

**NEW YORK STATE DEPARTMENT OF HEALTH
BUREAU OF NARCOTIC ENFORCEMENT**

***Guideline for Registered Community Pharmacy (Retail
Pharmacy) Operation of Automated Dispensing Systems in
Residential Health Care Facilities***

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Guideline Purpose

The purpose of this guideline is to provide information to registered community pharmacies (retail pharmacies) and Residential Health Care Facilities (RHCF) regarding licensing, installation, and operation of automated dispensing systems (ADS) containing controlled substances.

Benefits of Automated Dispensing Systems

The installation and operation of ADS by RHCF significantly benefit patient care through timely and efficient dispensing of prescriptions for controlled substances. An ADS may reduce the cost of medications remaining from wastage due to discontinued drug therapy while simultaneously decreasing the amount of controlled substances that are susceptible to diversion.

Summary of Title 10 NYCRR Part 80 Regulations for Automated Dispensing System

Section 80.1 Definitions. Except where different meanings are expressly specified, the terms used in this Part shall have the meanings set forth in Public Health Law, section 3302.

(g) Automated dispensing system means a system approved by the Department that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of controlled substances, and which collects, controls, and maintains all transaction information.

80.5 Licenses.

(a) Licenses for controlled substances privileges shall be issued by the department in the following classifications:

11 Registered Community Pharmacy--Automated dispensing system

(f) A registered community pharmacy licensed in class 11 and maintaining a separate registration with the Drug Enforcement Administration may install and operate automated dispensing systems in a Residential Health Care Facility ("RHCF") which is licensed or approved by the Department.

(g) A registered community pharmacy operating an automated dispensing system as provided in paragraph (f) of this section shall provide to such system only those controlled substances obtained under the Drug Enforcement Administration registration of the registered community pharmacy and not the Drug Enforcement Administration registration of the automated dispensing system.

80.50 Minimum security standards for institutional dispensers, institutional dispensers limited, treatment programs, license holders engaging in research, instructional activities and chemical analysis.

(b) Working stocks of controlled substances of a registered pharmacy may be dispersed throughout the stocks of no controlled substances in such a manner as to obstruct theft or diversion provided the conditions of section 80.6 of this Part are met and the pharmacy is locked when not in operation. If not dispersed, controlled substances in Schedules II, III and IV shall be kept in a stationary, securely locked cabinet of substantial construction.

(f) Only controlled substances shall be stored within the storage facilities described in this section, except in an automated dispensing system and as noted in subdivisions (b) and (d)(2) of this section.

80.106 Pharmacies.

(a) Pharmacies shall keep records of all controlled substances received and delivered or disposed of by them.

(e) Pharmacies shall keep a separate record of all controlled substances distributed to an automated dispensing system and returned to the pharmacy from such system.

(f) Pharmacies shall keep a separate record for an automated dispensing system for all records required by this Part.

Overview of Class 11 Requirements and Policies

Section 80.5(f) of Title 10 regulations authorizes a Drug Enforcement Administration (DEA) registered retail pharmacy¹ to install and operate an automated dispensing system (ADS) in a residential health care facility ("RHCF") which is licensed or approved by the Department of Health. Operation of an ADS must be in accordance with Article 33 of the Public Health Law, Part 80 regulations, and the laws and regulations of the New York State Board of Pharmacy.

¹ CFR 21 §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.

I. Licensure:

1. There are no fees associated with a class 11 license.
2. One class 11 license is issued to a specific pharmacy.
3. A separate ADS DEA registration is required for each Residential Health Care Facility (“RHCF”).
 - Prior to obtaining an ADS DEA registration for a RHCF, the pharmacy must verify that the RHCF is licensed by the Bureau of Narcotic Enforcement as an Institutional Dispenser, Limited (class 3A licensee). [Title 10 NYCRR Part 80 Section 80.21]
 - Nursing homes, convalescent homes, health-related facilities, adult care facilities subject to the provisions of Title 18 NYCRR Parts 487, 488 490, dispensaries or clinics not qualifying as institutional dispensers in license class 3 shall apply for an institutional dispenser, limited license. Such institutional dispensers qualifying for controlled substances privileges shall obtain a class 3A license. [Title 10 NYCRR Part 80 Section 80.47(a)]
 - An institutional dispenser licensed in class 3A may administer controlled substances to patients only pursuant to a prescription issued by an authorized physician or other authorized practitioner and filled by a registered pharmacy.
 - The RHCF must continuously maintain a Class 3A license.
4. The class 11 licensee shall conspicuously post the ADS DEA registration (original or copy) in the RHCF.
5. A Class 11 licensee must provide written notification to the Bureau of Narcotic Enforcement of each proposed facility where an ADS will be installed, operated and maintained.
6. The Department of Health Bureau of Narcotic Enforcement will perform an on-site inspection of the proposed RHCF before approval is granted to operate an ADS.
7. The ADS cannot contain controlled substances until the pharmacy is issued a class 11 license and the Department has provided a written approval letter for the operation and maintenance of the ADS at each individual site. The written approval letter will include the name and address of the class 3A facility and the specific approved uses of the ADS at said facility.
8. The Department of Health Bureau of Narcotic Enforcement shall be notified by the pharmacy of any change to the ADS (e.g., discontinuation of service, intent to increase the number of ADS’s at an approved facility, proposed change of approved ADS uses, removal of an ADS, etc.).

II. ADS Installation/Operation/Supply:

1. No person/entity other than a registered retail pharmacy may install and operate an automated dispensing system at a RHCF.
2. The ADS must be owned/rented/leased and maintained by the pharmacy.
3. Pharmacy stock of controlled substances within the ADS are owned by the pharmacy.
4. Controlled substances within the ADS must be identified by drug name, strength, lot number and expiration date.

5. Pharmacy personnel must supply, stock and maintain the ADS.
 - For security and accountability reasons, unit dose packaging is preferred for controlled substances in an ADS. Multi-dose containers of controlled substances are discouraged.
 - The pharmacy shall limit the amount of controlled substances within the ADS to the quantity necessary to appropriately meet the needs of RHCF patients.
 - A licensed pharmacist shall verify all controlled substances to be stocked in an ADS prior to delivery from the pharmacy.
 - A written or electronic record of the pharmacist's verification of controlled substances provided to an ADS should be maintained and readily retrievable at the pharmacy.
 - In an ADS equipped with functional electronic verification capabilities (e.g., bar code scanning, radio frequency ID), controlled substances may be stocked by one authorized pharmacy staff person who is not a registered pharmacist. In the absence of electronic verification capabilities, an ADS should be stocked by two such authorized pharmacy staff persons.
 - Records of all ADS transactions, other than records for the administration of a controlled substance, shall be maintained and readily retrievable by the pharmacy.
6. Pharmacy ADS stock shall only be maintained within the ADS.
7. Pharmacy ADS stock of controlled substances may not be stored at the RHCF outside of the ADS.
 - Controlled substances in an Emergency Medication Kit within the ADS may be administered to patients as provided in Title 10 NYCRR Part 80 Section 80.49(d).
 - Controlled substances that require special storage conditions not provided for by the ADS must be patient specific prescriptions stored according to Title 10 NYCRR Part 80 Section 80.50.
 - Emergency medication kits may be maintained external to an ADS pursuant to Title 10 NYCRR Part 80 Section 80.49(d).
 - In an emergency situation, a controlled substance from a sealed emergency medication kit may be administered to a patient by an order of an authorized practitioner. An oral order for such controlled substance shall be immediately reduced to writing and a notation made of the condition which required the administration of the drug. Such oral order shall be signed by the practitioner within 48 hours. [Title 10 NYCRR Part 80 Section 80.49(d)]
 - Emergency means that the immediate administration of the drug is necessary and that no alternative treatment is available. [Title 10 NYCRR Part 80 Section 80.49(d)(1)]
 - A separate record shall be maintained of the administration of controlled substances from an emergency medication kit. Such record shall indicate the date and hour of administration, name and quantity of controlled substances, name of the practitioner ordering the administration of the controlled substance, patient's name, signature of the person administering and the balance of the controlled substances in the emergency medication kit after such administration. [Title 10 NYCRR Part 80 Section 80.49(d)(2)]

- The institutional dispenser limited shall notify the pharmacy furnishing controlled substances for the emergency medication kit within 24 hours of each time the emergency kit is unsealed, opened, or shows evidence of tampering. [Title 10 NYCRR Part 80 Section 80.49(d)(3)]

8. Security of ADS:

- Each ADS shall be made stationary by removing all wheels and either bolting it to the floor or by using a substantial chain and key lock.
- The preferred location of an ADS is within a locked medication room.
- Persons operating an ADS are not relieved of their responsibility to detect and correct any diversion or mishandling of controlled substances by a delegation of responsibility.
- Persons operating an ADS shall promptly notify the Department of any theft or loss of any controlled substance. Such theft or loss shall be reported on form DOH-2094 furnished by the Department at <http://www.health.ny.gov/forms/doh-2094.pdf> [Title 10 NYCRR Part 80 Section 80.20]
- Each person who accesses an ADS shall have his/her own individual electronic, bio-metric or other authentication credentials permitting access. These credentials shall not be shared.
- In accordance with these guidelines, pharmacy ADS security policies shall address, but not be limited to:
 - How controlled substances will be packaged and labeled;
 - How controlled substances will be transported to the RHCF's;
 - How controlled substances will be stocked within the ADS; and,
 - How security will be maintained while controlled substances are stocked in the ADS.

III. RHCF (Institutional Dispenser, Limited) 3a Responsibilities:

1. Each facility is required to comply with all Public Health Law Article 33 and Title 10 NYCRR Part 80 requirements regarding the administration, record keeping and security of controlled substances.