

Using Automated Dispensing Systems in Illinois Long-Term Care Facilities

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Recent amendments to the Illinois Pharmacy Practice Act Rules expressly allow the use of automated medication dispensing systems in long-term care facilities. Although the old rules did not prohibit automated dispensing systems at long-term care facilities, their generic terms provided only that pharmacies could place such systems in “settings that ensure medication orders and prescriptions are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice.” The new rules expressly permit the use of these machines in any licensed hospital, long-term care facility, or hospice facility.

An automated dispensing system is conceptually similar to a vending machine: a pharmacy stores bulk drugs in the machine in separate bins or containers, and programs and controls the system remotely. A facility nurse then removes medication from the machines for administration to patients.

Such systems allow for immediate dispensing of controlled substances in emergency situations, without having to wait for an offsite pharmacy to deliver medications. They also help to prevent accumulation of unused medications at long-term care facilities, by allowing the pharmacist to dispense small amounts of prescribed drugs (e.g., daily doses) rather than the entire amount indicated on the prescription at one time. Because medications placed in the machine are not considered to be dispensed until they are removed, they can be administered to any patient who has a valid prescription.

The new regulations leave the definition of an automated dispensing system unchanged. Automated dispensing systems “include, but are not limited to, mechanical systems that perform operations or activities, other than counting, compounding or administration, relative to the storage, packaging or dispensing of medications, and that collect, control and maintain all transaction information.” Under the regulations, drugs in the system are not considered dispensed by the pharmacy until authorized employees of the long-term care facility remove the drugs from the system. Generally, drugs can only be released from the system pursuant to a prescription. Only the doses of medication needed for contemporaneous administration may be removed from the system at one time.

The facility does not need a state license or permit for an automated dispensing system; the machine operates under the same Illinois license as the pharmacy that places it at the facility. Pharmacies may not share an automated dispensing system at a facility, unless the pharmacies are under

common ownership.

Other changes to the Pharmacy Practice Act Rules may make placement of automated dispensing systems more prevalent. The new regulations require **offsite** institutional pharmacies to make medications available to patients when the pharmacy is closed or the pharmacist is absent, just as **onsite** institutional pharmacies are required to do. Under the regulations, the availability of necessary medications for immediate therapeutic use during those hours when the pharmacy is not open shall be met by (1) an after-hour cabinet, (2) an emergency kit or (3) an authorized facility nurse removing medications from the pharmacy. The new rules clarify that an automated dispensing system may be used as an after-hours cabinet or an emergency kit. When the automated dispensing system is used in this manner, pharmacist review of the prescription or medication order prior to removing medication is not required. This does not mean that a nurse can simply remove medication from the machine; s/he must still ensure that a physician issues a prescription or medication order.

The new regulations do not alter the other technical and procedural requirements for automated dispensing systems. These requirements include the following:

- The pharmacy must document the type of equipment, serial numbers, content of the machines, policies and procedures, and locations of the machines.
- The pharmacy must create adequate security systems and procedures, evidenced by written policies and procedures, to prevent unauthorized access or use, comply with applicable federal and state regulations, and maintain patient confidentiality.
- Systems must be in place for electronic recording of every time anyone accesses the dispensing systems, including the names, initials or other unique identifiers of the individuals accessing the system and removing the drugs, the name, strength, dosage form, and quantity of the drugs accessed, the names of the patients for whom the drugs were ordered, each patient's unique and permanent identifiers, the dates and times that employees removed medications from the system, and the identification of the persons stocking and restocking the machine.
- Only licensed pharmacists or registered pharmacy technicians may stock or restock medications.
- All medications placed in the system must be packaged as a unit of use for single-patient use, except for certain injectable medications and over-the-counter products.
- The pharmacy and facility must have documented policies and procedures for the use of automated dispensing systems.

Although an automated dispensing system must provide a mechanism for securing and accounting for medications removed from but then returned to the system, no medication or device may be returned for immediate reissue or reuse by the facility. Reuse requires the pharmacist's approval; the

pharmacist must determine that the medication is unopened and was stored in sealed, intact, and unaltered containers that meet standards for light, moisture, and air permeation as defined by the *United States Pharmacopeia*.

The Illinois regulations are consistent with federal Drug Enforcement Administration (DEA) rules on the use of emergency kits and automated dispensing systems. For more than three decades, the DEA has allowed pharmacies to place in long-term care facilities emergency kits that are routinely stocked with commonly dispensed controlled substances, provided that the facility is located in a state that regulates, among other things, the security safeguards for emergency kits. These kits are considered extensions of the pharmacy and are controlled under the pharmacy's DEA registration.

Since 2005, the DEA has allowed pharmacies to install automated dispensing systems at long-term care facilities, but unlike with emergency kits, the DEA requires the pharmacy to separately register each machine. The DEA's comments that accompanied the publication of its rules acknowledge the benefits of using automated dispensing systems.

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