4729:5-8-03 **Compliance.**

A nonresident terminal distributor of dangerous drugs shall:

(A) Maintain the following records of all dangerous drugs dispensed or personally furnished to persons in this state:

(1) Name, strength, dosage form, the serial number of the prescription, and quantity of the dangerous drug dispensed or personally furnished;

(2) Full name and date of birth of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals; and

(3) Residential address, including the physical street address and, if provided, the telephone number of the patient or owner.

(B) Maintain the following records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code for drugs sold or transferred into this state: name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale.

(C) Maintain all records and documents required by this chapter for a period of three years in a readily retrievable manner.

(D) Label all drugs dispensed or personally furnished into this state with the following minimum information:

(1) The name or "doing business as" (DBA) name, or other legal or contractually affiliated name and address of the terminal distributor.

(2) The full name of the patient for whom the drug is prescribed; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals.

(3) The full name of the prescriber or the first initial of the prescriber's first name and the full last name of the prescriber.

(4) Directions for use of the drug.

(5) The date of dispensing.

(6) Any cautions which may be required by federal or state law.

(7) The serial number of the prescription.

(8) The proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug dispensed, and the strength, if more than one strength of the drug is marketed.

(9) The quantity of drug dispensed.

(10) If the licensee is an institutional central fill pharmacy as defined in rule 4729:5-9-02.13 of the Administrative Code, the prescription label attached to the container shall contain the name and address of the originating pharmacy and the name of the central fill pharmacy. If applicable, the date on which the medication order was dispensed shall be the date on which the central fill pharmacy filled the order.

(11) If the licensee is a central fill pharmacy as defined in rule 4729:5-5-19 of the Administrative Code, the prescription label attached to the container shall contain the name and address of the originating pharmacy. The date on which the prescription was dispensed shall be the date on which the central fill pharmacy filled the prescription.

(a) If the originating pharmacy and the central fill pharmacy are not under common ownership, either of the following shall apply:

(i) The name of the central fill pharmacy shall be included on the prescription label or an auxiliary label; or

(ii) A statement is included on the prescription information accompanying the dangerous drug that indicates a central fill pharmacy was used to fill the prescription and includes the name of the central fill pharmacy.

(b) The originating pharmacy shall provide, upon the request of a patient or caregiver, the name and address of the central fill pharmacy and a contact phone number where the patient or caregiver can receive further assistance regarding prescriptions filled by a central fill pharmacy.

(E) Comply with all the statutory requirements of the state of Ohio set forth in Chapters 4729., 3719., 3715., and 2925. of the Revised Code for all drugs sold, dispensed or personally furnished into this state, unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements.

(F) Comply with the following regulatory requirements of the state of Ohio, unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements:

(1) The requirements set forth in this chapter;

(2) The requirements in Chapters 4729:5-1 and 4729:5-2 of the Administrative Code;

(3) Theft or significant loss reporting requirements in rule 4729:5-3-02 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(4) Inspection and corrective action requirements in rule 4729:5-3-03 of the Administrative Code;

(5) Licensure verification requirements in rule 4729:5-3-04 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(6) Patient confidentiality requirements in rule 4729:5-3-05 of the Administrative Code;

(7) Internet sales requirements in rule 4729:5-3-08 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(8) Occasional sale and drug transfer requirements in rule 4729:5-3-09 of the Administrative Code for all drugs sold, dispensed or personally furnished into this state;

(9) Remote medication order processing requirements in rule 4729:5-9-02.14 of the Administrative Code and remote outpatient prescription processing requirements in rule 4729:5-5-20 of the Administrative Code.

(10) The following central fill pharmacy requirements set forth in Chapters 4729:5-5 and 4729:5-9 of the Administrative Code:

(a) If the central fill pharmacy does not have the same owner as the originating pharmacy, the central fill pharmacy shall have a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law, rules and regulations. For central fill pharmacies dispensing outpatient prescriptions, the contract shall also

expressly state who is responsible for performing the patient counseling requirements in accordance with paragraph (L) of this rule.

(b) The central fill pharmacy shall maintain a record of all originating pharmacies, including name, address, terminal distributor number, and, if applicable, drug enforcement administration registration number, for which it processes a request for the filling or refilling of a medication order or prescription received by the originating pharmacy.

(c) The central fill pharmacy and originating pharmacy shall have access to common electronic files as part of a real time, online database or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the medication order or prescription.

(d) The central fill pharmacy and originating pharmacy shall adopt a written quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, resolve identified problems, and ensure compliance with this rule. The quality assurance plan shall be reviewed and updated annually.

(11) If engaged in the provision of medication therapy management, as defined in rule 4729:5-12-01 of the Administrative Code, for patients residing in this state the requirements set forth in Chapter 4729:5-12 of the Administrative Code.

(12) The delivery requirements in rule 4729:5-5-26 of the Administrative Code.

(G) Submit to the applicable disciplinary actions set forth in section 4729.57 of the Revised Code and rule 4729:5-4-01 of the Administrative Code.

(H) Operate in compliance with all applicable laws, regulations and standards set forth by the United States food and drug administration and the United States drug enforcement administration.

(I) Nonresident terminal distributors of dangerous drugs who are pharmacies shall dispense prescriptions into this state issued by either:

(1) An Ohio prescriber who is authorized pursuant rule 4729:5-1-02 of the Administrative Code; or

(2) A nonresident prescriber whose license is current and in good standing and who is authorized to issue prescriptions for dangerous drugs in the course of the prescriber's professional practice in a state other than Ohio.

(J) Supply, within three business days of a request, all information needed by the board of pharmacy to carry out its responsibilities as a licensing, regulatory, and drug law enforcement agency of the state of Ohio.

(K) Supply, within three business days of a request, all information needed by the board of pharmacy and any local, state, or federal agency to carry out its responsibilities in enforcing the federal and state laws governing the distribution of drugs in the state of Ohio.

(L) If the nonresident terminal distributor is a pharmacy, there must be an offer to counsel the patient issued with every prescription dispensed. The offer shall be made by telephone or in writing on a separate document and shall accompany the prescription. A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached. The telephone service must be available at no cost to the pharmacy's primary patient population. The pharmacy shall have sufficient telephone service to provide access to incoming callers.

(M) Nonresident terminal distributors shall permit properly identified and authorized state board of pharmacy agents and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles. A nonresident terminal distributor of dangerous drugs shall be responsible for all costs incurred by board of pharmacy agents in conducting an inspection. Upon completion of the inspection, the nonresident terminal distributor of dangerous drugs shall have ninety days to reimburse all inspection costs incurred after being notified, electronically or in writing, by the board.

In lieu of an inspection by the board, a nonresident terminal distributor of dangerous drugs may submit any of the following:

(1) Inspection reports by a state licensing agency demonstrating compliance with the requirements of this rule.

(2) Inspection reports demonstrating compliance with the requirements of this rule by one of the following organizations:

(a) The national association of boards of pharmacy's verified pharmacy program (VIPP);

(b) An organization approved by the board.

(N) Comply with all drug database reporting requirements pursuant to Chapter 4729. of the Revised Code and division 4729:8 of the Administrative Code.

(O) Unless approved by the board's executive director, a nonresident terminal distributor of dangerous drugs that is not a pharmacy shall not be permitted to sell or personally furnish controlled substances to patients residing in this state.

Effective: 6/30/2025

Five Year Review (FYR) Dates: 1/13/2025 and 06/30/2030

CERTIFIED ELECTRONICALLY

Certification

04/18/2025

Date

Promulgated Under: 119.03
Statutory Authority: 4729.26
Rule Amplifies: 4729.551, 4729.54, 4729.55
Prior Effective Dates: 08/16/1994 (Emer.), 12/15/1994, 10/19/2007, 03/01/2019, 02/01/2022