

4729:7-2-04**Record keeping.**

(A) In addition to the pharmacy record keeping requirements of agency 4729 of the Administrative Code, a pharmacy shall maintain records of all drugs compounded that include, at a minimum, all the following:

- (1) The name of the patient;
- (2) Name of drug, strength or activity, and dosage form;
- (3) Assigned internal identification number (e.g., prescription, order, lot number);
- (4) Date and time of preparation;
- (5) Name of each ingredient;
- (6) Vendor, lot number, and expiration date for each ingredient for compounded drug preparations prepared for more than one patient and for any sterile compounded product prepared from nonsterile ingredient(s);
- (7) Weight or volume of each ingredient;
- (8) Total quantity compounded;
- (9) The disposition of unused controlled substances drug(s) and amount;
- (10) Assigned beyond-use date;
- (11) The positive identification of the following:
  - (a) The pharmacy personnel responsible for preparing the compounded drug preparation;
  - (b) The pharmacist conducting the final check of the compounded drug preparation; and
  - (c) The pharmacist who dispenses the compounded drug preparation.
- (12) All other drug compounding records as required by USP 795, USP 797, and USP 800.

(B) All records maintained in accordance with this rule shall be readily retrievable and uniformly maintained for at least three years.

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

- (2) A pharmacy located in this state intending to maintain records pursuant to this rule at an alternate location must first send a written request to the state board of pharmacy. The request shall contain the pharmacy's name and license number and the name and address of the alternate location. The state board of pharmacy will send written notification to the pharmacy documenting the approval or denial of the request. A copy of the board's approval shall be maintained with the other records of dangerous drugs. Any such alternate location shall be secured and accessible only to authorized personnel or contractors of the pharmacy.

Replaces: 4729-16-06

Effective: 7/1/2021

Five Year Review (FYR) Dates: 07/01/2026

CERTIFIED ELECTRONICALLY

---

Certification

06/17/2021

---

Date

Promulgated Under: 119.03

Statutory Authority: 4729.26, 3719.28

Rule Amplifies: 4729.541, 4729.55, 3719.07, 4729.37

Prior Effective Dates: 05/01/2015