



The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Department of Public Health
 Division of Health Professions Licensure
Board of Registration in Pharmacy
 239 Causeway Street, Suite 500, 5th Floor
 Boston, MA 02114
<http://www.mass.gov/dph/boards/pharmacy>
 PH (617) 973-0960 ~ FAX (617) 973-0980
 TTY (617) 973-0895

Return application (s)
 with check or
 money order
 payable to:
**Commonwealth of
 Massachusetts**
Application Fee
\$750.00

*All fees are non-
 refundable*

APPLICATION FOR REGISTRATION OF AN OUTSOURCING FACILITY

Resident Non-Resident

Name & Location of Facility:

Company Name: _____ FEIN Number: _____

Street Address: _____

City/State/Zip: _____

Parent Company (if none, write "None"): _____

Type of Ownership: Sole Proprietorship Corporation LLC

Telephone: _____ Email: _____

DEA Number (if shipping controlled drugs): _____

Name of Owner(s): Indicate Individual, Partners (use additional paper if needed)

Name _____ Title _____

Address _____

City _____ State _____ Zip _____

Telephone _____ Email _____

For applicants located outside of Massachusetts: Is your company registered by an applicable licensing authority in the state of location? Yes * No** N/A

**If yes, you must attach a copy of your current home-state registration to this application.*

Is your company registered as a 503B Outsourcing Facility by the FDA? Yes No

Registration number _____

Has your company been inspected by the FDA? Yes No

Date of most recent FDA inspection: _____

Has the facility had an FDA inspection within the last two years? Yes No (if yes, attach proof of inspection)*

**Proof of inspection may include a copy of the FDA's Notice of Inspection or Form 483, or publication of the inspection date(s) on the FDA website listing 503 B registered outsourcing facilities.*

Has the applicant's outsourcing facility ever been suspended, revoked or otherwise disciplined? Yes* No

(If yes, attach a detailed explanation, along with copy of legal documentation of discipline)

Suitability of Applicant, Registrant or Interest Holder

The following questions pertain to any owner or corporate officer of the requesting facility.

Has an applicant, registrant or interest holder owned, operated, or held an interest in an outsourcing facility, pharmacy, healthcare facility, or other entity registered by the Federal Food and Drug Administration ("FDA") or the Federal Drug Enforcement Administration ("DEA") that was the subject of proceedings which resulted in the discipline, suspension, denial, or revocation of the outsourcing facility's registration or other professional license or registration? Yes No

Has an applicant, registrant, or interest holder owned, operated or held an interest in an outsourcing facility, pharmacy, healthcare facility, or other entity registered by the FDA or the DEA, that entered into a settlement agreement in resolution of a complaint against an outsourcing facility, pharmacy, healthcare facility, or other entity registered by the FDA or DEA resulting in the imposition of discipline upon the outsourcing facility registration or other professional license or registration? Yes No

Has an applicant, registrant or interest holder held a professional license or registration that was the subject of proceedings which resulted in the discipline, suspension, denial or revocation of the license or registration? Yes No

Has an applicant, registrant or interest holder entered into a settlement agreement in the resolution of a complaint against a professional license or registration resulting in imposition of discipline upon the professional license or registration? Yes No

Has an applicant, registrant or interest holder had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or other sanctions(s) by federal, state or local governmental agency of any license or registration currently or previously held by the applicant or licensee for the manufacture or distribution of any drugs, including controlled substances? Have any applications for licensure been denied by any federal or state agency? Yes No *List and explain. Attach additional sheets if necessary.*

If also shipping controlled drugs, provide the name, telephone#, fax# email address and & mailing address of the person to whom communication regarding controlled substance distribution records may be directed (a copy of your company's DEA permit must also be attached)

Name _____ Email _____
Address _____ City _____ State _____ Zip _____
Telephone _____ Fax _____ Email _____

Which of the following entities do you sell/ship to? (Check all that apply)

Patients Retail Pharmacies Hospital Pharmacies Licensed Clinics/Surgical Centers
Practitioners (MD, DMD, DVM, APRM, PA-C) Other _____

AFFIDAVIT (MUST BE COMPLETE AND NOTARIZED)

Pursuant to M.G.L. c. 62C, s. 49A, I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

I hereby state that I am the person authorized to sign this application for all licensure; that all statements are true and correct in all respects and are made under the penalties of perjury.

X _____
Signature of applicant, registrant or interest holder Date

Sworn and subscribed before me this _____ day of _____

Notary Public signature _____

Notary Seal

My commission expires _____

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RESIDENT OUTSOURCING

To be completed by resident outsourcing facilities only

APPLICATION FOR MA CONTROLLED SUBSTANCE REGISTRATION FEE: \$225.00

I hereby apply for Registration under Mass. Controlled Substances Act-M.G.L. 94C Section 7.

Applicant Name (Corporation) _____

Business Address _____
(No. and Street)

_____ (City or Town) (State) (Zip Code)

Registration Classification:

(a) _____ Retail Drug Store (Pharmacy / Pharmacy Dept.)

(b) _____ Wholesale Distributor

(c) _____ Nuclear

FEIN Number: _____

FOR BOARD USE ONLY

Cash _____ Check _____
No. _____ Date _____ M.O. _____

Drug Schedule

Please check applicable controlled substance(s):

- Schedule II Schedule III () Schedule IV () Schedule V () Schedule VI
() Non-Narcotic () Non-Narcotic
() Narcotic () Narcotic

If applicable, notate current Drug Store Permit Number: _____

If applicable, notate current Wholesale Distributor / Druggist License Number: _____

Signature of Applicant _____
(Owner of facility must sign application)

Name of Applicant whose signature appears above _____

Please submit check or money order for \$225.00 payable to the Commonwealth of Massachusetts.

WARNING:

In accordance with Chapter 94 M.G.L. Sec 13, the Board of Registration in Pharmacy in the case of a retail drug business or wholesale druggist, may suspend or revoke a registration to manufacture, distribute, dispense or possess a controlled substance after a hearing pursuant to the provisions of Chapter 34A and upon finding that the registrant has furnished false or fraudulent information in any application filed under the provisions of Chapter 94C.

ALL FEES ARE NON-REFUNDABLE AND NON-TRANSFERABLE

Attachments Required:

- If shipping controlled drugs, attach a copy of the facility's current DEA Registration Certificate.
- If a Resident outsourcing facility, a completed MA Controlled Substance Registration application.
- Non-Residents: If licensed or registered by your home-state, attach a copy of your current home-state license or registration.
- A copy of a valid, current registration with the FDA pursuant to section 503B of the Federal Food, Drug and Cosmetic Act.
- Proof of FDA Inspection within the last two years***

**Proof of inspection may include a copy of the FDA's Notice of Inspection or Form 483, or publication of the inspection date(s) on the FDA website listing 503 B registered outsourcing facilities.*

If the applicant is an entity you must submit the following items:

- A certificate of good standing and legal existence issued by the Secretary of State, or the equivalent, in the state in which the entity was organized or formed.
- A statement of the name and address of each officer, director, or partner of the entity and the position held;
 - The "doing business as" (DBA) name of the entity; and
 - If the corporation is not publicly owned, the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s); and
 - If the outsourcing facility is licensed or registered by another state, proof of good standing from the licensing or registering authority in that that was issued within three months and;

Controlled Substance Permit:

All **resident** applicants are required to complete both an outsourcing facility application and a controlled substance application. The controlled substance application can be found at

<http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/pharmacy-control-substance.pdf>

Non-resident applicants should only complete the outsourcing facility application. The controlled substance application does not apply.

For complete information regarding registration of a resident or non-resident outsourcing facility, please refer to 247 CMR 11.00 and 247 CMR 21.00. Board regulations may be found at www.mass.gov/dph/boards/ph. If additional information is needed, please contact the Board office at (800) 414-0168. All fees are non-refundable and non-transferable.