Mike DeWine, Governor Jon Husted, Lt. Governor Steven W. Schierholt, Executive Director

Sale of Non-Controlled Medications by Local Health Departments

Updated 9/9/2024

To assist local health departments licensed as terminal distributors of dangerous drugs, the Ohio Board of Pharmacy approved the following resolution:

The Board hereby authorizes a local health department, as defined in rule 4729:5-3-09 of the Administrative Code, to engage in the occasional sale of non-controlled dangerous drugs to any other local health department in this state holding a terminal distributor of dangerous drugs. Each local health department shall comply with the applicable recordkeeping rules set forth in division 4729:5 of the Administrative Code. (Authorized 9.6.2024)

For questions regarding this resolution, please review the frequently asked questions in this document. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Frequently Asked Questions

Q1) What is an occasional sale?

A1) Under Ohio law, an occasional sale allows a terminal distributor of dangerous drugs, under limited circumstances, to sell a drug at wholesale without needing a wholesale distributor license from the Board. The term sale is broadly defined in the Ohio Revised Code and can include a sale of drugs without the exchange of any money (sometimes referred to as a no-cost sale).

Q2) What does this resolution do?

A2) This resolution allows any local health department in Ohio, licensed as a terminal distributor of dangerous drugs, to engage in the occasional sales of non-controlled drugs.

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Non-controlled drugs are those medications, including vaccines, that are not listed as <u>controlled substances</u> under federal or state law.

For example, if a health department is purchasing vaccines for clients who are private pay (e.g., not eligible for the Vaccines for Children Program) and wants to distribute excess doses to other local health departments to help defray costs and reduce waste, it is now permitted to do so.

PLEASE BE ADVISED THAT, UNLESS OTHERWISE AUTHORZED BY THE OHIO DEPARTMENT OF HEALTH, LOCAL HEALTH DEPARTMENTS ARE NOT PERMITTED TO SELL OR TRANSFER VACCINES THAT ARE COVERED UNDER THE VACCINES FOR CHILDREN PROGRAM UNDER THIS RESOLUTION.

Q3) If I do engage in an occasional sale under this resolution, what type of records do I have to maintain?

A3) The Board's recordkeeping rules require the health department to maintain documentation, for three years, of 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.

In addition, the receiving health department must maintain a record or receipt which contains 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. It is highly recommended that the local health department that is acting as the "seller" provide a record (like an invoice) to the receiving health department to ensure compliance with this rule.

Lastly, it is important to verify that both health departments hold a current license as a terminal distributor of dangerous drugs prior to engaging in any sale. The local health department engaging in the sale (i.e., the seller) must query <u>Ohio's eLicense system</u> prior to making any sale. This query must be documented (e.g., print or electronically save the eLicense verification) and maintained with the sales records for every sale conducted (see OAC <u>4729:5-3-09</u>).

The local health department receiving the drugs (i.e., the purchaser) must also conduct an <u>annual</u> query of <u>Ohio's eLicense system</u> showing the health department engaged in the sale is licensed as a terminal distributor of dangerous drugs. This query must be documented and maintained in the sales records.

For more information on licensure verification for drug sales and purchases, see www.pharmacy.ohio.gov/verify.

Q4) How do I facilitate the sale of drugs under this resolution?

A4) All drugs, including vaccines, that are sold between local health departments under this resolution must be maintained under temperatures and conditions that maintain the integrity of the drug per the manufacturer's instructions (or if otherwise instructed by the Ohio Department of Health or the Centers for Disease Control and Prevention). This includes maintaining cold chain storage for the occasional sale of vaccines.

Q5) How does the Board define the term "occasional" when referring to an occasional sale?

A5) As long as local health departments are complying with the requirements listed in this document, the Board is not placing a limitation on the quantity of drugs or number of occasional sales a local health department may conduct.

Q6) Can a local health department engage in occasional sales of non-controlled drugs to other locations that are not local health departments?

A6) Yes. Per rule <u>4729:5-3-09 of the Administrative Code</u>, a local health department may engage in occasional sales of non-controlled drugs to other locations for the purpose of improving or promoting public health within the department's jurisdiction.

For example, a local health department provides no-cost treatment for a communicable disease to local physicians or pharmacies within the department's jurisdiction. The local health department must comply with all applicable recordkeeping requirements and must ensure that the location where the drugs are being sold are either: 1) licensed a terminal distributor of dangerous drugs; or 2) are exempted from licensure as a terminal distributor of dangerous drugs. For more information see: www.pharmacv.ohio.gov/verify.

For more information about terminal distributor licensing exemptions, visit:

- For prescriber practices: <u>www.pharmacy.ohio.gov/PresciberTDDD</u>
- For non-prescriber practices: <u>www.pharmacy.ohio.gov/NPPtddd</u>

IMPORTANT: A local health department is not permitted to engage in occasional sales outside of their jurisdictions unless it is another local health department (as authorized by this resolution). This also does not apply to the sale/distribution of naloxone or other overdose reversal drug.