

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

## Updated 3/7/2025

#### Applicable Rules:

- OARRS Reporting Division 4729:8 of the Administrative Code
- Suspicious Order Monitoring and Due Diligence <u>Rule 4729:6-3-05 of the Administrative</u> <u>Code</u>

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.

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

**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.

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

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

- 1. Go to the OARRS website (<u>www.ohiopmp.gov</u>) 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.

## **Drug Reporting Exclusions:**

- Transfers from one licensed drug distributor to another licensed drug distributor <u>should NOT</u> 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 <u>should NOT</u> be reported.
- 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 <u>accessed here.</u>
- Hospital pharmacies are not required to report transfers or sales to EMS agencies.

## How to Submit a Transaction, Zero Report, Suspicious Order, Void/Return

You have 3 options for submitting a transaction to OARRS:

- 1. Submit a file via FTP/SFTP to ftp.ohiopmp.gov or sftp.ohiopmp.gov
- 2. Submit a file via the "Sales File Upload" page.
- 3. Submit transaction details via the "<u>Manual Data Entry</u>" page.

**NOTE:** File format requirements follow the Drug Enforcement Administration's sales reporting system, <u>ARCOS</u>. More information on file formatting can be found in the next section of this document.

# For more information on submitting zero reports via FTP/SFTP or file upload, contact OARRS at <u>data@pharmacy.ohio.gov</u> or by telephone at 614-466-4143 (option 1).

## **Data File Formatting and Requirements**

**File Naming:** 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.

Field Description	*Required	Length	Start Position	End Position
Reporting Registrant	Required	9	1	9
Asterisk (*)	Required	1	10	10
Last Day of Reporting Period	Required	8	11	18
Reporting Frequency (M)	Required	1	19	19
Central Reporter's Number	Not Used	9	20	28
Compliance Officer Name <sup>2</sup>	Situational*	25	29	53
Compliance Officer Email	Situational*	50	54	103
Compliance Officer Phone	Situational*	10	104	113

#### File Format – ARCOS (modified) (UPDATE 3.7.2025)

Control Record Formatting

Field Description	Required	Length	Start	End
			Position	Position
Registrant DEA Number <sup>1</sup>	Required	9	1	9
Transaction Code	Required	1	10	10
Action Indicator	Not Used	1	11	11
NDC Number	Required	11	12	22
Quantity	Required	8	23	30
Unit	Optional	1	31	31
Assoc Registrant DEA Number	Required	9	32	40
Order Form Number	Not Used	9	41	49
Transaction Date (mmddyyyy)	Required	8	50	57
Correction Number	Optional	8	58	65
Strength	Optional	4	66	69
Transaction Identifier	Required	10	70	79
Blank Space	Required	1	80	80
Order Shipped (Y/N)	Situational*	1	81	81
Suspicious (Y/N)	Situational*	1	82	82
Previous Suspicious Orders in Past 24			83	83
Months (Y/N)	Situational*	1		
Reason Order is Suspicious (Detailed and			84	338
order specific)⁺	Situational*	255		
Reason Order Shipped (Detailed and order			339	593
specific)⁺	Situational**	255		
Misc Comments <sup>3</sup>	Optional	255	594	848

#### Transaction Record Formatting

**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.

**DEA**<sup>1</sup> - If the facility does not have a DEA number, you must log into the <u>OARRS Wholesale</u> <u>portal</u> 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).

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

Misc Comments<sup>3</sup>- This field has two purposes:

- Optionally to be used as an overflow for the "Suspicious Reason" or "Shipped Reason" fields.
- 2. Required when voiding a suspicious order. Used to provide an explanation for the void.

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

- Why was the order 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.

If you have questions about reporting wholesale transactions or suspicious orders, please contact OARRS at <u>data@pharmacy.ohio.gov</u> or by telephone at 614-466-4143 (Option 1).

## Sale/Zero Report Deadlines & Exemptions

#### What is a Zero Report for Sales?

Rule <u>4729:8-3-04</u> requires the submission of a zero report indicating the distributor did not engage in a wholesale sale of reported drugs.

#### For Drug Distributors:

If you have an applicable drug distributor license 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.** 

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:

• The requirement of rule <u>4729:8-3-04</u> 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: <a href="http://www.pharmacy.ohio.gov/exemptDD">www.pharmacy.ohio.gov/exemptDD</a>. 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: <a href="https://www.pharmacy.ohio.gov/3PLexempt">www.pharmacy.ohio.gov/3PLexempt</a>.

**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:

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

#### For Pharmacies:

If you <u>do not</u> 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.** 

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 <u>4729:8-3-04</u>. The form may be accessed here: <u>www.pharmacy.ohio.gov/exempt</u>.

**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.

## **Suspicious Order Reporting**

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.

For more information about suspicious order monitoring and reporting requirements, visit: <u>www.pharmacy.ohio.gov/suspicious</u>.

#### Exclusions

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.

#### **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.

#### **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.

#### **Suspicious Order Zero Report**

Rule <u>4729:6-3-05 (F)</u> requires the submission of a zero report indicating the drug distributor did not receive any orders identified as suspicious 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 via the "Submit Zero Report" page.

## Submit a Void or Return

#### Void/Return of a Sale

To submit a void/return of a sale you must include the following information to allow our system to identify the original record:

- A Transaction Code of 'V'
- Your DEA number
- Customer DEA number
- NDC code
- Quantity: This value must be less than or equal to the original sale's quantity.

#### Void/Return of a Suspicious Order

To submit a void/return of a suspicious order you must include the following information to allow our system to identify the original record:

- A Transaction Code of 'V'
- Your DEA number
- Customer DEA number
- NDC code
- Invoice date of the original record
- Quantity: This value must equal to the original record's quantity
- An explanation for the void must be provided in the "Misc Comments" ARCOS field

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

<u>Rule 4729:6-3-05 of the Ohio Administrative Code</u> 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 reporting of customers is submitted electronically via the <u>OARRS Customer Reporting</u> page. 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 <u>page 7</u>) is not required to submit customer information pursuant to rule 4729:6-3-05 of the Administrative Code.

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.

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

- The customer does not have a TDDD number/DEA registration because they are only ordering gabapentin; or
- 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 <u>data@pharmacy.ohio.gov</u>. **This option is only reserved for the situations outlined above.** 

Companies with multiple Ohio drug distributor licenses may utilize a single <u>OARRS wholesale</u> <u>data upload account</u> 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: <u>www.pharmacy.ohio.gov/DesignateAccount.</u>