WAC 246-945-585 Wholesaler—Suspicious orders and due diligence. (1) Wholesalers shall design and operate a system to identify and report suspicious orders of controlled substances and drugs of concern to the commission.

(a) Suspicious orders shall be submitted electronically through a commission approved system or to the commission or within five business days of the order being identified as suspicious by the wholesaler, and must include, but not necessarily limited to:

(i) Customer name;

(ii) Customer address;

(iii) Customer DEA registration number;

(iv) State license number(s);

(v) Transaction date;

(vi) Drug name;

(vii) NDC number;

(viii) Quantity ordered; and

(ix) Indication of whether the drug was shipped, and if not, the factual basis for the refusal to supply.

(b) Zero reports shall be submitted if no suspicious orders have been identified in a calendar month, and such reports shall be submitted within fifteen business days of the end of the calendar month.

(c) Wholesalers may apply to the commission for an exemption from the reporting requirements if they do not distribute controlled substances or drugs of concern.

(2) Except as provided in subsection (3) of this section, a wholesaler shall exercise due diligence to identify customers ordering or seeking to order controlled substances or drugs of concern, and establish the normal and expected transactions conducted by those customers, as well as to identify and prevent the sale of controlled substances or drugs of concern that are likely to be diverted from legitimate channels. Such due diligence measures shall include, but are not limited to, the following, which shall be conducted prior to an initial sale and on a regular basis, as necessary:

(a) Questionnaires and affirmative steps by the wholesaler to confirm the accuracy and validity of the information provided, it shall be considered illegal for a customer to provide false or misleading information;

(b) For a customer who is a prescriber, confirmation of prescriber type, specialty practice area, and if the prescriber personally furnishes controlled substances or drugs of concern, the quantity furnished;

(c) Review of drug utilization reports; and

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

(i) Methods of payment accepted and in what ratios;

(ii) The ratio of controlled versus noncontrolled prescriptions and overall sales;

(iii) Orders for controlled substances or drugs of concern from other wholesalers U.S. DEA's Automation of Reports and Consolidated Orders System (ARCOS); and

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

(3) A wholesaler receiving a request for an initial sale of a controlled substance or drugs of concern may conduct the sale before complying with subsection (2) of this section if all of the following apply:

(a) The sale is to a new customer;

(b) The wholesaler documents that the order is to meet an emergent need;

(c) The wholesaler completes the requirements of subsection (2) of this section no later than sixty business days from the date of sale.

(4) A wholesaler receiving a request from an existing customer to purchase a controlled substance or drug of concern, the size/quantity of which exceeds the established algorithm limitations or quota restrictions for such customer, may sell the drug of concern or controlled substance provided the customer submit documentation explaining the request.

(5) Any customer that is believed to be engaged in potential diversion activity, including those to whom a wholesaler refuses to sell, shall be electronically reported to the commission. Such reports shall include:

(a) Customer name;

(b) Customer address;

(c) DEA number;

(d) State license number(s);

(e) A detailed explanation of why the wholesaler identified the customer as a possible diversion risk; and

(f) Such reports shall be submitted within thirty days of refusal, cessation, or identification by wholesaler.

(6) All licensed wholesalers shall submit all reports to the commission in a DEA ARCOS format where applicable.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-585, filed 6/1/20, effective 7/1/20.]