

4729:5-21-04

Record Keeping.

- (A) An OTP 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 (L)(1) of rule 4729:5-21-03 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, address and date of birth of the person to whom or for whose use the dangerous drugs were personally furnished, the positive identification of the prescriber or delegated pharmacist personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver.
- (E)
- (1) Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration, and either:
 - (a) For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug.

- (b) For controlled substance dangerous drugs: the positive identification of the health care professional 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) 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 issued by a prescriber or protocol 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.
- (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 licensed health care professional 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 is performed on-site, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal, one of whom shall be the responsible person or the responsible person's designee.
- (2) If conducting the disposal of an unused portion of a controlled substance resulting from administration to a patient, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal.
- (H) 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.
- (I) Controlled substance inventory records shall be maintained in accordance with rule 4729:5-3-07 of the Administrative Code.
- (J) 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.

(K) 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; and

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

Effective: 3/1/2020

Five Year Review (FYR) Dates: 03/01/2025

CERTIFIED ELECTRONICALLY

Certification

12/06/2019

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26, 3719.28
Rule Amplifies: 4729.51