***** Submit This Cover Page With Application *****

FOR OFFICE USE ONLY	
Receipt #:	
ID#:	
Issue Date:	
License #	**DIS** **CDIS**

Rhode Island
Board of Pharmacy
Room 205
3 Capitol Hill
Providence, RI 02908-5097

Instructions and Application For

Distributor License and Controlled Substances Registration

☐ New Application ☐ Wholesaler ☐ Manufacturer

☐ Controlled Substances Registration

☐ Change of Location (License # _____)

☐ Change in Ownership (License # _____)

_____

Applicant - Print Pharmacy/Facility Name

Phone: (401) 222-2837 **TTY/TDD: (800) 745-5555** **Fax: (401) 222-2158**

Revised 12/10/2012 jcp

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GENERAL INFORMATION

Enclosures

The following materials and information should be enclosed within this application packet:

Licensure Requirements

Wholesaler

- **In State** - Application Fee of **$220.00** (add $100.00 for Controlled Substances Registration for a total of **$320.00**) Check or money order only (**NOTE:** All application fees are **non-refundable**)
- **Out-Of-State** - Application Fee of **$340.00** (add $100.00 for Controlled Substances Registration for a total of **$440.00**) Check or money order only (**NOTE:** All application fees are **non-refundable**)
- Federal Drug Enforcement Administration (DEA) Registration (if applicable)
- Licensure in state in which located (for Out-of-State Wholesalers)

Manufacturer

- **In State** - Application Fee of **$220.00** (add $100.00 for Controlled Substances Registration for a total of **$320.00**) Check or money order only (**NOTE:** All application fees are **non-refundable**)
- **Out-Of-State** - Application Fee of **$340.00** (add $100.00 for Controlled Substances Registration for a total of **$440.00**) Check or money order only (**NOTE:** All application fees are **non-refundable**)
- Federal Registration of Establishment/Facility
- Federal Drug Enforcement Administration (DEA) Registration (if applicable)
- Licensure in state in which located (for Out-of-State Manufacturers)

Every wholesale distributor and/or manufacturer, wherever located, who engages in wholesale distribution into, out of, or within this state, must be registered licensed by the Board in accordance with the laws and regulations of this state, before engaging in wholesale distribution of prescription drugs. Where operations are conducted at more than one location by a single wholesale distributor, each such location distributing into the state shall be registered licensed by the Board. Each board of pharmacy in the state(s) in which the applicant holds a registration or license shall submit to the Department in this state a statement confirming the applicant holds a current license in good standing in said state.

A "**Wholesaler**" is a person who buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers. A "Wholesale Distributor" is anyone engaged in the wholesale distribution of drugs, including, but not limited to, manufacturers, repackers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses, independent wholesale drug traders, and retail pharmacies that conduct wholesale distribution.

"**Manufacturer**" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or poisons. "Manufacturing" means the production, preparation, propagation, conversion or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substances or labeling or relabeling of its container, and the promotion and marketing of such drugs and devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacists, practitioners, or other persons.

GENERAL INFORMATION (CONTINUED)

Wholesale drug distributors and/or manufacturers that deal in controlled substances shall register with the Department of Health, and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulations.

"**Wholesale distribution**" means distribution of prescription drugs to person other than a consumer or patient, but does not include:

- intracompany sales;
- the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
- the sale, purchase or trade of a drug of an offer to sell, purchase, or trade a drug by a charitable organization to a non-profit affiliate of the organization to the extent otherwise permitted by law;
- the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control. For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;
- the sale, purchase or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;
- the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription.
- the lawful distribution of drug samples by manufacturers' representatives or distributors' representatives.
- the sale, purchase, or trade of blood and blood components intended for transfusion.

Where operations are conducted at more than one location by a single wholesale distributor, each such location distributing into the state shall be licensed by the Board. Each board of pharmacy in the state(s) in which the applicant holds a registration or license shall submit to the Department in this state a statement confirming the applicant holds a current license in good standing in said state.

Rules and Regulations

To obtain the Rules and Regulations for your profession visit the A-Z list on the Topics & Programs page at the following web site. From the list click on the letter for your profession.

http://www.health.ri.gov/atoz/

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APPLICATION PROCESS OVERVIEW

The licensure process in the State of Rhode Island is conducted by the Rhode Island Department of Health (HEALTH), Office of Health Professions Regulation, and the Rhode Island Board of Pharmacy (BOARD).

Application Process

This application is to be used for a new license as a drug distributor (out-of-state wholesaler or manufacturer),and to apply for a new license due to a change in ownership or location. A license will be issued to a person,owner, corporation, or other legal entity, hereinafter called the "Licensee". The license shall entitle the owner to operate such facility at the location specified and shall not be transferred. When there is a change in ownership, operation and/or location, the license immediately becomes void and shall be delivered by the licensee to the BOARD. It is the duty of the owner to immediately notify the BOARD of any proposed change of location or ownership, and to file the required application prior to the change. Changes in any information required bythis section shall be submitted to the Department within fifteen (15) days of change.

"Change of ownership" means:

a. In the case of a pharmacy, manufacturer or wholesaler which is a partnership which results in a new partner acquiring a controlling interest in the partnership;

b. In the case of a pharmacy, manufacturer or wholesaler which is a sole proprietorship, the transfer of the title and property to another person;

c. In the case of a pharmacy, manufacturer or wholesaler which is a corporation:

i. A sale, lease exchange, or other disposition of all, or substantially all of the property and assets of the corporation; or
ii. A merger of the corporation into another corporation; or
iii. The consolidation of two or more corporations, resulting in the creation of a new corporation; or
iv. In the case of a pharmacy, manufacturer or wholesaler which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in the corporation; or
v. In the case of a pharmacy, manufacturer or wholesaler which is a nonbusiness corporation, any change in membership which results in a new person acquiring a controlling vote in the corporation.

All items listed on the "checklist" (page 11) must be submitted for an application to be considered complete. All applications are considered valid for six months from the day they are received at HEALTH. If you do not complete the application process and obtain a license within those six months, a new application and fee must be submitted.

If the applicant has had criminal or disciplinary history in Rhode Island or another state, it may take an additional two or three months for all pertinent documentation to be received, and a decision to be made regarding the issuance of a license. This is an estimate of the amount of time that is required to become licensed. The entire process may take more or less time than estimated.

Licenses will be issued within five working days following the Board's approval of the completed application. Wall permits are mailed approximately two weeks from the date of issuance, and are mailed to the address furnished in the application. It is the applicant's responsibility to notify the BOARD, in writing, if there are changes during the interim, or at any time after the license is issued.

APPLICATION PROCESS OVERVIEW
(continued)

HEALTH will not, for any reason, accelerate processing of one applicant at the expense of other applicants. Once completed, the application will be reviewed, and will be contacted by the BOARD if further information is required. Be advised, the applicant may be required to appear for an interview.

NOTE:

Licensure application materials are public records as mandated by Rhode Island law and may be made available to the public, unless otherwise prohibited by State or Federal Law.

The license will expire on September 30th ***(regardless of the date issued)***, and a form will be mailed to renew the pharmacy license for the period October1st through September 30th. It is the licensee's responsibility to maintain an active license. If a renewal is not received, the licensee is to contact the BOARD to follow-up on the status of the renewal:

https://healthri.mylicense.com/Verification/

Please continue to review the remaining portions of this application packet for instructions and other materials necessary to complete the Board application. If you have any questions about this application process, or would like to check on the status of your BOARD application, please contact the BOARD at (401) 222-2837.

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INSTRUCTIONS FOR COMPLETING THE BOARD APPLICATION

Read the following instructions and those throughout the application packet carefully before completing the Board application. **Only complete applications with the appropriate fee will be accepted.** Failure to submit all required information and appropriate documentation may result in processing delays. All of the information provided is subject to change.

General Instructions

1. Make a copy of the application and forms before you begin in case you make a mistake.

2. Type the information or print in blue or black ball-point pen. Board staff will not make assumptions about illegible information. Be sure to print the licensee's name in the box provided on the cover page.

3. Provide a response to each section or question; otherwise mark "N/A" for Not Applicable.

4. It is suggested that a copy of the completed application be made before submitting it to the Board.

5. It is the applicant's responsibility to check on the status of the application.

Completing your Board Application

1. Complete the **Board Application** pages (6-10). Respond to all components of the application as instructed. If you attach separate pages in continuation of the Board application, such pages MUST clearly indicate the section for which such information is being reported.

2. Make a check or money order (in U.S. Funds only) for the application fee(s) per the instructions, payable to **General Treasurer, State of Rhode Island** and staple it to the upper left-hand corner of the cover page of the application.

A Controlled Substances Registration (CSR) is mandatory for all new pharmacies that will dispense controlled substances. The fees are NONREFUNDABLE. A Drug Enforcement Administration (DEA) Registration is also required. **Contact the DEA at 617-557-2200 for the application**

http://www.deadiversion.usdoj.gov./drugreg/reg_apps/index.html

The RI CSR is contingent upon a DEA Registration being issued.

Complete all application materials as instructed and arrange them in order as they appear in the application checklist (see page 11). Do not submit applications without all applicable information, documentation and fee. Mail these components of the application to:

Rhode Island Department of Health
Board of Pharmacy, Room 205
3 Capitol Hill
Providence, RI 02908-5097

State of Rhode Island
Board of Pharmacy

Application for Distributor License and Controlled Substances Registration

Refer to the Application Instructions when completing these forms. Type or block print only. Do not use felt-tip pens.

1. Facility Name:

Facility Name

2. Contact Person

Provide the name of an individualt who is responsible for the day-to-day operations of the facility.

Title (Mr., Mrs., Ms., etc.)

First Name

Middle Name

Surname, (Last Name)

Suffix (i.e., Jr., Sr., II, III) | Area Code | Phone Number | Extension | ☐ Unlisted?

3. Facility Mailing Information:

Please provide the mailing information for all communication regarding this license. It is your responsibility to notify the board of all address changes.

This information <u>will NOT</u> appear on the HEALTH Web site.

First Line Address

Second Line Address

Third Line Address

City | State | Zip Code

Country, If <u>NOT</u> U.S. | Postal Code, If <u>NOT</u> U.S.

Mailing Address Phone | Extension | Mailing Address Fax

Email Address (Format for email address is Username@domain e.g. applicant@isp.com)

4. Facility Location Information:

It is your responsibility to notify the board of all address changes.

This information <u>will</u> appear on the HEALTH Web site.

First Line Address

Second Line Address

Third Line Address

City | State | Zip Code

Country | Postal Code, If <u>NOT</u> U.S.

Facility Phone | Extension | Facility Fax

Email Address (Format for email address is Username@domain e.g. applicant@isp.com)

5. Type of Ownership

Please Check ONE

☐ Corporation ☐ Limited Liability Company ☐ Partner

☐ Sole Proprietorship ☐ Limited Partnership ☐ Partnership

☐ Governmental Entity ☐ Other (Describe):

Applicant: Print your complete business name >

6. Ownership Information:

Provide the name address and telephone number(s) of the facility/ business owner in the spaces provided.

NOTE:

If practitioner ownership, please provide aggregate financial interest and attach information to this application.

Name of Owner

D.B.A. (Doing Business As)

First Line Address

Second Line Address

Third Line Address

City | State/Province | Zip Code

Country, If NOT U.S. | Postal Code, If NOT U.S.

Facility Phone | Extension | Facility Fax

Email Address (Format for email address is Username@domain e.g. applicant@isp.com)

U.S. Social Security Number (SSN)

Federal Employer Identification Number (FEIN)

"Pursuant to Title 5, Chapter 76, of the Rhode Island General Laws, as amended, I attest that I have filed all applicable tax returns and paid all taxes owed to the State of Rhode Island, and I understand that my Social Security Number (SSN)//Federal Employer Identification Number (FEIN) will be transmitted to the Divison of Taxation to verify that no taxes are owed to the State."

NOTE: If you are the sole proprietor of a facility or business, then you must supply your Social Security Number (SSN). If you are an individual representing a facility or a business that is seeking licensure, then you must supply the Federal Employer Identification Number (FEIN) for the facility or the business.

7. Rhode Island Controlled Substances Registration (CSR)*

Complete this area to apply for a registration to dispense and possess controlled substances in the State of Rhode Island (*additional fee required*).

NOTE: The CSR is renewed at the same time as the pharmacy license.

Do you wish to apply for a Rhode Island Controlled Substances Registration?

☐ Yes ☐ No **If "Yes", the additional fee must be included in the attached payment**

Drug Schedules - Check all applicable

☐ Schedule I **Attach Protocol** ☐ Schedule II ☐ Schedule III ☐ Schedule IV ☐ Schedule V

Drug Enforcement Administration (DEA Registration)

DEA Number ☐ Pending**

*A CSR is not required if there are no controlled substances stored or dispensed on the premises.

****A copy of the DEA Registration must be provided to the BOARD within 60 Days of issuance**.

8. Discipline Question

1. Have any of your licenses to manufacture, distribute, or dispense been denied or disciplined in any state or jurisdiction? ☐ Yes ☐ No

NOTE: If you answer "Yes" to this question, you are **required** to furnish complete details, including date, place, reason and disposition of the matter.

Carefully read this section.

IMPORTANT INFORMATION

Licensed pharmacies cannot dispense or possess controlled substances in the State of Rhode Island without a valid professional license, Rhode Island Controlled Substances Registration (CSR), and a federal Drug Enforcement Administration (DEA) Registration. "Controlled Substances" for purposes of this application, means a prescription drug in Schedules II through V, pursuant to the Rhode Island Uniform Controlled Substances Act, and 21 CFR 1300 of the Federal Code of Regulations. Schedule I drugs are used by researchers, and require the submission of a protocol.

Without a Rhode Island CSR, and federal DEA Registration, pharmacies may dispense or possess non-controlled prescription medications under its pharmacy license. No CSR will be granted to a pharmacy applicant whose application is "pending" in this state.

All applicants must make application to the U.S. Drug Enforcement Administration for a federal registration. Federal regulations require that applicants comply with individual state requirements before they are issued a DEA Registration.

Registration Unit
US Drug Enforcement Administration
JFK Federal Building
15 New Sudbury Street
Boston MA 02203-0131
(617) 557-2200

Issuance of a Rhode Island Controlled Substances Registration is contingent upon registration from the U.S. Drug Enforcement Administration. If denied a "DEA Registration", the Rhode Island Controlled Substances Registration becomes "VOID".

*****A copy of the DEA Registration must be provided to the BOARD within 60 days of its issuance.***

9. Affidavit of Applicant

Complete this section and sign in the presence of a notary public.

Make sure that you and the notary public have completed all components accurately and completely.

I, _____, being first duly sworn, depose and say that I am the person referred to in the foregoing application and supporting documents.

I hereby authorize all hospital(s), institution(s) or organizations(s), my references, personal physicians, employers (past and present) and all governmental agencies and instrumentality's (local, state, federal or foreign) to release to the Rhode Island Board of Pharmacy any information which is material to my application for licensure.

I have read carefully the questions in the foregoing application and have answered them completely, without reservations of any kind, and I declare under penalty of perjury that my answers and all statements made by me herein are true and correct. Should I furnish any false information in this application, I hereby agree that such act shall constitute cause for denial, suspension or revocation of my license to practice pharmacy in the State of Rhode Island.

I understand that this is a continuing application and that I have an affirmative duty to inform the Rhode Island Board of Pharmacy of any change in the answers to these questions after this application and this affidavit is signed.

_____ _____

Signature of Applicant Date of Signature (MM/DD/YY)

The foregoing instrument was acknowledged before me this _____ day of _____, 20_____, by _____, who is personally known to me or has produced _____ as documentation and did / did not take an oath.

_____ _____

Name of Notary (Print, Type or Stamp) Signature of Notary

Notary Seal

_____ _____

Notary No/Commission No. Commission Expiration Date (MM/DD/YY)

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APPLICATION CHECKLIST

Please review the following checklist to ensure that all the components of the application process have been satisfied. Some items may not apply.

Board Application

- ☐ I have read and understand the "Instructions for Completing the Application".
- ☐ I have completed the Rhode Island Board application as instructed (pages 7-10).
- ☐ I have removed the "General Information", "Overview" and "Instructions" sections and have attached the cover page to the top of the remainder of the application.
- ☐ I have completed Section 8, **"Affidavit of Applicant"**, and had the form notarized by a notary public.
- ☐ I have a **check** or **money order** (preferred), made payable (in U.S. funds only) to the ***"RI General Treasurer"*** and attached it to the upper left-hand corner of the cover (Top) page of the application.
- ☐ I have arranged my Board Application materials in the following order.

    1. Fee (attached as instructed).
    2. Board Application (includes cover page and pages 7-10).
    3. Supporting documentation as required [**Note:** Pages containing additional information in continuation of the Board application MUST indicate the section for which the information is being reported].
    4. A complete list of all direct or indirect owners with percentages of ownership indicated.

- ☐ I have mailed the above application materials directly to the Rhode Island Department of Health, Board of Pharmacy.
- ☐ I have contacted the Drug Enforcement Administration concerning a federal DEA Controlled Substances Registration (CSR), if applicable.