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Ohio Administrative Code

Rule 4729-16-06 Recordkeeping For Compounding.

Effective: May 1, 2015

(A) This rule applies to all of the following:

(1) Drugs compounded in a pharmacy, including a fluid therapy pharmacy; and

(2) Drugs compounded by a prescriber pursuant to rule 4729-16-04 of the Administrative Code.

(B) The responsible pharmacist or prescriber shall maintain the following records:

(1) A record of all drugs purchased, the quantity received, and the name, address, and wholesale or terminal distributor of dangerous drugs license number of the person from whom the drugs were purchased.

(2) 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. In addition, if an alternate recordkeeping system is utilized, these records may be stored on any storage medium that meets industry standards for quality or any other mutually acceptable method and has stability for a period of at least three years. Records on an automated data processing system, or subsequent storage of such records, must be readily retrievable within seventy-two hours.

(3) Records of drugs dispensed or personally furnished shall include, but are not limited to:

(a) The name, strength, and quantity of drugs dispensed or personally furnished;

(b) The date of dispensing or personally furnishing;

(c) The name of the patient to whom, or for whose use, the drug was dispensed or personally furnished;

(d) Positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code for all pharmacists or prescribers involved in each function of dispensing or personally furnishing; and

(e) Except as provided in paragraph (E) of this rule, disposal record of any unused drug(s).

(4) All other records relating to the compounding of drugs, other than dispensing or personally furnishing, shall include, but are not limited to:

(a) The name of the patient to whom, or for whose benefit the activity was performed;

(b) The activity performed;

(c) Documentation of all personnel involved in each function of the activity.

(5) A record of all drugs compounded which shall include at least the following:

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

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

(c) Except as provided in paragraph (E) of this rule, disposition of unused drug(s) and amount;

(d) Manufacturers lot number or distributors control number;

(e) Manufacturer's or distributor's name, if a generic drug is used and the record keeping system is capable of specifically tracking the manufacturer's or distributors name as part of the documentation;

(f) Pharmacy control number, if prepared in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(g) Date of compounding;

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(h) Manufacturer's or distributor's expiration date;

(i) The expiration date or beyond-use date;

(j) Positive identification of the registered pharmacist or prescriber responsible for the compounding or repackaging of each drug product.

(C) All records must provide accountability and ensure that patients do not receive more drugs than intended by the prescriber. All records shall be readily retrievable and uniformly maintained in an unalterable and secure manner for at least three years from the date of the last dispensing or personal furnishing.

(D) An outsourcing facility shall comply with recordkeeping requirements pursuant to rule 4729-16-02 of the Administrative Code.

(E) Paragraphs (B)(3)(e) and (B)(5)(c) of this rule do not apply to a hospital registered with the department of health under section 3701.07 of the Revised Code.