FAQ: Suspicious Order Monitoring and Due Diligence

Updated 8/2/2021

All updates are notated in red (i.e. **UPDATE 8.2.2021***)*

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:

1. Design and operate a system to identify and report suspicious orders by customers for reported drugs. Suspicious orders shall include, but are not limited to, the following:

    - Orders of unusual size;
    - Orders deviating substantially from a normal pattern; and
    - Orders of unusual frequency.

    All suspicious orders, regardless of actual sale, must be submitted to the Board of Pharmacy within five days of the order being identified as suspicious by the drug distributor.

2. 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.

3. 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 electronic submission of such customers shall be submitted within five days of refusal, cessation or identification.

    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.

4. Develop and implement policies and procedures that include all the following:

a. The design and operation of a suspicious order monitoring and reporting system.

b. A system to collect the necessary information on customers to conduct the required due diligence activities.

c. Mandatory training, to be conducted annually, for staff responsible for the processing of all orders for reported drugs that includes all the following:
   i. The drug distributor's suspicious order monitoring system;
   ii. The process to collect all required information on customers;
   iii. The process for submission of suspicious orders and customers who may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels to the Board of Pharmacy; and
   iv. Information on submitting a confidential report of a suspicious order or customer engaging in possible activities that may cause reported drugs to be diverted from legitimate channels by using the board's online electronic complaint form that can accessed by visiting: www.pharmacy.ohio.gov/complaint. The training shall remind all employees that complaints and all information submitted that identifies a complainant shall remain confidential pursuant to section 4729.23 of the Revised Code.

To assist licensees with the implementation of these new rules, the Board has developed the following frequently asked questions 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. Select "Compliance/Enforcement Information" as your subject line. The Board will be updating this FAQ regularly to ensure compliance with the rules.

Suspicious Order Monitoring and Reporting

1. What is a reported drug?

A reported drug means any dangerous drug (i.e. prescription drug) that must be reported to OARRS. Currently, this includes Schedule II – V controlled substances and gabapentin.

NOTE: Rules on OARRS reporting clarify that naltrexone is not a reported drug as it pertains to wholesale sales. Therefore, such sales **should not** be included as part of a suspicious order monitoring program. For further guidance, visit: www.pharmacy.ohio.gov/naltrexone.

2. How does the Board define a suspicious order?

The Board's criteria of a suspicious order mirrors current Drug Enforcement Administration (DEA) regulations. The Board expects those engaged in the sale of reported drugs (i.e. Schedule II – V controlled substances and gabapentin – see question 1), to develop internal controls to identify and report suspicious orders.

The DEA has also provided additional guidance, stating in a 2007 letter:

> *If an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a ''normal pattern'' to develop over time before determining where a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of a particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.*[1]

3. How do I report a suspicious order to the Board of Pharmacy?

A suspicious order starts out as an order. Therefore, a suspicious order would contain all of 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 to be able to receive both typical sales as well as suspicious orders.

More information on reporting suspicious orders can be accessed here:
www.pharmacy.ohio.gov/wholesalereport

IMPORTANT: At this time, the online reporting mechanism utilized by the Board requires the reporting of suspicious orders and zero reports to be tied to a specific license (**NOTE:** Reporting of suspicious customers can be delegated, see question 21). This allows the Board to monitor for compliance. The Board is examining the feasibility of allowing companies with multiple Ohio drug

[1] Letter from Joseph T. Rannazzisi, Deputy Assistant Adm'r, Office of Diversion Control, U.S. Drug Enforcement Admin. to DEA Registrants, Feb. 7, 2007

distributor licenses to utilize a single OARRS wholesale data upload account to report suspicious orders and zero reports. Any changes to the reporting process will be communicated to licensees prior to implementation. **(UPDATE 4.4.2019)**

IMPORTANT NOTICE ON SUSPICIOUS ORDER REPORTING (UPDATE 5.14.2019)

Information submitted to the Board must be detailed and order-specific, as specified on page 9 of the reporting guidance (www.pharmacy.ohio.gov/wholesalereport).

Including generic phrases, such as "exceeded threshold," or incomplete statements does not provide added value nor does it meet the requirements set forth in paragraph (E) of rule 4729:6-3-05 of the Ohio Administrative Code.

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.

4. Who is required to develop a suspicious order monitoring system and submit suspicious order reports?

Only licensees that control the sale and disposition of reported drugs are required to submit suspicious order reports. Therefore, the rule requires the following drug distributors that sell to Ohio licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers to develop a suspicious order monitoring system and submit suspicious order reports:

(1) Wholesale distributors of dangerous drugs;

(2) Virtual wholesalers;

(3) Manufacturers of dangerous drugs; and

(4) Outsourcing facilities.

NOTE: The following are not required to develop a suspicious order monitoring system or submit suspicious order reports:

- Ohio licensed wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs and outsourcing facilities that do not sell reported drugs to Ohio-

licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers. Examples include:

- A wholesale distributor of dangerous drugs that only sells insulin products in Ohio;
- A wholesale distributor of dangerous drugs that only sells to other wholesale distributors or manufacturers. **(UPDATE 8.2.2021)**

All drug distributors that are exempted must submit an exemption request form electronically. The form may be accessed here: www.pharmacy.ohio.gov/exemptDD.

If you use a third-party logistics provider to conduct sales of reported drugs (controlled substances and gabapentin) to Ohio-licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers, see Q26 of this document. **(UPDATE 5.9.2019)**

- Pharmacies that conduct drug transfers or occasional wholesale sales of reported drugs are not required to develop a suspicious order monitoring system or submit suspicious order reports. For example, the transfer of a reportable drug from one pharmacy to another pharmacy (even under the same common ownership) or the sale of a reportable drug from a pharmacy to a prescriber's office. **NOTE:** Pharmacies are required to report these sales to OARRS as wholesale transactions.

More information on reporting suspicious orders and wholesale transactions to OARRS can be accessed here: www.pharmacy.ohio.gov/wholesalereport

5. What is the timeframe for the reporting of 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.

6. Am I required to report information to the Board if I do not identify any suspicious orders?

Yes. 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.

More information on submitting a zero report can be accessed here: www.pharmacy.ohio.gov/wholesalereport

7. Am I required to submit a zero report to the Board if I do not sell reported drugs?

No. If you are a licensed wholesale distributor of dangerous drug, virtual wholesaler, manufacturer of dangerous drugs or outsourcing facility that does not sell reported drugs (controlled substances and gabapentin) to Ohio-licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers, you may submit a reporting exemption request to the Board of Pharmacy. This request will exempt you from all the following requirements:

1. Reporting suspicious orders;
2. Reporting wholesale drug transactions to OARRS;
3. Reporting 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; and
4. The policy and procedure requirements of 4729:6-3-05 (J).

IMPORTANT: ***The Board recently transitioned to a new electronic system for approving exemption requests, which requires the submission of a new request even if you have previously submitted and have been granted an exemption from the Board.*** The form may be accessed here: www.pharmacy.ohio.gov/exemptDD. All initial exemption requests must be submitted no later than May 1, 2019.

If you use a third-party logistics provider to conduct sales of reported drugs (controlled substances and gabapentin) to Ohio-licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers, see Q26 of this document. **(UPDATE 5.9.2019)**

8. If my system identifies a suspicious order but I do not ship the order, am I required to report it?

Yes. Paragraph (E) of rule 4729:6-3-05 requires that all suspicious orders, regardless of actual sale, must be submitted to the board.

9. If my system identifies a suspicious order, am I still permitted to ship that order?

The Board recognizes that there may be situations whereby an order may be flagged as suspicious but, upon further review, may not present a diversion risk. The order may still be shipped. However, the rule requires two persons designated by the drug distributor's responsible person to independently analyze the order. Those persons must determine that the order is not likely to be diverted from legitimate channels. The order must still be reported to the Board as suspicious.

More information on submitting this information as part of a suspicious order can be accessed here: www.pharmacy.ohio.gov/wholesalereport

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.

- If it is your company's policy to cancel all suspicious orders flagged in your system, then this provision of the rule would not apply. **UPDATE (3.26.2019)**

Customer Due Diligence

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 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.

10. Who is required to conduct due diligence activities as stipulated in the rule?

Only licensees that control the sale and disposition of reported drugs are required to conduct customer due diligence activities. Therefore, the rule requires the following drug distributors to review current and potential customers:

(1) Wholesale distributors of dangerous drugs;

(2) Virtual wholesalers;

(3) Manufacturers of dangerous drugs; and

(4) Outsourcing facilities.

NOTE: Due diligence requirements are only required for customers ordering reported drugs located in Ohio.

11. What are the customer due diligence requirements of the rule?

The customer due diligence requirements must include, but are not limited to, the following which must be conducted ***prior to an initial sale and on an annual basis***:

(1) Questionnaires and affirmative steps by the drug distributor to confirm the accuracy and validity of the information provided.

NOTE: Sales of reported drugs to terminal distributors operated under the same common ownership as the drug distributor (ex. Company A's drug distributors to Company A's terminal distributors) are not required to conduct questionnaires if the drug distributor is able to obtain and document the required information using other means (ex. centralized records maintained by the corporation). **(UPDATE 4.4.2019)**

(2) For a customer who is a prescriber, confirmation of prescriber type (physician, dentist, veterinarian, etc.), specialty practice area (oncology, geriatrics, pain management, etc.), and if the prescriber personally furnishes reported drugs and the quantity personally furnished.

IMPORTANT: As due diligence requirements must be conducted annually, the quantity personally furnished should be reported for a one-year period. **(UPDATE 3.26.2019)**

(3) Review of drug utilization reports.

IMPORTANT: The drug utilization report is specific to pharmacies and provides an overview of the dispensing history of the pharmacy based upon NDC or DEA drug code. ***It is not required for customers that are not pharmacies.*** **(UPDATE 6.24.2019)**

(4) Obtaining and conducting a review of the following information:

(a) The methods of payment accepted (cash, insurance, Medicaid, Medicare) and in what ratios*;

(b) The ratio* of controlled vs. non-controlled drug orders and overall sales;

(c) Orders for reported drugs from other drug distributors made available by the Drug Enforcement Administration's Automation of Reports and Consolidated Orders System; and

(d) The proportion* of out-of-state patients served compared to in-state patients.

***NOTE: The ratios and proportions required by the rule should be used as part of the overall determination as to whether the customer (or potential customer) may be engaged in the diversion of reported drugs. It is expected that drug distributors have a clear and justified methodology for how the distributor incorporates such information in its determination.** **(UPDATE 3.26.2019)**

12. What does it mean to "personally furnish" a reported drug?

Ohio prescribers are permitted to personally furnish (sometimes referred to as prescriber dispensing) medications for take-home use. It should be note that, except for veterinarians, Ohio law generally limits prescribers to the following:

- In any thirty-day period, personally furnish to or for patients, taken as a whole, controlled substances in an amount that exceeds a total of two thousand five hundred dosage units.
- In any seventy-two-hour period, personally furnish to or for a patient an amount of a controlled substance that exceeds the amount necessary for the patient's use in a seventy-two-hour period.

NOTE: "Dosage unit" means any of the following:

(1) A single pill, capsule, ampule, tablet;
(2) In the case of a liquid solution, one (1) milliliter;
(3) In the case of a cream, lotion or gel, one (1) gram; or
(4) Any other form of administration available as a single unit.

Drug distributors should consider these limits when reviewing customer information. Please review Ohio law for the exemptions to these limits.

13. How does a drug distributor confirm that the information provided on customer questionnaires is accurate?

A drug distributor should have policies and procedures in place to review customer information to ensure that answers provided by a customer correspond with the customer's business operations. Should any irregularities, discrepancies, errors or omissions occur, it is expected that the drug distributor will conduct additional outreach to correct or verify any information. Failure of the customer to provide the required information (or accurate information) is grounds to refuse sale and should trigger reporting of that customer to the Board (see question 17 of this document).

14. Are customers under any legal obligation to provide accurate answers and information necessary for a drug distributor to satisfy the due diligence requirements?

Yes. Per rule 4729:5-4-01 of the Administrative Code, effective March 1, 2019, a holder of an Ohio terminal distributor license (which is required to purchase controlled substances and, with some exceptions, most prescription drugs) may be subject to administrative action by the Board for furnishing of false or fraudulent information or omitting information on due diligence questionnaires and/or attestation documents regarding the purchase or receipt of dangerous drugs.

15. How does a drug distributor obtain information on orders for reported drugs from other drug distributors made available by the United States Drug Enforcement Administration's Automation of Reports and Consolidated Orders System (ARCOS)?

The Drug Enforcement Administration (DEA) developed a tool within the ARCOS system to assist drug distributors with their regulatory obligations under the federal Controlled Substances Act. The tool allows a distributor to enter the DEA registration number of a prospective purchaser (e.g., pharmacy, hospital, doctor, etc.) as well as a drug code for the controlled substance the buyer wishes to purchase and the ARCOS application will return a count of the number of registrants who have sold that particular controlled substance to that prospective purchaser in the last 6 months. This query application is intended to help distributors identify red flags indicative of suspicious orders.

The Board is aware that ARCOS does not include all drugs that fall under the definition of a reported drug and that querying the ARCOS system for every drug may be onerous for customers that purchase a variety of ARCOS reported drugs. ***Therefore, the Board has determined that this requirement is satisfied if the customer's top five ARCOS reported drugs based on purchase history are queried using this feature.***

For this requirement, top five drugs are based on DEA drug code based upon active ingredient (ex. 9143, 1625, 2767, 9050 & 9064). (UPDATE 4.4.2019)

To determine the top five drugs to query, a drug distributor should comply with the following:

For new customers: Query the top five ARCOS reported drugs based upon the customer's first order or review of the customer's drug utilization report. The top five drugs should be based upon

DEA drug code (ex. 9143, 1625, 2767, 9050 & 9064). An ARCOS report containing the previous 6-months of data meets the requirements of the rule. **(UPDATE 4.4.2019)**

For existing customers: Query the top five ARCOS reported drugs based upon sales totals from the drug distributor. The top five drugs should be based upon DEA drug code (ex. 9143, 1625, 2767, 9050 & 9064). An ARCOS report containing the previous 6-months of data meets the requirements of the rule. **(UPDATE 4.4.2019)**

NOTE: This requirement does not apply if the drug distributor does not sell any ARCOS reported drugs or if the customer does not purchase any ARCOS reported drugs. If the customer purchases fewer than five ARCOS reported drugs (based upon DEA drug code), then the drug distributor is only required to query up to the number of ARCOS reported drugs that are purchased or used by that customer. **(UPDATE 4.4.2019)**

16. Is there any provision in the rule for the sale of drugs to meet an emergent or critical need?

Yes. A drug distributor may conduct an initial sale for a reported drug without initially complying with the rule's due diligence requirements if all the following apply:

1. The sale is to an institutional facility that is a new customer of the distributor. Currently, an institutional facility includes the following entities: Hospitals, convalescent homes, developmental facilities, long term care facilities, nursing homes, psychiatric facilities, rehabilitation facilities, developmental disability facilities, level III sub-acute detoxification facilities certified by the Ohio Department of Mental Health and Addiction Services and state/local correctional facilities.

2. The drug distributor documents that the order is to meet an emergent need; and

3. The drug distributor completes the customer due diligence requirements set forth in the rule no later than sixty days from the date of sale.

17. How does the Board define "customer" for the purpose of implementing the rule's due diligence requirements? (UPDATE 3.26.2019)

The rule defines a customer as a terminal distributor of dangerous drugs or an individual prescriber. All Ohio locations ordering controlled substances must be licensed as terminal distributors of dangerous drugs.

18. When will the first annual requirement to collect a customer due diligence information?

Due diligence requirements must be conducted at least annually but the first round of must be conducted on or before May 1, 2020 (for existing customers) and prior to initial sale (for new customers).

For existing customers, a drug distributor may start the annual collection of due diligence information anytime between April 30, 2019 and May 1, 2020. This allows a distributor to stagger the collection of such information to reduce operational burdens. **(UPDATE 4.4.2019)**

A drug distributor must ensure that due diligence information is collected and reviewed for existing customers at least every twelve months.

Please be advised that due to COVID-19, due diligence requirements have been temporarily extended. For more information click **here**. **(UPDATE 5.8.2020)**

18.5) Are there any exceptions to customer due diligence requirements for hospitals and other institutional facilities? (UPDATE 6.5.2020)

The only exception for hospitals and institutional facilities is the delay outlined in Q16, which is intended for new customers to meet an emergent or critical need.

To ensure consistency in complying with the rule, drug distributors must obtain all required data to meet the due diligence requirements outlined in the rule. The distributor is responsible for determining a customer's overall risk of diversion based on the due diligence information collected (which can include additional information not required in rule).

Reporting Customers

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.

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.* ***If you have not refused to sell to or stopped selling to an Ohio customer within the past three years, you are not required to report anything at this time.*** **(UPDATE 5.9.2019)**

19. How does a drug distributor report customers that may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels?

Customer information must be submitted electronically via the OARRS wholesale data upload website: https://wholesale.ohiopmp.gov/.

A guidance document on submitting this information can be accessed here: www.pharmacy.ohio.gov/wholesalereport

20. What type of information is required to be reported?

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.

21. When is a drug distributor required to report customers that may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels?

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

22. I am a company with multiple Ohio drug distributor accounts. Can I submit customer data using a single account?

Yes. 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

23. Am I required to report customers if I do not sell reported drugs?

No. If you are a licensed wholesale distributor of dangerous drugs, virtual wholesaler, manufacturer of dangerous drugs or outsourcing facility that does not sell reported drugs (controlled substances and gabapentin) to Ohio-licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers, you may submit a reporting exemption request to the Board of Pharmacy. This request will exempt you from all the following requirements:

1. Reporting suspicious orders;
2. Reporting wholesale drug transactions to OARRS;
3. Reporting 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; and
4. The policy and procedure requirements of 4729:6-3-05 (J).

IMPORTANT: ***The Board recently transitioned to a new electronic system for approving exemption requests, which requires the submission of a new request even if you have previously submitted and have been granted an exemption from the Board.*** The form may be accessed here: www.pharmacy.ohio.gov/exemptDD. All initial exemption requests must be submitted no later than May 1, 2019.

If you use a third-party logistics provider to conduct sales of reported drugs (controlled substances and gabapentin) to Ohio-licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers, see Q26 of this document. **(UPDATE 5.9.2019)**

Policies and Procedures

24. What are the policies and procedures that must be developed and maintained in accordance with the rule?

Wholesale distributors of dangerous drugs, virtual wholesalers, manufacturers of dangerous drugs and outsourcing facilities must maintain and implement policies and procedures that include all the following:

1. The design and operation of a suspicious order monitoring and reporting system.

2. A system to collect the necessary information on customers to conduct the required due diligence activities.

3. Mandatory training, to be conducted annually, for staff responsible for the processing of all orders for reported drugs that includes all the following:

    a. The drug distributor's suspicious order monitoring system;

    b. The process to collect all required information on customers;

    c. The process for submission of suspicious orders and customers who may be engaging in possible activities that may cause reported drugs to be diverted from legitimate channels to the Board of Pharmacy; and

    d. Information on submitting a confidential report of a suspicious order or customer engaging in possible activities that may cause reported drugs to be diverted from legitimate channels by using the board's online electronic complaint form that can accessed by visiting: www.pharmacy.ohio.gov/complaint. The training shall remind all employees that complaints and all information submitted that identifies a complainant shall remain confidential pursuant to section 4729.23 of the Revised Code.

All policies and procedures must be reviewed and updated on an annual basis.

25. I am not engaged in the sale of reported drugs, am I required to maintain and implement the policies and procedures outlined in question 22?

No. A drug distributor that does not sell reported drugs (controlled substances and gabapentin) to Ohio-licensed terminal distributors of dangerous drugs (clinics, pharmacies, hospitals, etc.) or Ohio prescribers is not required to maintain and implement the policies and procedures outlined in question 22. A drug distributor must submit an exemption request as outlined in question 21 of this document to be exempt from the policies and procedure requirements of the rule.

Sales by Third-Party Logistics Providers (UPDATE 5.9.2019)

26. I use an Ohio-licensed third-party logistics provider (3PL) to conduct sales of reported drugs to Ohio pharmacies, prescribers, and other terminal distributors of dangerous drugs. The 3PL reports all sales for reported drugs to OARRS and maintains a suspicious order monitoring system. Is there a way I can officially designate the 3PL to conduct these requirements on my behalf?

Yes. 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.

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.