Ohio Administrative Code

Rule 4729:7-2-03 Drugs compounded in a pharmacy.

Effective: July 1, 2021

(A) For all non-sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <795>. This paragraph does not apply to non-sterile compounded preparations exempted from the requirements of this chapter in accordance with paragraph (C) of rule 4729:7-2-01 of the Administrative Code.

(B) For all sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <797>. This paragraph does not apply to sterile compounded drugs exempted from the requirements of this chapter in accordance with rule 4729:7-2-02 of the Administrative Code.

(C) For all antineoplastic compounded hazardous drug preparations listed in table one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code, the pharmacy shall comply with United States pharmacopeia chapter <800>.

(D) For all non-antineoplastic compounded hazardous drug preparations listed in table one on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code and for all compounded hazardous drug preparations listed in table two or three on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code, the pharmacy shall comply with either:

(1) United States pharmacopeia chapter <800>; or

(2) All the following:

(a) Conduct a risk assessment for any hazardous drug preparations listed in paragraph (D) of this rule

to determine if any additional containment strategies, work practices, and/or training is required to minimize occupational exposure. Risk assessments shall be made readily retrievable for review by an agent, inspector or employee of the state board of pharmacy. The risk assessment must be reviewed at least every twelve months and the review documented. If a risk assessment is not performed, the compounded drug preparations shall be prepared in accordance with paragraph (D)(1) of this rule. The risk assessment must, at a minimum, consider the following:

(i) Type of hazardous drug (e.g., non-antineoplastic or reproductive risk only);

(ii) Dosage form;

(iii) Risk of exposure;

(iv) Packaging; and

(v) Manipulation.

(b) Ensure that any employees of reproductive capability confirm in writing that they understand the potential risks of handling drugs listed in paragraph (D) of this rule.

(E) Comply with Title 21 U.S. Code section 353a (11/27/2013).

(F) Only the following may engage in compounding at a pharmacy:

(1) A pharmacist;

(2) A pharmacy intern under the personal supervision of a pharmacist;

(3) A certified pharmacy technician or pharmacy technician trainee under the personal supervision of a pharmacist; and

(4) A registered pharmacy technician under the personal supervision of a pharmacist, but only with respect to non-sterile drug compounding.

(G) For all compounded drug preparations, a pharmacist shall:

(1) Conduct the final check of the compounded drug preparation; and

(2) Be responsible for the dispensing of a compounded drug preparation.

(H) For all compounded drug preparations, a pharmacist shall be responsible for the following:

(1) All compounding records pursuant to rule 4729:7-2-04 of the Administrative Code;

(2) The proper maintenance, cleanliness, and use of all equipment used in compounding.

(I) A drug shall be compounded and dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(J) In addition to the requirements of this rule, compounded drug preparations dispensed to an outpatient shall comply with the following requirements:

(1) Be labeled according to rule 4729:5-5-06 of the Administrative Code; and

(2) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(K) In addition to the requirements of this rule, compounded drug preparations dispensed to an inpatient shall be labeled according to the inpatient labeling requirements in agency 4729 of the Administrative Code; and

(L) Labels for a compounded drug that is prepared in anticipation of a patient-specific prescription shall also contain the following:

(1) The name, strength, and quantity of each active ingredient used in the compounded drug

preparation;

(2) Pharmacy control number;

(3) The assigned beyond-use date;

(4) The identification of the repackager or outsourcing facility by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any other board approved identifier;

(5) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(M) A prescription for a schedule II controlled substance narcotic to be compounded for the direct administration to a patient may be transmitted to a pharmacy by facsimile. The prescription shall comply with the requirements of 21 CFR 1306.11 (3/31/2010).

(N) The pharmacy shall maintain a system for the safe disposal of drug waste in accordance with all state and federal laws, rules and regulations.

(O) The pharmacy shall comply with the drug database reporting requirements pursuant to division 4729:8 of the Administrative Code.

(P) A pharmacy shall report to the state board of pharmacy within seventy-two hours upon discovery, and in a manner determined by the board, any product quality issue attributed to a compounded drug preparation dispensed by the pharmacy.

(1) As used in this paragraph, a product quality issue means any of the following:

(a) Any incident that causes the compounded drug preparation or its labeling to be mistaken for, or applied to, another article;

(b) Contamination of the compounded drug preparation, including but not limited to mold, fungal, bacterial, or particulate contamination; or

(c) Any significant chemical, physical, or other change or deterioration of the dispensed compounded drug preparation within the compounded drug preparation's assigned beyond-use date.

(2) A product quality issue does not include an isolated allergic reaction to a substance included in a compounded drug preparation.

(Q) A pharmacy shall report to the state board of pharmacy within seventy-two hours of issuance or receipt, and in a manner determined by the board, any warning letters, injunctions, or decrees issued in relation to the pharmacy by the United States food and drug administration.