Mike DeWine, Governor Jim Tressel, Lt. Governor Steven W. Schierholt, Executive Director

Discontinuation of Business as a Terminal Distributor of Dangerous Drugs

Date Issued: 10/3/2025

Comments Due: 10/27/2025

In accordance with Chapter 119. of the Revised Code, the Ohio Board of Pharmacy proposes amendments to OAC 4729:5-2-04, which governs the process of discontinuing business as a terminal distributor of dangerous drugs.

Comments on the proposed rule amendments will be accepted until close of business on **Monday, October 27, 2025**.

Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov.



Rule 4729:5-2-04 | Procedure for discontinuing business as a terminal distributor of dangerous drugs <u>and upon suspension or revocation of license</u>. (AMEND)

- (A) A terminal distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the board of pharmacy. The notice shall be submitted, in a manner determined by the board, within thirty days of discontinuation of business as a terminal distributor of dangerous drugs. This notice shall include the following information:
- (1) The name, address, and license number of the terminal distributor discontinuing business.
- (2) The name, address, and license number of the terminal distributor or other authorized entity where the dangerous drugs will be transferred **or sold, if applicable**.
- (3) The name and address of the secured location where the records of purchase and sale will be kept in accordance with this division of the Administrative Code.
- (4) The proposed date of discontinuing business.
- (B) Unless the licensee is informed by the executive director before the proposed date of discontinuing business that the transfer of dangerous drugs and records may not occur, the licensee discontinuing business may transfer the dangerous drugs and patient records.
- (B) A licensee discontinuing business may do one or more of the following:
- (1) Conduct a one-time transfer or sale of dangerous drug inventory and patient records to another licensed terminal distributor of dangerous drugs or an entity exempted under section 4729.541 of the Revised Code.

The terminal distributor of dangerous drugs discontinuing business shall provide an invoice or transfer record to the purchaser or recipient that contains the name, strength, dosage form, and quantity of the dangerous drugs transferred or sold; the name and address of the terminal distributor of dangerous drugs that is discontinuing business; the name and address of the location where the drugs were transferred or sold; and the date of transfer or sale. All transfers or sales shall be conducted on or before the proposed date of discontinuing business submitted in accordance with paragraph (A) of this rule.

(2) Disposal of its stock of dangerous drugs in accordance with the requirements of Chapter 4729:5-3 of the Administrative Code.

The terminal distributor that is discontinuing business shall create a record of such disposal in accordance with the applicable record keeping provisions of Chapter 4729:5-5 of the Administrative Code. Disposal of inventory shall be conducted on or before the proposed date of discontinuing business submitted in accordance with paragraph (A) of this rule.

- (a) All patient-specific drug stock maintained by the terminal distributor of dangerous drugs in accordance with rule 4729:5-3-24 of the Administrative Code shall be provided to the patient on or before the proposed date of discontinuing business submitted in accordance with paragraph (A) of this rule.
- (b) Any patient-specific drug stock that cannot be provided to the patient shall be disposed of on or before the proposed date of discontinuing business submitted in accordance with paragraph (A) of this rule.
- (3) Pursuant to paragraph (F) of this rule, a person or entity that is exempted from licensure in accordance with section 4729.541 of the Revised Code may maintain dangerous drugs on-site that do not require licensure as a terminal distributor of dangerous drugs to possess.
- (C) On the date of discontinuing business <u>and prior to any disposal conducted in</u>

 <u>accordance with paragraph (B) of this rule</u>, a complete inventory of all controlled substances being transferred, or disposed of, in accordance with rule <u>4729:5-3-01</u> of the Administrative Code, shall be <u>made conducted</u>. The inventory shall list the name, strength, dosage form, and quantity of all controlled substances transferred, <u>sold</u>, or disposed.

This inventory shall serve as the final inventory of the licensee discontinuing business and the initial inventory of the licensee to whom the controlled substances are being transferred <u>or</u> <u>sold</u>. A copy of the inventory shall be included in the records of each licensee involved in the transfer.

(D) A terminal distributor of dangerous drugs licensed as a pharmacy that is permanently closing shall:

- (1) Provide notification, using the information on file with the pharmacy, to each patient who has filled a prescription within the previous six months. This notification must be made a minimum of fifteen calendar days prior to closing and must include:
- (a) The last day the pharmacy will be open;
- (b) Name, address, and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;
- (c) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and
- (d) The last day a transfer may be initiated.
- (2) The notification shall be made via:
- (a) Direct mail, e-mail, or text message; and
- (b) Posting a closing notice on each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g., website, social media, mobile applications).
- (3) Provide any new patients filling prescriptions during the fifteen-calendar day period prior to the pharmacy closing with written notification that includes:
- (a) The last day the pharmacy will be open;
- (b) Name, address, and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;
- (c) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and
- (d) The last day a transfer may be initiated.
- (E) Except as provided in paragraph (F) of this rule, a terminal distributor of dangerous drugs that has had its license suspended or revoked shall dispose of and/or transfer all dangerous drugs within ten business days of receiving notice from the board of such a suspension or revocation.

- (1) Disposal of drug stock. A terminal distributor of dangerous drugs that has had its license suspended or revoked shall dispose of all drug stock maintained by the terminal distributor.
- (a) Non-controlled dangerous drugs shall be disposed of in accordance with rule 4729:5-3-06 of the Administrative Code. To demonstrate compliance with the requirements of Chapter 4729. of the Revised Code, the suspended or revoked licensee shall maintain a record for all non-controlled drugs disposed. The records shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed; the date of disposal; the method of disposal; and the identification of the licensed health care professional that performed the disposal.
- (b) Controlled substances shall be disposed in accordance with rule 4729:5-3-01 of the Administrative Code. To demonstrate compliance with the requirements of Chapter 4729. of the Revised Code, the suspended or revoked licensee shall maintain records for all controlled substance drugs disposed in accordance with rule 4729:5-3-01 of the Administrative Code.
- (c) All disposal records shall be maintained for three years from the date of disposal for immediate inspection by an agent, officer, or inspector of the board to demonstrate compliance with section 4729.51 of the Revised Code.
- (2) One-time transfer or sale of drug stock. Except as provided in paragraph (E)(3) of this rule, a terminal distributor of dangerous drugs that has had its license suspended or revoked may conduct a one-time transfer or sale of dangerous drugs to another terminal distributor of dangerous drugs or an entity exempted under section 4729.541 of the Revised Code. Any dangerous drugs that are not transferred or sold shall be disposed of in accordance with paragraph (E)(1) of this rule.

The terminal distributor of dangerous drugs that has had its license suspended or revoked shall provide the following records to the purchaser or recipient:

(a) An invoice or transfer record that contains the name, strength, dosage form, and quantity of the dangerous drugs transferred or sold; the name and address of the terminal distributor of dangerous drugs that is suspended or revoked; the name and

- address of the location where the drugs were transferred or sold; and the date of transfer or sale; and
- (b) A complete inventory of all controlled substances being transferred or sold in accordance with rule 4729:5-3-01 of the Administrative Code. The inventory shall list the name, strength, dosage form, and quantity of all controlled substances transferred, sold, or disposed.
- (3) A terminal distributor of dangerous drugs listed in paragraph (E)(2) that receives a one-time transfer or sale of drug stock in accordance with this rule may conduct a one-time transfer or sale of dangerous drugs back to the original owner of the drugs if all the following conditions are satisfied:
- (a) The original owner's terminal distributor of dangerous drugs license has been reinstated by the board and there are no limitations or restrictions on the license.
- (b) The one-time transfer or sale back to the original owner is conducted within ten business days of reinstatement of the terminal distributor of dangerous drugs license.
- (c) The drug stock received from the original owner has been stored separately from the stock of drugs maintained by the terminal distributor of dangerous drugs conducting the transfer or sale to avoid any comingling of inventory.
- (d) The terminal distributor of dangerous drugs conducting the transfer or sale maintains a record of the transfer or sale for a period or three years in a readily retrievable format. The record shall include the name, strength, dosage form, 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.
- (e) The terminal distributor of dangerous drugs receiving the drugs maintains a record of the transfer or sale for a period of three years in a readily retrievable format. The record shall include the name, strength, dosage form, and quantity of the dangerous drugs received; the name and address of the seller; the name and address of the recipient; and the date of receipt.
- (F) A terminal distributor of dangerous drugs that meets the exemptions specified in division (A)(1) to (A)(3) of section 4729.541 may maintain dangerous drugs on-site that

do not require licensure as a terminal distributor of dangerous drugs. This shall not include any of the following:

- (1) A schedule I, II, III, IV, or V controlled substance, as defined in section 3719.01 of the Revised Code; and
- (2) Except for dangerous drugs that meet the exemptions listed in paragraph (A) of rule 4729:7-3-02 of the Administrative Code, dangerous drugs that are compounded or used for the purpose of compounding including bulk drug substances and active pharmaceutical ingredients used in compounding.