

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17748e Out-of-state pharmacy; facilitation of delivery or trade; use of wholesale distributor-broker; requirements; liability; license requirements; transaction records; notification; investigation; definitions.

Sec. 17748e.

(1) An out-of-state pharmacy that is not licensed under this part as a pharmacy may deliver or trade a drug or device salable on prescription only to a person located in this state only if the out-of-state pharmacy meets both of the following requirements:

(a) The out-of-state pharmacy holds a license in good standing as a pharmacy from the state in which it is located.

(b) The out-of-state pharmacy uses a wholesale distributor-broker that is licensed in this state to facilitate the transaction.

(2) Except as otherwise provided in this part, a pharmacy that is using a wholesale distributor-broker shall only deliver or trade a drug or device salable on prescription only that it receives from 1 or more of the following:

(a) A manufacturer.

(b) A wholesale distributor.

(c) Subject to subsection (3), a pharmacy.

(d) Subject to subsection (3), a qualified pharmacy.

(3) A drug salable on prescription only must not be delivered or traded between pharmacies, or between a pharmacy and a qualified pharmacy that is using a wholesale distributor-broker, unless all of the following are met:

(a) The pharmacy or qualified pharmacy from which the drug is being obtained receives a request for the drug that identifies the drug's brand name or generic name, lot number, expiration date, quality, quantity, and size.

(b) The drug is approved by the United States Food and Drug Administration.

(c) The drug is not expired at the time of the delivery or trade.

(d) The drug is not a controlled substance.

(e) Before delivering or trading the drug, the pharmacy or qualified pharmacy from which the drug is being obtained confirms with the pharmacy or qualified pharmacy receiving the drug that the drug is available for delivery or trade.

(f) The pharmacy or qualified pharmacy from which the drug is being obtained includes with the drug a packaging checklist, confirming that the drug being delivered or traded matches the information identified on the request described in subdivision (a).

(g) The drug is delivered or traded in the original manufacturer's packaging, whether sealed or unsealed, with the drug's national drug code, lot number, and expiration date conspicuously identified on the packaging. If the original manufacturer's packaging is unsealed at the time of the delivery or trade, the delivery or trade may include a quantity of the drug that is less than the quantity contained in the original manufacturer's packaging. However, the pharmacies, or the pharmacy and qualified pharmacy, shall not trade or deliver more than 1 unsealed or partial quantity of the drug during any consecutive 90-day period.

(h) If 1 of the pharmacies involved in the delivery or trade is a qualified pharmacy, the delivery or trade is intended to fill a prescription for an identified patient.

(4) A wholesale distributor-broker is not liable in a civil action for personal injury or death resulting from a drug or device salable on prescription only that was delivered or traded by a pharmacy or qualified pharmacy under this section, regardless of whether the wholesale distributor-broker is subject to disciplinary action under this part, if the wholesale distributor-broker's conduct does not amount to gross negligence as that term is defined in section 7 of 1964 PA 170, MCL 691.1407.

(5) To receive a license as a wholesale distributor-broker under this part, an applicant shall meet the requirements for licensure established by the department in consultation with the board by rule. The rules must require the applicant to demonstrate to the satisfaction of the board that, at the time of the application for initial licensure, the applicant facilitates deliveries or trades for at least 50 qualified pharmacies that are each licensed in good standing in their state of licensure. If the number of qualified pharmacies described in this subsection with which a wholesale distributor-broker facilitates deliveries and trades falls below 50, the wholesale distributor-broker may continue to do business in this state. However, a wholesale distributor-broker seeking renewal of its license shall, in addition to meeting any requirements for renewal under section 16201, demonstrate to the satisfaction of the board that the wholesale distributor-broker facilitates deliveries and trades for at least 50 qualified pharmacies at the time of license renewal.

(6) A wholesale distributor-broker shall provide a transaction history, transaction statement, or transaction information to a pharmacy purchasing a drug or device from a pharmacy or qualified pharmacy through the wholesale distributor-broker under this section if any of the following are met:

(a) A transaction history, transaction statement, or transaction information is required under the drug supply chain security act, Public Law 113-54.

(b) The qualified pharmacy provided the transaction history, transaction statement, or transaction information to the wholesale distributor-broker, and the wholesale distributor-broker receives a request for the document from the purchasing pharmacy. A wholesale distributor-broker that receives a document described in this subdivision shall retain the document for at least 7 years.

(7) A wholesale distributor-broker that receives notification from a pharmacy or qualified pharmacy that a delivery or trade facilitated by the wholesale distributor-broker involved a drug or device salable on prescription only that is a suspect product or illegitimate product shall immediately notify each of the following:

(a) The department.

(b) The United States Food and Drug Administration.

(c) Each pharmacy that received the product from the pharmacy or qualified pharmacy.

(8) Before facilitating the delivery or trade of a drug or device salable on prescription only to a pharmacy, the wholesale distributor-broker shall notify the pharmacy, in writing, that the wholesale distributor-broker will not examine the drug or device for quality or accuracy before the pharmacy receives the drug or device.

(9) A wholesale distributor-broker shall not facilitate a delivery or trade of a drug or device salable on prescription only between a pharmacy and a qualified pharmacy unless both of the following are met:

(a) The pharmacy's or qualified pharmacy's license is in good standing in its state of licensure at the time of the delivery or trade and the wholesale distributor-broker has no knowledge of pending disciplinary action against the pharmacy or qualified pharmacy in its state of licensure.

(b) The wholesale distributor-broker has, for the quarter in which the delivery or trade will occur, received from the pharmacy and qualified pharmacy a signed attestation that the pharmacy or qualified pharmacy holds a license in good standing in its state of licensure and that the pharmacy or qualified pharmacy is in compliance with all applicable federal and state laws. The wholesale distributor-broker shall make an attestation received under this subdivision available to the department on the department's request.

(10) A wholesale distributor-broker shall cooperate with the department if the department is investigating a transaction involving the wholesale distributor-broker or a qualified pharmacy with which the wholesale distributor-broker facilitates transactions.

(11) As used in this section:

(a) "Illegitimate product" means that term as defined in 21 USC 360eee.

(b) "Out-of-state pharmacy" means a facility or part of a facility that is located outside of this state and that dispenses prescription drugs or prepares prescription drugs for delivery or distribution under the laws of the state in which it is located.

(c) "Qualified pharmacy" means an out-of-state pharmacy that meets the requirements described in subsection (1).

(d) "Suspect product" means that term as defined in 21 USC 360eee.

(e) "Transaction history" means that term as defined in 21 USC 360eee.

(f) "Transaction information" means that term as defined in 21 USC 360eee.

(g) "Transaction statement" means that term as defined in 21 USC 360eee.

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