

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

***Guidelines 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 document is to provide information to registered community pharmacies (retail pharmacies) and Residential Health Care Facilities (RHCF) licensed as a New York State Department of Health Bureau of Narcotic Enforcement (BNE) Class 3A Institutional Dispensers – Limited, regarding licensing, installation, and operation of automated dispensing systems (ADS) containing controlled substances.

Benefits of Automated Dispensing Systems

The installation and operation of an ADS at a BNE licensed Class 3A RHCF significantly benefits 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. An ADS can also improve overall recordkeeping and security of controlled substances to assist in reducing the potential of diversions.

Approved Uses of Automated Dispensing Systems

Automated Dispensing Systems, storing and dispensing controlled substances, may be used only for emergency medication kits (E-kits) and ***may not be used for continuous dosing.***

Emergency Medication Kits at a Class 3A RHCF

Regulations authorize a pharmacy to provide sealed E-kits containing controlled substances to RHCF's licensed as a Class 3A Institutional Dispenser – Limited. Such kits may contain up to a 24-hour supply of up to 10 different controlled substances, in unit dose packaging, with no more than three being injectables, and in a double-locked system. Controlled substances from an E-kit may be administered to a patient in an emergency situation pursuant to an order from an authorized practitioner. The Class 3A RHCF must notify the pharmacy that supplies the emergency kit within 24 hours of each time the emergency kit is unsealed, opened, or shows evidence of tampering.

10 NYCRR §80.49(d) states as follows: *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 (emphasis added).***

The pharmacy supplying the E-kits should work with the RHCF to determine how many individual kits are needed at the RHCF to meet the needs of the patient population. This process should take into consideration the length of time it will take the pharmacy to replenish an E-kit once it has been unsealed. Some pharmacies and RHCF's have opted to have

seven E-kits in their facility (one kit for each day of the week). This affords the pharmacy additional time to replenish an opened E-kit, especially during times of a disaster, inclement weather, or dramatic increase in patient population at the RHCF.

Emergency Medication Kits and Automated Dispensing Systems

Each ADS manufacturer has hardware and software differences on how their automated dispensing systems may be operated. In order to meet the spirit of the regulation regarding E-kits containing only a 24-hour supply of medications, it is recommended that the ADS have a separate locked drawer or individually locked section for each 24-hour supply of E-kit medications. In most instances, pharmacies have opted to use one drawer of the ADS as a separate E-kit. In the case of a RHCF having one E-kit for each day of the week, this would mean that the ADS has at least seven individually locked/accessible drawers. One drawer for each E-kit. In some instances, this may be accomplished through software programming and setup within the ADS.

Summary of Title 10 NYCRR Part 80 Regulations for ADS

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:

Class 11 Registered Community Pharmacy—Automated Dispensing System

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

(g) A registered community pharmacy operating an ADS 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 ADS.

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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 ADS 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 ADS and returned to the pharmacy from such system.

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

Overview of Class 11 Requirements and Policies

Section 80.5(f) of Title 10 authorizes a Drug Enforcement Administration (DEA) registered retail pharmacy¹ to install and operate an ADS in a 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, 10 NYCRR Part 80, 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 ADSs at long term care facilities.

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(a) A retail pharmacy may install and operate ADSs, 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 ADS 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 and is valid for 2 years.
- 3) A separate ADS DEA registration is required for each RHCF 3A address.
 - Prior to obtaining an ADS DEA registration for a RHCF, the pharmacy must verify that the RHCF is licensed by the BNE as an Institutional Dispenser, Limited (class 3A licensee). [Title 10 NYCRR Part 80 Section 80.21].
 - 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 along with the BNE ADS approval letter.
- 5) A Class 11 licensee must apply to BNE for each proposed RHCF facility where an ADS will be installed, operated and maintained.
- 6) BNE will perform an on-site inspection of the proposed RHCF and installed ADS before approval is granted to operate the ADS.
 - a) BNE may, in its sole discretion, conditionally approve the proposed ADS prior to an on-site inspection. In these cases, BNE will perform an on-site inspection at the RHCF within one year of conditional approval. The Class 11 pharmacy must provide a report for the previous 30 days of the inspection reflecting all ADS transactions that have occurred.
- 7) The ADS may not 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) Once the ADS location has obtained final approval from BNE, a class 11A license will be issued for the RHCF class 3A location. The 11A license will not have an expiration date and will be mailed to the class 11 pharmacy. The 11A license must be prominently displayed in the proximity of the ADS unit at the RHCF.
- 9) The BNE 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.).
- 10) Upon application for renewal of the pharmacy's Class 11 license, a list of all ADS units owned and operated by the pharmacy must accompany the renewal application. This list must contain the class 3A license number, facility name, address, total number of ADS units at the facility, the corresponding DEA registration, and inventory of controlled substances supplied to the ADS.

II. ADS Installation/Operation/Supply:

1. No person or entity other than a class 11 registered retail pharmacy may install and operate an ADS at a RHCF.
2. The ADS must be owned, rented, or leased and maintained by the pharmacy.

3. The pharmacy stock of controlled substances within the ADS is owned by the pharmacy.
4. Bulk supplies of controlled substances are not allowed in the ADS or at the RHCF and must be supplied in single unit doses and packaging.
5. Controlled substances within the ADS must be identified by drug name, strength, lot number and expiration date.
6. **Pharmacy personnel must supply, stock and maintain the ADS.**
 - At no time shall an employee or other person from the RHCF accept delivery of or be in possession of controlled substances delivered to the facility to replenish the ADS.
 - For security and accountability reasons, unit dose packaging is required for controlled substances in an ADS.
 - 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 shall 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.
7. Pharmacy ADS stock shall be maintained only within the ADS.
8. Pharmacy ADS stock of controlled substances may not be stored at the RHCF outside of the ADS.
 - Controlled substances in an E-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.
 - E-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 E-kit is unsealed, opened, or shows evidence of tampering. [Title 10 NYCRR Part 80 Section 80.49(d)(3)].

9. Security of ADS:

- Each ADS shall be secured to reduce potential theft of the ADS. This shall include tethering the ADS to the floor or wall by using a substantial chain and key lock.
- The preferred location of an ADS is within a locked medication room.
- It is preferred to have security cameras focused on the ADS and the entrance and exit to the room where the ADS is located. Security cameras should have recording ability and recordings should be kept as long as possible.
- All ADS's should be connected to an electrical source that has emergency back-up electricity in case of power failures.
- 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 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) Class 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.

ADS Photographs

To reduce the timeline for approval of new ADS applications, BNE has developed a process for applicants to submit digital photographs of the ADS. This enables BNE the capability to conditionally approve the ADS application while waiting for a final on-site inspection.

Photographs submitted must include, at a minimum:

- Entrance and exit doors to the room where the ADS is installed
 - If installed in a more open area, photos of all four directions around the ADS
- All areas of the room (all walls, 360-degree view)
- All sides of the ADS unit including:
 - Photo of make, model, and serial number
 - The tethering system to secure the unit to an immovable object, e.g. wall, showing someone pulling on the tether as well as each connection point of the tether
- Picture of electrical outlet with unit plugged in
- Picture of each step of the log-in process and security features seen on the screen of the ADS that a user would see to gain access to the unit's medications – also screenshot of timeout length
- Picture of unit unlocked with one or more drawers open
- Any and all security components in the room, e.g., cameras, alarm system, locked doors, etc.
- Any other pictures that would assist BNE in making an informed decision

Submission Procedure

- Photos must be “attached” to the email and NOT embedded into the body of the email
- Digital photograph files must be in JPG, JPEG, GIF, TIFF, or BMP format and of high enough resolution to allow for enlargement during viewing with limited distortion
- Cloud storage services are not preferred due to internet restrictions within DOH
- Zip files with photographs and other application documents are allowed
- If needed, photographs could be inserted into an MS Word document or PowerPoint, but this method is not preferred

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This page contains a list of items required to be submitted with each request for a new ADS to be installed by a pharmacy with a current Class 11 BNE license. All items should be submitted in the same email to improve the tracking and approval process.

1. DOH – 5290 Attestation of Compliance Automated Dispensing System
2. Digital photographs of ADS unit installed
3. ADS Questionnaire (available upon request from BNE)
4. Policies and Procedures for the ADS unit that are specific for the 3A facility where it will be located
 - a. ADS Policy must state the date and version of said policy;
 - b. ADS Policy must be specific to controlled substance activity (Note: Questions regarding the use of an ADS for non-controlled medications must be addressed to the NYS BOP);
 - c. ADS Policy must be specific to New York State and adhere to all PHL Article 33 laws and Title 10 NYCRR Part 80 regulations regarding controlled substance activity;
 - d. Other than stating “ADS use shall be limited to emergency medication kit only and continuous dosing activities are expressly prohibited”, an emergency medication kit only ADS policy should not refer to continuous dosing activities and must adhere to all Title 10 NYCRR Part 80 requirements regarding emergency medication kit use;
 - e. Who, how and when the ADS inventory will be replenished.
5. Complete inventory of each ADS emergency kit to be installed
6. Documentation confirming Class 11 pharmacy owns, rents, or leases the ADS unit
7. DEA Registration for ADS at the 3A facility (DEA may require state approval prior to issuing)

All applications and required documents must be emailed to bnelicensing@health.ny.gov