

Class 11 Pharmacy – ADS ‘New’

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for ‘New’ Class 11 Pharmacy – Automated Dispensing System (ADS) license applications:

Cover Letter Information Required:

- ✓ 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 (attach copy of purchase order or rental/lease agreement); and,
- ✓ Description of the intended use of the ADS – emergency medication kit only, continuous dosing only or emergency medication kit and continuous dosing.
 - At this time, requests for Department of Health approval of ADS continuous dosing of controlled substances will be “held for review” until the guidelines are approved and posted.

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 RHCF’s current/active Department of Health 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); and,
- ✓ Copy of Pharmacy’s ADS Policy.
 - ADS Policy must state the date and version of said policy;
 - 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);
 - 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; and,
 - 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.

Class 11 Pharmacy – ADS ‘Renewal’

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for Class 11 Pharmacy - Automated Dispensing System (ADS license) ‘Renewal’ applications:

Documentation Required:

- ✓ Copy of current New York State Board of Pharmacy (BOP) ‘Pharmacy’ registration;
- ✓ Copy of current DEA registration for the pharmacy;
- ✓ Copy of Pharmacy’s current ADS policy; and,
 - ADS Policy must state the date and version of said policy;
 - 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);
 - 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;
- ✓ Copy of DEA registration for each ADS currently operated.

Class 11 Pharmacy – ADS ‘Amendment’ (Proposed Installation)

The following information and documentation are required of a current Class 11 Pharmacy – Automated Dispensing System (ADS) licensee prior to said licensee installing, operating and maintaining an ADS at a residential health care facility (“RHCF”). The Department of Health Bureau of Narcotic Enforcement will perform an on-site inspection of the proposed ADS at the RHCF before approval is granted to operate said ADS. (see *Guideline for Registered Community Pharmacy (Retail Pharmacy) Operations of Automated Dispensing Systems in Residential Health Care Facilities – January 2015 (Revised)* at:

- https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/docs/ads_guideline.pdf

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for Class 11 Pharmacy – Automated Dispensing System (ADS) license ‘Amendment’ applications:

Cover Letter 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 (attach copy of purchase order or rental/lease agreement); and,
- ✓ Description of the intended use of the ADS – emergency medication kit only, continuous dosing only or emergency medication kit and continuous dosing.
 - At this time, requests for Department of Health approval of ADS continuous dosing of controlled substances will be “held for review” until the guidelines are approved and posted.

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 Department of Health Class 11 Pharmacy – ADS license;
- ✓ Copy of the RHCF’s current/active Department of Health 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 ADS Policy.
 - ADS Policy must state the date and version of said policy;
 - 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);
 - 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; and,
 - 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.