmacist's absence, then the pharmacist shall close the pharmacy and remove all staff from the pharmacy during the pharmacist's absence.

(C) During the pharmacist's absence, no dangerous drugs shall be dispensed unless the pharmacist has conducted a final association of the drug with a patient and has complied with all other applicable rules prior to dispensing a dangerous drug.

(D) During such times that the pharmacist is temporarily absent from the pharmacy, the pharmacy staff may continue to perform the non-discretionary duties authorized in accordance with Chapter 4729. of the Revised Code and agency 4729 of the Administrative Code. However, any duty performed by any member of the staff shall be reviewed by the pharmacist upon the pharmacist's return to the pharmacy.

(E) The institutional facility shall have written policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist. The policies and procedures shall include the authorized duties of pharmacy staff, the pharmacist's responsibilities for checking all work performed by staff, and the pharmacist's responsibility for maintaining the security and control of the drug stock.

(F) Unless otherwise authorized in agency 4729 of the Administrative Code, this rule does not permit non-pharmacist personnel from having unsupervised access to drug stock when an institutional pharmacy is closed.

4729:5-9-07 – Patient profiles.

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

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

(1) The patient's data record, which shall consist of, but is not limited to, the following information:

(a) Full name of the patient for whom the drug is intended.

(b) Patient's date of birth.

(c) Patient's gender.

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

(i) Drug related allergies;

(ii) Previous drug reactions;

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

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

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

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

(a) The original medication order;

(b) Date and time of issuance of the medication order by the prescriber;

(c) Full name of the prescriber;

(d) The prescriber's credential (MD, NP, PA, etc.);

(e) Directions for use;

(f) The proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug or device dispensed;

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

(B) An institution facility shall make a reasonable effort to obtain a patient's medical history necessary to conduct a prospective drug utilization review.

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

4729:5-9-08 – Pharmacist drug utilization review.

(A) Except as provided in paragraph (F) of this rule, prior to dispensing any inpatient prescription, a pharmacist shall conduct a prospective drug utilization review of the patient profile for the purpose of identifying the following:

(1) Over-utilization or under-utilization of medications dispensed in the institutional facility;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment; and

(9) Food-nutritional supplements-drug interactions.

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

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

(2) Consulting with the prescriber; or

(3) Counseling the patient.

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

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

(2) American hospital formulary service drug information; and

(3) United States pharmacopeia drug information.

(D) Prior to dispensing a controlled substance dangerous drug, at a minimum, a pharmacist shall review if the patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, over-utilization, patient assessment, medical history, and diagnosis of addiction.

(E) Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about safe and appropriate use and the legitimacy of medication order. A pharmacist shall not dispense a medication from a prescriber order of doubtful, questionable, or suspicious origin.

(F) The requirement to conduct a prospective drug utilization review in accordance with paragraph (A) of this rule does not apply to drugs personally furnished or administered from floor stock or an automated medication system in either of the following circumstances:

(1) A prescriber controls the ordering, preparing, and administering of the drug; or

(2) Delay would harm the patient in urgent situations.

(G) A pharmacist shall conduct a retrospective review of inpatient prescriptions and make a determination about the safe and appropriate use and the legitimacy of the order in either of the following circumstances:

(1) Any drug removed from the pharmacy or contingency stock in accordance with paragraph (A) of rule 4729:5-9-03 of the Administrative Code; and

(2) Override medications pursuant to policies developed in accordance with paragraph (D)(4)(b) of rule 4729:5-9-03 of the Administrative Code.

4729:5-9-09 Drug orders for inpatients, outpatient prescriptions and personally furnishing dangerous drugs.

(A) Drugs shall be dispensed by a pharmacist for inpatients pursuant to an original patient-specific order issued by a prescriber or a protocol or pre-printed order as authorized in accordance with rule 4729:5-3-12 of the Administrative Code.

(1) Drug orders for inpatients of an institutional facility transmitted to a pharmacy by use of an electronic drug record keeping system may be considered an original order for the dispensing of drugs. Access to such system for entering and transmitting original orders shall be restricted to licensed health care professionals. If the licensed health care professional entering the order into the system is not the prescriber, there shall be a system in place requiring the positive identification of the prescriber for each order within a reasonable period of time which shall be made readily retrievable.

(2) Oral orders issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacist by personnel authorized by, and in accordance with, written policies and procedures of the facility. Such orders shall be transcribed by the pharmacist, noting the full name(s) of the authorized personnel transmitting the order. Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility.

(a) Oral orders for non-controlled substances issued by a prescriber for inpatients of an institutional facility may be transmitted to a pharmacy intern by personnel authorized by, and in accordance with, written policies and procedures of the facility if the pharmacist on duty who is personally supervising the activity of the intern determines that the intern is competent to perform this function.

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

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

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

(iv) Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility.

(b) Oral orders for non-controlled substances issued by a prescriber for inpatients of an institutional facility may be transmitted to a certified pharmacy technician in pursuant to rule

4729:3-3-04 of the Administrative Code by personnel authorized by, and in accordance with, written policies and procedures of the facility. Oral orders issued by a prescriber and transmitted by authorized personnel shall be verified by the prescriber using positive identification within a reasonable time and as required by the written policies and procedures of the facility.

(3) Drug orders for inpatients of an institutional facility transmitted to a pharmacy by use of a facsimile machine to facsimile machine transfer shall be transmitted by personnel authorized by, and in accordance with, written policies and procedures of the facility. The pharmacy receiving the facsimile shall have in place written policies and procedures allowing only authorized personnel access to the drug order facsimile. The pharmacy shall maintain the facsimile showing the origin of the order as a part of the drug order record. This facsimile must be maintained if it is the only record showing the pharmacist responsible for dispensing the drug.

(B) All orders for drugs for inpatients shall include the following:

(1) Name of patient;

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

(3) Directions for use, including route of administration;

(4) Date prescribed; and

(5) Prescriber's positive identification.

(C) Drugs may be dispensed for outpatients by an institutional pharmacy pursuant to an original prescription of a prescriber in accordance with rule 4729:5-5-15 of the Administrative Code. All outpatient prescriptions dispensed by an institutional pharmacy shall comply with the following outpatient pharmacy requirements:

(1) Labeling requirements in accordance with rule 4729:5-5-06 of the Administrative Code;

(2) Record keeping requirements in accordance with rule 4729:5-5-04 of the Administrative Code;

(3) Patient counseling requirements pursuant to rule 4729:5-5-09 of the Administrative Code;

(4) Prescription filing requirements pursuant to rule 4729:5-5-03 of the Administrative Code;

(5) Manner of processing requirements pursuant to rule 4729:5-5-10 of the Administrative Code;

(6) Serial numbering requirements pursuant to rule 4729:5-5-13 of the Administrative Code;

(7) Pick-up station requirements pursuant to rule 4729:5-5-14 of the Administrative Code;

(8) Patient profile requirements pursuant to rule 4729:5-5-07 of the Administrative Code; and

(9) Reporting of all drugs pursuant to division 4729:8 of the Administrative Code; and

(10) Prospective drug utilization review requirements pursuant to rule 4729:5-5-08 of the Administrative Code

(E) Outpatient prescriptions may be transferred by an inpatient pharmacy to an outpatient pharmacy in accordance with rule 4729:5-5-11 of the Administrative Code.

(F) A pharmacist may modify an outpatient prescription pursuant to rule 4729:5-5-16 of the Administrative Code.

(G) An original signed prescription for a schedule II controlled substance prepared in accordance with federal and state requirements and issued for a resident in a long-term care facility may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription and shall be received and maintained pursuant to rules 4729:5-5-10 and 4729:5-5-15 of the Administrative Code. The original signed prescription must remain with the patient's records at either the prescriber's office or the long-term care facility.

(H) Dangerous drugs personally furnished from an institutional facility shall comply with the following:

(1) Rule 4729:5-19-02 of the Administrative Code; and

(2) The reporting requirements of division 4729:8 of the Administrative Code.

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

4729:5-9-10 Labeling of prescriptions for patients.

(A) All dangerous drugs dispensed for use by inpatients in an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall meet the following requirements:

(1) The label of a single unit package of an individual-dose or unit-dose system of packaging of drugs shall include:

(a) The non-proprietary or proprietary name of the drug;

(b) Dosage form;

(c) The strength and volume, where applicable, of the drug;

(d) The control number and expiration date;

(e) National drug code or universal product code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label.

(f) Identification of the manufacturer, packer or distributor, or, if the repackager is the dispensing pharmacy, identification of the repackager shall be by name or by the final seven digits of their terminal distributor of dangerous drugs license number, and such identification shall be clearly distinguishable from the rest of the label; and

(g) Special storage conditions, if required.

(2) When a multiple-dose drug distribution system is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:

(a) Identification of the dispensing pharmacy;

(b) The patient's full name;

(c) The date of dispensing;

(d) The non-proprietary and/or proprietary name of the drug;

(e) National drug code or universal product code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label.

(f) The strength of the drug.

(3) At least the name of the patient must be placed on all medication containers too small to bear a complete label and dispensed in a container bearing a complete label.

(B) All drugs dispensed to inpatients for self-administration shall be labeled in accordance with 4729:5-5-06 of the Administrative Code.

(C) Whenever any drugs are added to parenteral solutions, such admixtures shall bear a distinctive label indicating:

(1) The patient's full name;

(2) The name and amount of the parenteral solution;

(3) The name and amount of the drug(s) added;

(4) The expiration date or beyond-use date;

(5) The name and address of the institutional facility pharmacy;

(6) National drug code or universal product code, if applicable, which may be embedded in a barcode or quick response (QR) code on the label.

(7) Cautionary statements, if required.

(D) Supplemental labels created by a pharmacy that contain a barcode or QR code for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

(1) Association of the barcode to the drug product;

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

(E) All drugs dispensed for use by outpatients shall be labeled in accordance with 4729:5-9-10 of the Administrative Code.

4729:5-9-11 Hospital self-service employee prescription kiosks.

(A) As used in this rule:

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

(2) "Self-service employee prescription kiosk" or "kiosk" means a self-service kiosk for the pickup of new or refill prescriptions only for hospital employees and their family members.

(B) A self-service employee prescription kiosk shall meet all the security requirements of this rule and be located either:

(1) On the campus of a hospital licensed as a terminal distributor of dangerous drugs and located in the immediate proximity of a pharmacy, unless otherwise approved by an agent of the board; or

(2) At a location that is licensed as a terminal distributor of dangerous drugs that not located on the campus of a hospital but is owned by the hospital.

(C) Only a dangerous drug prescription dispensed by a hospital-owned pharmacy may be provided to the patient or employee representative of the patient via a self-service kiosk. A kiosk shall not provide any of the following:

(1) Any drug that must be refrigerated; or

(2) Any hazardous drug, except for conventionally manufactured hazardous drugs that are tablets or capsules that do not require any further manipulation other than counting or repackaging.

(D) A kiosk located in accordance with paragraph (B)(2) of this rule shall be placed in an area that is restricted to hospital employees and is secured by both a physical barrier with suitable locks and an electronic barrier to detect unauthorized entry.

(E) All kiosks shall be continuously monitored by one or more video cameras that possess the capability of having its picture recorded. The video camera(s) shall provide one hundred per cent video coverage of the kiosk. Camera recordings shall be maintained for at least ninety days and shall made available within three business days of a request by an agent of the state board of pharmacy. The kiosk location must have adequate lighting to produce clear digitally recorded and still picture production.

(F) A kiosk shall only be stocked by a hospital employed pharmacist, pharmacy intern, certified pharmacy technician or registered pharmacy technician.

(G) A dispensing pharmacy described in paragraph (C) of this rule shall maintain an appropriate recordkeeping system that will provide accountability for proper receipt of all prescriptions provided to a patient or employee representative of the patient via a self-service kiosk.

(H) A kiosk shall employ a method of two-factor authentication to identify a patient or employee representative of the patient such that a finished prescription is delivered from a kiosk only to its intended recipient.

(I) A kiosk must prominently display notification that patient counseling is available pursuant to rule 4729:5-5-09 of the Administrative Code. Counseling may be provided by a pharmacist reachable at a toll-free telephone number who has access to the patient profile. Instructions on how to contact a pharmacist via toll-free telephone must be displayed by the kiosk and must also be printed on the customer receipt or included with the patient instructions.

(J) A self-service employee prescription kiosk shall meet all the following:

(1) Is electronically protected against unauthorized access;

(2) Be bolted to the floor or installed in a wall;

(3) Be constructed in such manner as to prevent tampering, break-in and theft of inventory; and

(4) Is able to either:

(a) Sound an alarm if a break-in is attempted; or

(b) Transmit a notification to on-site security if a break-in is attempted.

(K) Prior to the deployment of a kiosk, the responsible person at the location licensed as a terminal distributor of dangerous drugs shall test the kiosk to ensure that it releases drugs properly. The responsible person shall monitor performance of the kiosk on an ongoing basis and test the kiosk for accuracy whenever any change or upgrade is made.

(L) All drugs and devices in a kiosk shall be maintained in a clean and orderly condition. Kiosks shall be maintained at temperatures which will ensure the integrity of the drugs as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(M) Dangerous drugs stored in a kiosk that are not picked up by a patient may be returned to stock shelves in accordance with rule 4729:5-9-14 of the Administrative Code.

(N) Prior to the operation of a kiosk, the board shall receive a request for approval from the responsible person on the terminal distributor of dangerous drugs license. Upon notification, the board shall conduct an inspection of the area where the kiosk shall be located and review system specifications to determine if it meets the requirements of this rule.

(O) If an inspection does not result in the approval of a kiosk, the responsible person named on the terminal distributor of dangerous drugs license may request an in-person meeting with the board to appeal the denial.

4729:5-9-12 Use of hospital and other institution D.E.A. registrations.

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

(B) A prescriber who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, personally furnish, or prescribe controlled substances under the "Drug Enforcement Administration" (D.E.A.) registration of the hospital.

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

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

(E) Each person so authorized must be assigned a specific internal code number by the hospital or other institution which will be used as a suffix to the hospital D.E.A. registration number. Such internal code number shall consist of numbers, letters, or a combination thereof, shall be preceded by a hyphen, and no more than ten characters in length, excluding the hyphen. A current list of the internal codes and the corresponding individual prescribers must be kept by the hospital or other institution and made available at all times to other registrants, state board of pharmacy designated agents, investigators of the state medical board, and federal, state, county, or municipal law enforcement agencies for verification.

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

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

4729:5-9-13 Returned drugs.

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

(1) Drugs dispensed for inpatients or personally furnished to inpatients provided that:

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

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

(2) Drugs dispensed for outpatients in accordance with rule 4729:5-5-22 of the Administrative Code.

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

4729:5-9-14 – Multi-Med dispensing by an institutional pharmacy.

In lieu of dispensing two or more dangerous drugs in separate containers, a pharmacist may dispense a customized patient medication package, known as a patient med pak. A patient med pak is a package for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms that complies with the following requirements:

(A) The patient med pak is designed, or each container is labeled, to indicate the day and time or period of time when the contents within each container are to be taken by the patient.

(B) The number of drugs placed in each container cannot exceed the capability of the container to prevent damage to the dosage forms.

(C) The quantity of the patient med pack dispensed may not be more than a thirty-one-day supply.

(D) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required in accordance with this chapter of the Administrative Code, including the use of accessory labels.

(E) The patient med pak must include a beyond-use date of not more than sixty days from the date the drugs were placed in the package.

(F) Dangerous drugs which have been dispensed in a patient med pak and have been picked up by or delivered to patients are considered adulterated if returned to the pharmacy for any reason and shall not be returned to stock or re-dispensed.

(G) The containers of a patient med pak are sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(H) Any pharmacy dispensing patient med paks in accordance with this rule must implement policies and procedures that will exclude drugs having the any of the following characteristics from such packaging:

(1) The U.S.P. monograph or official labeling requires dispensing in the original container, unless there is documentation from the manufacturer stating otherwise;

(2) The drugs or dosage forms are incompatible with packaging components or each other;

(3) The drugs are therapeutically incompatible when administered simultaneously;

(4) The drugs require special packaging.

4729:5-9-15 – Drugs repackaged or relabeled by an institutional pharmacy.

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

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

(2) National drug code or universal product code, if applicable.

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

(4) Pharmacy control number;

(5) Pharmacy's expiration date or beyond-use date, which shall be within the proven period of stability of the drug. This expiration or beyond-use date shall be no later than the manufacturer's expiration date of a not previously opened manufacturer's container.

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

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

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

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

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

(5) Pharmacy control number;

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

(7) The pharmacy's expiration date or beyond-use date;

(8) Positive identification of the following persons responsible for the repackaging of the drug:

(a) The individual repackaging the drug; and

(b) If not the person who repackaged the drug, the pharmacist dispensing the drug.

(D) Supplemental labels created by a pharmacy that contain a barcode or QR code for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

(1) Association of the barcode to the drug product;

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

(C) Supplemental labels created by a pharmacy that contain a barcode for the purpose of identifying a drug shall contain a means of identifying the positive identification of the pharmacist responsible for:

(1) Association of the barcode to the drug product;

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