



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

***License Application to Engage in a Controlled Substance Activity Instructions***

***New  
Renewal  
Amendment***

***Instructions for Form DOH-4330***

*[Instructions and Application are available on the DOH Web site as separate downloads]*

[www.health.ny.gov/professionals/narcotic/](http://www.health.ny.gov/professionals/narcotic/)

New York State Department of Health  
Bureau of Narcotic Enforcement  
Riverview Center  
150 Broadway  
Albany, New York 12204  
(866) 811-7957

Public Health Law (PHL) requires any person acting as a manufacturer, distributor, importer, exporter, institutional dispenser or institutional dispenser limited of controlled substances, or conducting research, instructional activities or chemical analysis with controlled substances in New York State to obtain a license from the Department of Health (DOH).

In order to obtain a controlled substance license, you must submit a *License Application to Engage in a Controlled Substance Activity* (DOH-4330) to the DOH Bureau of Narcotic Enforcement (BNE). The application will document that you have satisfied the licensing requirements as outlined in PHL Article 33 and the Part 80 Rules and Regulations on Controlled Substances in New York State, both of which can be found on the DOH Web site at [www.health.ny.gov/professionals/narcotic/](http://www.health.ny.gov/professionals/narcotic/).

***This package outlines the general requirements for a controlled substance license. It does not present the requirements in their entirety. It is incumbent upon the applicant to fully familiarize him/herself with all applicable Sections of PHL Article 33 and Title 10 NYCRR Part 80.***

**INSTRUCTIONS**

1. Read these instructions and the *License Application to Engage in a Controlled Substance Activity* in their entirety before completing your application.
2. Complete the application as follows (please print or type).

**APPLICANT INFORMATION** – Enter the applicant information as it should appear on your license. The address is the address where the controlled substance activity will take place. If a P.O. Box is used, a street address **must** also be included. If you are renewing or amending a license, enter your controlled substance license number.

Licenses are name - and address - specific and are non-transferrable. Class 3 (Institutional Dispenser) and Class 3A (Institutional Dispenser, Limited) licenses shall be issued as indicated on the facility's Operating Certificate.

***Upon licensing and prior to engaging in controlled substance activity, all Classes (excluding 3A) must obtain a Federal Drug Enforcement Administration (DEA) registration in the equivalent classification. Said DEA registration must coincide to the licensed location. Class 11 Pharmacy – ADS licensees must obtain written residential health care facility specific approval from BNE prior to placing controlled substances within an ADS.***

**CONTACT INFORMATION** – Enter the name, title, telephone and fax numbers and E-mail address of the contact person for the license application.

**APPLICATION TYPE** – Identify the type of application being submitted: New, Renewal or Amendment.

APPLICATION TYPE
<p><b><u>New</u></b> – If you are submitting an application for a new license, check the corresponding box and enter the date proposed for the controlled substance activity to begin.</p> <p>New applicants, as well as those reporting a relocation or change in ownership (operator), will be subject to an on-site facility inspection by BNE (excluding out-of-state applicants).</p>
<p><b><u>Renewal</u></b> – If there have been no changes to the licensee's controlled substance activity, name (legal, trade or d/b/a), ownership (operator), address and approved controlled substance schedules, check the corresponding box.</p>
<p><b><u>Amendment</u></b> – If you are submitting an application to amend your current license, check the corresponding box and attach to the application a narrative outlining the specific change(s) being requested.</p> <p>Amendments are designated as '<i>Relocation</i>', '<i>Add a Manufacturing or Distribution Activity</i>', '<i>Add a Controlled Substance and/or Schedule</i>' or '<i>Add a Further Activity</i>'. Dependent on the license class, a licensee may not qualify to apply for an amendment and shall be treated as an applicant for a new license.</p> <p>Only Class 1, 1A, 2, 2A, 9, 9A, 10 &amp; 10A licensees are eligible to apply for a relocation 'Amendment', all other licensees intent on relocating controlled substance activity shall be treated as an applicant for a new license.</p>

**LICENSE CLASSIFICATION** – Identify the license classification for which you are applying. Note the applicable fee.

Licenses are issued in the following classifications:

- Class 1 Manufacturer
- Class 1a Manufacturer (Out-of-State)
- Class 2 Distributor
- Class 2a Distributor (Out-of-State)
- Class 3 Institutional Dispenser
- Class 3a Institutional Dispenser Limited
- Class 4 Researcher (Schedules II-V) (*Individual and Institutional*)
- Class 5 Instructional Activities (Schedules II-V)
- Class 7 Research and Instructional Activities (Schedule I) (*Individual and Institutional*)
- Class 8 Analytical Laboratory
- Class 9 Importer
- Class 9a Importer Broker
- Class 10 Exporter
- Class 10a Exporter Broker
- Class 11 Pharmacy - Automated Dispensing System

A separate application and fee is required for each license classification sought. New York State, county and municipal agencies are exempt from licensing fees.

Licenses are valid for two years from their effective date. While BNE currently provides a renewal reminder notification at least 90-days prior to a license expiration, the licensee remains responsible for filing a satisfactory renewal application prior to the expiration of said license.

<b>SUBMISSION REQUIREMENTS</b>	
<b>All applicants currently licensed by BNE</b>	
Submit	✓ Copy of current controlled substance license.
<b>All applicants registered with the New York State Board of Pharmacy</b>	
Submit	✓ Copy of New York State Board of Pharmacy registration.
<b>All applicants registered with the Drug Enforcement Administration (DEA)</b>	
Submit	✓ Copy of DEA registration.
<b>Class 1 1A 2 &amp; 2A Applicants</b>	
Submit	✓ Name, residential address, and title of each officer, director and any person having 10% or greater proprietary, beneficial, equitable or credit interest in the applicant.
<b>Class 1 1A 2 2A 9 9A 10 &amp; 10A Applicants</b>	
Submit	✓ List of all Schedule I controlled substances to be manufactured, distributed, imported and/or exported.
<b>Class 3 &amp; 3A Applicants</b>	
Submit	✓ Copy of facility's legal authority to operate (e.g., operating certificate issued by DOH, OASAS, OCFS, OMH, OPWDD, etc.). In the event that the authorizing state agency has yet to issue the facility's operating certificate, secure and provide a letter from the authorizing state agency showing the temporary authority to operate pending issuance of the official operating certificate. Said written letter must identify the authorizing state agency, identify the owner/operator, identify the facility's name and address, and describe the type of facility to be operated.
<b>Class 4 5 &amp; 7 Individual Researcher <u>or</u> Instructional Activities Applicants (PHL Section 3325 &amp; Section 80.36)</b>	
Submit	✓ Completed Class 4 & 7 Individual Researcher Protocol (see Appendix A1) <b>or</b> ✓ Completed Class 5 & 7 Instructional Activities Protocol (See Appendix A2)
<b>Class 4 &amp; 7 Institutional Researcher Applicants (PHL Section 3326 &amp; Section 80.36)</b>	
Submit	✓ Completed Class 4 & 7 Institutional Researcher Statement (see Appendix B)
<b>Class 8 Analytical Laboratory Applicants (PHL Section 3326 &amp; Section 80.36)</b>	
Submit	✓ Completed Class 8 Analytical Laboratory Protocol (see Appendix C)
<b>Class 11 Pharmacy – ADS Applicants</b>	
Submit	✓ (see Appendix D)

**CONTROLLED SUBSTANCE SCHEDULE(S) TO BE UTILIZED** -- List all controlled substance schedules to be utilized. (see PHL Section 3306 for schedules of controlled substances)

**STORAGE OF CONTROLLED SUBSTANCES** -- Identify the controlled substance storage standards that are in place at your facility and provide a description. Be sure to refer to the Controlled Substance Storage Minimum Requirements that are included as part of this package.

In the event that a current licensee (*excluding Classes 1A and 2A*) intends to change the physical security of controlled substances, said storage must be inspected by a Bureau Narcotic Investigator and approved by the Bureau of Narcotic Enforcement prior to implementation to ensure the storage meets minimum security standards. Written notification, including a description of the intended storage, is to be made to New York State Department of Health, Bureau of Narcotic Enforcement, Riverview Center, 150 Broadway, Albany, NY 12204 or [narcotic@health.ny.gov](mailto:narcotic@health.ny.gov)

**SUPERVISOR OF CONTROLLED SUBSTANCE ACTIVITY** -- If an individual other than you (as the applicant or authorized representative) will be supervising the controlled substance activity, provide the application to that person and ask that he/she enter his/her name, title and type of professional license and number, and sign it.

**APPLICANT ACKNOWLEDGEMENTS** -- Read the applicant acknowledgements and answer each question presented. Applicants who answer 'YES' to any of the questions must submit a statement of explanation with documentation to support the explanation.

**APPLICANT (OR AUTHORIZED REPRESENTATIVE) SIGNATURE** -- Enter your name and title; sign and date.

3. Make a copy of your application and all supporting information/documentation for your records. Send the application, along with the requisite fee (if applicable) in the form of a check or money order made payable to the New York State Department of Health, Bureau of Narcotic Enforcement, as well as any other information/documentation required, addressed to:

New York State Department of Health  
Bureau of Narcotic Enforcement  
Riverview Center  
150 Broadway  
Albany, New York 12204

**\*\*If you are licensed and no longer engage in controlled substance activity, you must notify the Bureau of Narcotic Enforcement immediately\*\***

#### APPLICATION CHECKLIST

Did you remember to:

- Read the applicant acknowledgements then complete, sign and date the application?
- Have the Supervisor of Controlled Substance Activity sign in the applicable area of the application if he/she is an individual other than the applicant (or authorized representative)?
- Attach the requisite fee (if applicable) in the form of a check or money order made payable to the New York State Department of Health, Bureau of Narcotic Enforcement?
- Attach to your application all other information/documentation required?
- Make a copy of your completed application and all supporting information/documentation for your records?

Questions? Call (866) 811-7957 or email [narcotic@health.ny.gov](mailto:narcotic@health.ny.gov)

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<b>CONTROLLED SUBSTANCE MINIMUM STORAGE REQUIREMENTS</b>	
<b>LICENSE CLASS 1 1a 2 2a 9 9a 10 10a</b>	
<b>Schedules I and II (Section 80.13)</b>	<b>Schedules III, IV and V (Section 80.14)</b>
<p><b>VAULT</b></p> <p><u>Vaults constructed before April 1, 1973</u> must be of substantial construction with a steel door, combination or key lock and alarm system subject to approval by the Department of Health.</p> <p><u>Vaults constructed on or after April 1, 1973</u> must have walls, floors and ceilings constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half inch steel rods tied six inches on center (or structural equivalent to such reinforced walls, floors and ceilings).</p> <p>The door of the vault must contain a multiple position combination lock (or equivalent), a relocking device (or equivalent) and steel plate with a thickness of at least one-half inch (e.g., GSA Class 5 rated steel door). <i>Class M modular panels with a GSA Class 5 rated door are deemed to be equivalent to the vaults described above. Vaults must be six-sided or have floors constructed as described above.</i></p> <p>The walls or perimeter of the vault must be equipped with a tamper-proof closed circuit alarm approved by Underwriter's Laboratories with an ability to transmit a signal directly to a central protection company, local police agency or 24-hour control station operated by the licensee. If necessary, "hold-up buttons" may be required at strategic points of entry to the perimeter area of the vault.</p> <p>The vault must have a device designated to detect illegal entry and the vault door must be equipped with a contact switch.</p> <p>Vaults that remain open for frequent access must be equipped with a "day gate" (or equivalent), which is self-closing and self-locking. <b>OR</b></p>	<p><b>VAULT</b> (as for Schedules I and II ) <b>OR</b></p> <p><b>SAFE</b> (as for Schedules I and II) <b>OR</b></p> <p><b>SEPARATE ROOM OR STORAGE AREA</b></p> <p>Controlled substances must be separated from all other merchandise unless they are stored in a separate room or storage area within a building if there is limited access to the room or storage area. During working hours, the controlled substances must be kept under constant surveillance by a supervisor or other responsible party.</p> <p>An alarm system must be installed on the outer perimeter of the building, inside the storage area or on the vault or safe. The alarm system must have an ability to transmit a signal directly to a central protection company, local police agency or 24-hour control station operated by the licensee. <b>OR</b></p> <p><b>BUILDING/AREA WITHIN BUILDING</b></p> <p>The building or area within the building must have walls or perimeter fences of sufficient height and construction to provide security from burglary. The building or area within the building must have substantial doors which must be locked during non-working hours by a multiple position combination or key lock.</p>
<p><b>SAFE</b> (for small quantities only)</p> <p>GSA Class 5 rated (or equivalent). <i>Safes with a TL rating of 30 or higher are deemed to be equivalent to the GSA Class 5 rating.</i></p> <p>Safes weighing less than 750 lbs must be bolted or cemented to the floor or wall.</p> <p>The safe must be equipped with a tamper-proof closed circuit alarm system approved by Underwriter's Laboratories with an ability to transmit a signal directly to a central protection company, local police agency or 24-hour control station operated by the licensee.</p>	

The below information is provided as guidance only. It is not intended to replace law or regulation. It is incumbent upon the applicant to fully familiarize him/herself with all applicable Sections of Article 33 and Part 80.

CONTROLLED SUBSTANCE MINIMUM STORAGE REQUIREMENTS	
LICENSE CLASS 3 4 5 7 8 RESERVE AND MAIN STOCK	
Schedules I and II (Section 80.50) <i>(Schedule I is applicable to Class 7 and 8 applicants only)</i>	Schedules III, IV and V (Section 80.50)
<p><b>VAULT</b></p> <p>Existing vaults must be of substantial masonry and have a multiple position combination lock, relocating device (or equivalent) and a door having a thickness of steel plate of at least one-half inch.</p> <p>Newly constructed vaults must have walls, floors and ceilings constructed of at least eight inches of reinforced concrete. Less may be accepted where other safeguards are in place. <i>Class M modular panels with a GSA Class 5 rated door are deemed to be equivalent of the above. Vaults must be six-sided or have floors constructed as described above. OR</i></p> <p><b>SAFE OR CABINET</b></p> <p>GSA Class 5 rated (or equivalent). Safes with a TL rating of 30 or higher are deemed to be equivalent to a GSA Class 5 rating.</p> <p>The door of the safe or cabinet must contain a multiple-position combination lock, a relocking device (or equivalent) and a steel plate having a thickness of at least one-half inch.</p> <p>Safes weighing less than 750 lbs must be bolted or cemented to the floor or wall.</p>	<p><b>CABINET</b></p> <p>Stationary, securely locked and of substantial construction (i.e., metal).</p>
<p>When an institution orders/obtains Schedule I or Schedule II controlled substances, said stock is deemed to be reserve/main stock and minimum security standards must meet 80.50(a)(1)(i) or 80.50(a)(1)(ii) requirements regardless of the amount or preparation of the Schedule I or Schedule II controlled substance.</p>	
LICENSE CLASS 3 3a 4 5 7 8 WORKING STOCK	
Schedules I, II, III and IV (Section 80.50) <i>(Schedule I is applicable to Class 7 and 8 applicants only)</i>	Schedule V (Section 80.50)
<p><b>CABINET</b></p> <p>Stationary, locked, double cabinet. Both cabinets must have key-locked doors with separate keys. Cabinets must be made of steel or other approved metal.</p>	<p><b>CABINET</b></p> <p>Stationary, securely locked and of substantial construction (i.e., metal).</p>
<p>In order for an institution (<i>excluding Class 3A</i>) to store working stock of a controlled substance, said institution must maintain a reserve/main stock of said controlled substance on-site.</p>	
<p>As outlined in Section 80.50, controlled substances prescribed or ordered for a specific patient in quantities which would not exceed a 72-hour supply may be stored with the patient's other medications at the patient care unit, provided that they are kept in a securely locked medication cart or other storage unit approved by the department. In addition, certain Institutional Dispensers, Limited licensees may possess limited supplies of controlled substances in sealed emergency medication kits.</p>	
LICENSE CLASS 11	
Schedule I	Schedules II, III, IV and V (Sections 80.1, 80.5, 80.50 & 80.106)
	<p><b>AUTOMATED DISPENSING SYSTEM (ADS)</b></p> <p>An ADS inspected and approved by the Bureau of Narcotic Enforcement may be used to store Schedule II-V controlled substances in a residential health care facility ("RHCF") licensed as a Class 3a Institutional Dispensers, Limited, in accordance with associated guidelines.</p>