Ohio Administrative Code

Rule 4729:5-16-03 Record keeping.

Effective: March 1, 2020

(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, 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, the name and address of the animal's owner, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patients 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 professionals 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 shall be deemed to meet the requirements of this paragraph.

(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.