



STATE OF
OHIO
BOARD OF PHARMACY

Updated Guidance Issued for Reporting of Suspicious Orders and Customer Due Diligence

Effective April 30, 2019, [rule 4729:6-3-05 of the Ohio Administrative Code](#) will require entities licensed as wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities to comply with the following:

- Design and operate a system to identify and report suspicious orders by customers for reported drugs. **NOTE:** The reporting of suspicious orders must be conducted electronically.
- Exercise due diligence to identify customers ordering or seeking to order reported drugs to establish the normal and expected transactions conducted by those persons and to identify and prevent the sale of reported drugs that are likely to be diverted from legitimate channels.
- Submit to the Board information on any customer or potential customer that may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels, including those to whom a drug distributor refuses to sell.
- **IMPORTANT:** No later than July 29, 2019, a drug distributor (wholesale distributor, virtual wholesaler, manufacturer, and outsourcing facility) must submit information on all Ohio customers the distributor has refused to sell to or has stopped selling to within the past three years because the distributor has identified the customer as engaging in possible activities that may cause reported drugs to be diverted from legitimate channels. While the rule requiring this reporting does not go into effect until April 30, 2019, a licensee may begin submitting this information prior to rule's effective date.
- Develop and implement policies and procedures, including training, on the implementation of the rule.

To assist licensees in complying with this rule, the State of Ohio Board of Pharmacy recently updated the following guidance documents:

[Suspicious Order Monitoring and Due Diligence](#)

[Instructions for Reporting Wholesale Transactions, Suspicious Orders and Customers to OARRS](#)

As a reminder, this rule only applies to drug distributors licensed as wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities.

The updated [FAQ document](#) includes information on obtaining an exemption to the requirements of the rule if a licensee does not engage in the sale of controlled substances or gabapentin.
