4729:7-3-06 **Record Keeping.**

(A) The responsible person shall maintain the following records relating to the compounding of dangerous drugs:

(1) All drug orders and records, including logs, relating to the compounding of drugs. Such drug orders and records may be retained by any process providing an exact duplicate of the original order or prescription.

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

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

(b) A record or entry in a record, once created, shall be unalterable but may be added to or annotated as necessary if the identification of the individual that made the addition or annotation to the record or entry is captured by the recordkeeping system and complies with the requirements of this rule;

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

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

(3) A record of all drugs compounded which shall include all the following:

(a) The full name of the patient, unless compounded in accordance with paragraph (G)(2) of rule 4729:7-3-04 of the Administrative Code;

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

(c) Quantity of drug(s) added to each container;

(d) If a controlled substance, the disposition of unused drug(s) and amount;

(e) Date and time of compounding;

(f) The expiration date or beyond-use date of the compounded drug;

(g) The positive identification of the personnel responsible for compounding the drug;

(h) The positive identification of either of the following:

(i) Person or persons whom performed medication validation prior to the compounded drug being administered; or

(ii) The prescriber personally furnishing the compounded drug.

(i) Any sterile compounded drug that is produced in batches shall include documented lot numbers and expiration dates or beyond-use dates for those batches.

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

(C) Records of the disposal of compounded drugs containing controlled substances shall comply with the requirements of rule 4729:5-3-01 of the Administrative Code.

(1) If the disposal of a compounded drug containing a controlled substance is performed on-site, records shall also include the positive identification of two licensed healthcare professionals conducting and witnessing the disposal.

(2) If conducting the disposal of an unused portion of a compounded drug containing 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.

(D) All records shall be readily retrievable and uniformly maintained for at least three years from the date of preparation.

(E) Drug compounding records which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this rule.

(F)

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

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

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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