NEW YORK STATE DEPARTMENT OF HEALTH

BUREAU OF NARCOTIC ENFORCEMENT

License Application to Engage in a Controlled Substance Activity Instructions

FOR ALL LICENSE TYPES:

New
Renewal
Amendment

Instructions for Form DOH-4330

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

New York State Department of Health
Bureau of Narcotic Enforcement
Riverview Center
150 Broadway
Albany, New York 12204
(866) 811-7957
bnelicensing@health.ny.gov

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).

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). Through the application process, you 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 online at www.health.ny.gov/professionals/narcotic/.

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

Duty of Notification by Licensee (10 NYCRR Part 80.110)

Persons licensed or certified pursuant to Article 33 of the Public Health Law and persons authorized to possess controlled substances in connection with the authorized activities shall promptly notify the department of:

(a) Each incident or alleged incident of theft, loss, or possible diversion of controlled substances manufactured, ordered, distributed or possessed by such person; a form of this purpose furnished by the department shall be filed with the Bureau of Narcotic Enforcement, New York State Department of Health.
(b) Any charge or proceeding brought in any court or before any governmental agency, State or Federal, in which it is alleged that the licensee, its employees, subsidiaries, managing officers, or directors has failed to comply with the provisions of the Federal Controlled Substances Act or the law of any State relating to controlled substances.

The form, DOH-5733, Notification of Disciplinary Action, can be found on the "Forms" page of our website.

License Class 3A – Institutional Dispenser Limited

Requirements:

1. Facility does not meet the requirements to apply for class 3 license, i.e. does not have a NYS registered pharmacy in the facility.
2. ***Applicants must have the regulatory operating authority to administer medications to their residents by a NYS licensed healthcare provider whose scope of practice allows the provider to administer controlled substances.***
3. Nursing home, convalescent home, health-related facility, adult care facility subject to the provisions of Title 18 NYCRR Parts 487, 488, and 490.
    a. 487.2 Definitions. (a) An **adult home** is defined as an adult care facility established and operated for the purpose of providing long-term residential care, room, board, housekeeping, personal care and supervision to five or more adults unrelated to the operator.
    b. 488.2 Definitions. (a) An **enriched housing program** means an adult care facility established and operated for the purpose of providing long-term residential care to five or more adults, primarily persons 65 years of age or older, in community-integrated settings resembling independent housing units. Such programs must provide or arrange for the provision of room,

and provide board, housekeeping, personal care and supervision.

i. *Note: Enriched housing programs without additional Department approved services ("**ALR", "EALR", or "SNALR"**), stated on their operating certificate, are not eligible for a class 3a license.*

c. 490.2 Definition. A residence for adults is an **adult care facility** established and operated for the purpose of providing long-term residential care, room, board, housekeeping, case management, activities and supervision to five or more adults, unrelated to the operator, who are unable or substantially unable to live independently.

4. Must meet the definition of a **Residential Health Care Facility** (RHCF) as defined in Public Health Law 2801(4)(b).
   a. Provide "service in a facility or facilities which provide or offer lodging, board and physical care including, but not limited to, the recording of health information, dietary supervision and supervised hygienic services incident to such service".
5. Will secure and administer controlled substances to residents only pursuant to a prescription written by a practitioner and filled by a registered pharmacy.
6. Additional NYS DOH Long Term Care Facilities that may meet the requirements for BNE licensure:
   a. Adult Homes
   b. Enriched Housing Programs certified as Assisted Living Residence approval (ALR)
   c. Enriched Housing Programs with Enhanced Assisted Living Residence approval (EALR)
   d. Enriched Housing Programs certified as Special Needs Assisted Living Residents (SNALR)

DOH-4330 APPLICATION COMPLETION INSTRUCTIONS

1. ***Please 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). It is preferable that you use Adobe to complete the application, using the "Fill & Sign" function. Electronic signatures using Adobe Certificates and Signatures are acceptable.

APPLICANT INFORMATION – Enter the applicant information as it should appear on your license.

LEGAL NAME – This is the name of the company or person to whom the license will be issued. This name must match all other legal documents submitted with the application. E.g., DEA registration.

ADDRESS - The address is the address of the exact location where the controlled substance activity will take place, including the room number, floor, etc.

MAILING ADDRESS – Use this section **ONLY** if the physical location of where the controlled substance activities will occur cannot receive U.S.P.S mail.

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 state-issued Operating Certificate.

BNE CS License # - Current BNE licensees enter your current BNE license number for renewal.

NYS Department of State ID# - Corporations and business entities registered with the NYS Department of State (DOS) Division of Corporations, must supply their DOS ID number. You may search for your DOS information on their web site at: https://www.dos.ny.gov/corps/. The legal name used on the application must match the legal name registered with the DOS. This is required for businesses, not for profit corporations, limited partnerships, limited liability companies and limited liability partnerships, as well as other miscellaneous businesses.

NYS BOP Registration # - Classes 1, 1A, 2, 2A, 2R, 3 and 11, must be registered with the NYS Board of Pharmacy (BOP) or submit a letter of exemption from the NYS BOP.

DEA Registration # -*Upon BNE licensing but prior to engaging in any controlled substance activity, all Classes (excluding 3A) must obtain a Federal Drug Enforcement Administration (DEA) registration in the equivalent classification. The DEA registration must coincide to the licensed location. A copy of the DEA registration must be sent to the BNE licensing unit upon receipt.*

REPRESENTATIVE CONTRACT INFORMATION – This is the person the licensee has designated to receive correspondence from BNE on behalf of the licensee. This may or may not be the same person who signs the application. This section is required to be completed.

APPLICATION TYPE – Identify the type of application being submitted:

APPLICATION TYPE
NEW – If you are submitting an application for a new license, check this box and enter the date proposed for the controlled substance activity to begin. New applicants, as well as those reporting a ***relocation or change in ownership (operator),*** within NYS, will be subject to an on-site facility inspection by BNE (excluding out-of-state applicants).
CHANGE **–** Licensee changes including official name, address, or ownership must submit a new DOH-4330. Enter current and new information. Requires inspection. A new BNE license number may be issued. May require facility inspection by BNE (excluding out-of-state applicants).
RENEWAL – If there have been no changes to the licensee's controlled substance activity, name (legal, trade or d/b/a), ownership (operator), address, storage, and approved controlled substance schedules, check this corresponding box. **Licensees whose license has been expired for more than 60 days are not eligible to renew their license, cannot conduct controlled substance activities, and must submit a "New" application. No extensions of expiration dates are allowed.**

AMENDMENT – If you are submitting an application to amend your current license, check this box and attach to the application a narrative outlining the specific change(s) being requested.

Amendments are designated as '*Relocation*' of storage, '*Add a Manufacturing or Distribution Activity*', '*Add a Controlled Substance and/or Schedule*' or '*Add a Further Activity*'. 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. ***An amendment may also be submitted for a change in or adding to the currently BNE approved storage for controlled substances.***

Classes 4A, 4B, 5, 7A, and 7B are required to submit an application for amendment to their license for any change in research protocol that requires the addition or removal of a controlled substance or any other change in approve controlled substance activities.

Changes in licensed storage may be submitted as an amendment. Changes in storage may require an onsite inspection to be performed.

May require facility inspection by BNE (excluding out-of-state applicants).

LICENSE CLASSIFICATION – Identify the license classification for which you are applying.

Class 1	Manufacturer
Class 1a	Manufacturer (Out-of-State)
Class 2	Distributor
Class 2a	Distributor (Out-of-State)
Class 2R	Reverse Distributor
Class 3	Institutional Dispenser
Class 3a	Institutional Dispenser Limited
Class 3c	Emergency Medical Services
Class 4	Researcher (Schedules II-V) (*Individual 4C or Institutional 4B*)
Class 4a	Researcher Special Industrial
Class 5	Instructional Activities (Schedules II-V)
Class 7	Research and Instructional Activities (Schedule I) (*Institutional 7A or Individual 7B*)
Class 8	Analytical Laboratory
Class 9	Importer
Class 9a	Importer Broker
Class 10	Exporter
Class 10a	Exporter Broker
Class 11	Pharmacy – Registered Community Pharmacy for ADS Operations

Additional information pertaining to each class and their legal requirements, may be found at: https://www.nysenate.gov/legislation/laws/PBH/A33 and https://regs.health.ny.gov/volume-1a-title-10/content/part-80-rules-and-regulations-controlled-substances.

A separate application and fee is required for each license classification sought, as well as for each location where controlled substance activities will take place. New York State, county and municipal agencies are exempt from licensing fees. Employees of an exempt entity are NOT exempt. **Licensing fees are non-refundable**.

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

Renewal applications may be received up to 90 days prior to the expiration date of the current license. Renewal applications will be processed approximately 3 weeks prior to the current expiration date.

CONTROLLED SUBSTANCE SCHEDULE(S) TO BE USED – Check the boxes for all controlled substance schedules to be used. (see PHL Section 3306 for NYS schedules of controlled substances). New York State's Controlled Substance Schedule does differ from the DEA's schedule. For class 4, 5, and 7 license applications, only those scheduled control substances for the specific research or protocol will be approved.

STORAGE OF CONTROLLED SUBSTANCES - Identify all controlled substance storage that is in place at your facility and provide a full description. Be sure to refer to the Controlled Substance Storage Minimum Requirements that are included as part of this document. Attach additional pages for descriptions if necessary. Policies and procedures for how controlled substances are secured and the methods to be used to reduce potential diversion at all times must be included. **Digital photographs of storage are required to be submitted with the application package.**

Storage Photographs – Digital photographs of all storage to be utilized under the proposed license must be submitted with the license application. Acceptable digital photograph file types are JPG, JPEG, GIF, TIFF, or BMP. Photographs of storage should depict all aspects of the storage and surrounding area, to include, but not limited to:

- Entrance and exits to the room where storage is installed
- All areas of the room (all walls to provide 360-degree view)
- All storage closed/locked and open to reveal all locking mechanisms in place and all doors and/or separated compartments

All storage and security must be installed, operational, and ready to be inspected at the time the application is submitted to BNE. Failure to assure this may lead to denial of your application.

- All security measures in-place (cameras, alarm system, biometric access, locked doors, etc.)

If a current licensee (*excluding Classes 1A and 2A*) intends to change the physical security of controlled substances, said storage must be inspected by a BNE Investigator and approved by BNE prior to usage to ensure your storage meets minimum security standards. Written notification, including a description and digital photographs of the intended storage, is to be made to bnelicensing@health.ny.gov.

SUPERVISOR OF CONTROLLED SUBSTANCE ACTIVITY – This is the individual who will be supervising the controlled substance activity at the licensed location. This may be the person who oversees inventory and record-keeping on behalf of the licensee. However, this does not exclude the licensee from his/her regulatory responsibilities. Manufacturers and distributors must meet all requirements for a supervisor of controlled substances as outlined in NYS Title 10, Part 80.11.

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 or the application may be denied.

APPLICANT SIGNATURE -- Enter your name and title, sign and date. This must be the person who has authority to make decisions that affect controlled substance activities and the overall responsibilities for the facility and licensed activities. This is typically the owner, partner, COO, CEO, or other authorized person. For Classes 3 and 3A, this is the Administrator of the facility and the person responsible for the state-issued operating authority.

Make a copy of your application and all supporting information/documentation for your records. Email the application, along with a copy of 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, to bnelicensing@health.ny.gov. Mail **only** a copy of the DOH-4330 and the application fee to:

New York State Department of Health
Bureau of Narcotic Enforcement
Attn: Licensing Unit

Riverview Center
150 Broadway
Albany, New York 12204

****If you are licensed and no longer wish to engage in controlled substance activity, you must notify the Bureau of Narcotic Enforcement immediately. All licenses must be returned to the Bureau of Narcotic Enforcement.****

SUBMISSION REQUIREMENTS **All applicants not currently licensed by BNE - New**
All applicants registered with the New York State Board of Pharmacy
Submit ✓ Copy of current New York State Board of Pharmacy registration or exemption letter
All applicants registered with the Drug Enforcement Administration (DEA)
Submit ✓ Copy of current DEA registration.
New License Applications (includes change in name, address, or ownership)
Title 10 NYCRR Part 80 Section 80.5(a)&(b): The following locations shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed: ✓ a warehouse where controlled substances are stored by or on behalf of a licensed person, unless such substances are distributed directly from such warehouse other than the licensed location from which the substances were delivered or to persons not required to be licensed in accordance with section 3305 of the Public Health Law; ✓ an office used by agents of a licensee where sales of controlled substances are solicited, made or supervised, but which neither contains such substances nor serves as a distribution point for filling sales orders. Holders of licenses shall register with the appropriate Federal agency or agencies in the comparable controlled substances schedule and license class provided for under Federal regulations.
Class 1 Manufacturer
✓ Completed DOH-4330 application with all appropriate signatures
✓ Digital photographs of all storage
✓ Letter on company letterhead specifying if final product(s) manufactured will or will not be for human and/or animal consumption
✓ 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; Each such person, if an individual, or lawful representative if a legal entity, shall submit an affidavit with the DOH-4330 setting forth: ○ any position of management or ownership during the preceding ten years of a ten percentum or greater interest in any other business, located in or outside this state, manufacturing or distributing drugs; and ○ whether such person or any such business has been convicted, fined, censured or had a license suspended or revoked in any administrative or judicial proceeding relating to or arising out of the manufacture or distribution of drugs
✓ Affidavit that managing officers are of good moral character
✓ Copy of lease or deed to show sufficient land, buildings and equipment to carry on activity as a manufacturer
✓ Policies, procedures and/or other documents revealing what mechanisms are in place to maintain effective control against diversion of the controlled substances for which the license is sought
✓ Copy of current NYS Board of Pharmacy registration as a Manufacturer, Repacker, or Outsourcing Facility or exemption letter
✓ Copy of current DEA registration as a Manufacturer
✓ Name and pharmacist registration/permit number of full-time pharmacist employed; notarized document stating person is a United States citizen or an alien lawfully admitted for permanent residence in the United States, is 21 years of age or over, has a bachelor of science or bachelor of arts degree in chemistry, pharmacology or equivalent specialization and not less than four years of experience in the manufacture of drug products; has not been convicted of a misdemeanor or felony by any court of the State of NY or by any court of the United States or any other state, and has not been or currently is a habitual user of narcotics or any other habit-forming drug(s); an affidavit signed by either the Sheriff of the county of residence, local police official, or other such person acceptable to the Department attesting that this person is of good moral character
✓ Supervisor of controlled substances (only required if final product manufactured IS intended for human consumption): name, resume/CV, and license of chemist or pharmacist employed
✓ Copy of NYS Department of State Division of Corporations entity information reflecting validity of company to conduct business in NYS https://dos.ny.gov/

✓ List of all Schedule I controlled substances to be manufactured, distributed, imported and/or exported
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 1A Manufacturer (out-of-state)
✓ Copy of home state's license and/or registration to conduct controlled substance activities or letter of exemption
✓ All other items from Class 1 Manufacturer listed above
Class 2 Distributor
✓ Completed DOH-4330 application with all appropriate signatures
✓ Digital photographs of all storage
✓ Notarized statement as to whether or not applicant will bottle or rebottle, pack or repack, label or relabel controlled substances
✓ Affidavit that managing officers are of good moral character
✓ Copy of lease or deed to show sufficient land, buildings and equipment to carry on activity as a distributor
✓ Policies, procedures and/or other documents revealing what mechanisms are in place to maintain effective control against diversion of the controlled substances for which the license is sought
✓ 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; Each such person, if an individual, or lawful representative if a legal entity, shall submit an affidavit with the DOH-4330 setting forth: o any position of management or ownership during the preceding ten years of a ten percentum or greater interest in any other business, located in or outside this state, manufacturing or distributing drugs; and o whether such person or any such business has been convicted, fined, censured or had a license suspended or revoked in any administrative or judicial proceeding relating to or arising out of the manufacture or distribution of drugs
✓ Name and pharmacist registration of full-time pharmacist employed; notarized document stating person is a United States citizen or an alien lawfully admitted for permanent residence in the United States, is 21 years of age or over, has not been convicted of a misdemeanor or felony by any court of the State of NY or by any court of the United States or any other state, and has not been or currently is a habitual user of narcotics or any other habit-forming drug(s); an affidavit signed by either the Sheriff of the county of residence, local police officials, or other such person acceptable to the Department attesting to this person is of good moral character
✓ Copy of NYS Board of Pharmacy registration as a Wholesaler
✓ Copy of NYS Department of State Division of Corporations entity information reflecting validity of company to conduct business in NYS https://dos.ny.gov/
✓ List of all Schedule I controlled substances to be manufactured, distributed, imported and/or exported.
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 2A Distributor (out-of-state)
✓ Copy of home state's license and/or registration to conduct controlled substance activities or letter of exemption ✓ All other items from Class 2 Distributor listed above
Class 3 Institutional Dispensers
✓ Completed DOH-4330 application with all appropriate signatures
✓ Digital photographs of all storage
✓ Copy current NYS DOH Article 28 operating certificate or equivalent State Agency operating authority documentation (name on DOH-4330 application must match the name found on the operating certificate)
✓ Copy of NYS Department of State Division of Corporations entity information reflecting validity of company to conduct business in NYS https://dos.ny.gov/
✓ Copy of current NYS BOP registration as a Pharmacy
✓ Copy of current DEA registration as a Hospital/Clinic
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 3A Institutional Dispensers Limited
✓ Completed DOH-4330 application with all appropriate signatures
✓ Digital photographs of all storage
✓ Copy of current NYS DOH operating certificate or equivalent State Agency operating authority documentation (name on the DOH-4330 application must match the name found on the operating certificate); County and State correctional facilities are exempt from submitting an operating certificate

✓ Copy of NYS Department of State Division of Corporations entity information reflecting validity of company to conduct business in NYS https://dos.ny.gov/
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 3C EMS Applicants
✓ Completed DOH-3826
✓ Copy of current BEMS operating certificate
✓ Digital photographs of all storage
✓ Copy of agency and/or Medical Director DEA registration
✓ List full address of all locations/bases where controlled substances are stored
✓ Copy of current controlled substance plan to include version number/date
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 4 Institutional Researcher (Schedules II – V)
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix B
✓ Digital photographs of all storage and security
✓ Qualifications for members of the research committee overseeing all research activities under the license sought
✓ Description of the system within the institution for approving, supervising, and evaluating all research projects
✓ Upon institutional approval of any research project, a description of the research, the names and qualifications of the individuals designated to supervise the research shall be submitted to the Department along with Appendix B for each research project
✓ Biannual reports on status of all projects sent to the Department (January and June)
✓ List of all locations (room number, booth, etc.) where controlled substances will be stored
✓ Policies and procedures for safe storage of controlled substance and methods used to reduce the potential for diversion
Class 4 Individual Researcher (Schedules II – V)
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix A1
✓ Digital photographs of all storage and security
✓ Copies of all research documents including, but not limited to, FDA filings, and Investigational New Drug submissions, complete research protocol, etc.
✓ Biannual reports on status of all projects sent to the Department (January and June)
✓ List of all locations (room number, booth, etc.) where controlled substances will be stored
✓ Policies and procedures for safe storage of controlled substance and methods used to reduce the potential for diversion
✓ Copy of DEA registration as a Researcher OR copy of Practitioner DEA registration if DEA deems research is incidental to a Practitioners' practice (DEA will require a state license prior to obtaining DEA registration – copy may be sent to the Department once received)
✓ Policies and procedures for safe storage of controlled substance and methods used to reduce the potential for diversion
Class 5 Instructional Activities (Schedules II – V)
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix A2
✓ Digital photographs of all storage
✓ Identification of the institution or law enforcement agency authorizing the controlled substance activities
✓ Copy of DEA registration as a Researcher OR copy of Practitioner DEA registration if DEA deems research is incidental to a Practitioners' practice (DEA will require a state license prior to obtaining DEA registration – copy may be sent to the Department once received) (Police canine licenses will submit a copy of DEA Canine registration)
✓ List of all locations (room number, booth, etc.) where controlled substances will be stored
✓ Policies and procedures for safe storage of controlled substance and methods used to reduce the potential for diversion
Class 7 Institutional Researcher (Schedule I)
✓ All items included in Class 4 Institutional Researcher
Class 7 Individual Researcher (Schedule I)

✓ All items included in Class 4 Individual Researcher
Class 7 Instructional (Schedule I)
✓ All items included in Class 5 Instructional Activities
Class 8 Analytical Laboratory Applicants (PHL Section 3326 & Section 80.36)
✓ Completed DOH-4330 application with all appropriate signatures
✓ Digital photographs of all storage
✓ Completed Class 8 Analytical Laboratory Protocol (Appendix C)
✓ List of all locations (room number, booth, etc.) where controlled substances will be stored
✓ Policies and procedures for safe storage of controlled substance and methods used to reduce the potential for diversion
✓ Copy of current DEA registration or submitted to the Department upon receipt
✓ Copy of NYS Department of State Division of Corporations entity information reflecting validity of company to conduct business in NYS https://dos.ny.gov/
Class 9 Importer – Researcher
✓ Completed DOH-4330 application with all appropriate signatures
✓ Digital photographs of all storage
✓ Affidavit of Good Moral Character for Supervisor of Controlled Substance Activity
✓ List of all locations (room number, booth, etc.) where controlled substances will be stored
✓ List of all controlled substances to be imported to New York State
✓ Identification of out-of-country manufacturer of controlled substances to be imported
✓ Copy of current DEA registration or submitted to the Department upon receipt
✓ Copy of NYS Department of State Division of Corporations entity information reflecting validity of company to conduct business in NYS https://dos.ny.gov/
Class 9 Importer – for Distribution
✓ Completed DOH-4330 application with all appropriate signatures
✓ Digital photographs of all storage
✓ Copy of NYS Board of Pharmacy registration as a Wholesaler
✓ Name, residential address, and title of each officer and director
✓ List of all schedule I controlled substances to be imported to New York State
✓ Identification of out-of-country manufacturer of controlled substances to be imported
✓ Copy of lease or deed to show sufficient land, buildings and equipment to carry on activity as an importer
✓ Affidavit of Good Moral Character for Supervisor of Controlled Substance Activity ○ If Supervisor of Controlled Substance Activity is a pharmacist, include a copy of NYS Board of Pharmacy "Pharmacist" registration is sufficient in lieu of affidavit
✓ 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; Each such person, if an individual, or lawful representative if a legal entity, shall submit an affidavit with the DOH-4330 setting forth: ○ any position of management or ownership during the preceding ten years of a ten percentum or greater interest in any other business, located in or outside this state, manufacturing or distributing drugs; and ○ whether such person or any such business has been convicted, fined, censured or had a license suspended or revoked in any administrative or judicial proceeding relating to or arising out of the manufacture or distribution of drugs
✓ Copy of NYS Department of State Division of Corporations entity information reflecting validity of company to conduct business in NYS https://dos.ny.gov/
Class 9 Importer Broker
✓ Completed DOH-4330 application with all appropriate signatures
✓ Digital photographs of all storage
✓ Copy of NYS Board of Pharmacy registration as a Wholesaler

- ✓ Name, residential address, and title of each officer and director
- ✓ List of all schedule I controlled substances to be imported to New York State
- ✓ Identification of out-of-country manufacturer of controlled substances to be imported
- ✓ Copy of lease or deed to show sufficient land, buildings and equipment to carry on activity as an importer
- ✓ Affidavit of Good Moral Character for Supervisor of Controlled Substance Activity
  - If Supervisor of Controlled Substance Activity is a pharmacist, include a copy of NYS Board of Pharmacy "Pharmacist" registration is sufficient in lieu of affidavit
- ✓ 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; Each such person, if an individual, or lawful representative if a legal entity, shall submit an affidavit with the DOH-4330 setting forth:
  - any position of management or ownership during the preceding ten years of a ten percentum or greater interest in any other business, located in or outside this state, manufacturing or distributing drugs; and
  - whether such person or any such business has been convicted, fined, censured or had a license suspended or revoked in any administrative or judicial proceeding relating to or arising out of the manufacture or distribution of drugs
- ✓ Copy of NYS Department of State Division of Corporations entity information reflecting validity of company to conduct business in NYS https://dos.ny.gov/

Class 10 Exporter

- ✓ Completed DOH-4330 application with all appropriate signatures
- ✓ Digital photographs of all storage
- ✓ Copy of NYS Board of Pharmacy registration as a Wholesaler
- ✓ Affidavit of Good Moral Character for Supervisor of Controlled Substance Activity
  - If Supervisor of Controlled Substance Activity is a pharmacist, include a copy of NYS Board of Pharmacy "Pharmacist" registration is sufficient in lieu of affidavit

Class 11 Pharmacy – Registered Community Pharmacy for ADS Applicants

- ✓ Completed DOH-4330 application with all appropriate signatures
- ✓ Copy of NYS Board of Pharmacy registration as a Pharmacy
- ✓ Copy of DEA registration as a Pharmacy
- ✓ Copy of pharmacy's policies and procedures for ADS units; must include at minimum:
  - Date and version number
  - Specific to controlled substances and E-kits
  - Assurance ADS will not be utilized for continuous dosing
  - Each E-kit will have a lock-out feature after 24-hours of initial use
  - Itemized inventory of all E-kits
    - Maximum of ten different controlled substances in unit dose packaging
      - No more than three of which may be injectable drugs
    - E-kits must meet requirements of Title VIII of Education Law as follows:
      - Medications other than controlled substances:
        - Sublingual nitroglycerin; and
        - Up to five noninjectable, prepackaged medications, not to exceed 24-hour supply
        - Total of noninjectables may not exceed 25 medications for the entire facility
        - Each E-kit shall be kept and secured within or near the nurses' station
  - How all orders, oral orders, and prescriptions will be handled
  - Approval processes in-place for the contents of E-kits and approval by RHCF's medical director, pharmacist, and DON
  - Timetable and process of replenishing E-kit inventories and by whom
  - Process for approving appropriate users to access E-kit
  - Log-in and all security measures in-place for ADS for use by authorized users

Class 11 Pharmacy – ADS Installation Requests

- ✓ Completed DOH-5290
- ✓ Copy of DEA ADS registration for location of the ADS – may be submitted after BNE approval is received
- ✓ Inventory of all E-kit contents
- ✓ Documentation affirming Class 11 pharmacy owns, rents, or leases the ADS to be installed

✓	Copy of facilities 3A license
✓	Copy of Class 11 pharmacy license
✓	Digital photographs of all sides of ADS including tethering mechanism, entrance and exits for room where ADS is to be installed, as well as all walls of the room and any and all security measures in-place (e.g., security cameras, biometrics, locked doors). Contact bnelicensing@health.ny.gov for further assistance if needed
✓	Pharmacy and facility's policies and procedures for all aspects of the ADS unit; to include at a minimum: o Date and version number o Adherence to all aspects of PHL Article 33 laws and Title 10 NYCRR Part 80 regulations o ADS to be limited to E-kit usage and no continuous dosing o Timetable and process of replenishing E-kit inventories and by whom o Process for approving appropriate users to access E-kit o Log-in and all security measures in-place for ADS for use by authorized users o How all orders, oral orders, and prescriptions will be handled o Process for approving users for the ADS o Timetable and process of replenishing E-kit inventories and by whom o Destruction procedures for discontinued controlled substances and single doses

Renewal of Currently Licensed Licensees (if license is expired, contact BNE)

BNE emails renewal reminder notices at least 90 days prior to the licensee's current expiration date. Notifications are sent to the address or email address provided on the most recent application submitted to BNE. Licensees are legally responsible to submit a complete renewal application prior to their expiration date regardless of whether the reminder notice is received or not. Licensees should set reminders for when they need to submit their renewal application to reduce the potential of unlicensed periods. Renewal applications should be sent to BNE 30 – 45 days before the current expiration date. Incomplete or otherwise deficient applications are not timely. ***If a renewal application remains deficient or incomplete by the expiration date of the license, the license is not eligible to remain valid under the NYS Administrative Procedure Act and will expire.*** Unlicensed controlled substance activities are not allowed and must immediately cease until a new license is issued.

Class 1 Manufacturer – Renewal	
✓	Completed DOH-4330 application with all appropriate signatures
✓	Copy of current NYS Board of Pharmacy registration as a Manufacturer, Repacker, or Outsourcing Facility or exemption letter
✓	Copy of current DEA registration as a Manufacturer
✓	All other items from Class 1 Manufacturer new application listed above that have changed or been updated
✓	Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 1A Manufacturer (out-of-state) – Renewal	
✓	Copy of home state's license and/or registration to conduct controlled substance activities or letter of exemption
✓	Copy of current NYS Board of Pharmacy registration as a Manufacturer, Repacker, or Outsourcing Facility or exemption letter
✓	Copy of current DEA registration as a Manufacturer
✓	All other items from Class 1 Manufacturer new application listed above that have changed or been updated
✓	Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 2 Distributor – Renewal	
✓	Completed DOH-4330 application with all appropriate signatures
✓	Copy of NYS Board of Pharmacy registration as a Wholesaler
✓	Copy of DEA Distributor registration
✓	All other items from Class 2 Distributor new application listed above that have changed or been updated
✓	Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 2A Distributor (out-of-state) – Renewal	
✓	Copy of home state's license and/or registration to conduct controlled substance activities or letter of exemption
✓	Copy of NYS Board of Pharmacy registration as a Wholesaler
✓	Copy of DEA Distributor registration
✓	All other items from Class 2A Distributor new application listed above that have changed or been updated
✓	Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement

Class 3 Institutional Dispensers – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Copy current NYS DOH Article 28 operating certificate or equivalent State Agency operating authority documentation (name on DOH-4330 application must match the name found on the operating certificate)
✓ Copy of current NYS BOP registration as a Pharmacy
✓ Copy of current DEA registration as a Hospital/Clinic
✓ All other items from Class 3 Institutional Dispenser new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 3A Institutional Dispensers Limited – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Copy of current NYS DOH operating certificate or equivalent State Agency operating authority documentation (name on the DOH-4330 application must match the name found on the operating certificate); County and State correctional facilities are exempt from submitting an operating certificate
✓ All other items from Class 3A Institutional Dispenser Limited new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 3C EMS Applicants – Renewal
✓ Completed DOH-3826
✓ Copy of current BEMS operating certificate
✓ Copy of agency and/or Medical Director DEA registration
✓ All other items from Class 3C EMS new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 4 Institutional Researcher (Schedules II – V) – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix B
✓ Copy of DEA registration as a Researcher OR copy of Practitioner DEA registration if DEA deems research is incidental to a Practitioners' practice
✓ All other items from Class 4 Institutional Researcher new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 4 Individual Researcher (Schedules II – V) – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix A1
✓ Copy of DEA registration as a Researcher OR copy of Practitioner DEA registration if DEA deems research is incidental to a Practitioners' practice
✓ All other items from Class 4 Individual Researcher new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 5 Instructional Activities (Schedules II – V) – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix A2
✓ Copy of DEA registration as a Researcher OR copy of Practitioner DEA registration if DEA deems research is incidental to a Practitioners' practice (Police canine licenses will submit a copy of DEA Canine registration)
✓ All other items from Class 5 Instructional Activities new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 7 Institutional Researcher (Schedule I) – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix A2
✓ Copy of DEA registration as a Researcher OR copy of Practitioner DEA registration if DEA deems research is incidental to a Practitioners' practice (Police canine licenses will submit a copy of DEA Canine registration)

✓ All other items from Class 7 Institutional Researcher new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 7 Individual Researcher (Schedule I) – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix A2
✓ Copy of DEA registration as a Researcher OR copy of Practitioner DEA registration if DEA deems research is incidental to a Practitioners' practice
✓ All other items from Class 7 Individual Researcher new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 7 Instructional (Schedule I) – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Appendix A2
✓ Copy of DEA registration as a Researcher OR copy of Practitioner DEA registration if DEA deems research is incidental to a Practitioners' practice
✓ All other items from Class 7 Institutional Researcher new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 8 Analytical Laboratory Applicants (PHL Section 3326 & Section 80.36) – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Class 8 Analytical Laboratory Protocol (Appendix C)
✓ Copy of current DEA registration or submitted to the Department upon receipt
✓ All other items from Class 8 Analytical Laboratory new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 9 Importer – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Class 8 Analytical Laboratory Protocol (Appendix C)
✓ Copy of NYS Board of Pharmacy registration as a Wholesaler
✓ Copy of current DEA registration or submitted to the Department upon receipt
✓ All other items from Class 9 Importer new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 9 Importer – for Distribution – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Class 8 Analytical Laboratory Protocol (Appendix C)
✓ Copy of NYS Board of Pharmacy registration as a Wholesaler
✓ Copy of current DEA registration or submitted to the Department upon receipt
✓ All other items from Class 9 Importer new application listed above that have changed or been updated
✓ Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 9A Importer Broker – Renewal
✓ Completed DOH-4330 application with all appropriate signatures
✓ Completed Class 8 Analytical Laboratory Protocol (Appendix C)
✓ Copy of NYS Board of Pharmacy registration as a Wholesaler
✓ Copy of current DEA registration or submitted to the Department upon receipt
✓ Copy of home states license for controlled substance activities as an Importer
✓ All other items from Class 9 Importer new application listed above that have changed or been updated

✓	Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 10 Exporter – Renewal	
✓	Completed DOH-4330 application with all appropriate signatures
✓	Copy of NYS Board of Pharmacy registration as a Wholesaler
✓	Copy of current DEA registration
✓	All other items from Class 10 Exporter new application listed above that have changed or been updated
✓	Check or money order made out to the NYS DOH Bureau of Narcotic Enforcement
Class 11 Pharmacy – Registered Community Pharmacy for ADS Applicants – Renewal	
✓	Completed DOH-4330 application with all appropriate signatures
✓	Copy of NYS Board of Pharmacy registration as a Pharmacy
✓	Copy of DEA registration as a Pharmacy
✓	List of all locations of ADS installations; include facility name, address, BNE 3A license number, BNE 3A license expiration date, number of E-kits and inventory of each
✓	All other items from Class 10 Exporter new application listed above that have changed or been updated
Class 11 Pharmacy – ADS Installation Requests – No Renewal Required	

Applicants for Class 4 and/or Class 7 (institutional) researcher licenses. ***As of 2020, the DEA has stated it may not accept the NYS Class 4 or 7 Institutional license for application of a DEA registration. We strongly encourage any applicant wishing to obtain an Institutional license to contact the DEA first and discuss potential options.***

Reporting of Dispensing Information Class 4 and Class 7

- In addition to the above, practitioners who dispense controlled substances are required to file with the Department of Health information regarding such dispensing. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by lawful means and includes the packaging, labeling or compounding necessary to prepare the substance for such delivery

- Researchers holding Class 4 and/or Class 7 controlled substance licenses are practitioners pursuant to Article 33 of the Public Health Law. Researchers who dispense controlled substances to research subjects as part of their protocols (as authorized by their controlled substance license) are required to report such dispensing to the Department. Researchers are not required to report the prescribing or administration of a controlled substance to a research subject

- Through the Department of Health's Health Commerce System, practitioners must also report specific controlled substance dispensing information electronically by the 15th of the month following the month in which the controlled substance was dispensed

- Researchers who dispense controlled substances as part of their research protocols must apply online at https://commerce.health.state.ny.us/pub/ to establish a Health Commerce System account

- The dispensing information requirements noted above are outlined in PHL Section 3331(6) and 80.71(e)

Licensee Reporting Requirements

- Researchers, as well as all licensees, are also under a continuing duty to promptly notify the Bureau of Narcotic Enforcement of any theft, loss or possible diversion of controlled substances using the Loss of Controlled Substances Report (DOH-2094)

- The theft or loss requirements noted above are outlined in PHL Section 3374 and Part 80.20

- NYS Public Health Law (PHL) requires licensees to notify BNE of certain changes affecting the licensee or an approved license, as well as certain changes in other facts or circumstances. Specifically, PHL §3322(3) states as follows:

  > 3. Any person licensed under this title or operating a registered outsourcing facility shall forthwith notify the department of any incident involving the theft, loss or possible diversion of controlled substances manufactured, compounded, delivered or distributed by the licensee or operator.

  - Furthermore, PHL §3374 states as follows:

    > Notification by licensee. Persons licensed or certified pursuant to this article shall be under a continuing duty to promptly notify the department of:
    >
    > 1. Each incident or alleged incident of theft, loss or possible diversion of controlled substances manufactured, ordered, distributed or possessed by such person;
    >
    > 2. Any charge or proceeding brought in any court or before any governmental agency, state or federal, in which it is alleged that the licensee, its employees, subsidiaries, managing officers, or directors has failed to comply with the provisions of the federal controlled substances act or the laws of any state relating to controlled substances.

- BNE has a form to be completed by licensees who need to submit a report. Form DOH-5723 is found online at https://www.health.ny.gov/forms/doh-5723.pdf. For each reportable incident, you must submit details describing what corrective measures you have taken to address the incident and implemented to prevent the incident from occurring again. Additional BNE forms you may find useful to ensure compliance may be found at https://www.health.ny.gov/professionals/narcotic/forms.htm.

- All of the above requirements, as outlined in Article 33 and Part 80, can be viewed on the Department of Health Web site at www.nyhealth.gov/professionals/narcotic/laws_and_regulations.htm

The Bureau of Narcotic Enforcement is committed to ensuring a smooth transition to this process. In this regard, you are encouraged to contact the Bureau with any questions via email at bnelicensing@health.ny.gov.

Questions? Email bnelicensing@health.ny.gov

Check our website often for the most up-to-date information and forms
www.health.ny.gov/professionals/narcotic/

APPENDICES

Minimum Storage Requirements for Controlled Substances:

The below information is provided as guidance only. It is not intended to replace law or regulation. It is incumbent upon applicants to fully familiarize themselves with all applicable sections of Public Health Law Article 33 and 10 NYCRR Part 80.

<table>
<tr><th colspan="2">CONTROLLED SUBSTANCE MINIMUM STORAGE REQUIREMENTS</th></tr>
<tr><th colspan="2">LICENSE CLASS 1 1a 2 2a 2R 9 9a 10 10a</th></tr>
<tr><th>Schedules I and II (Section 80.13)</th><th>Schedules III, IV and V (Section 80.14)</th></tr>
<tr><td rowspan="4">VAULT

<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.

<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).

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). 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.

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.

The vault must have a device designated to detect illegal entry and the vault door must be equipped with a contact switch.

Vaults that remain open for frequent access must be equipped with a "day gate" (or equivalent), which is self-closing and self-locking. OR</td><td>VAULT (as for Schedules I and II) OR</td></tr>
<tr><td>SAFE (as for Schedules I and II) OR</td></tr>
<tr><td>SEPARATE ROOM OR STORAGE AREA

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.

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</td></tr>
<tr><td>BUILDING/AREA WITHIN BUILDING

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.</td></tr>
</table>

SAFE (for small quantities only) GSA Class 5 rated (or equivalent). *Safes with a TL rating of 30 or higher are deemed to be equivalent to the GSA Class 5 rating.* Safes weighing less than 750 lbs must be bolted or cemented to the floor or wall. 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.	

LICENSE CLASS 3 4 5 7 8 RESERVE AND MAIN STOCK

"Main stock" is considered to be the amount of controlled substance that is ordered and received at the facility/location of the licensed activity.

Schedules I and II (Section 80.50) *(Schedule I is applicable to Class 7 and 8 applicants only)*	**Schedules III, IV and V (Section 80.50)**
VAULT 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. 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. *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**	**CABINET** Stationary, securely locked and of substantial construction (i.e., metal).
SAFE OR CABINET 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.* 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. Safes weighing less than 750 lbs must be bolted or cemented to the floor or wall.	

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.

LICENSE CLASS 3 3a 4 5 7 8 WORKING STOCK

"Working stock" is considered to be the amount of controlled substance that will be required for a specific working shift, research task, or time-period of no more than 72-hours.

Schedules I, II, III and IV (Section 80.50) *(Schedule I is applicable to Class 7 and 8 applicants only)*	**Schedule V (Section 80.50)**

CABINET Stationary, locked, double cabinet. Both cabinets must have key-locked doors with separate keys. Cabinets must be made of steel or other approved metal.	**CABINET** Stationary, securely locked and of substantial construction (i.e., metal).
In order for an institution (*excluding Class 3A*) to store working stock of a controlled substance, said institution must maintain a reserve/main stock of said controlled substance on-site.	
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.	
LICENSE CLASS 11	
Schedule I	**Schedules II, III, IV and V (Sections 80.1, 80.5, 80.50 & 80.106)**
	AUTOMATED DISPENSING SYSTEM (ADS) 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. All ADS's must be tethered or secured to the wall or floor to reduce the ability to remove the ADS from its location. Refer to the current version of the "Guidelines for Registered Community Pharmacy (Retail Pharmacy) Operation of Automated Dispensing Systems in Residential Health Care Facilities", found on our website.
REFRIGERATED STORAGE	
The storage of controlled substances within a refrigerator must meet Title 10 NYCRR Part 80 Rules and Regulations on Controlled Substances section 80.50(c)(1) requirements. Section 80.50(f). Only controlled substances shall be stored within the storage facilities described in this section. A single-lock lockbox in a refrigerator or freezer that can also be locked is permitted. The single-lock lock box must be bolted or otherwise secured to an immovable shelf within the refrigerator or freezer, or the refrigerator or refrigerator itself, in such a way that it cannot be removed. Refrigeration device weighing less than 750 pounds shall be bolted to floor or wall.	

Questions? Email bnelicensing@health.ny.gov

Check our website often for the most up-to-date information and forms
www.health.ny.gov/professionals/narcotic/

Appendix A1
Class 4 & 7 Individual Researcher Protocol

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for Class 4 & 7 Researcher (Individual) applications. All sections must be completed. **Do not enter "See Attached" as an answer**.

Applicant Name:_____

1. Applicant/Researcher/PI:

(i) Qualifications & competence (Curriculum Vitae) of the applicant to engage in controlled substance research. (Attach CV)

A typical CV will include the following information:

- *Name & Contact Information*
- *Publications & Presentations*
- *Education*
- *Grants, Honors & Awards*
- *Employment & Experience*
- *Scholarly or Professional Memberships*

If applicant is a practitioner, provide their DEA Practitioner registration: _____

DEA Practitioner Address:_____

(ii) Institution or company applicant is affiliated with for this research (name and address):_____

_____

2. Research Project:

(i) Nature & objective of the project. (Attach additional sheets as necessary)

Title of approved project:

State of purpose of research (Concise Summary):

(ii) Name, schedule & quantity of the controlled substance(s) involved. (Attach additional sheets as necessary)

Name	Schedule	Quantity

(iii) Name, DEA registration & NYS controlled substance license of suppliers of the controlled substance(s). **All suppliers must have a NYS BNE license number.** Applicant should obtain a copy of the suppliers BNE license for their records.

Company Name	DEA Registration	NYS Board of Pharmacy #	BNE Controlled Substance License #

If controlled substances are to be obtained by any means other than via a DEA registered distributor or manufacturer, explain:

_____

_____

_____. Attach additional sheets as necessary

(iv) If animals are to be utilized in the research, provide: ☐ N/A

Species	Number of Animals	Dose Regimen (e.g., 10mg/kg, three times/week for five weeks)	Route of Administration

Must include copy of approval from Institutional Animal Care and Use Committee (IACUC) for animal studies.

(v) Will controlled substances be administered or dispensed to humans? ☐ Yes ☐ No

If administering or dispensing controlled substances to humans, attach the corresponding Institutional Review Board (IRB) approval & a detailed protocol setting forth:

- Provisions for the safe administration or dispensing of controlled substances to humans
- The proposed method of selecting humans.
- Notice of Claimed Investigational Exemption for a New Drug (IND) for clinical studies

Appendix A2
Class 5 & 7 Instructional Activities Protocol

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for Class 5 & 7 Instructional Activities applications.

1. Applicant:

(iii) Applicant Name:_____

(iv) Institution authorizing the controlled substance instruction activities:

Name:_____

Address:_____

(Attach the institution's controlled substance instructional activities policy – e.g., effective controls against diversion, etc.)

2. Instructor(s):

(i) Qualifications & competence (Curriculum Vitae) of the controlled substance instructor(s) (e.g., K-9 handler, professor, etc.). (Attach CV)

A typical CV will include the following information:

- *Name & Contact Information*
- *Grants, Honors & Awards*
- *Publications & Presentations*
- *Employment & Experience*
- *Education*
- *Scholarly or Professional Memberships*

If the *Supervisor of Controlled Substance Activity* is not a controlled substance instructor, attach his/her CV as well.

3. Instructional Activities:

(vi) Nature & objective of the instructional activities. (Attach additional sheets as necessary)

Course Title:

Nature & Objective (Concise Summary):

(vii) Name, schedule & quantity of the controlled substance(s) involved. (Attach additional sheets as necessary)

Name	Schedule	Quantity

(viii) Name, DEA registration NYS BOP & NYS BNE controlled substance license of the distributor or manufacturer providing the controlled substance(s).

Company Name	DEA Registration #	NYS Board of Pharmacy #	BNE Controlled Substance License #

If controlled substances are to be obtained by any means other than via a DEA registered distributor or manufacturer, explain:
(Attach additional sheets as necessary)

Appendix B
Class 4 & 7 Institutional Researcher Statement

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for Class 4 & 7 Researcher (Institutional) applications.

1. Applicant/Institution:

i. Controlled Substance Project Approval Committee List: Name, qualifications & competence (e.g., degree & department) of each member of the institution's controlled substance project approval committee. (Attach committee list)

ii. *Controlled Substance Project System*: Description of the system within the institution for approving, supervising & evaluating controlled substance research projects. (Attach system description)

2. Research Project(s):

i. Description (Title) of the project(s). (Attach additional sheets as necessary)
ii. Name & schedule of the controlled substance(s) involved.
iii. Name(s) & qualifications (e.g., degree, position) of the individual(s) working on the project and of the individual(s) designated to supervise the project:
iv. Name, DEA registration & NYS controlled substance license of the provider(s) of controlled substance(s). All sources must have a NYS BNE license number.

2(i)	2(ii)	2(iii)	2(iii)	2(iv)	2(iv)
Controlled Substance Research Project Description (Title)	Controlled Substance: Name & Schedule	Project Participant: Name & Qualifications (degree/position)	Project Supervisor: Name & Qualifications (degree/position)	Controlled Substance Provider(s)	DEA Registration / NYS BNE License

If controlled substances are to be obtained by any means other than via a DEA registered distributor or manufacturer, explain (Note: Identify the specific project and method of obtaining):

_____
_____. (Attach additional sheets as necessary)

(ix) Will controlled substances be administered or dispensed to humans? ☐ Yes ☐ No

If a project involves administering or dispensing controlled substances to humans, attach the corresponding Institutional Review Board (IRB) approval & a detailed protocol setting forth:

- Provisions for the safe administration or dispensing of controlled substances to humans
- The proposed method of selecting humans.

Appendix C
Class 8 Analytical Laboratory Protocol

In addition to the *License Application to Engage in a Controlled Substance Activity* (DOH-4330), complete and submit the following information for Class 8 Analytical Laboratory applications.

1. Applicant:

(v) Institution authorizing the controlled substance chemical analysis activities: _____
(Attach the institution's controlled substance chemical analysis policy – e.g., effective controls against diversion, etc.)

(vi) Qualifications & competence of the analytical laboratory. (Attach any lab certifications)

2. Supervisor of Controlled Substances:

(ii) Qualifications & competence (Curriculum Vitae) of the controlled substance supervisor. (Attach CV)

A typical CV will include the following information:

- *Name & Contact Information*
- *Grants, Honors & Awards*
- *Publications & Presentations*
- *Employment & Experience*
- *Education*
- *Scholarly or Professional Memberships*

3. Chemical Analysis Activities:

(x) Nature & objective of the chemical analysis activities. (Attach additional sheets as necessary)

Title:

Nature & Objective (Concise Summary):

(xi) Name, schedule & quantity of the controlled substance(s) involved. (Attach additional sheets as necessary)

Name	Schedule	Quantity

(xii) Name, DEA registration & NYS controlled substance license of the distributor or manufacturer providing the controlled substance(s).

Company Name	DEA Registration #	NYS Board of Pharmacy #	BNE Controlled Substance License #

If controlled substances are to be obtained by any means other than via a DEA registered distributor or manufacturer, explain:
(Attach additional sheets as necessary)

(xiii) Will controlled substances be administered or dispensed to humans? ☐ Yes ☐ No

If a project involves administering or dispensing controlled substances to humans, attach the corresponding Institutional Review Board (IRB) approval & a detailed protocol setting forth:

- Provisions for the safe administration or dispensing of controlled substances to humans
- The proposed method of selecting humans.

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement

License Application to Engage in a Controlled Substance Activity

Refer to step-by-step Instructions for Applying to Engage in a Controlled Substance Activity

https://www.health.ny.gov/professionals/narcotic/licensing_and_certification/

****PLEASE USE ADOBE TO FILL-IN****

APPLICANT INFORMATION			MAILING ADDRESS	
Legal Name			**Use ONLY if U.S.P.S Mail cannot be delivered to the location where the controlled substance activities will occur.**	
d/b/a			Street/PO Box	
Street *			Address Line	
City			City	
State	Zip	County	State	Zip

BNE License # (if currently licensed)	NYS Department of State ID#	NYS BOP Registration #	DEA Registration #	**Licenses will be issued only for the physical address where the controlled substance activity will occur.**

REPRESENTATIVE CONTACT INFORMATION		
Name		Title
Telephone	Fax	Email

APPLICATION TYPE

☐ **NEW**	**Note**: New applicants and those reporting a relocation or a change in ownership will be subject to an on-site facility inspection (excluding out-of-state applicants).	Date proposed for controlled substance activity to begin. _____/_____/_____
☐ **CHANGE****	☐ **Name Change**	Prior:
		New:
	☐ **Address Change** ☐ Postal Only ☐ Physical Relocation	Prior:
		New:
	☐ **Ownership/Operator Change** ☐ **Change in Storage Only**	Prior:
		New:
☐ **RENEWAL**	☐ **No Change** since last application	
☐ **AMENDMENT**	Attach narrative outlining change(s) requested.	

LICENSE CLASSIFICATION (see instructions for multiple class requests)	New/Change/ Renewal Non-Refundable Fee	Amendment Non-Refundable Fee
☐ Class 1 Manufacturer	$1200	$250
☐ Class 1a Manufacturer (Out-of-State)	$1200	$250
☐ Class 2 Distributor	$1200	$250
☐ Class 2a Distributor (Out-of-State)	$1200	$250
☐ Class 2R Reverse Distributor	NO FEE	NO FEE
☐ Class 3 Institutional Dispenser — Operating Certificate #	$100	NO FEE
☐ Class 3a Institutional Dispenser Limited — Operating Certificate # ADS Unit Currently On-Site ☐ New ADS Unit On-Site Since Last Application ☐	$100	NO FEE
☐ Class 4 Researcher (Schedules II-V) ☐ Individual ☐ Institutional	$40	$20
☐ Class 5 Instructional Activities (Schedules II-V)	$40	$20
☐ Class 7 Research/Instructional (Schedule I) ☐ Individual ☐ Institutional	$40	$20
☐ Class 8 Analytical Laboratory	$40	$20
☐ Class 9 Importer	$1200	$250
☐ Class 9a Importer Broker	$1200	$250
☐ Class 10 Exporter	$1200	$250
☐ Class 10a Exporter Broker	$1200	$250
☐ Class 11 Pharmacy – Registered Community Pharmacy for ADS Operations	NO FEE	NO FEE

Office Use Only

Cashline:

☐ Approved ____/____/____

☐ Initial Review ____/____/____

Comment(s)

_____

_____

_____

_____

_____

_____

Reviewer:_____

** Changes to current licenses may result in the issuance of a new BNE license number.

✓ New York State, county and other municipal agencies are **exempt** from licensing fees only if they are the applicant for licensure. Employees of an exempt entity are **NOT exempt** from licensing fees.

CONTROLLED SUBSTANCE SCHEDULE(S) TO BE UTILIZED (check all that apply)

☐ I ☐ II ☐ III ☐ IV ☐ V

STORAGE OF CONTROLLED SUBSTANCES (check all that apply)

☐ Vault	**Storage must be installed and ready for inspection upon submission of this form. Describe storage and security used along with make and model numbers; photos must be submitted in a separate document:**
☐ Safe	
☐ Cabinet	
☐ Cameras	
☐ Other	

SUPERVISOR OF CONTROLLED SUBSTANCE ACTIVITY

Name	Title and Type of Professional License and Number
Signature	Email Address

APPLICANT ACKNOWLEDGEMENTS

The applicant fully understands that the license to be issued hereon shall be subject to the following stipulations and conditions:

1. The applicant is knowledgeable concerning all laws and regulations, both State and Federal, regarding the licensed activity and shall comply with such requirements.
2. The licensee shall be under a continuing duty to inform the Department of Health of any changes, such as name, address or any substantial change to the physical security and means of record keeping regarding the controlled substance(s).
3. The license privilege herein applied for, if granted, shall not be transferred. Changes in name or ownership shall be immediately reported to the Department of Health.
4. Any license so issued as a result of the application for license shall be promptly returned to the Department of Health upon revocation or suspension of the license or the Federal license for the activity or activity for which the applicant was licensed has been discontinued.
5. Licensee shall promptly report to the Department of Health each incident or alleged incident of theft, loss or possible diversion of either controlled substances or Official New York State Prescriptions. Such notification shall be by contacting the Central Office of the Department of Health's Bureau of Narcotic Enforcement and then shall be reported on the applicable Department of Health forms. **Reporting of such incident to other government agencies does not relieve the applicant of this responsibility**.
6. Manufacturers and Distributors shall comply with NYS PBH Article 33, Title 2 §3322 and Title 6 §3374 to include a tested and authenticated process for suspicious ordering monitoring and reporting requirements pertaining to order size, unusual ordering frequency, and unusual ordering patterns at a minimum.
7. Applications are valid for 90 days from date of receipt. After 90 days, if application is not approved or denied for licensure, the application will be deemed insufficient. Applicants may reapply, if they so choose, by submitting a new application and fee.

Has the applicant or Supervisor of Controlled Substance Activity been convicted of an offense in any jurisdiction relating to any substance listed in PHL Article 33 as a controlled substance? Has the applicant, its employees, subsidiaries, managing officers, or directors failed to comply with the provisions of the Federal Controlled Substance Act or the laws of any State relating to controlled substances? ☐ YES * ☐ NO	Has the applicant or Supervisor of Controlled Substance Activity ever had a State or Federal controlled substance license or registration or professional license or registration revoked, suspended, denied or restricted or been placed on probation? ☐ YES * ☐ NO	**If the applicant is a partnership, stockholder, proprietor or corporation (other than a corporation whose stock is owned and traded by the public)**: Has the business, any officer or the Supervisor of Controlled Substance Activity been convicted, fined, censured or had a license (State or Federal) suspended or revoked in any administrative or judicial proceeding relating to or arising out of the manufacture or distribution of drugs? ☐ YES * ☐ NO

***** Applicants who answer 'YES' to any of the above questions must submit a statement of explanation with documentation to support the explanation.

APPLICANT SIGNATURE

Under the penalties of perjury, I affirm that the statements herein are true, to the best of my knowledge, and that I am knowledgeable regarding the requirements of the licensed activity for which I am applying.

Name	Title
Signature of Applicant (Owner, Partner, COO, or Other Authorized Person)	Date

SUBMISSION REQUIREMENTS

Email the following to bnelicensing@health.ny.gov

- ✓ Completed DOH-4330 application
- ✓ Photocopy or scan of your check or money order issued for application fee
- ✓ All supporting, required documentation, images of all storage, and forms for the class of license being applied for

Submit to mailing address:

NYS DOH Bureau of Narcotic Enforcement
Riverview Center
Attn. Licensing Unit
150 Broadway
Albany, NY 12204

- ✓ Check or money order for licensing fee made out to:
  NYS DOH Bureau of Narcotic Enforcement
- ✓ Photocopy of DOH-4330 that was emailed – no additional documentation