Ohio Administrative Code

Rule 4729:6-3-05 Suspicious Order Monitoring and Due Diligence.

Effective: April 30, 2019

(A) As used in this rule:

(1) "Customer" means a person located in this state that orders or seeks to order a reported drug from an Ohio licensed drug distributor and includes the following:

(a) A licensed terminal distributor of dangerous drugs; or

(b) A prescriber who possesses, or possesses for sale or sells, at retail, a dangerous drug.

(2) "Prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(3) "Reported drug" means any dangerous drug whose sale is required to be reported to the drug database pursuant to agency 4729 of the Administrative Code.

(B) This rule only applies to the following drug distributors licensed in accordance with section 4729.52 of the Revised Code:

(1) Wholesale distributors of dangerous drugs;

(2) Virtual wholesalers;

(3) Manufacturers of dangerous drugs; and

(4) Outsourcing facilities.

(C) Drug distributors listed in paragraph (B) of this rule shall 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:

(1) Orders of unusual size;

(2) Orders deviating substantially from a normal pattern; and

(3) Orders of unusual frequency.

(D) Prior to any shipment of an order that a distributor has identified as suspicious, two persons designated by the distributor's responsible person must independently analyze the order. In order to proceed with the shipment and complete the sale, each of the two persons must determine that the order is not likely to be diverted from legitimate channels.

(E) All suspicious orders, regardless of actual sale, shall be submitted electronically in a manner and format determined by the board. The electronic submission of suspicious orders shall include all information as required by the board and shall be submitted within five days of the order being identified as suspicious by the drug distributor.

(F) All drug distributors listed in paragraph (B) of this rule shall submit a zero report, in a manner determined by the board, if no suspicious orders have been identified by the distributor in a calendar month. The zero report shall be submitted within fifteen days of the end of the calendar month.

(1) Except as provided in paragraph (G)(2) of this rule, a drug distributor listed in paragraph (B) of this rule shall 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. Such measures shall include, but are not limited to, the following which shall to be conducted prior to an initial sale and on an annual basis:

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

(b) 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.

(c) Review of drug utilization reports.

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

(i) The methods of payment accepted (cash, insurance, medicaid, medicare) and in what ratios;

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

(iii) Orders for reported drugs from other drug distributors made available by the United States drug enforcement administrations automation of reports and consolidated orders system; and

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

(2) A drug distributor receiving a request for an initial sale for a reported drug may conduct the sale without complying with paragraph (G)(1) of this rule if all the following applies:

(a) The sale is to an institutional facility as defined in agency 4729 of the Revised Code that is a new customer of the distributor;

(b) The drug distributor documents that the order is to meet an emergent need; and

(c) The drug distributor completes the requirements set forth in paragraph (G)(1) of the rule no later than sixty days from the date of sale.

(H) Any 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, shall be electronically reported by the drug distributor in a manner and format determined by the board. The electronic submission of such customers shall include all information as required by the board and shall be submitted within five days of refusal, cessation or identification by the drug distributor.

(I) Within ninety days of the effective date of this rule, a drug distributor shall provide, in a manner

and format determined by the board, information on all customers in this state 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. The submission of information shall contain the customer's name, address, drug enforcement administration registration (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.

(J) All drug distributors described in paragraph (A) of this rule shall 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 in accordance with paragraph (G) of this rule.

(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 relevant information on customers in accordance with paragraph (G) of this rule;

(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; 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. 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.

(K) All policies and procedures maintained in accordance with paragraph (J) of this rule shall be reviewed and updated on an annual basis.