

Kansas Administrative Regulations

State Board of Pharmacy

Article 9.—Automated Prescription Systems

68-9-2. Automated drug delivery systems in pharmacies.

(a) For purposes of this regulation, "automated drug delivery system" shall mean an automated dispensing system, as defined by K.S.A. 65-1626 and amendments thereto, that is located in a Kansas pharmacy and uses a robotic, mechanical, or computerized device to perform operations or activities other than compounding or administration, involving the storage, packaging, or labeling of, or any other step before dispensing, drugs. Each prescription medication prepared by an automated drug delivery system shall be verified and documented by a Kansas-licensed pharmacist as part of the dispensing process.

(b) A pharmacist-in-charge of any licensed pharmacy, licensed health care facility, or other location that is required to be supervised by a pharmacist-in-charge and that uses an automated drug delivery system shall perform the following before allowing the automated drug delivery system to be used:

(1) Ensure that the automated drug delivery system is in good working order and accurately selects the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

(2) ensure that the automated drug delivery system has a mechanism for securing and accounting for all drugs removed from and subsequently returned to the system;

(3) ensure that the automated drug delivery system has a mechanism for securing and accounting for all wasted or discarded drugs, including a manual override for the pharmacist, pharmacy intern, or pharmacy technician to clear a jammed, blocked, or malfunctioning automated drug delivery system;

(4) ensure compliance with an ongoing continuous quality improvement program pursuant to K.S.A. 65-1695, and amendments thereto, or a risk management program that monitors total system performance and includes the requirement for accuracy in the drug and strength delivered;

(5) ensure that the automated drug delivery system is loaded accurately and according to the original manufacturer's storage requirements;

(6) approve and implement an operational policy that limits the personnel responsible for the loading and unloading of drugs to or from the automated drug delivery system to any of the following:

(A) A Kansas-licensed pharmacist;

(B) a Kansas-registered pharmacy intern;

(C) a Kansas-registered pharmacy technician; or

(D) a nurse with a license issued pursuant to K.S.A. 65-1115, and amendments thereto;

(7) at the location of the automated drug delivery system, maintain a current list of those approved individuals who are authorized to unload any drug from the automated drug delivery system;

(8) approve and implement security measures that meet the requirements of all applicable state and federal laws and regulations in order to prevent unauthorized individuals from accessing or obtaining drugs;

(9) preapprove all individuals who are authorized to unload any drug from the automated drug delivery system;

(10) ensure that all drugs loaded in the automated drug delivery system are packaged in the manufacturer's original packaging or in repackaged containers, in compliance with K.A.R. 68-7-15 and K.A.R. 68-7-16, or in containers with the lot number and expiration date tracked by the automated drug delivery system;

(11) provide the board with prior written notice of the installation or removal of the automated drug delivery system; and

(12) ensure that a system of preventive maintenance and sanitation for the automated drug delivery system is established and followed.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 2017 Supp. 65-1637 and 65-1642; effective July 6, 2001; amended Feb. 7, 2003; amended Aug. 19, 2016; amended Jan. 4, 2019.)