Remote Automated Dispensing Machines in Long Term Care

This technology is supported by DEA, CMS, EPA, and many state boards of pharmacy. See below for the NABP model rules, DEA Title 21 Sec. 1301.27 pertaining to remote automated dispensing.

Proposed Language
Remote Automated Dispensing Based on the
Model State Pharmacy Act and Model Rules of the
National Association of Boards of Pharmacy August 2011

Section 3. Pharmacy Practice.
(e) Labeling
   (1) All Drugs Dispensed for use by inpatients of a hospital or other health care facility, whereby the Drug is not in the possession of the ultimate user prior to Administration, shall meet the following requirement: When a multiple-dose Drug Distribution system is utilized, including Dispensing of single unit packages, the Drugs shall be Dispensed in a container to which is affixed a label containing the following information:
   (A) identification of the Dispensing Pharmacy;
   (B) the patient’s name;
   (C) the date of Dispensing;
   (D) the nonproprietary and/or proprietary name of the Drug Dispensed; and
   (E) the strength, expressed in the metric system whenever possible.

(o) Remote Pharmacy Services
   (3) Remote Dispensing Site
      A Remote Dispensing Site shall utilize an Automated Pharmacy System located in an area accessible only to authorized personnel.
   (4) Personnel
      The Pharmacist-in-Charge of the Coordinating Pharmacy:
      (A) is responsible for the pharmacy services performed at Remote Dispensing Sites, including the supervision of any Automated Pharmacy System and compliance with these Rules;
      (B) is responsible for ensuring that the Coordinating Pharmacy and Remote Dispensing Site have entered into a written agreement that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the agreement in compliance with federal and state laws and regulations. Such contract or agreement is not required if the Remote Dispensing Site are under common control or ownership of the Coordinating Pharmacy;
      (C) shall ensure the Coordinating Pharmacy has sufficient Pharmacists on duty for the safe operation and supervision of all Remote Dispensing Sites; and
      (D) shall ensure that the Automated Pharmacy System is in good working order and accurately Dispenses the correct strength, dosage form, and quantity of the Drug prescribed while maintaining appropriate recordkeeping and security safeguards.
   (5) Operations
      Remote Dispensing Sites:
      that are located within an Institutional Facility shall utilize an Automated Pharmacy System for the purposes of Dispensing. The Pharmacist at the Coordinating Pharmacy shall have the necessary patient information to perform a Prospective Drug Utilization Review (DUR) prior to Dispensing
   (6) Security
      (i) Drugs shall be stored in compliance with state and federal laws and in accordance with these Rules, including those addressing temperature, proper containers, and the handling of outdated drugs.
      (ii) Drugs stored at Remote Dispensing Sites shall be stored in an area that is:
(A) separate from any other Drugs used by the health care facility; and
(B) locked by key or combination, so as to prevent access by unauthorized personnel.

(ii) Access to the area where Drugs are stored at the Remote Pharmacy or Remote Dispensing Site must be limited to:
(A) Pharmacists, Certified Pharmacy Technicians, Pharmacy Technicians, or Pharmacy Interns who are employed by the Coordinating Pharmacy; or
(B) Personnel employed at the Institutional Facility where the Remote Dispensing Site is located who:
   (-a-) are licensed health care providers;
   (-b-) are designated in writing by the Pharmacist-in-Charge or the Person responsible for the supervision and on-site operation of the facility where the Automated Pharmacy System is located; and
   (-c-) have completed documented training concerning their duties associated with the remote site.

(iii) Remote Dispensing Sites shall have adequate security to:
(A) comply with federal and state laws and regulations; and
(B) maintain patient confidentiality.

(iv) The Coordinating Pharmacy shall have procedures that specify that Drugs may only be Delivered to the Remote Dispensing Site in accordance with the policies and procedures of the Coordinating Pharmacy.

(7) Policies and Procedures
(i) The Coordinating Pharmacy and Remote Dispensing Site shall operate in compliance with written policies and procedures that are established by the Coordinating Pharmacy. The policy and procedure manual shall include, but not be limited to, the following:
(A) a current list containing the name and business address of the Pharmacist-in-Charge and personnel designated by the Pharmacist-in-Charge to have access to the area where Drugs are stored at the Remote Dispensing Site;
(B) duties that may only be performed by a Pharmacist;
(C) a copy of the written agreement between the Coordinating Pharmacy and the Institutional Facility where the Remote Dispensing Site is located. Such contract or agreement is not required if the Remote Dispensing Site is under common control or ownership of the Coordinating Pharmacy;
(D) date of last review and revision of policy and procedure manual; and
(E) policies and procedures for:
   (-a-) operation of the video/audiovisual communication system;
   (-b-) security;
   (-c-) sanitation;
   (-d-) storage of Drugs;
   (-e-) Dispensing;
   (-f-) supervision;
   (-g-) Drug procurement, receipt of Drugs, and Delivery of Drugs.
      1. Drugs may only be Delivered to the Remote Dispensing Site in a sealed container with a list of Drugs Delivered.
      2. Drugs Delivered to the Remote Dispensing Site must be checked by personnel designated by the Pharmacist-in-Charge to verify that the Drugs sent were actually received. The designated Person who checks the order shall document the verification by signing and dating the list of Drugs Delivered.

   (-h-) Recordkeeping.

(ii) A Coordinating Pharmacy providing pharmacy services at a Remote Dispensing Site shall, at least annually, review and revise as necessary its written policies and procedures, and document such review.

(iii) A Coordinating Pharmacy providing pharmacy services at a Remote Dispensing Site shall maintain a written plan for recovery from an event that interrupts the ability of a Pharmacist to electronically
supervise the Dispensing of Drugs at the Remote Dispensing Site. The written plan for recovery shall include:

(A) a statement that Drugs shall not be Dispensed at the Remote Dispensing Site if a Pharmacist is not able to electronically supervise such Dispensing;
(B) procedures for response when the video/auditory communication system is experiencing downtime; and
(C) procedures for the maintenance and testing of the written plan for recovery.

(iv) All policies and procedures must be maintained and made available for inspection by the Board in the Coordinating Pharmacy responsible for the Automated Pharmacy System and at the Remote Dispensing Site where the Automated Pharmacy System is being used.

(8) Quality Assurance

(i) A Coordinating Pharmacy that provides pharmacy services via a Remote Dispensing Site shall operate according to a written program for quality assurance that:

(B) requires a Pharmacist of the Coordinating Pharmacy to be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System located at the Remote Dispensing Site; and

(C) establishes procedures to test the operation of all Automated Pharmacy Systems and all video/auditory communication systems at a minimum of every six months and whenever any upgrade or change is made to the system and document the testing of each such system.

(9) Recordkeeping

(i) Required Records

(A) A Coordinating Pharmacy shall keep a record of all Drugs received, Dispensed, and Distributed from the Coordinating Pharmacy.

(B) A Coordinating Pharmacy shall keep a record of all Drugs received, Dispensed, and Distributed from each Remote Dispensing Site.

(C) All records of receipt, Dispensing, and Distribution shall be kept at the Coordinating Pharmacy. Coordinating Pharmacy and Remote Dispensing Site records must be kept separate from each other.

(ii) Inventory

(A) A Coordinating Pharmacy shall keep a perpetual inventory of controlled substances, and other Drugs required to be inventoried according to state and federal law, that are held in the Coordinating Pharmacy and each Remote Dispensing Site.

(B) All inventory records shall be kept at the Coordinating Pharmacy. The Coordinating Pharmacy and Remote Dispensing Site inventory records must be kept separate from each other.

Automated Pharmacy Systems

Automated Pharmacy Systems can be utilized in licensed pharmacies, Remote Pharmacies, and Remote Dispensing Sites located within an Institutional Facility or clinic. A Pharmacist is not required to be physically present at the site of the Automated Pharmacy System if the system is supervised electronically by a Pharmacist. Automated Pharmacy Systems shall comply with the following provisions.

(1) Documentation as to type of equipment, serial numbers, content, policies and procedures, and Remote Dispensing Site location shall be maintained on site in the Pharmacy (or Coordinating Pharmacy) for review by the Board of Pharmacy. Such documentation shall include, but is not limited to:

(i) name and address of the Pharmacy (or Coordinating Pharmacy) and the Remote Dispensing Site where the Automated Pharmacy System(s) is being used;

(ii) Manufacturer’s name and model;

(iii) description of how the Device is used;

(iv) quality assurance procedures to determine continued appropriate use of the automated Device;

(v) policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, and malfunction; and

(vi) documentation evidencing that the Automated Pharmacy System has been tested prior to initial use and on a periodic basis at each location to ensure that the Automated Pharmacy System is operating properly.
(2) Automated Pharmacy Systems should be used only in settings where there is an established program of Pharmacist Care that ensures medication orders are reviewed by a Pharmacist in accordance with established policies and procedures and good Pharmacy practice.
   (i) A Pharmacist shall be accessible to respond to inquiries or requests pertaining to Drugs Dispensed from the Automated Pharmacy System.
(3) All policies and procedures must be maintained in the Pharmacy (or Coordinating Pharmacy) responsible for the Automated Pharmacy System and at the Remote Dispensing Site where the Automated Pharmacy System is being used.
(4) Automated Pharmacy Systems shall have adequate security systems and procedures, evidenced by written policies and procedures, to:
   (i) prevent unauthorized access;
   (ii) comply with federal and state regulations; and
   (iii) prevent the illegal use or disclosure of Protected Health Information.
(5) Records and/or electronic data kept by Automated Pharmacy Systems shall meet the following requirements.
   (i) All events involving the contents of the Automated Pharmacy System must be recorded electronically.
   (ii) Records must be maintained by the Pharmacy and must be readily available to the Board. Such records shall include:
       (A) identity of system accessed;
       (B) identification of the individual accessing the system;
       (C) type of transaction;
       (D) name, strength, dosage form, and quantity of the Drug accessed;
       (E) name of the patient for whom the Drug was ordered; and
       (F) such additional information as the Pharmacist-in-Charge may deem necessary.
(6) Access to and limits on access (eg, security levels) to the Automated Pharmacy System must be defined by policy and procedures and must comply with state and federal regulations.
(7) The Pharmacist-in-Charge shall have the sole responsibility to:
   (i) assign, discontinue, or change access to the system;
   (ii) ensure that access to the medications comply with State and Federal regulations;
   (iii) ensure that the Automated Pharmacy System is filled/stocked accurately and in accordance with established, written policies and procedures.
(8) The filling/stocking of all medications in the Automated Pharmacy System shall be completed by a pharmacist or pharmacy technician under the direct supervision of a pharmacist, except as provided below:
   (i) If the automated pharmacy system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by an FDA approved repackager.
   (ii) The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:
       (A) a pharmacist verifies the cartridge or container has been properly filled and labeled;
       (B) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and
       (C) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.
       (D) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote site by the provider pharmacy.
(9) A record of medications filled/stocked into an Automated Pharmacy System shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.
(10) All containers of medications stored in the Automated Pharmacy System shall be packaged and labeled in accordance with federal and state laws and regulations.
(11) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.
(12) The Automated Pharmacy System shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the Automated Pharmacy System, all in accordance with existing state and federal law.
(13) The Automated Pharmacy System shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

CHAPTER II--DRUG ENFORCEMENT ADMINISTRATION - DEPARTMENT OF JUSTICE
TITLE 21--FOOD AND DRUGS
Sec. 1301.27 Separate registration by retail pharmacies for installation and operation of automated dispensing systems at long term care facilities.

(a) A retail pharmacy may install and operate automated dispensing systems, as defined in 1300.01 of this chapter, at long term care facilities, under the requirements of 1301.17. No person other than a registered retail pharmacy may install and operate an automated dispensing system at a long term care facility.

(b) Retail pharmacies installing and operating automated dispensing systems at long term care facilities must maintain a separate registration at the location of each long term care facility at which automated dispensing systems are located. If more than one registered retail pharmacy operates automated dispensing systems at the same long term care facility, each retail pharmacy must maintain a registration at the long term care facility.

(c) A registered retail pharmacy applying for a separate registration to operate an automated dispensing system for the dispensing of controlled substances at a long term care facility is exempt from application fees for any such additional registrations.

[70 FR 25465, May 13, 2005]

To reduce waste, CMS proposes regulation for short-cycle dispensing in LTCFs

ACA mandate affects brand-name drugs covered by Part D.

Addressing the problem of waste related to unused medications in long-term care facilities (LTCFs), section 3310 of the Affordable Care Act (ACA) (P.L. 111–148) calls for short-cycle dispensing, that is, providing residents’ medications in quantities that last 7 days or less.

Implementing revisions to Medicare in 2012 and various provisions included in ACA, CMS issued a proposed rule in the Federal Register on November 22. Specifically, the proposed rule requires all pharmacies working with LTCFs to dispense no more than a 7-day supply of brand-name medications covered by Part D, with certain exceptions, starting on January 1, 2013. Excluded from the proposed requirements are medications that are difficult to dispense in a 7-days-or-less supply—such as eye drops, ear drops, inhalers and inhalation medications, nasal sprays, reconstituted antibiotics and medications given by injection, medications that that must stay in their original container, and topical medications—and medications that are dispensed for acute illnesses.

Currently, LTC pharmacies dispense medications in 30–90-day cycles. “It stands to reason that if fewer drugs are available to be wasted, fewer drugs will be wasted,” CMS explained in the proposed rule. Waste may occur when unused dispensed medications remain after various scenarios, including discontinuation of treatment, and discharge, hospitalization, or death of the LTCF resident, according to CMS. Just 20% of medications dispensed to LTCFs generate 75%–80% of the cost of waste, and that 20% consists entirely of brand-name medications, according to CMS’s discussions with industry.

Cost is not the only reason to minimize waste, CMS said. Smaller dispensing quantities will help DEA to guard against diversion and the Environmental Protection Agency to reduce the amount of pharmaceutical waste.
According to CMS, several types of short-cycle dispensing are already in use by LTCFs. These include dispensing a 7-day supply; dispensing a 2-day supply, followed by another 2-day supply, followed by a 3-day supply; dispensing a 4-day supply followed by a 3-day supply; daily dispensing; and automated shift or dose dispensing. While the proposed rule currently applies only to brand-name medications, CMS said, LTC pharmacies and facilities are welcome to expand short-cycle dispensing to other medications as well.