



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

License Application to Engage in a Controlled Substance Activity

***New
Renewal
Amendment***

Instructions and Application (DOH-4330)

[Instructions and Application are available on the DOH Web site as separate downloads]
www.health.ny.gov/professionals/narcotic/

New York State Department of Health
Bureau of Narcotic Enforcement
Riverview Center
150 Broadway
Albany, New York 12204
1-866-811-7957 (Option #1)

Public Health Law 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.

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 Department of Health's Bureau of Narcotic Enforcement. The application will document that you have satisfied the licensing requirements as outlined in Article 33 of the Public Health Law (PHL) and the Part 80 Rules and Regulations on Controlled Substances in New York State, both of which can be found on the Department of Health Web site at 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 Article 33 and Part 80.

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) (<i>Individual and Institutional</i>)
Class 5	Instructional Activities (Schedules II-V)
Class 7	Research and Instructional Activities (Schedule I) (<i>Individual and Institutional</i>)
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. New York State, county and municipal agencies are exempt from licensing fees.

Licenses are valid for two years from their effective date. Prior to the expiration date of your license, you will be provided with the materials necessary for renewal.

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. If you are using a P.O. Box, a street address **must** be included. If you are renewing or amending a license, enter your license number.

Contact Information -- Enter the name, title, telephone and fax numbers and E-mail address of the contact person for the license.

Application Type -- Indicate the type of application being submitted. **Note:** New applicants, as well as applicants who are reporting a relocation and/or a change in ownership, will be subject to an on-site inspection by the Bureau of Narcotic Enforcement (excluding out-of-state applicants).

Application Type
<p><u>New</u> -- If you are submitting an application for a new license, enter the date proposed for the controlled substance activity to begin.</p> <p>New applicants will be subject to an on-site facility inspection by the Bureau of Narcotic Enforcement (excluding out-of-state applicants). As part of the inspection, you will be required to submit information and documentation relative to the facility and its operations. You should also be prepared to demonstrate that your storage is consistent with standards outlined in Section 80.51. The Bureau of Narcotic Enforcement will contact you to establish an inspection date.</p>
<p><u>Renewal</u> -- If there have been no changes since your most recent license, check the corresponding box. Changes in name, address and/or ownership should be entered where indicated.</p> <p>Applicants who are reporting a relocation and/or a change in ownership will be subject to an on-site inspection by the Bureau of Narcotic Enforcement (excluding out-of-state applicants).</p>
<p><u>Amendment</u> -- If you are submitting an application to amend your current license, attach to the application a narrative outlining the change(s) being requested.</p>

License Classification -- Indicate the license classification for which you are applying. Note the applicable fee.

All Classes (excluding 3a) must obtain a Federal Drug Enforcement Administration (DEA) registration in the equivalent classification.

Submission Requirements	
All applicants registered with the New York State Board of Pharmacy	
Submit	✓ New York State Board of Pharmacy registration.
Class 1a 2a	
Submit	✓ DEA registration.
Class 3a	
Submit	✓ Department of Health Operating Certificate number and/or a copy of any other New York State agency license.
Class 4 5 7 8 (individual applicants) (PHL Section 3325 and Section 80.36)	
Submit	<ul style="list-style-type: none"> ✓ The curriculum vitae of the individual responsible for overseeing the controlled substance activity. ✓ A controlled substance protocol, which includes the nature and objective of the project(s), a listing of controlled substances to be utilized, the quantity of the substances and the DEA registration number of both the researcher ordering and the distributor or manufacturer providing the substances. ✓ If animals are used in the research, the species, number of animals, dose regimen and route of administration of controlled substances must be included. ✓ If the research involves the dispensing, administration or prescribing of controlled substances to human subjects, the corresponding Institutional Review Board approval must be submitted.
Class 4 7 (institutional applicants) (PHL Section 3326 and Section 80.36)	
Submit	<ul style="list-style-type: none"> ✓ A description of the system within the institution (e.g., committee) for approving, supervising and evaluating projects. ✓ The name of each committee member that will approve specific projects and his/her qualifications to serve on the committee. ✓ A listing of each currently approved and active project involving controlled substances, including the name of the project, names and qualifications of the individuals working on and supervising the project, the controlled substances being utilized, the quantity of the substances and the DEA registration number of both the researcher ordering and the distributor or manufacturer providing the substances. ✓ If the research involves the dispensing and administering of controlled substances to human subjects, the corresponding Institutional Review Board approval must be submitted.

Note to Class 4 and Class 7 Institutional Researcher Applicants: Section 3326 of the Public Health Law requires that upon approval of each project, the institution shall provide specific information related to the project to the Department of Health.

Controlled Substance Schedule(s) to be Utilized -- Indicate all controlled substance schedules to be utilized.

Storage of Controlled Substances -- Indicate the controlled substance storage standards that are in place at your facility and provide a description. Be sure to reference the Controlled Substance Storage Minimum Requirements that are included as part of this package.

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 where indicated.

Applicant Acknowledgements -- Read the applicant acknowledgements and provide an answer to each question presented.

Applicant (or Authorized Representative) Signature -- Enter your name and title; sign and date your application.

3. Make a copy of your application 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 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 no longer engaged in controlled substance activity,
you must notify the Bureau of Narcotic Enforcement immediately****

APPLICATION CHECKLIST

Did you remember to:

- Complete, sign and date the application?
- If an individual other than you (as the applicant or authorized representative) will be supervising controlled substance activity, obtain his/her name, title and type of professional license and number, and signature in the applicable area of the application?
- 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 any other documentation required?
- Make a copy of your completed application for your records?

Questions?? Call 1-866-811-7957 (Option #1)

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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 1 1a 2 2a 9 9a 10 10a	
Schedules I and II (Section 80.13)	Schedules III, IV and V (Section 80.14)
<p>VAULT</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. OR</p>	<p>VAULT (as for Schedules I and II) OR</p> <p>SAFE (as for Schedules I and II) OR</p> <p>SEPARATE ROOM OR STORAGE AREA</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. OR</p> <p>BUILDING/AREA WITHIN BUILDING</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>SAFE (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>	

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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>VAULT</p> <p><u>Existing vaults</u> 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><u>Newly constructed vaults</u> 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>CABINET</p> <p>Stationary, securely locked and of substantial construction (i.e., metal).</p>
<p>SAFE OR CABINET</p> <p>GSA Class 5 rated (or equivalent). <i>Safes with a TL rating of 30 or higher are deemed to be equivalent to a GSA Class 5 rating.</i></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>	
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>CABINET</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>CABINET</p> <p>Stationary, securely locked and of substantial construction (i.e., metal).</p>
<p>Institutional dispensers and institutional dispensers limited may utilize medication carts to stock Schedule III-V controlled substances as outlined in Section 80.50. Also in accord with Section 80.50, certain institutional dispensers limited may possess limited supplies of controlled substances in sealed emergency medication kits.</p>	
LICENSE CLASS 11	
Schedule I	Schedules II, III, IV and V (Section 80.50)
	<p>AUTOMATED DISPENSING SYSTEM</p> <p>Automated Dispensing Systems approved by the Bureau of Narcotic Enforcement may be used to store Schedule II-V controlled substances in facilities licensed as Class 3a institutional dispensers limited, in accordance with associated guidelines.</p>