



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

January 13, 2017

Dear Class 11 Pharmacy – Automated Dispensing System (ADS) Licensee:

**Subject: System Requirements for Continuous Dosing Use 'Update' & eKit
Reconciliation Notification**

As stated in the October 13, 2016 'System Requirements for Continuous Dosing Use' notification to all Class 11 - ADS licensed pharmacies and as posted on the New York State Department of Health (DOH), Bureau of Narcotic Enforcement (BNE) website (https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/docs/2016-10-13_continuous_dosing_notice.pdf), BNE is developing guidelines for system requirements for continuous dosing of controlled substances.

At this time, requests for Department approval of ADS continuous dosing of controlled substances will be "held for review" until the guidelines are approved and posted.

Questions regarding the use of an ADS for non-controlled medications must be addressed to the New York State Board of Pharmacy.

If a Class 11 Pharmacy – ADS licensee intends to install and maintain an ADS at a residential health care facility for emergency medication kit use only, the following documentation must be submitted in order for an on-site inspection by a BNE Narcotic Investigator to be assigned:

Information Required:

- ✓ Pharmacy's Class 11 license number and contact information (name, phone and email);
- ✓ Residential health care facility's ("RHCF") Class 3A license number and contact information (name, phone and email);
- ✓ Confirmation that the ADS is owned/rented/leased by the Class 11 Pharmacy (copy of purchase order or rental/lease agreement); and,
- ✓ Description of the intended use of the ADS – emergency medication kit only.

Documentation Required:

- ✓ Copy of the Pharmacy's current/active New York State Board of Pharmacy (BOP) 'Pharmacy' registration;
- ✓ Copy of the Pharmacy's current/active DEA Pharmacy registration;
- ✓ Copy of the Pharmacy's current/active DOH Class 11 Pharmacy – ADS license;
- ✓ Copy of the RHCF's current/active DOH Class 3A Institutional Dispenser, Limited license;
- ✓ Copy of New York State agency Operating Certificate authorizing the RHCF authority to operate (Note: adult care facilities subject to the provisions of Title 18 NYCRR Parts 487, 488 & 490 are prohibited from emergency medication kit use);

- ✓ Copy of the proposed RHCF's active DEA ADS registration (Note: RHCF name and address on DEA ADS registration must match RHCF name and address on Operating Certificate/Class 3A Institutional Dispenser, Limited license); and,
- ✓ Copy of Pharmacy's current ADS (eKit only) Policy (Note: other than stating "ADS use shall be limited to eKit only and continuous dosing activities are expressly prohibited", an eKit only ADS policy should not make reference to continuous dosing activities and must adhere to all Title 10 NYCRR Part 80 requirements regarding eKit use)

If the ADS software configuration allows for more than one emergency medication kit, the ADS may store multiple emergency medication kits – each of which must meet Title 10 NYCRR Part 80 Section 80.50(e)(1) regulatory requirements. In other words, an ADS configured to have five (5) separate emergency medication kits (eKit #1, eKit #2, etc.) may contain up to fifty (50) different controlled substances in unit dose packaging; however, it is the responsibility of the pharmacy to reconcile controlled substance inventory within the ADS and reconcile all controlled substances removed from the ADS. Once a controlled substance emergency medication kit has been accessed, any controlled substances within said eKit should not be accessible by facility personnel beyond 24-hours as each kit may only contain up to a 24-hour supply – ADS software configuration must include lockout capabilities if the ADS stores multiple emergency medication kits. Pharmacy reconciliation must occur prior to the pharmacy restocking of an eKit.

Should you have any questions, please contact BNE at narcotic@health.ny.gov.

Michele Mulloy

Regulatory Compliance Section Manager
NYS DOH Bureau of Narcotic Enforcement