Automated Pharmacy Systems

Updated 6/11/2021

To promote uniform review and approval of automated pharmacy systems, the State of Ohio Board of Pharmacy implemented rule 4729:5-3-17 of the Administrative Code. This rule provides a process by which automated pharmacy systems are approved by the Board.

As used in the rule, "automated pharmacy system" means a mechanical system that performs operations or activities, other than administration, relative to storage, packaging, compounding, dispensing, or distribution of dangerous drugs that collects, controls, and maintains transaction information and records. It **does not** include an "automated drug storage system" (e.g., Pyxis, etc.) utilized by institutional facilities or other locations licensed as terminal distributors of dangerous drugs.

For questions regarding automated pharmacy systems, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Q1) Where can I find the rule text for automated pharmacy systems?

The full text of the Board's automated pharmacy systems rule can be accessed here: http://www.registerofohio.state.oh.us/pdfs/4729/5/3/4729$5-3-17_PH_FF_N_RU_20210524_1307.pdf

Q2) How does a terminal distributor of dangerous drugs obtain approval of an automated pharmacy system?

An automated pharmacy system must be approved by the Board prior to its implementation by the terminal distributor of dangerous drugs. Except in extraordinary circumstances, the approval will be made by field staff conducting the inspection of the system.

Prior to the approval of an automated pharmacy system, the Board shall receive a request from the responsible person on the terminal distributor of dangerous drugs license. Requests must be submitted using the Automated Pharmacy Systems Request Form.

REMINDER: All approvals are site-specific.

Upon notification, the Board shall conduct an inspection of the system to determine if it meets the requirements of this rule.

Q3) What are the requirements for approval of an automated pharmacy system?

The following are the requirements for approval of an automated pharmacy system:

1. An automated pharmacy system shall be located on the premises of a licensed terminal distributor of dangerous drugs.

2. Except for an automated pharmacy system in a long-term care facility, a pharmacist shall be physically present at the terminal distributor of dangerous drugs to provide supervision of the automated pharmacy system.

3. The automated pharmacy system shall have security to prevent unauthorized individuals from accessing or obtaining dangerous drugs and include safeguards to detect the diversion of dangerous drugs. This shall include the use of tamper-evident containers, canisters, or other storage devices for use in long-term care facilities.

   NOTE: "Tamper evident" means a package, storage container or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

4. A terminal distributor of dangerous drugs operating an automated pharmacy system shall maintain the following documentation on-site in a readily retrievable manner (i.e., accessible within 72-hours upon request):

- The manufacturer's name and model;
- A description of how the automated pharmacy system is used; and
- Policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction.

5. For automated pharmacy systems that do not require final verification (i.e., the final check) by a pharmacist, the terminal distributor is required to have a pharmacist verify for accuracy all dangerous drugs dispensed by the system for a continuous 45-day period.

   The responsible person shall compile metrics, using a form developed by the Board, documenting the performance of the system during this period.

   Unless otherwise approved by the board, the accuracy metrics during the 45-day pharmacy review period shall be no less than 99.985 percent.

   To assist licensees in compiling these metrics, the Board created a standardized reporting spreadsheet that can be accessed here: www.pharmacy.ohio.gov/APSmetrics

Q4) Are there any additional requirements for automated pharmacy systems that do not require final verification (i.e., the final check) by a pharmacist?

In addition to the submission of verification metrics (see Q3, #5), a terminal distributor of dangerous drugs is required:

1. To ensure the system captures the positive identification of the pharmacist authorizing the patient-specific prescription in the system prior to its dispensation.

2. To implement a quality assurance program to determine continued appropriate use of the automated pharmacy system. The quality assurance program shall monitor the performance of the automated pharmacy system, ensure the system is in good working order and accurately prepares the correct strength, dosage form, and quantity of the drug prescribed or ordered. At a minimum, the quality assurance program shall consist of a review of at least **5 percent** of all dispensed prescriptions over the daily operational hours of the automated pharmacy system.

3. If the system selects an incorrect drug, the terminal distributor shall immediately institute a one-hundred percent pharmacist verification of all drugs dispensed. The one-hundred percent verification procedure shall continue until such time as the terminal distributor can document that the cause of the error has been determined and addressed and that the system is no longer making errors.

REMINDER: These requirements **only apply** for automated pharmacy systems where a pharmacist is not performing the final physical verification of a drug (i.e., the final check) prior as part of the dispensing process.

Q5) My system was approved by the Board under the previous rule (OAC 4729-5-35) do I need to resubmit it for approval?

No. Any system that was approved under the previous automated systems rule is approved under the new rule.

REMINDER: Any automated pharmacy system that does not require final verification by a pharmacist must comply with the requirements listed in Q4 of this rule. This applies to any system that was approved under the previous rule.

Q6) Does this apply to systems operated by non-resident pharmacies (i.e., out-of-state)?

No. Approval of systems is for in-state pharmacies only.