Rules for Refile with JCARR

4729:5-9-02.4 - Dispensing of controlled substances by an institutional pharmacy.

All controlled substances dispensed in quantities exceeding a seventy-two-hour supply shall be packaged in tamper-evident, unit-of-use containers except when unit-of-use packaging is not available including, but not limited to, multi-dose liquids and injectables ~~where unit-of-use packaging is not available~~.

Rationale: Re-worded to reflect that more than just multi-dose liquids and injectables may not be able to be packaged in unit-of-use containers.

4729:7-2-02 - Sterile compounding exemptions.

(A) The following sterile drug compounding is exempted from the requirements of this chapter:

(1) Preparation of a non-hazardous, conventionally manufactured sterile products in accordance with the directions contained in approved labeling provided by the product's manufacturer if preparation complies with all the following:

(2) Administration of the drug product must begin within one hour of beginning the preparation (e.g., within one hour of initial entry into or puncture of a single- dose container).

(3) Aseptic technique must be followed. Procedures must be in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other products or compounded sterile preparations.

(4) A pharmacist or prescriber performs the final check of the product and documents that it was conducted using positive identification.

(5) Any unused starting ingredient that is not labeled as a multiple dose container must be discarded after preparation is complete.

(6) Unless administered immediately, the drug product described in this paragraph shall bear a label listing the name of the drug (if not legible) and date and time prepared or beyond-use date.

~~(B) Preparation of non-hazardous, compounded sterile preparations for a single patient using only sterile starting ingredients if preparation complies with all the following:~~

~~(1) Administration of the preparation must begin within one hour of beginning the preparation (e.g., within one hour of initial entry into or puncture of a single- dose container).~~

~~(2) Aseptic technique must be followed. Procedures must be in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other products or compounded sterile preparations.~~

~~(3) A pharmacist or prescriber performs the final check of the preparation and documents that it was conducted using positive identification.~~

~~(4) Any unused starting ingredient that is not labeled as a multiple dose container must be discarded after preparation is complete.~~

~~(5) Unless administered immediately, the preparation described in this paragraph shall bear a label listing the name of the drug and date and time prepared or beyond-use date.~~

Rationale: A review of USP 797 finds that the language in paragraph (B) is already included in the immediate-use CSPs provision of the chapter. Therefore, to avoid any confusion, Board staff propose the removal of this language.

Immediate-use CSP language from 797:

1. *The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.*
2. *Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.*
3. *During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.*
4. *Administration begins not later than 1 hour following the start of the preparation of the CSP.*
5. *Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and*

amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.

6. *If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.*

Outpatient Pharmacy Recordkeeping Rule for Filing with CSI and JCARR

The purpose of this rule update is to clarify that all outpatient pharmacy records must be readily retrievable. This is a set standard used for all Board of Pharmacy licensees and means the following (See OAC 4729:5-5-01):

> *(K) "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.*

One Comment Received:

The use of the word "dangerous" to describe medical cannabis comes across to this reader as subjective and biased. The rule overall appears to be very burdensome on the business.

4729:5-5-24 Drug inventory records and other record keeping provisions.

(A) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt.

(B) Temperature logs maintained in accordance with paragraph (B) of rule 4729:5-5-23 of the Administrative Code shall include either:

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

(2) For automated systems that provide temperature monitoring, 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.

(C) Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the positive identification of the licensed or registered health care professional that performed the disposal.

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

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

(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 or registered healthcare professionals conducting and witnessing the disposal.

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

(F) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;

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

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

(G) All records maintained in accordance with this chapter shall be readily retrievable and uniformly maintained for a period of three years.

(H)

(1) Except as provided for in paragraph (H)(2) of this rule, all records maintained in accordance with this chapter shall be maintained on-site.

(2) An outpatient pharmacy located in this state intending to maintain records at a location other than the location licensed by the state board of pharmacy shall send a request in a manner determined by the board. The board will provide written or electronic notification to the outpatient pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained at the licensed location. Any such alternate location used to store records shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(I) All records required in accordance with this chapter shall comply with the following:

(1) Be maintained under appropriate supervision and control to restrict unauthorized access, including security features to prevent unauthorized access to computerized records; and

(2) All computerized records shall contain daily back-up functionality to protect against record loss.

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

Rules for Reporting Theft or Loss of Dangerous Drugs for Filing with CSI and JCARR

Rationale: The purpose of these rule amendments is to update cross references to the Code of Federal Regulations and the Ohio Revised Code. **NOTE:** No comments were received on these rules during the initial stakeholder comment period.

4729:5-3-02 Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents.

(A) A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location:

(1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss;

(2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (~~19~~/~~219~~/~~2016~~2014);

(3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

(B) The theft or significant loss of controlled substances shall be reported by a licensee using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss.

(1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.

(2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.

(C) The theft or significant loss of non-controlled dangerous drugs shall be reported to the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss of non-controlled dangerous drugs. The report shall be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.

(1) An exemption may be obtained upon sufficient cause if the form cannot be filed within thirty days.

(2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.

(D) A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed and original prescription order(s) that have been dispensed.

(E) A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. ~~1305.12~~ 1305.16 (~~19~~/~~219~~/~~2016~~2014) of the theft or loss of any ~~official written order form(s) as defined in division (Q) of section~~ 3719.01 ~~of the Revised Code.~~DEA Form 222.

4729:6-3-02 Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents.

(A) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the administrative code shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location:

(1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss;

(2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (~~1/21/2016~~9/9/2014);

(3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

(B) The theft or significant loss of controlled substances by a licensee shall be reported by using the federal DEA report form regardless if the controlled substances are subsequently recovered and/or the responsible parties are identified and action is taken. Information reported in the federal form regarding such theft or significant loss shall be filed with the state board of pharmacy, in a manner determined by the board, by the licensee within thirty days following the discovery of such theft or significant loss.

(1) An exemption may be obtained upon sufficient cause if the federal form cannot be filed within thirty days.

(2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.

(C) The theft or significant loss of non-controlled dangerous drugs shall be reported by a licensee to the state board of pharmacy, in a manner determined by the board, within thirty days following the discovery of such theft or significant loss of non-controlled dangerous drugs. The report shall be filed regardless if the dangerous drugs are subsequently recovered and/or the responsible parties are identified and action is taken.

(1) An exemption may be obtained upon sufficient cause if the form cannot be filed within thirty days.

(2) A request for a waiver of the thirty-day limit must be requested in a manner determined by the board.

(D) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of uncompleted prescription blank(s) used for writing a

prescription, written prescription order(s) not yet dispensed and original prescription order(s) that have been dispensed.

(E) A person licensed in accordance with section 4729.52 of the Revised Code or this division of the Administrative Code shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.~~12~~ 16 (9/9/2014~~1/21/2016~~) of the theft or loss of any ~~official written order form(s) as defined in division (Q) of section~~ 3719.01 ~~of the Revised Code.~~ DEA 222 Form.

STATE OF OHIO BOARD OF PHARMACY

Chemical Capture Rules for Filing with CSI and JCARR

Entity	Comment	Draft Board Response
OVMA, Ohio Animal Welfare Foundation, Cleveland APL	Relative to the chemical capture drugs outlined in draft rule 4729:5-15-05 (A) (4) we respect the expertise of the members of the Ohio Veterinary Medical Licensing Board in reviewing the appropriateness of the drugs listed. In (D) (2) of the same draft rule the use of the word "potential" , as in …"known *potential* complications/side effects"… may be too broad in scope and should be replaced with " common" so as to read …"known *common* complications/side effects"… Finally in draft rule 4729:5-15-04 , to be consistent with statutory language in ORC 4729.532 and to eliminate any possible confusion , we would ask that the following be included after the comma in the first line: …"Code, <u>except for a licensed veterinarian or registered veterinary technician</u>, no agent…" Both veterinarians and registered veterinary technicians are commonly employed at shelters and obviously governed relative to their permissible medical activities in Chapter 4741 of Ohio Revised and Administrative Codes.	Rule updated to reflect comments.
Ohio Animal Welfare Foundation	We would like to specifically call out his last recommendation regarding draft rule 4729:5-15-04 and ask that licensed veterinarians and registered veterinary technicians be added as the exception. We need to ensure that the medical activities of veterinarians and registered veterinary technicians, including the performance of euthanasia, who are employed by animal shelters continue to be governed by ORC/OAC 4741.	Rule updated to reflect comments.

4729:5-15-01 Animal shelters and dog wardens - definitions.

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

(A) "Animal shelter" means a facility licensed as terminal distributor of dangerous drugs in accordance with section 4729.531 of the Revised Code or section 4729.54 of the Revised Code. An animal shelter shall be operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code and shall comply with all requirements set forth in this chapter.

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

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

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

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

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

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

(1) Immobilize and capture;

(2) Attempt to immobilize and capture; or

(3) Attempt to immobilize or capture.

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

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

~~(B)~~(F) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

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

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

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

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

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

~~Pursuant to division (A) of section 4729.532 of the Revised Code, the board approves xylazine as a substance to be administered by euthanasia technicians only for the purpose of sedating an animal as part of the euthanasia process.~~

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

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

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

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

~~(I)~~(M)

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

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

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

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

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

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

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

~~(J)~~(N) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

~~(K)~~(O) "Registered veterinary technician" has the same meaning as in section 4741.01 of the Revised Code.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(4) In the case of a key lock, all keys shall be maintained in a secure place that is inaccessible to anyone other than a veterinarian if not being used by a veterinarian or

veterinary technician in accordance with paragraph (C)(6)(a), (C)(6)(b), or (C)(6)(c) of this rule. All locks shall be kept in good working order with keys removed therefrom.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(H)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs.

(O) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a date opened. Multiple-dose vials shall be examined prior to use for evidence of physical or chemical contamination. Vials that have any of the following characteristics shall be deemed adulterated:

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

(2) Mislabeled; or

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

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

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

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

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

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

(B) Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement.

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

(1) For temperature logs, either:

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

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

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

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

(E)

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

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

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

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

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

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

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

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

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

(1) If the disposal of controlled substance drug inventory, including drugs maintained in accordance with paragraph (E) of rule 4729:5-15-02 of the Administrative Code, is performed on-site, records shall also include the positive identification of two persons conducting and witnessing the disposal, one of whom shall be the responsible person or a veterinarian, registered veterinary technician, or certified euthanasia technician.

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

(H) Records of transfer or sale conducted in accordance with chapter 4729. of the Revised Code and rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, expiration date, and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale.

(I) Records of controlled substances transferred in accordance with paragraph (L) of rule 4729:5-15-02 of the Administrative Code shall contain the name, strength, dosage form, and quantity of the dangerous drugs transferred, the name or identification of the animal, name and address of the animal's owner or caregiver if the owner or caregiver is

not the animal shelter, the positive identification of the animal shelter employee or volunteer transferring the drug, the date the drug is transferred, and the date the drug is received by the animal's owner or caregiver.

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

(K) In addition to the inventory requirements set forth in rule 4729:5-3-07 of the Administrative Code, the responsible person for an animal shelter that maintains controlled substance dangerous drugs used to perform euthanasia listed in paragraph (B) ~~(C)(2)~~ of rule ~~4729:5-15-01~~ 4729:5-15-04 of the Administrative Code shall be responsible for completing a monthly inventory, in accordance with rule 4729:5-3-07 of the Administrative Code, of those drugs to deter and detect diversion.

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

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

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

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

(N) All records maintained pursuant to this rule and rule 4729:5-15-02 of the Administrative Code may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) Complies with the requirements of this rule;

(2) All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;

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

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

4729:5-15-04 Drugs approved for euthanasia. (NEW)

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

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

(1) Ketamine;

(2) Tiletamine and zolazepam; and

(3) Xylazine.

4729:5-15-05 - Chemical capture classification. (NEW)

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

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

(2) The animal shelter or county dog warden shall maintain documentation that certified officers have completed the required training in accordance with section 4729.534 of the Revised Code.

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

(4) A certified officer may use any of the following drugs for chemical capture:

(a) Ketamine;

(b) Xylazine; and

(c) Tiletamine and zolazepam.

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

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

(1) Recordkeeping requirements of rule 4729:5-15-03 of the Administrative Code; and

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

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

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

(2) The protocol shall include the following: drug, dose, concentration, approved uses for drug delivery, approved equipment for use, circumstances for use, contraindications, any

known ~~potential~~ common complications/side effects, and weight ranges with corresponding volume of drug to be administered.

(3) A documented review of the protocol shall be conducted by a veterinarian licensed under Chapter 4741. of the Revised Code at least once every five years.
(E) All equipment used in chemical capture shall:

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

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

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

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

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

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

(a) The procedure for removing the dart from a captured animal;

(b) First aid for the animal, with particular reference to the dart wound and potential emergencies (including: hyperthermia, hypothermia, shock, bloat, respiratory distress, and cardiac arrest); and

(c) Appropriate location and handling for the animal during recovery from the capture event.

(G) A terminal distributor of dangerous drugs with a chemical capture classification shall maintain records for every certified officer that has completed training in accordance section 4729.534 of the Revised Code. Such documentation shall be made readily retrievable and shall be maintained for one year from the date the certified officer is no longer employed by or affiliated with the licensee.

4729:5-3-13 Temporary removal of dangerous drugs from a licensed location. (AMEND)

No licensed terminal distributor of dangerous drugs shall engage in the sale or other distribution of dangerous drugs at retail or maintain possession, custody, or control of dangerous drugs for any purpose at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor, except as follows:

(A) A licensed health professional authorized to prescribe drugs may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/ NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(B) A person authorized to personally furnish or dispense naloxone in accordance with a physician approved protocol. The naloxone shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The authorized person shall maintain direct supervision and control over the naloxone removed from the terminal distributor. If direct supervision is not provided, the naloxone shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/ or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(C) A licensed health care professional, in accordance with their applicable scope of practice, who provides immunizations or any other non-controlled substance dangerous drugs that may be administered in accordance with a protocol or valid prescriber's order may temporarily remove dangerous drugs from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients. The dangerous drugs shall be returned to the licensed terminal distributor of dangerous drugs within twenty-four hours, unless otherwise approved by the board. The licensed health professional shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. The responsible person on the terminal distributor of dangerous drugs license shall be responsible for compliance with the requirements of this paragraph.

(D) An emergency medical service (EMS) organization providing emergency medical services and in accordance with Chapter 4729:5-14 of the Administrative Code.

(E) A veterinarian licensed pursuant to Chapter 4741. of the Revised Code may maintain a supply of dangerous drugs obtained from a licensed terminal distributor of dangerous drugs at another location in order to treat current or prospective patients. A veterinarian shall maintain direct supervision and control over the dangerous drugs and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Any drugs maintained pursuant to this paragraph are subject to inspection by a board of pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss reporting, disposal and inventory requirements of division 4729:5 of the Administrative Code. Records shall be maintained by the terminal distributor of dangerous drugs in accordance with Chapter 4729:5-20 of the Administrative Code. The responsible person on the terminal distributor of dangerous drugs license from which the drugs are obtained shall be responsible for compliance with the requirements of this paragraph. A veterinarian maintaining dangerous drugs in accordance with this rule shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs. The terminal distributor of dangerous drugs shall also maintain the following records for controlled substance dangerous drugs removed from the terminal distributor of dangerous drugs that are stored off-site for more than twenty-four hours: name, strength, dosage form, and quantity of the controlled substance dangerous drugs, the positive identification of the veterinarian who removed the drugs, and the address of the location where the drugs are maintained. Corresponding records shall also be maintained for any controlled substances returned to the terminal distributor's inventory of dangerous drugs from the off-site location. All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return. Failure by a veterinarian to exercise supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code or adequate safeguards as required in division (C) of section 4729.55 of the Revised Code shall be deemed a violation of this rule.

(F) A person licensed or certified under Chapter 4765. of the Revised Code may maintain a supply of medical oxygen and/or naloxone obtained from a licensed terminal distributor of dangerous drugs in order to treat current or prospective patients in the event of an emergency. The medical oxygen and/or naloxone shall be maintained for an amount of time as determined by written authorization from the licensee's medical director. Medical oxygen and naloxone shall only be administered in accordance with the licensee's protocol or valid prescriber order. The individuals authorized by to this paragraph shall maintain personal supervision and control over the medical oxygen and/or naloxone removed from the terminal distributor. If personal supervision is not provided, the medical oxygen and/or naloxone shall be physically secured in a manner to prevent unauthorized access and shall be stored at temperatures and conditions which will ensure the integrity of the medical oxygen and/or naloxone prior to its use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(G) A certified officer, as defined in section 4729.533 of the Revised Code, may maintain a supply of dangerous drugs, as authorized in rule 4729:5-15-05 of the Administrative Code, obtained from a licensed terminal distributor of dangerous drugs with a chemical capture classification at another location in order to engage in chemical capture. A certified officer shall maintain direct supervision and control over the dangerous drugs, equipment, and any hypodermics removed from the terminal distributor. If direct supervision is not provided, the dangerous drugs, equipment, and any hypodermics shall be physically secured in a manner to prevent unauthorized access and all reasonable efforts shall be made to store the drugs at temperatures and conditions which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Any drugs maintained pursuant to this paragraph are subject to inspection by a board of pharmacy agent and shall be subject to all recordkeeping, labeling, theft or significant loss reporting, disposal and inventory requirements of division 4729:5 of the Administrative Code. Records shall be maintained by the terminal distributor of dangerous drugs in accordance with Chapter 4729:5-15 of the Administrative Code. The responsible person on the terminal distributor of dangerous drugs license from which the drugs are obtained shall be responsible for compliance with the requirements of this paragraph. A certified officer maintaining dangerous drugs in accordance with this rule shall only obtain the drugs from single terminal distributor and shall not co-mingle drug stock from another terminal distributor of dangerous drugs. The terminal distributor of dangerous drugs shall also maintain the following records for all approved chemical capture drugs removed from the terminal distributor of dangerous drugs. Corresponding records shall also be maintained for any drug used for chemical capture returned to the terminal distributor's inventory of dangerous drugs from the off-site location. All records required in accordance with this paragraph shall be readily retrievable and maintained for at least three years from the date of removal or return. Failure by a certified officer to exercise supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code or adequate safeguards as required in division (C) of section 4729.55 of the Revised Code shall be deemed a violation of this rule.

(H) As used in this rule, "direct supervision" means an individual authorized pursuant to this rule is in the immediate area and within visual range of dangerous drugs and/or hypodermics to deter and detect diversion.

STATE OF OHIO BOARD OF PHARMACY

Pharmacy Pilot or Research Projects Rule for Filing with CSI and JCARR

4729-5-3-~~18~~ 20 – Pharmacy Pilot or Research Projects

(A) The purpose of this rule is to specify the process and procedures to be followed when a licensee petitions for approval of a pilot or research project for innovative system applications in the practice of pharmacy that are not currently permitted under agency 4729 of the Administrative Code. In reviewing projects, the Board shall consider only projects that expand pharmaceutical care services that contribute to positive patient outcomes.

(B) A project shall not expand the definition of the practice of pharmacy as set forth in Chapter 4729. of the Revised Code and shall not apply to licensees regulated under Chapter 3796. of the Revised Code.

(C) Approval of a project by the board may include the grant of a limited exception to or a waiver of rules adopted under Chapter 4729. of the Revised Code. Project approval, including limited exception to or waiver of board rules, shall initially be for a specified period of time not exceeding eighteen months from commencement of the project.

(D) Following the completion of the project period, the board may do any of the following based upon a review of the final project report submitted in accordance with paragraph (I) of this rule and any other factors or information the board deems necessary:

(1) Refuse to extend or renew the project;

(2) Approve the extension or renewal of a project following consideration of a petition that clearly identifies the need for extension and must include a report similar to the final project report, which should describe and explain any proposed changes to the originally approved and implemented project, and that justifies the need for extending or renewing the term of the project; or

(3) Approve the project in perpetuity following a consideration of a petition that clearly identifies and justifies the need to continue the project indefinitely.

(E) A licensee who wishes the board to consider approval of a project shall submit to the board a petition for approval that contains at least the following information:

Commented [MC1]: Cleveland Clinic: We have some general concerns with the rule that we have detailed below. First, we suggest that the Board provide a definition for the use of the words "pilot", "research project" "innovative system applications" and "project." Because these are not defined in the rule, it is difficult for us to determine which, if any, of our projects or initiatives would fall under the scope of the authority described. Today, Cleveland Clinic has hundreds of research projects and quality initiatives that are being conducted within our organization, and it appears that this rule would include many of them.

Commented [MC2]: NACDS Recommendation:

Extend project approval from 18 months to 24 months.

Commented [MC3R2]: Cleveland Clinic: We are concerned with the time limit of 18 months as many research projects or quality initiatives go well beyond that timeframe. The time period is oftentimes dependent on the nature of the disease state being studied or the outcome timeframe for an implementation project. Applying a limit of 18 months will limit our ability to effectively undertake and execute projects. We suggest that the Board allow for timeframes longer than 18 months with appropriate restrictions.

Commented [MC4]: Cover My Meds / Script Hero: Clarification may be needed to understand who is responsible for notification of the end of pilot is approaching. Is this the responsibility of the licensee or the BOP?

Commented [MC5]: NACDS Recommendation:

Project initiatives or waivers that yield benefits for patients, such as enhanced delivery of patient care, while maintaining or improving patient safety or create a safer and more efficient work environment shall be recommended for permanent codification via statute or regulation changes.

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(1) Responsible pharmacist. Name, address, telephone number, and pharmacist license number of each pharmacist responsible for overseeing the project.

(2) Location of project. Name, address, and telephone number of each specific location and, if a location is a pharmacy, the pharmacy's terminal distributor of dangerous drugs license number where the proposed project will be conducted.

(3) Project summary. A detailed summary of the proposed project that includes at least the following information:

(a) The goals, hypothesis, and objectives of the proposed project.

(b) A full explanation of the project and how it will be conducted.

(c) The time frame for the project including the proposed start date and length of ~~study~~the project. The time frame may not exceed eighteen months from the proposed start date of the project.

(d) Background information or literature review to support the proposed project.

(e) The rule or rules to be waived in order to implement the project, an explanation of why such a waiver would not be a detriment to the public, to include procedures to be used during the project to ensure that the public health and safety are not compromised as a result of the waiver, and a request to waive the rule or rules.

(F) Projects submitted shall be reviewed as follows:

(1) Staff review. Upon receipt of a petition for approval of a project, board staff shall initially review the petition. If the petition is incomplete or fails to meet the board's outlined purpose, staff shall return the petition to the requestor with a letter explaining the reason the petition is being returned. A petition that has been returned pursuant to this paragraph may be amended or supplemented as necessary and submitted for reconsideration. A petition that is deemed appropriate and complete shall move on the board member review process.

(2) Board member review. After initial staff review, two members of the board, appointed by the board president, shall be provided the petition and any additional materials. Board members shall conduct a review, in consultation with appropriate staff, and make a recommendation to the full board. Board members conducting a review may request additional documentation and information from the petitioner as part of this review process.

(3) Board review. Following the board member review, the board shall consider the project request at a regularly scheduled meeting of the board. Upon review, the board shall either approve or deny the petition. The Board shall not approve any such project if

Commented [MC6]: **Cover My Meds / Script Hero:** Consider adding Certified Pharmacy Technicians and registration numbers.

NOTE: This provision is only for a person overseeing a project.

Commented [MC7]: **NACDS Recommends Striking.**

Commented [MC8]: **NACDS Recommendation to Insert:**

This review may not exceed 3 months from the date of submission.

Commented [MC9]: **Cover My Meds / Script Hero:** Please consider only referring those projects that the appointed Board Members are unable to align on a recommendation. This streamlines the process and shortens the time to approval/denial to the licensees.

such proposal might jeopardize public health or welfare. If the board approves the petition, the approval:

(a) Shall be specific for the project requested, with any modifications the Board deems necessary for patient safety;

(b) Shall approve the project for a specific time period; and

(c) May include conditions or qualifications applicable to the project, including limited waivers of applicable/related rules.

(G) The project site and project documentation shall be available for inspection and review by the board or its representative(s) at any time during the approval or denial processes and, if a project is approved, throughout the approved term of the project.

(H) Project documentation shall be maintained in a readily retrievable manner and available for inspection, review, and copying by the Board or its representative for at least three years following completion or termination of the project.

(I) The pharmacist responsible for overseeing a project shall be responsible for submitting to the board any reports required as a condition of a project, including the final project report.

(1) The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within three months after completion or termination of the project.

Commented [MC10]: Summa Health: Change to 90 days.

(2) The board shall review any required report regarding the progress of a project and the final project report at a regularly scheduled meeting of the board.

(J) The Board may rescind approval and terminate a project at any time, including those it has approved in perpetuity, if it deems the public interest is not fully protected or if the project does not the comply with the requirements of its approval.

Commented [MC11]: Cover My Meds / Script Hero: Please consider defining "The Board" and laying out the process for termination of the projects and timeline for rescinding the approval of a previously approved projects. Should this be voted on by the Board of Pharmacy members or is this the Board employees revoking approvals?

The petitioner and/or project's responsible person may terminate the project earlier than requested but shall provide notice within three business days of termination and a final project report to the Board to include an explanation of why the project was terminated early. Upon either recission of approval or early project termination, any waivers granted will be immediately revoked and the licensee will be required to adhere to those rules that had been excepted or waived.

Commented [MC12]: Cleveland Clinic: If the Board has the ability to terminate the project without notice, we are concerned that this could compromise patient care if the research is the sole source of medication treatment for a patient. We suggest that the Board allow for a hearing in which the party has an opportunity to respond to any allegations and address the Board's concerns prior to termination to protect patient safety.

(K) All documents pertaining to the application, project, and reports are considered a public record under section 149.43 of the Revised Code and will be provided upon request, without notice to the project's petitioners and/or responsible person. Petitioners asserting that some or all of an application contains information exempt from disclosure under Ohio law shall comply with the following:

Commented [MC13]: Cover My Meds / Script Hero: Please reconsider this section as this may prohibit licensees to come forward with innovative ideas and processes that could greatly benefit the citizens of Ohio.

(1) Submit a memorandum identifying the content not subject to disclosure under section 149.43 of the Revised Code, including supporting legal authority for each assertion.

(2) Submit a redacted version of the materials that the applicant agrees may be released without prior notice to the applicant.

(L) By submitting the application, the petitioner understands, acknowledges, and agrees to all of the following:

(1) The board may independently assess the merits of any public records exception claims made by the petitioner.

(2) The board may reject a claim that information in an application is trade secret or a security or infrastructure record if it determines that the petitioner has not established that the content in question meets a delineated exception to public disclosure under Ohio law, including the use of generic language encompassing substantial portions of the application submission or simple assertions of a document containing information exempt from public disclosure, without substantive explanation of the basis.

(3) The state of Ohio does not assume liability for the use or disclosure of any unredacted material.

(4) The board is required to comply with section 149.43 of the Revised Code, which is construed liberally in favor of broad access, and any doubt shall be resolved in favor of disclosure of public records.

(M) The board shall be required to make the initial approval or denial of a project submission within one hundred and eighty days of the submission of a completed project petition in accordance with paragraph (E) of this rule. This timeframe may be extended by the board for good cause.

(N) Unless otherwise approved by the board, a petition shall be deemed abandoned if the petitioner fails to submit any requested documentation or information within thirty days after being notified by the board. The board shall not be required to act on any abandoned petition and the petition may be destroyed by board staff. If the petition is abandoned, the petitioner shall be required to resubmit a new petition for consideration pursuant to the requirements of this rule.

Commented [MC14]: **NACDS Recommendation:**

Change to 3 months.

Commented [MC15R14]: **Cover My Meds / Script Hero:** Please consider shortening this period of review to 90 days. Technology is fast moving and an approval process of one hundred and eighty days by the Board of Pharmacy may cause issues with dedicated support on the pilot as well as those projects that may be supported by experiential student pharmacists.

Commented [MC16R14]: **Cleveland Clinic:** We are concerned with the 180 day window for either an approval or denial from the Board as it could lead to delays in care for patients eligible for specific medication treatments that are only available through research studies (i.e., chemotherapy). For some patients, this delay in care could be life-threatening.

We suggest that the approval or denial window be shortened to no more than 60 days.

Entity	Comment	Draft Board Response
NACDS	**Recommendation 1: Amend deadlines and timelines for project logistics to foster meaningful, timely pilot or research programs.** o Extend project approval from 18 months to 24 months. o Condense Board review timeframe to not exceed 3 months of petition submission date. • **Recommendation 2: Ensure successful project initiatives have the ability to be made permanent through regulatory changes to ensure all Ohioans can benefit from successes and learnings of pilot projects.** ***NACDS Rationale:*** Pharmacy care has been a component within the expansion of care transformation, and community pharmacies have acquired knowledge of care delivery models that can play a major role in complex health and poor health outcomes. In an effort to ensure enhanced innovation and modernization for the practice of pharmacy, it is imperative that proposed rule 4729-5-3-18 have minimal administrative limitations and restrictions, in addition to supporting timely and meaningful research pilots. **Recommendation 1: Amend deadlines and timelines for project logistics to foster meaningful, timely pilot or research programs.** • Extend project approval from 18 months to 24 months. • Condense Board review timeframe to not exceed 3 months of petition submission date. Depending on the research initiative, it may be beneficial for researchers to have up to 24 months to run a pilot project. Consider the time necessary to plan, train, collect baseline data, implement the intervention, collect and analyze data, along with other project logistics. Also, given the month-to-month variation in pharmacy care and workflow (for example: January looks different than summer months which look different than peak flu season), it can sometimes be helpful for research teams to compare baseline information from particular months to the same month during the	

	implementation year. For example, a research team may like to evaluate baseline data for the months of January, July, November and December compared to implementation data from January, July, November and December of the following year. This type of scientific approach could require the project be active for at least 24 months, depending on which months researchers would like to evaluate. While other projects may not need the full 24 months, NACDS believes this extension would not only raise the potential caliber of research that could be conducted, but also may prevent the Board from needing to expend resources to approve multiple extensions when project delays inevitably occur. For these reasons, NACDS recommends the Board modify the current timeline from eighteen months to twenty four months. Additionally, to guarantee a timely process of review and approval on the front end, we recommend the Board to provide the petitioner feedback and review within 3 months, instead of the proposed 180 days, of petition submission. This timeframe would hopefully provide the Board sufficient time for thorough review and also the ability to request additional information and explanation within a timely manner. Also, because pilot projects will be designed to improve patient care and may often seek to implement timely clinical interventions, a 180-day approval process could result in missed opportunities to implement the most relevant pilot projects. As an example, if a pharmacy today wanted to provide a pilot that supported COVID-19 recovery efforts, even a 3-month timeline for approval may alter the maximum impact of the implementation. Please see below for NACDS' proposed modification: **Extend project approval from 18 months to 24 months.** *(C) Approval of a project by the board may include the grant of a limited exception to or a waiver of rules adopted under Chapter 4729. of the Revised Code. Project approval,*	

	including limited exception to or waiver of board rules, shall initially be for a specified period of time not exceeding twenty-four ~~eighteen~~ months from commencement of the project. (page 2) *E.3.c The time frame for the project including the proposed start date and length of study. The time frame may not exceed twenty-four eighteen months from the proposed start date of the project.* (page 3) **Condense Board review timeframe to not exceed 3 months of petition submission date.** *F.2. Board member review. After initial staff review, two members of the board, ~~appointed by the board president,~~ shall be provided the petition and any additional materials. Board members shall conduct a review, in consultation with appropriate staff, and make a recommendation to the full board. Board members conducting a review may request additional documentation and information from the petitioner as part of this review process. This review may not exceed 3 months from the date of submission.* (page 3) *(M) The board shall be required to make the initial approval or denial of a project submission within three months ~~one hundred and eighty days~~ of the submission of a completed project petition in accordance with paragraph (E) of this rule. This timeframe may be extended by the board for good cause.* (page 5)	
NACDS	As projects prove to be of benefit for Ohio patients, the proposed rule should directly support the ability for permanent changes. For example, states such as Iowa and Wisconsin have conducted successful demonstration projects for pharmacy technician product verification (TPV), demonstrating maintained or improved patient safety, in addition to observed reallocation of pharmacist time toward patient care activities.v Correspondingly, permanent changes were made to allow technicians to permanently perform TPV, outside of pilot programs, to foster widespread and meaningful improvements to care across the state.vi Conducting a comprehensive assessment and modernizing pharmacy care rules and regulations on an ongoing basis is one of the	

	critical means to ensuring the health, safety and welfare of its citizens. As such, NACDS urges the Board to ensure that a process is in place to allow effective pilot project initiatives to be made permanent across the state for maximum patient benefit and to prevent multiple pilots on the same topics as this may lead to duplicative, wasted resources. NACDS' suggested edits can be found below: *D.3. Approve the project in perpetuity following a consideration of a petition that clearly identifies and justifies the need to continue the project indefinitely. Project initiatives or waivers that yield benefits for patients, such as enhanced delivery of patient care, while maintaining or improving patient safety or create a safer and more efficient work environment shall be recommended for permanent codification via statute or regulation changes.* (page 2)	
Cover My Meds/Script Hero	The following are suggested comments for review on the proposed rule: **(D) Following the completion of the project period, the board may do any of the following based upon a review of the final project report and any other factors or information the board deems necessary.** SHP: Clarification may be needed to understand who is responsible for notification of the end of pilot is approaching. Is this the responsibility of the licensee or the BOP? **(E)(1) Responsible pharmacist.** SHP: Consider adding Certified Pharmacy Technicians and registration numbers. **(F)(3) Board Review.** SHP: Please consider only referring those projects that the appointed Board Members are unable to align on a recommendation. This streamlines the process and shortens the time to approval/denial to the licensees. **(J) The Board may rescind approval and terminate a project at any time, including those it has approved in perpetuity, if it deems the public interest is not fully protected or if the project does not the comply with the requirements of its approval.** SHP: Please consider defining "The Board" and laying out the process for termination of	

	the projects and timeline for rescinding the approval of a previously approved projects. Should this be voted on by the Board of Pharmacy members or is this the Board employees revoking approvals? **(K) All documents pertaining to the application, project, and reports are considered a public record under section 149.43 of the Revised Code and will be provided upon request, without notice to the project's petitioners and/or responsible person. Petitioners asserting that some or all of an application contains information exempt from disclosure under Ohio law shall comply with the following:** SHP: Please reconsider this section as this may prohibit licensees to come forward with innovative ideas and processes that could greatly benefit the citizens of Ohio. **(M) The board shall be required to make the initial approval or denial of a project submission within one hundred and eighty days of the submission of a completed project petition in accordance with paragraph (E) of this rule. This timeframe may be extended by the board for good cause.** SHP: Please consider shortening this period of review to 90 days. Technology is fast moving and an approval process of one hundred and eighty days by the Board of Pharmacy may cause issues with dedicated support on the pilot as well as those projects that may be supported by experiential student pharmacists.	
Cleveland Clinic	We have some general concerns with the rule that we have detailed below. First, we suggest that the Board provide a definition for the use of the words "pilot", "research project" "innovative system applications" and "project." Because these are not defined in the rule, it is difficult for us to determine which, if any, of our projects or initiatives would fall under the scope of the authority described. Today, Cleveland Clinic has hundreds of research projects and quality initiatives that are being conducted within our organization, and it appears that this rule would include many of them. Without clear guidance, the Board of Pharmacy may have to review hundreds of projects or initiatives from Cleveland Clinic and other	

	hospital systems and pharmacies around the state, and we are concerned about the Board's capacity to undertake the reviews in a timely manner. A delay in the commencement of a project or initiative might result in postponement of timely, quality patient care. Further, the research within the Cleveland Clinic health system undergoes a robust review by our Institutional Review Board (IRB). These reviews apply guidelines that are seemingly stricter than those set forth in the proposed rules, as IRBs have rigorous established standards with a focus on patient safety. The review the Board is proposing seems both duplicative and burdensome. Finally, we are concerned that releasing project proposals or data could compromise proprietary information or prematurely release data intended for publication in scientific literature. Our comments on the proposed language in the rule are as follows: 4729-5-3-18 (C) Proposed Language Approval of a project by the board may include the grant of a limited exception to or a waiver of rules adopted under Chapter 4729 of the Revised Code. Project approval, including limited exception to or waiver of board rules, shall initially be for a specified period of time not exceeding eighteen months from commencement of the project. Cleveland Clinic Comments We are concerned with the time limit of 18 months as many research projects or quality initiatives go well beyond that timeframe. The time period is oftentimes dependent on the nature of the disease state being studied or the outcome timeframe for an implementation project. Applying a limit of 18 months will limit our ability to effectively undertake and execute projects. We suggest that the Board allow for timeframes longer than 18 months with appropriate restrictions. 4729-5-3-18 (J) Proposed Language	

	The Board may rescind approval and terminate a project at any time, including those it has approved in perpetuity, if it deems the public interest is not fully protected or if the project does not comply with the requirements of its approval. The petitioner and/or project's responsible person may terminate the project earlier than requested but shall provide notice within three business days of termination and a final project report to the Board to include an explanation of why the project was terminated early. Upon either rescission of approval or early project termination, any waivers granted will be immediately revoked and the licensee will be required to adhere to those rules that had been excepted or waived. Cleveland Clinic Comments If the Board has the ability to terminate the project without notice, we are concerned that this could compromise patient care if the research is the sole source of medication treatment for a patient. We suggest that the Board allow for a hearing in which the party has an opportunity to respond to any allegations and address the Board's concerns prior to termination to protect patient safety. 4729-5-3-18 (M) Proposed Language The board shall be required to make the initial approval or denial of a project submission within one hundred and eighty days of the submission of a completed project petition in accordance with paragraph (E) of this rule. This timeframe may be extended by the board for good cause Cleveland Clinic Comments We are concerned with the 180 day window for either an approval or denial from the Board as it could lead to delays in care for patients eligible for specific medication treatments that are only available through research studies (i.e., chemotherapy). For some patients, this delay in care could be life-threatening. We suggest that the approval or denial window be shortened to no more than 60 days.	

Summa Health	In section E (3)(c) I would suggest that the word study be changed to "project". This provides consistency throughout the documents. Also, the word study can have ramifications regarding the need for review by an Investigational Review Board prior to commencement of the project. *(c) The time frame for the project including the proposed start date and length of study. The time frame may not exceed eighteen months from the proposed start date of the project.* In section I (1) I would suggest changing three months to "ninety days". This provides consistency with section M of the proposed rule and removes the inconsistency of how many days three months is due to the different number of days in the months of the year. For example Jan-March can be 90 or 91 days while March through May is 92 days. *(1) The final project report shall include a written summary of the results of the project and the conclusions drawn from those results. The final project report shall be submitted to the board within three months after completion or termination of the project.*	