



# Instructions for Reporting Wholesale Transactions, Suspicious Orders and Customers to OARRS

Updated 2/18/2020

All updates are notated in red (i.e. **UPDATE 2.18.2020**)

## Applicable Rules:

- OARRS Reporting - [Division 4729:8 of the Administrative Code](#)
- Suspicious Order Monitoring and Due Diligence - [Rule 4729:6-3-05 of the Administrative Code](#)

Ohio law and rules require the reporting of wholesale transactions, suspicious orders, and customer information to the Ohio Automated Rx Reporting System (OARRS). This document outlines how licensees are required to report this data to OARRS. **NOTE:** This is a summary document and is not intended to replace applicable statutes or rules.

For more information on suspicious order and customer reporting visit:

[www.pharmacy.ohio.gov/suspicious](http://www.pharmacy.ohio.gov/suspicious).

Please review this document in its entirety. If you have any additional questions or need support, please contact OARRS at [data@pharmacy.ohio.gov](mailto:data@pharmacy.ohio.gov) or by telephone 614-466-4143 (option 1) during normal business hours.

This guidance document features the following sections:

1. [Registration Process for an OARRS Wholesale Data Upload Account](#)
2. [Reporting Wholesale Transactions](#)
3. [Reporting Deadlines for Wholesale Transactions & Reporting Exemptions](#)
4. [Reporting Suspicious Orders](#)
5. [Reporting Process for Wholesale Transactions and/or Suspicious Orders](#)
6. [OARRS Data Submission for Wholesale Transactions and Suspicious Orders](#)
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8. [Reporting Process for Submitting Zero Reports](#)
9. [Reporting Customers Engaged in Possible Drug Diversion](#)

**IMPORTANT:** Drug distributor, as used in this guidance document, refers to the following license types:

- Wholesale distributors of dangerous drugs;
- Virtual wholesalers;



- Manufacturers of dangerous drugs; and
- Outsourcing facilities.

### **Registration Process for an OARRS Wholesale Data Upload Account**

Prior to submitting wholesale transaction or suspicious order/customer data, a drug distributor must register for a wholesale data upload account.

1. Go to the OARRS website ([www.ohiopmp.gov](http://www.ohiopmp.gov)) and click on the button titled "Register"
2. Select "Wholesale Data Upload"
3. Enter the contact information for the person who will be responsible for reporting data to OARRS

**NOTE: If you do not have a Board of Pharmacy drug distributor license number, you may use your terminal distributor license number (i.e. if reporting wholesale transactions conducted by a pharmacy).**

4. Type in your preferred password for this account
5. Click on the submit button
6. You will receive confirmation of the account creation to the email address specified

Each organization licensed as a drug distributor or terminal distributor must have ONE account for reporting. Every person who submits data for a drug distributor or terminal distributor will use the same username and password.

**NOTE:** This is not the same username and password that pharmacists or prescribers use to access patient data.

## **Reporting Wholesale Transactions**

Wholesale reporting to OARRS is required for all controlled substances and gabapentin products. For the purposes of reporting wholesale transactions, the following entities are required to submit data to OARRS:

- Wholesale distributors of dangerous drugs;
- Virtual wholesalers;
- Manufacturers of dangerous drugs;
- Outsourcing facilities; and
- Pharmacies conducting wholesale drug transfers and occasional wholesale sales to other terminal distributors or prescribers.

*(NOTE: Drug distributors, as used in this guidance, include the following licensees: wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities.)*

A wholesale transaction involves transfer of possession to an Ohio terminal distributor or an Ohio prescriber, regardless of the exchange of money. In other words, if the drug moves from the DEA number of a drug distributor or a terminal distributor to the DEA number of a pharmacy, hospital, physician, clinic, researcher, etc., it must be reported. **This includes pharmacies conducting transfers or occasional sales of controlled substances or gabapentin to other pharmacies and prescribers.**

### **IMPORTANT REMINDERS:**

- Transfers from one licensed drug distributor to another licensed drug distributor **should NOT** be reported (for example, the sale of a reported drug from one wholesaler to another wholesaler).
- Transfers of reported drugs to a reverse distributor for disposal **should NOT** be reported. **(UPDATE 6.24.2019)**
- This reporting is separate from reporting prescriptions that are dispensed by pharmacies or personally furnished by prescribers. A separate manual for uploading this data can be accessed [here](#).

Reporting wholesale transactions can be submitted in one of three ways:

1. Via the FTP/SFTP (File Transfer Protocol) site;
2. Uploaded via a file using your [OARRS wholesale data upload account](#); or
3. Manually filed using your OARRS wholesale data upload account.

**NOTE:** The data requested for sales is based on the format required by the Drug Enforcement Administration's sales reporting system, [ARCOS](#).

**More information on this process can be found on [page 7](#) of this document.**

## **Reporting Deadlines for Wholesale Transactions & Reporting Exemptions**

### *For Drug Distributors:*

If you have an applicable drug distributor license (wholesale distributor, virtual wholesaler, manufacturer or outsourcing facility) from the Board of Pharmacy, you must submit a report at least once every month, no later than 45 days after the earliest transaction being reported. If there is no transaction to report during the month, you must submit a zero report. **Failure to report a transaction is not the same as a zero report. The zero report shall be submitted within fifteen days of the end of the calendar month.**

Zero reports can be submitted in one of three ways:

1. Via the FTP/SFTP (File Transfer Protocol) site;
2. Uploaded via a file using your [OARRS wholesale data upload account](#); or
3. Manually file using your OARRS wholesale data upload account (see [page 11](#) for instructions).

***For more information on submitting zero reports via FTP/SFTP or file upload, contact OARRS at: [data@pharmacy.ohio.gov](mailto:data@pharmacy.ohio.gov) or by telephone 614-466-4143 (option 1).***

All Ohio licensed wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities that do not sell controlled substances or gabapentin to Ohio licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, EMS, etc.) or Ohio prescribers may submit a request for an exemption from the requirement to submit zero reports to OARRS. The request permits an exemption from the following:

- o The requirement of rule [4729:8-3-04](#) to submit a zero report indicating the distributor did not engage in the wholesale sale of reported drugs; and
- o The requirement of rule [4729:6-3-05 \(F\)](#) to submit a zero report indicating the distributor did not receive any orders identified as suspicious (this also exempts a drug distributor from having to report 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 as well as the policy and procedure requirements of [4729:6-3-05 \(J\)](#) – see [Page 13](#) of this document for information on customer reporting).

All drug distributors that qualify for an exemption must submit an exemption request form electronically. The form may be accessed here: [www.pharmacy.ohio.gov/exemptDD](http://www.pharmacy.ohio.gov/exemptDD). ***A distributor that fails to obtain an exemption request and does not submit a zero report to the Board may be subject to disciplinary action.***

A drug distributor that uses a 3PL to report drug sales as well as suspicious orders/customers may file an official exemption with the Board. The form can be accessed here: [www.pharmacy.ohio.gov/3PLexempt](http://www.pharmacy.ohio.gov/3PLexempt).

**IMPORTANT:** Be advised that Ohio rules put the responsibility for compliance on the drug distributor and not the 3PL. The drug distributor submitting an exemption accepts responsibility to ensure that the 3PL complies with all the following:

- o The drug database reporting requirements of Chapter 4729. of the Ohio Revised Code and division 4729: 8 of the Ohio Administrative Code; and
- o The requirements of rule 4729:6-3-05 of the Ohio Administrative Code.

For Pharmacies:

If you **do not** have a drug distributor license but you are a pharmacy that has performed a wholesale transaction as an “occasional sale” or a transfer, you must submit a report at least once every month, no later than 45 days after the earliest wholesale transaction being reported. If there is no transaction to report during the month, you must submit a zero report. **Failure to report a transaction is not the same as a zero report. The zero report shall be submitted within fifteen days of the end of the calendar month.**

Zero reports can be submitted in one of three ways:

1. Via the FTP/SFTP (File Transfer Protocol) site;
2. Uploaded via a file using your [OARRS wholesale data upload account](#); or
3. Manually file using your OARRS wholesale data upload account (see [page 11](#) for instructions).

**For more information on submitting zero reports via FTP/SFTP or file upload, contact OARRS at: [data@pharmacy.ohio.gov](mailto:data@pharmacy.ohio.gov) or by telephone 614-466-4143 (option 1).**

If you have previously conducted wholesale transactions of controlled substances or gabapentin but no longer do so, you may submit a request for an exemption from the requirement to submit zero reports to OARRS as required by rule [4729:8-3-04](#). The form may be accessed here: [www.pharmacy.ohio.gov/exempt](http://www.pharmacy.ohio.gov/exempt). **IMPORTANT:** If you are a pharmacy that has never conducted a wholesale transaction of a controlled substance or gabapentin, then you are not required to submit an exemption request at this time.

## **Reporting Suspicious Orders**

The following drug distributors are required to report suspicious orders:

- Wholesale distributors of dangerous drugs;
- Virtual wholesalers;
- Manufacturers of dangerous drugs; and
- Outsourcing facilities.

*(NOTE: Drug distributors, as used in this guidance, include the following licensees: wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs and outsourcing facilities.)*

***Unlike the reporting of wholesale transactions, pharmacies licensed as terminal distributors that are engaged in transfers or occasional wholesale sales of controlled substances or gabapentin to other pharmacies and prescribers are not required to report suspicious orders.***

For more information about suspicious order monitoring and reporting requirements, visit: [www.pharmacy.ohio.gov/suspicious](http://www.pharmacy.ohio.gov/suspicious)

A suspicious order starts out as a regular order from a customer. Therefore, a suspicious order would contain all the same data elements as a typical order plus some additional information regarding what makes it suspicious. The Board has made modifications to the existing wholesale sale data collection system in OARRS (i.e. ARCOS format) to be able to receive both typical sales as well as suspicious orders. More information on this process can be found on [page 7](#) of this document.

### **IMPORTANT REMINDERS:**

- If an order is reported as suspicious and was indicated as shipped by the drug distributor as part of a suspicious order report, it should not be reported as part of the monthly wholesale sales data. This will lead to the duplication of data.
- If an order is initially reported as suspicious and eventually shipped but it was not originally indicated as shipped by the drug distributor as part of a suspicious order report, it should be reported as part of the monthly wholesale sales data.

## **Reporting Process for Wholesale Transactions and/or Suspicious Orders**

***OARRS uses the standard [ARCOS](#) data reporting format used by the United States Drug Enforcement Administration to report wholesale transactions. To report suspicious orders, the ARCOS data reporting format has been modified to collect additional information on what makes the order suspicious.***

For more information on the requirements for reporting suspicious orders and customers, the Board developed a guidance document that can be accessed here:

[www.pharmacy.ohio.gov/suspicious](http://www.pharmacy.ohio.gov/suspicious)

There are three options for reporting wholesale transactions and/or suspicious orders:

### **Method 1: Manual Reporting**

1. Navigate to the OARRS website ([www.ohiopmp.gov](http://www.ohiopmp.gov))
2. Click the "Wholesale Login" button
3. Log into the reporting website
4. Choose the "Manual Sale Entry" menu option on the left.
5. Enter the information in the fields provided
6. If you are reporting a suspicious order, check the box at the bottom. Enter the information into the additional fields which will appear. All fields must be completed. **NOTE:** *The compliance officer information should be a primary point of contact to assist the Board with providing any additional information about the nature of the suspicious order.*
7. Click "Add Transaction" to report the sale or suspicious order.
8. If you have another sale or suspicious order for the same customer, simply enter the additional information. Otherwise, click "Clear Form" to enter sales or suspicious orders for a different customer.

### **Method 2: HTTP File Upload**

1. Navigate to the OARRS website ([www.ohiopmp.gov](http://www.ohiopmp.gov))
2. Click the "Wholesale Login" button
3. Log into the reporting website
4. Choose the "Sale File Upload" menu option on the left
5. Click the button to locate the properly formatted ARCOS file containing the sales/suspicious orders that you are reporting (See format on [page 8](#) of this document)
6. Click "Submit" to begin uploading the file.
7. You will be notified via email of the success or failure of your submission, as well as any errors there might have been in the file.

### **Method 3: FTP/SFTP method**

1. Using your choice of FTP/SFTP software, connect to [ftp.ohiopmp.gov](ftp://ohiopmp.gov) or [sftp.ohiopmp.gov](sftp://ohiopmp.gov), depending on the type of file transfer protocol you chose, using your OARRS wholesale data upload account information.
2. Locate the properly formatted ARCOS file containing the sales/suspicious orders that you are reporting. (See format on [page 8](#) of this document)
3. Upload this file to your FTP/SFTP account directory
4. You will be notified via email of the success or failure of your submission, as well as any errors there might have been in the file.

## OARRS Data Submission for Wholesale Transactions and Suspicious Orders

### Format

Submit the data in the modified ARCOS format, see the table below. The filename should include ###.mmddyyy.arcos, where ### is the drug distributor's/seller's DEA number and mmddyyyy is the last date of the reporting period.

### **File Format – ARCOS (modified)**

#### **Control Record**

Field Description	*Required	Length
Reporting Registrant	Required	9
Asterisk (*)	Required	1
Last Day of Reporting Period	Required	8
Reporting Frequency (M)	Required	1
Central Reporter's Number	Optional	9
Compliance Officer Name <sup>2</sup>	Situational*	25
Compliance Officer Email	Situational*	50
Compliance Officer Phone	Situational*	10

#### **Transaction Record**

Field Description	Required	Length
Registrant DEA Number <sup>1</sup>	Required	9
Transaction Code	Required	1
Action Indicator	Required	1
NDC Number	Required	11
Quantity	Required	8
Unit	Required	1
Assoc Registrant DEA Number	Required	9
Order Form Number	Optional	9
Transaction Date (mmddyyyy)	Required	8
Correction Number	Optional	8
Strength	Required	4
Transaction Identifier	Required	10
Blank Space	Required	1
Order Shipped (Y/N)	Situational*	1
Suspicious (Y/N)	Situational*	1
Previous Suspicious Orders in Past 24 Months (Y/N)	Situational*	1
Reason Order is Suspicious (Detailed and order-specific) <sup>+</sup>	Situational*	255
Reason Order Shipped (Detailed and order-specific) <sup>+</sup>	Situational**	255
Misc Comments	Optional	255

**Required** - This information is required. If the data is not present, the file will be rejected.



**Situational\*** - This information is required for suspicious orders only. If the order is suspicious and the data is not present, the file will be rejected.

**NOTE:** If a drug distributor indicates "N" in the "Order Shipped" field, the Board will recognize that the "S" transaction code is not an actual sale, but simply receipt of an order. (**UPDATE 3.27.2019**)

**Compliance Officer Name<sup>2</sup>** - This information is required for suspicious orders only. The compliance officer information should be a primary point of contact to assist the Board with providing any additional information about the nature of the suspicious order.

**Situational\*\*** - This information is only required for suspicious orders that were shipped. If the order is suspicious and shipped, but the data is not present, the file will be rejected.

**Optional** - Data for this field is not required; however, you must leave the specified number of spaces if no data is present.

**DEA<sup>1</sup>** - If the customer does not have a DEA number, you must log into the [OARRS Wholesale portal](#) and go to the "OH DEA Numbers" page to create an "OH" DEA Number to use for reporting. This may occur with transfers of gabapentin (a non-controlled substance). (**UPDATE 2.18.2020**)

**Reason Order is Suspicious/Reason Order Shipped** - Licensees must include details that are order-specific, including, but not limited to, the following:

- Why the order was identified as suspicious. Provide specific criteria used by your suspicious order monitoring system. Including phrases such as "order is of unusual size" without any additional detail is not acceptable and does not meet the requirements of the rule.
- If it was shipped, provide the rationale for its shipment that is specific to that purchaser (increase in customer demand due to recent closure of nearby pharmacy, customer is a long-term care pharmacy that has taken on new clients, etc.). Indicating that it was "reasonable" without any further justification is not acceptable and does not meet the requirements of the rule. (**UPDATE 5.14.2019**)

***If you have questions about reporting wholesale transactions or suspicious orders, please contact OARRS at [data@pharmacy.ohio.gov](mailto:data@pharmacy.ohio.gov) or by telephone 614-466-4143 (Option 1)***

## **Reporting Deadlines for Suspicious Orders**

The reporting of suspicious orders must be submitted within five calendar days of the order being identified as suspicious by the drug distributor.

Wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities, must submit a zero report if no suspicious orders have been identified by the distributor in a calendar month. The zero report must be submitted within fifteen days of the end of the calendar month. ***At this time, the process for submitting a zero report for suspicious orders can only be conducted manually using a licensee's [OARRS wholesale data upload account](#) (see [page 11](#) of this guidance for instructions).***

All Ohio licensed wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities that do not sell controlled substances or gabapentin to Ohio licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers may submit a request for an exemption from the requirement to submit zero reports to OARRS. The request permits an exemption from the following:

- The requirement of rule [4729:6-3-05 \(F\)](#) to submit a zero report indicating the distributor did not receive any orders identified as suspicious (this also exempts a drug distributor from having to report 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 as well as the policy and procedure requirements of [4729:6-3-05 \(J\)](#) – see [Page 13](#) of this document for information on customer reporting).
- The requirement of rule [4729:8-3-04](#) to submit a zero report indicating the distributor did not engage in the wholesale sale of reported drugs.

All drug distributors that qualify for an exemption must submit an exemption request form electronically. The form may be accessed here: [www.pharmacy.ohio.gov/exemptDD](http://www.pharmacy.ohio.gov/exemptDD). ***A distributor that fails to obtain an exemption request and does not submit a zero report to the Board may be subject to disciplinary action.***

## **Reporting Process for Submitting Zero Reports**

Zero reports are required for either of the following:

- **Requirement #1:** Rule [4729:8-3-04](#) requires the submission of a zero report indicating the distributor did not engage in a wholesale sale of reported drugs. More information on the timeframe for submitting reports can be found on [page 4](#).

For Requirement #1, zero reports can be submitted in one of three ways:

1. Via the FTP/SFTP (File Transfer Protocol) site;
2. Uploaded via a file using your [OARRS wholesale data upload account](#); or
3. Manually file using your OARRS wholesale data upload account (see below for instructions).

***For more information on submitting zero reports via FTP/SFTP or file upload, contact OARRS at: [data@pharmacy.ohio.gov](mailto:data@pharmacy.ohio.gov) or by telephone 614-466-4143 (option 1).***

- **Requirement #2:** Rule [4729:6-3-05 \(F\)](#) requires the submission of a zero report indicating the drug distributor did not receive any orders identified as suspicious. More information on the timeframe for submitting reports can be found on [page 10](#).

For Requirement #2, zero reports can only be submitted manually using a licensee's [OARRS wholesale data upload account](#) (see below for instructions).

**All zero reports must be submitted within fifteen days of the end of the calendar month.**

### Manual Submission of Zero Reports

1. Navigate to the OARRS website ([www.ohiopmp.gov](http://www.ohiopmp.gov))
2. Click the "Wholesale Login" button
3. Log into the reporting website
4. Choose the "Submit Zero Report" menu option on the left.
5. On the Zero Transaction Report screen, you will have the option to select one or both boxes.  
**NOTE:** If you are submitting a zero report indicating no wholesale transactions using an FTP/SFTP or via file upload, then do not check the first box.

### ZERO TRANSACTION REPORT

For more information on submitting zero reports, [click here](#).

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**SELECT YOUR DEA NUMBER AND THE MONTH/YEAR FOR THIS REPORT**

Drug distributor/Terminal distributor DEA #:

Month:  Year:

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**SELECT THE TYPE OF REPORT YOU ARE SUBMITTING**

I am submitting a zero report stating the licensee associated with this account has not engaged in any reportable drug sales for the time period indicated on this page (OAC 4729:8-3-04).

I am submitting a zero report stating the licensee associated with this account (drug distributor ONLY) has not identified any suspicious orders for the time period indicated on this page (OAC 4729:6-3-05).

6. Enter the DEA registration number of the licensee and the timeframe the report covers. If the licensee does not have a DEA registration, please contact OARRS at [data@pharmacy.ohio.gov](mailto:data@pharmacy.ohio.gov) or by telephone 614-466-4143 (option 1) to determine an alternate identifier.
7. Prior to clicking the submit button, select the box to acknowledge your report is true, accurate and complete.

**IMPORTANT REMINDERS:**

- o A licensee may use the manual feature to submit either or both required zero reports.
- o The manual feature **must** be used to submit a suspicious order zero report.
- o Exemptions to submitting zero reports may also be requested. More information on this process can be found on [page 4](#) and [page 10](#) of this document.

## **Reporting Customers Engaged in Possible Drug Diversion**

[Rule 4729:6-3-05 of the Ohio Administrative Code](#) requires wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs, and outsourcing facilities to 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.

The following information is to be reported:

- Customer name;
- Address;
- DEA registration number (if applicable);
- Terminal distributor of dangerous drugs license number (if applicable); and
- A detailed explanation of why the distributor identified the customer as a possible diversion risk.

The reporting of customers is submitted electronically via the OARRS wholesaler data upload website: <https://ohiopmp.gov/>. More information on this process can be found below.

The electronic submission of such customer information must be submitted within five days of refusal, cessation or identification by the drug distributor.

A drug distributor that submits and receives an exemption request (see [page 10](#)) is not required to submit customer information pursuant to rule 4729:6-3-05 of the Administrative Code.

**IMPORTANT:** No later than **July 29, 2019**, a drug distributor 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.

### **How to Submit Customer Information**

1. Navigate to the OARRS website ([www.ohiopmp.gov](http://www.ohiopmp.gov))
2. Click the "Wholesale Login" button
3. Log into the reporting website
4. Choose the "Customer Reporting" menu option on the left.
5. To submit customer information, enter the customer's DEA number or Ohio Board of Pharmacy license number (terminal distributor of dangerous drugs [TDDD]) and click the "Search" button. **NOTE:** The TDDD license number must be exactly as it appears on the Ohio [eLicense verification page](#).
6. Click select on the customer listed and complete the detailed explanation of why you identified the customer as a possible diversion risk.
7. Once completed, click the "Submit" button.
8. The customer information will be added to the list that is submitted to the Board.

9. To edit or view the list of submitted customers, click on the "View/Edit Customer List" button.

**IMPORTANT:** There may be limited situations where a customer cannot be added. For example:

- o The customer does not have a TDDD number/DEA registration because they are only ordering gabapentin; or
- o The customer cannot be matched in the system.

In these instances, a licensee may conduct a manual submission that includes the licensee's name, address, Ohio license number, contact person information (name, email and telephone number) and all the required customer information to [data@pharmacy.ohio.gov](mailto:data@pharmacy.ohio.gov).

**This option is only reserved for the situations outlined above.**

Companies with multiple Ohio drug distributor licenses may utilize a single [OARRS wholesale data upload account](#) to report customers. To do so, a licensee must designate a single account by submitting a request form to the Board. This form may be accessed by visiting: [www.pharmacy.ohio.gov/DesignateAccount](http://www.pharmacy.ohio.gov/DesignateAccount)