New Automated Pharmacy Systems Rule Now Effective

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 on 6/4/2021. This rule provides a process by which automated pharmacy systems are approved by the Board. This rule replaces the previous automated systems rule, 4729-5-35.

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, the Board created a frequently asked questions document: www.pharmacy.ohio.gov/APS.

IMPORTANT REMINDERS:

- This rule applies to in-state automated pharmacy systems only.
- Systems that were approved under the previous rule (OAC 4729-5-35) do not need to be re-approved. However, there are new requirements for quality assurance plans for approved systems (see OAC 4729:5-3-17 (F)).