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# Ohio Administrative Code

## Rule 4729:5-8-04 Drugs compounded by a nonresident pharmacy.

Effective: July 1, 2021

(A) Except as otherwise provided in this rule, the terms and references used in this rule have the same meaning as in rules 4729:7-1-01 and 4729:7-2-01 of the Administrative Code.

(B) For all non-sterile compounded drug preparations, a pharmacy licensed as a nonresident terminal distributor of dangerous drugs shall comply with United States pharmacopeia chapter <795>. The requirements of this rule do not apply to the preparation of non-hazardous, conventionally manufactured non-sterile products in accordance with the directions contained in the approved labeling provided by the product's manufacturer.

(C) For all sterile compounded drug preparations, a pharmacy licensed as a nonresident terminal distributor of dangerous drugs shall comply with United States pharmacopeia chapter <797>.

(D) 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, a pharmacy licensed as a nonresident terminal distributor of dangerous drugs shall comply with United States pharmacopeia chapter <800>.

(E) 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, a pharmacy licensed as a nonresident terminal distributor of dangerous drugs 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 (E) 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 (E)(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 (E) of this rule.

(F) In addition to the labeling requirements set forth in this rule, the statement "Compounded Drug" or other similar statement shall be displayed prominently on the label of all compounded drug preparations sold in this state.

(G) A pharmacy licensed as a nonresident terminal distributor of dangerous drugs that engages in drug compounding shall comply with the following:

(1) Except as provided in paragraph (G)(2) of this rule, shall not sell, ship, mail, or deliver, in any manner, compounded drugs into Ohio unless it is pursuant to a patient specific prescription.

(2) May sell, ship, mail, or deliver, in any manner, non-patient specific compounded drugs for animal use pursuant to rule 4729:7-2-04 of the Administrative Code. Such compounding for office use shall comply with applicable federal laws and regulations.

(3) A pharmacy licensed as a non-resident pharmacy that is engaged in drug compounding shall have an Ohio licensed pharmacist as the responsible person on its license. This provision shall take effect on August 1, 2021.

(H) If a pharmacy is applying for an initial nonresident terminal distributor of dangerous drugs license, renewal, or the pharmacy's license has lapsed, the pharmacy must provide any of the following, in a manner determined by the board, as part of the initial or renewal application:

(1) The most recent inspection report that is less than two years old that demonstrates applicable compliance with this rule conducted by an agent of the regulatory or licensing agency in the pharmacy's resident jurisdiction or an agent of a regulatory or licensing agency from another licensing jurisdiction;

(2) The most recent inspection report that is less than two years old that demonstrates applicable compliance with this rule by the national association of boards of pharmacy's verified pharmacy program;

(3) The most recent inspection report that is less than two years old that demonstrates applicable compliance with this rule conducted by accreditation commission for health care inspection services (a.k.a. ACHC inspection services or AIS);

(4) Proof of a current pharmacy compounding accreditation board (PCAB) accreditation provided by the accreditation commission for health care (ACHC); or

(5) Proof of a current medication compounding certification from the joint commission.

(I) A pharmacy licensed as a nonresident terminal distributor 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.

(J) A pharmacy licensed as a nonresident terminal distributor 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.

(K) This rule does not apply to a pharmacy licensed as a nonresident terminal distributor of dangerous drugs that prepares radiopharmaceuticals as defined in agency 4729 of the Administrative Code.