

Kansas Administrative Regulations

State Board of Pharmacy

Article 14.—Wholesale Distributors

68-14-9. Requirements.

(a) Each of the following terms, as used in this regulation, shall have the meaning specified in this subsection:

(1) “Registrant” means a trading partner as defined by K.S.A. 65-1626.

(2) “High risk product” means a product that has at least one of the following factors:

(A) Within 24 hours after determining or being notified by the FDA or a trading partner that there is a high risk that a product that the manufacturer has reason to believe is in an immediate trading partner’s possession is an illegitimate product.

(B) Within 24 hours after determining or being notified by the FDA or a trading partner that there is a specific high risk that could increase the likelihood that an illegitimate product will enter the U.S. pharmaceutical distribution supply chain.

(C) Within 24 hours after determining or being notified by the FDA or a trading partner that there exists an “other high risk” as determined by the FDA in guidance pursuant to 21 U.S.C. 360eee-1 subsection (h).

(3) “Illegitimate product” means a product for which credible evidence shows that the product:

(A) is counterfeit, diverted, or stolen;

(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(C) is the subject of a fraudulent transaction; or

(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

(b) Each registrant shall operate in accordance with the requirements specified in 21 U.S.C. 353, 21 U.S.C. 360eee, 21 U.S.C. 360eee-1, 21 U.S.C. 360eee-2, 21 U.S.C. 360eee-3, and any implementing regulations.

(c) Each registrant shall adopt policies and procedures to ensure that each trading partner the registrant trades with is properly licensed or registered with Kansas and the state from which the trading partner is conducting business or if the state where the trading partner is conducting business from has not established a licensure requirement, is licensed by the secretary of health and human services.

(d) Each registrant shall notify the board in writing and provide the board with a copy of the completed form 3911, as issued by the FDA, within 24 hours of determining that a product in the possession or control of the registrant is an illegitimate product.

(e) Each manufacturer shall notify the board in writing and provide the board with a copy of the completed form 3911, as issued by the FDA, within 24 hours if the manufacturer has reason to believe that a trading partner may have in their possession a high risk product manufactured by or purported to be manufactured by the manufacturer.

(f) Each registrant shall not be required to meet the applicable requirements of subsection (b) if they have a waiver or exemption from the federal government or meet the exception specified in subsection (a)(3) of 21 U.S.C. 360eee-1.

(g) Each registrant shall notify the board in writing within 30 days of discovery if any of the following occur:

(1) The registrant identifies a trading partner that is not properly licensed or registered with Kansas and the state from which the trading partner is conducting business or if the state where the trading partner is conducting business from has not established a licensure requirement, is not licensed by the secretary of health and human services; or

(2) the registrant receives approval from the FDA granting the registrant a waiver, exception, or exemption from the requirements of subsection (a)(3) of 21 U.S.C. 360eee-1.

(h) Each registrant shall utilize a system approved by the board to respond to requests from the board for information required by subsection (b).

(Authorized by K.S.A. 65-1630, K.S.A. 2025 Supp. 65-1643d, K.S.A. 65-1655, and K.S.A. 65-1655a; implementing K.S.A. 65-1642, K.S.A. 2025 Supp. 65-1643, K.S.A. 2025 Supp. 65-1643d, K.S.A. 65-1648, K.S.A. 65-1655, and K.S.A. 65-1655a; effective Aug. 14, 2026.)

***** Authenticated Kansas Administrative Regulation *****