Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Pharmacy

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Regulation/Package Title (a general description of the rules' substantive content):

FYR Laboratories

Rule Number(s): 4729:5-16-01, 4729:5-16-02, 4729:5-16-03

Date of Submission for CSI Review: 4/29/2025

Public Comment Period End Date: 5/30/2025

Rule Type/Number of Rules:

New/___ rules
No Change/____ rules (FYR? __)
Amended/__3__ rules (FYR? _Y_)
Rescinded/____ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   ▪ 4729:5-16-01: Definition section for the approved laboratories rule chapter. Makes grammatical changes and rewords part of the "positive identification" definition.
   ▪ 4729:5-16-02: Provides the requirements of the responsible person on the license which includes establishing standards for security, control, and storage of dangerous drugs. Makes small grammatical changes.
   ▪ 4729:5-16-03: Provides the requirements for record keeping for an approved laboratory. Makes small grammatical changes, clarifies the requirement to list a group of animals in the records for personally furnishing section, and adds a requirement that a laboratory must have current IACUC protocol available to review during an inspection.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

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

4. **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?**

If yes, please briefly explain the source and substance of the federal requirement.

These rules do not implement a federal requirement.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

This rule package exceeds federal requirements because the regulation of dangerous drugs has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio Board of Pharmacy. Additionally, ORC 3719. also requires the Board to develop standards for the operation of laboratories that possess controlled substances.

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

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the distribution of dangerous drugs.

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

Without these regulations, the Board would not be able to provide uniform standards for laboratories, including security and control of dangerous drugs and record keeping requirements.

7. **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.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
If applicable, please include the date and medium by which the stakeholders were initially contacted.

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

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

The Board did not receive any comments during the initial comment period. Therefore, no changes were made to the draft regulations.

11. **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.

12. **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?**
Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the operation of laboratories, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. **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 Ohio Board of Pharmacy regulation.

14. **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.

Additionally, the Board has developed inspection guides that licensees can use to conduct self-inspections. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

- Laboratories licensed as terminal distributors of dangerous drugs.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

There may be a small increase in administrative costs for laboratories to have records of current IACUC protocol available for review during an inspection.

In general, 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.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. ***(Reductions in regulatory burden***

may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).

Yes. The Board eliminated the need to include the expiration date on transfer records.

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

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by implementing security and control of dangerous drugs at laboratories that possess controlled substances and other dangerous drugs.

Regulatory Flexibility

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

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

19. 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 Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. 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.

The Board has also developed inspection guides that licensees can use to conduct self-inspections. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Rule 4729:5-16-01 | Laboratories - definitions. (AMEND)

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

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

(1) A laboratory licensed under Chapter 3796. of the Revised Code; or

(2) Any other person or facility licensed as a terminal distributor of dangerous drugs that is specifically defined and required to comply with another chapter of this division (EMS organization, veterinary clinic, pain management clinic, animal shelter, etc.).

(B) "Anonymous sample" means an unknown substance submitted to a laboratory for qualitative ~~and~~ and/or quantitative analysis.

(C) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code but shall not include exempt chemical preparations as defined in paragraph (E) of this rule.

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

(E) "Exempt chemical preparation" means a chemical or compound approved by the United States drug enforcement administration pursuant to 21 CFR 1308.23 (12/30/2016).

(F) "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.

(G) "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) "Personally furnish" or "personally furnishing" means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting. A prescriber at a laboratory who personally furnishes a dangerous drug shall

comply with the requirements of rule 4729:5-19-02 or 4729:5-20-02 of the Administrative Code.

(I)

(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 such as the following:

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

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board 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.

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

Rule 4729:5-16-02 | Security, control, and storage of dangerous drugs. (AMEND)

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

(B) Except as provided in paragraph (H) of this rule, controlled substances shall be stored in a securely locked, substantially constructed cabinet or safe to deter and detect unauthorized access.

(1) The cabinet or safe shall be placed in an area that is not readily accessible to the public.

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

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

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

(5) When the laboratory is not in use by authorized 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 (B)(6)(a), (B)(6)(b), or (B)(6)(c) of this rule, only the responsible person or the responsible person's designee shall have possession of keys, combinations, or access codes to the cabinet or safe.

(a) A responsible person or the responsible person's designee may provide a laboratory employee or researcher with a temporary key for the purposes of accessing the cabinet or safe. An employee or researcher shall return the key provided in accordance with this paragraph to the responsible person or responsible person's designee or a secured location

with restricted access (such as a lockbox) no later than the end of the employee's shift, the end of the researcher's activity, or if there is no longer a responsible person or designee available to provide personal supervision.

(b) A responsible person or the responsible person's designee may provide an employee or researcher 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 the responsible person or the responsible person's designee;

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

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

(C) An employee or researcher of the laboratory may have access to controlled substances only under the personal supervision of the laboratory's responsible person or the responsible person's designee. A responsible person may have more than one designee. All designees shall meet the requirements of the responsible person set forth in rule 4729:5-2-01 of the Administrative Code. A laboratory shall maintain a current list of all approved designees for immediate inspection by an agent, officer, or inspector of the board.

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

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

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

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

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

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

(2) The cabinet or safe shall be placed in an area that is not readily accessible to the public.

(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 codes.

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

(6) When the laboratory is not in use by authorized 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 the responsible person or the responsible person's designee shall have possession of the key, combination, or access code to the safe or cabinet.

(8) This paragraph does not apply to exempt chemical preparations as defined in rule 4729:5-16-01 of the Administrative Code.

(I) When the laboratory is not in use by authorized personnel, non-controlled dangerous drugs, exempt chemical preparations, and hypodermics shall be stored in an area secured by

a physical barrier with suitable locks, which may include a substantially constructed cabinet or safe, drawer, locked room, or secured facility.

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

(K) All areas where dangerous drugs and controlled substances are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Unless otherwise required by a documented research study, 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 controlled substances 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 and controlled substances.

(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 and controlled substances.

(L) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.

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

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

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

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

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

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

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

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

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

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

(3) Records for the disposal of the drug or substance shall contain the actual identification of the drug or substance, form, and quantity disposed~~,~~; the date disposed~~,~~; the method of disposal; and, if disposal is conducted on-site, the positive identification of the two personnel conducting and witnessing the disposal.

Rule 4729:5-16-03 | Record keeping. (AMEND)

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

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

(C) Records of receipt shall contain a description of the drug or substance and all the following if obtained from a person licensed in accordance with section 4729.52 or 4729.54 of the Revised Code:

(1) The name, strength, dosage form, and quantity of the drug;

(2) The name and address of the seller;

(3) The name and address of the recipient; and

(4) The date of receipt.

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

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

(F) Except as provided in paragraphs (G) and (H) of this rule, records of administration shall contain the name, strength, dosage form, and quantity of the drugs administered~~,~~; the name

and date of birth of the person to whom or for whose use the drugs were administered~~,~~; the identification of the person administering the drug~~,~~; and the date of administration.

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

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

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

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

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

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

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

requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification.

(H) Records of administration for non-human research purposes shall contain the name of the drugs administered~~,~~; the name or identifier of the animal, group of animals, or group of cells for whose use the drugs were administered~~,~~; and the date the research protocol began. Administration to an animal or group of animals shall be pursuant to an institutional animal care and use committee (IACUC) protocol which outlines the name, strength, dosage form, and quantity of the drug to be administered, and a timeline for subsequent administration(s). Documentation within a lab notebook or research ~~record of~~record shall be deemed to meet the requirements of this paragraph. The laboratory shall have the current IACUC protocol available for immediate inspection by an agent, inspector, or employee of the board.

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

(1) The name of the drug or controlled substance.

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

(3) The quantity utilized in any manner by the laboratory including the date and manner of utilization.

(4) The identification of the person or persons conducting the chemical analysis or research. If a controlled substance, the positive identification of the person or persons conducting the chemical analysis or research.

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

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

(1) Date the sample is received;

(2) Purported contents and actual identification;

(3) Quantity received;

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

(5) Description of sample;

(6) Quantity utilized in analysis; and

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

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

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

(1) If the disposal of controlled substance dangerous drug inventory is performed on-site, records shall also include the positive identification of two laboratory employees 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 dangerous drug, records shall also include the positive identification of two laboratory employees conducting and witnessing the disposal.

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

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

(O) 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, ~~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.

(P) Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-16-02 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.

(Q) All records maintained in accordance with this rule 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.

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

(1) 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 to the records; and

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