Wholesale Sales of Non-Controlled Dangerous Drugs Conducted Local Health Departments

Updated 8/5/22

Effective August 4, 2022, local health departments licensed as terminal distributors of dangerous drugs are permitted to conduct wholesale sales in accordance with rule 4729:5-3-09 of the Administrative Code of non-controlled dangerous drugs for the purposes of improving or promoting public health within the department's jurisdiction as authorized under the following Board Resolution:

> *Pursuant to division (A)(3)(c) of section 4729.51 of the Revised Code, the Board authorized amendments to rule 4729:5-3-09 of the Administrative Code to permit occasional wholesale sales of non-controlled dangerous drugs by a local health department licensed as a terminal distributor of dangerous drugs for the purpose of improving or promoting public health within the department's jurisdiction and to exempt such authorization from the current limitations set forth in paragraph (B) of the rule. The Board hereby finds it is in the public interest to authorize this practice while the rule is pending. Licensees shall comply with all required recordkeeping requirements to conduct a sale of dangerous drugs in accordance with rule 4729:5-3-09 of the Administrative Code.*

A local health department is defined as follows:

> *"Local health department" means a department operated by a board of health of a city or general health district or the authority having the duties of a board of health as described in section 3709.05 of the Revised Code.*

This resolution and guidance may be subject to change on or after November 27, 2023, to comply with new federal requirements (DSCSA). The Board will notify local health departments of any changes at least 30-days prior to any change of this resolution or the rule implementing this resolution.

To assist licensees in complying with these rules, the Board developed a set of frequently asked questions that begins on the next page of this document.

If you need additional information, you may e-mail the Board at contact@pharmacy.ohio.gov.

Q1) What are the record keeping requirements necessary to comply with this resolution?

A1) The local health department must maintain a record of sale (even if the sale is no-cost) the includes all the following information:

> *Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, expiration date 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.*

REMINDER: All records of sales must be maintained by the terminal distributor for three years from the date of creation.

Q2) Is the local health department required to verify appropriate licensure prior to conducting a wholesale sale?

A2) Yes. A licensee must comply with the requirements of rule 4729:5-3-04 of the Administrative Code, which requires the local health department to verify the receiver of the drugs is appropriately licensed as either:

1. A terminal distributor of dangerous drugs. Verification can be documented using Ohio's eLicense system: https://elicense.ohio.gov/OH_HomePage

2. If selling to a prescriber office or other location who is exempted from Board of Pharmacy licensure, comply with all the following:

    a. Provide the purchaser the requirements in Ohio law of when a purchaser shall hold a license as a terminal distributor of dangerous drugs. For a prescriber this document can be accessed here: www.pharmacy.ohio.gov/PrescriberTDDD. For another facility (such as a camp/school), this can be achieved by providing the language directly from ORC 4729.541 (A)(4) thru (A)(15).

    b. If a prescriber, verify the prescriber is appropriately licensed in this state to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice. Verification can be documented using Ohio's eLicense system: https://elicense.ohio.gov/OH_HomePage

c. Require the purchaser who claims an exemption to the terminal distributor of dangerous drug licensing requirement to annually attest in writing, which may include an electronic signature, that the purchaser meets the licensing exemptions in section 4729.541 of the Revised Code.

d. Ensure that all attestations are maintained by the terminal distributor for a period of three years following the date the attestation is signed by the purchaser.

IMPORTANT: Verification must be conducted prior to initial sale and then at least annually if the local health department is continuing to conduct wholesale sales to the purchaser (even if a no-cost sale).

Q3) Are there any restrictions to the amount of non-controlled drugs that may be distributed via this resolution?

A3) No. Currently, there are no limitations for non-controlled drugs.

Q4) If my local health department has an on-site pharmacy, does this resolution apply?

A4) Pharmacies are already permitted by rule to conduct occasional wholesale sales under OAC 4729:5-3-09.

Q5) How does the Board define "improving or promoting public health within the department's jurisdiction"?

A5) Local health departments should be able to demonstrate any sales conducted under this resolution are to the benefit of public health. Some examples include, but are not limited to, the following:

- Vaccine or therapeutics distribution;
- Distribution of medications to local clinics to address STIs and other communicable diseases;
- School-based programs aimed at promoting adherence to medication use.