CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE

BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: DPR.DELAWARE.GOV
EMAIL: customerservice.dpr@state.de.us

APPLICATION FOR DISTRIBUTOR (PHARMACY-WHOLESALE) PERMIT
INSTRUCTION SHEET

When to File Application

This is the application for facilities that distribute on a wholesale basis:

- Drugs, toilet preparations, dentifrices, and cosmetics to persons other than the ultimate consumer (24 *Del. C*. §§2540)
- Medical gases ***to other facilities*** authorized to possess medical gases.

Note: If you are a facility that sells medical gases ***directly to patients*** in Delaware, the correct application form is *Application for Medical Gas License*.

File this application for a Pharmacy-Wholesale license when applying for an initial license OR re-applying when a previous Delaware license has lapsed and is no longer renewable. Since these licenses are not transferable, you must also file this application to report when a distributor already licensed in Delaware:

- Changes ownership (controlling interest), or
- Relocates.

A Pharmacy-Wholesale permit terminates automatically when the controlling interest in the facility changes, the facility's legal existence ends, or the business ceases to operate (24 *Del. C*. §2540 (d)).

Requirements for All Applicants

Please read and follow instructions carefully. Failure to follow instructions may delay your application.

☐ Submit completed, signed and notarized *Application for Distributor (Pharmacy-Wholesale) Permit*.
- Applications that are incomplete, unsigned or not notarized will be rejected.

☐ Enclose non-refundable processing fee by check or money order made payable to the "State of Delaware."

☐ Enclose *Distributor Permit–Information about Ownership* forms for ***all*** of the following:
- Designated Representative (DR) or most senior person responsible for facility operations, purchasing, and inventory control
- Supervisor of the DR or most senior person responsible for facility operations, purchasing and inventory control
- If the distributor is not a publicly held company, ***all*** principals and owners who directly or indirectly own more than 10% interest in the company

☐ Each person who is required to complete a *Distributor Permit–Information about Ownership* form must also complete a *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.

☐ If the facility is not located in Delaware, arrange for the Board office to receive a *License Verification for Distributors* form from the licensing agency for the state where the facility is located.

☐ Enclose a drawn plan ***and*** full description of this distributor's site—including each area utilized for drug storage, distribution, or both—*at this location*. The description should include:
- square footage
- security and alarm system descriptions
- terms of lease or ownership
- quarantined area for damaged, outdated, deteriorated, misbranded, or adulterated drugs
- temperature and humidity controls.

☐ Enclose a copy of the deed or lease for the property on which the wholesale distributor's establishment is located.
- If leased, the lease must be for an original term of not less than one calendar year.

☐ If the distributor is a repackager or manufacturer with the Food and Drug Administration, enclose a copy of the regulatory letter.

Reporting a Distributor Name Change

If the facility's name changes, but ***there is no change in ownership nor in location***, it is not necessary to submit an *Application for Distributor (Pharmacy-Wholesale) Permit*. Instead, submit:

☐ Letter notifying the Board of the change that includes the distributor's old name and new name, license number and effective date of the change.

☐ Duplicate license fee by check or money order made payable to the "State of Delaware."
- The duplicate license will show the new name, but the license number will not change.

Controlled Substances Registration

If the facility also distributes controlled substances, a separate *Controlled Substances Application for Facilities* application is required.

A distributor must have a Delaware Distributor (Pharmacy-Wholesale) permit, Delaware controlled substance registration and federal DEA permit before storing and/or distributing controlled substances in Delaware.

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STATE OF DELAWARE

BOARD OF PHARMACY

For Board of Pharmacy Use Only
- ☐ **Verification**
- ☐ **Background**
- ☐ **Office Approval**
- ☐ **Inspection**

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APPLICATION FOR DISTRIBUTOR (PHARMACY-WHOLESALE) PERMIT

TYPE OF APPLICATION

1. Select the items that describe the type of application:

   ☐ Initial Application –
   - ☐ This distributor has never held a Delaware Pharmacy-Wholesale license.
   - ☐ This distributor previously held Pharmacy-Wholesale license number **A4-** _____ that has lapsed and is no longer renewable.

   ☐ Application Due to Change of Ownership – Pharmacy-Wholesale license number **A4-** _____

   ☐ Application Due to Relocation of Facility – Pharmacy-Wholesale license number **A4-** _____

2. Select type of items distributed: ☐ Drugs ☐ Medical Gases ***Only***

CONTACT AND LOCATION INFORMATION

3. Name of Business (as it should appear on license): _____

4. Enter all other trade or business names you use (or have used) such as "doing business as" or "formerly known as" names: _____ _____ _____

5. ***Location* Address**: _____
   Street (*No PO Boxes*)

   _____ _____ _____
   City State Zip

   Enclose a drawn plan and full description of this distributor's site—including each area utilized for drug storage, distribution, or both—*at this location*. See Instruction Sheet for details that must be included in the description. Also, attach a copy of the deed or lease for the property on which the wholesale distributor's establishment is located. If leased, the lease must be for an original term of not less than one calendar year.

6. Phone: _____ Email: _____

7. ***Mailing* Address** (*if different from physical location*): _____

   _____ _____ _____
   City State Zip

INFORMATION ABOUT OWNERSHIP

8. Form of Business (check one): ☐ Corporation ☐ Partnership ☐ Sole Proprietorship
   ☐ Individual with federal employee identification number

9. Enter the name of the Designated Representative (DR) or most senior person responsible for facility operations, purchasing, and inventory control: _____

   Enclose a *Distributor Permit–Information about Ownership* form for this person. This person must also complete a *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.

10. Enter the name of the supervisor of the person named above: _____ **Enclose a *Distributor Permit–Information about Ownership* form for this person. This person must also complete a *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.**

11. Is this distributor a publicly held company? Yes ☐ No ☐ **If no, list the names of the principals and owners who directly or indirectly own more than 10% interest in the company.**

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

Enclose a *Distributor Permit–Information about Ownership* form for *each* person listed. Each person listed must also complete a *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.

LICENSURE HISTORY

12. Does the distributor hold any state or federal licenses, registrations, or permits authorizing the wholesale distributor to purchase, possess and distribute drugs? Yes ☐ No ☐ **If yes, attach a list of license/registration/permit numbers and the jurisdiction that issued them.**

    If the distributor is not located in Delaware, arrange for the Board office to receive a *License Verification for Distributors* form from the licensing agency for the state where the facility is located.

13. Has this wholesale distributor ever been disciplined by any state or federal agency? Yes ☐ No ☐ **If yes, attach a list of all disciplinary actions by state and federal agencies against the wholesale distributor.**

POLICIES AND PROCEDURES

14. Are the policy and procedures required by Section 8.0 of the Board's Rules and Regulations and the FDA available on site for inspection? Yes ☐ No ☐

REPORTING CHANGES

15. Do you agree to report any changes in the foregoing information to the Board office, in writing, within 30 days of the change as required by Section 8.2.1 of the Board's Rules and Regulations? Yes ☐ No ☐

CONTROLLED SUBSTANCES

16. Will you distribute controlled substances? Yes ☐ No ☐

17. Will you reverse distribute controlled substances? Yes ☐ No ☐

A distributor must have a Delaware Distributor (Pharmacy-Wholesale) permit, Delaware controlled substance registration and federal DEA permit before storing and/or distributing controlled substances in Delaware.

OUTSOURCING INFORMATION

18. Will this facility compound sterile drugs and distribute them to Delaware? Yes ☐ No ☐ ***If yes,* the facility is an outsourcing facility as defined in Section 503B, *Registration of Outsourcing Facilities and Reporting of Drugs*, of the federal Food, Drug, and Cosmetics Act. *You must complete and submit an Application for Outsourcing Facility* in addition to this application.**

REPACKAGER/MANUFACTURER INFORMATION

19. Are you a repackager or manufacturer with the Food and Drug Administration? Yes ☐ No ☐ **If yes, enter the following information and enclose a copy of the regulatory letter:**

    Registration Number: _____ Date of Last GMP Inspection: _____

When your application is complete, please allow 4-8 weeks to receive your license. A complete application is one that includes all required documentation and correct payment. Applications that are not complete within six months of filing may be considered abandoned and discarded.

AFFIDAVIT

I do hereby make application to the Board of Pharmacy for license or registration under the provisions of an Act to regulate the practice of Pharmacy in the State of Delaware and solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

Printed Name: _____ Title: _____

Signature: _____ Date: _____

State of _____ County of _____

Subscribed and sworn to before me this_____day of_____, 2_____

Witness my hand and seal hereunto attached.

Notary Signature:_____

SEAL

My Commission expires: _____

APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY THE REQUIRED PROCESSING FEE WILL BE REJECTED.

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DISTRIBUTOR (PHARMACY-WHOLESALE) PERMIT–INFORMATION ABOUT OWNERSHIP

INSTRUCTIONS

Complete and submit one of these forms for each of the following persons listed on the *Application for Distributor (Pharmacy-Wholesale) Permit*:

- **Designated Representative (DR) or most senior person responsible for facility operations, purchasing, and inventory control**
- **Supervisor of the DR or most senior person responsible for facility operations, purchasing and inventory control**
- **If not a publicly held company, *all* principals and owners who directly or indirectly own more than 10% interest in the company**

Each person completing one of these forms must also complete the *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks.

1. Name of Distributor:_____

2. Name: _____ _____ _____
   Last Name First Name Middle

3. Type of Interest in Distributor Named Above (check one):
   ☐ Sole Proprietor ☐ Partner ☐ Individual with federal employee identification number
   ☐ Corporate Officer – Position: _____
   ☐ Designated Representative ☐ Designated Representative's Supervisor

4. Social Security Number: _____ Date of Birth: _____

5. Mailing Address: _____
   _____ _____ _____
   City State Zip

6. Phone: _____ Email: _____

7. Has any state or federal agency taken any type of disciplinary action against you or is any such action pending?
   Yes ☐ No ☐ **If yes, enclose a list of all disciplinary actions by state and federal agencies against you.**

8. Have you ever been arrested, interviewed, interrogated, convicted, received a criminal summons, received a civil citation by any police/law enforcement agency, college/university or campus police or security agency? ***Note:*** This includes DUI's and all juvenile arrests and cases even if dismissed for any reason whatsoever. The *only* exceptions are minor traffic citations. Yes ☐ No ☐ **If yes, list each charge separately below and give details on a separate page.**

ARREST DATE	ORIGINAL CHARGE	LOCATION OF ARREST (city and state)	ARRESTING POLICE DEPARTMENT	DISPOSITION (e.g., guilty, not guilty, dismissed, etc.)

9. Has a criminal indictment, information, or complaint ever been returned against you, but for which you were not arrested or which you were named as an un-indicted co-party? Yes ☐ No ☐ **If yes, give details on a separate page.**

10. Have you ever received a pardon or expungement for any criminal offense? Yes ☐ No ☐ **If yes, give details on a separate page. Include the charge, date, city, county and state.**

11. Have you ever been, or are you now, on parole/probation to any court? Yes ☐ No ☐ **If yes, give details on a separate page. Include the charges, the name of your parole/probation officer, location including city, county and state where probation was/is served.**

12. Have you ever been civilly or criminally subpoenaed to appear to testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☐ **If yes, give details on a separate page. Include the location and reason for being subpoenaed**.

13. Have you ever been civilly or criminally subpoenaed to appear to testify before a federal, state or county grand jury, board or commission? Yes ☐ No ☐ **If yes, give details on a separate page. Include location and reason for being subpoenaed.**

Complete the *Criminal History Record Check Authorization* form to request State of Delaware and Federal Bureau of Investigation criminal background checks. Follow instructions on the form for submitting fingerprints. The State Bureau of Identification will send the reports directly to the Board office.

AFFIDAVIT

I solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

Signature: _____ Date: _____

State of _____ Country of _____

Subscribed and sworn to before me this_____day of_____.2_____

Witness my hand and seal hereunto attached.

Notary Signature:_____

SEAL

My Commission expires: _____

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LICENSE VERIFICATION FOR DISTRIBUTORS (PHARMACY-WHOLESALE)

INFORMATION ABOUT APPLICANT

Representative of Distributor applying for Delaware licensure completes this section and sends to the licensing agency for the state where the Distributor is located. Before forwarding form, check whether agency charges a fee for license verification.

1. Name of Distributor Applicant: _____

2. Mailing Address: _____

   _____ _____ _____
   City State Zip

3. Phone: _____ Email: _____

4. Type of Operation (check one): ☐ Distributor ☐ Manufacturer ☐ Repackager ☐ Relabeler

5. Type of Distribution Activities (check all that apply):
   ☐ Prescription ☐ Controlled Substances ☐ Over-the-Counter ☐ Cosmetics ☐ Dentifrices

I authorize release of the information requested below to the State of Delaware Board of Pharmacy.

Printed Name: _____ Title: _____

Signature: _____ Date: _____

LICENSE VERIFICATION

Official of home State licensing agency completes this section.

1. License Number: _____ Issue Date: _____ Expiration Date: _____

2. Has this license been encumbered in any way? Yes ☐ No ☐ If yes, what type of encumbrance (check one):
   ☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation ☐ Lapsed

   ***Attach certified copies of all pertinent legal documents*.**

3. Has the applicant been convicted under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? Yes ☐ No ☐ If yes, explain: _____

   _____

4. Has the applicant furnished any false or fraudulent material in any application made in connection with drug manufacturing or distribution? Yes ☐ No ☐ If yes, explain: _____

   _____

5. Does your licensing agency routinely inspect the facility? Yes ☐ No ☐ If yes, complete this information:
   Date of Last Inspection: _____ Has any inspection resulted in deficiencies? Yes ☐ No ☐ If yes, explain:

   _____

6. Has the applicant met all licensing requirements of your State? Yes ☐ No ☐ If no, explain:_____

   _____

Printed Name of Official: _____ Title: _____

Signature: _____ Date: _____

AFFIX OFFICIAL SEAL OF STATE LICENSING AGENCY.

Instructions for Requesting a Criminal Background Check

Both State of Delaware and Federal Bureau of Investigation criminal background checks are required.

Applicant Notification

Your fingerprints will be used to check the criminal history records of the Federal Bureau of Investigation (FBI). You have the opportunity to challenge the accuracy of the information contained in the FBI identification record. See Title 28, CFR 16.34 for the procedure to obtain a change, correction or update in the FBI record.

Locations

Kent County – Primary Facility
State Bureau of Identification
Blue Hen Mall & Corporate Center
655 S. Bay Rd. Suite 1B
Dover, DE 19901
Walk-ins accepted: Mon 8:30 am – 6:30 pm, Tue - Fri 8:30 am – 3:30 pm
Customer Service: (302) 739-2134

New Castle County - Satellite Facility
State Police Troop Two
100 LaGrange Ave
Newark, DE 19702
(between Rts. 72 and 896 on Rt. 40)
By appointment only
Scheduling: (302) 739-2528 (local)
(800) 464-4357 (toll free)

Sussex County – Satellite Facility
Thurman Adams State Service Center
546 S. Bedford Street, Rm. 202
Georgetown DE 19947
(across from DelDOT & Troop 4)
By appointment only
Scheduling: (302) 739-2528 (local)
(800) 464-4357 (toll free)

Applicants in Delaware

1. If you are using the New Castle County or Sussex County locations, call **(800) 464-HELP (4357)** to schedule an appointment. No appointments are needed at the Kent County location.

2. Take the completed *Authorization for Release of Information* form to one of the offices listed above with the fee of $65.00, to cover both the State of Delaware and Federal Bureau of Investigation criminal checks. Money orders and credit cards other than American Express are accepted at all locations. New Castle and Kent Counties accept cash; Sussex County does not accept cash. ***Personal checks are not accepted in any county.*** As fees are subject to change, contact the agency where you plan to submit your forms for current fees.

Applicants Not in Delaware (including Out-of-State or Outside the United States)

1. Your local police agency can fingerprint you. All types of fingerprint cards are accepted. Or, you may print a FD-258 fingerprint form available on the FBI website at www.fbi.gov – click *Services*, then *Identity History Summary Checks*, then scroll down to Option 1, Step 2, and click the link for *standard fingerprint form (FD-258)*. You may print the form on regular paper.

2. Your *Authorization for Release of Information* form and the fingerprint card must be complete. If identifying information is missing (such as name, date of birth, race, gender, etc.), your form will be returned.

3. ***Mail*** the *Authorization* form, fingerprint card, and *certified* check or money order ***(personal checks are not accepted)*** for $65.00 made payable to "Delaware State Police" to:

Delaware State Police
State Bureau of Identification (SBI)
PO Box 430
Dover, DE 19903-0430

DO NOT SEND THIS FORM OR FEE TO YOUR PROFESSION'S BOARD OFFICE.

DO NOT SEND THIS FORM OR FEE TO THE DIVISION OF PROFESSIONAL REGULATION.

⇨***ALLOW FOUR WEEKS FOR RECEIPT OF RESULTS.***

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AUTHORIZATION FOR RELEASE OF INFORMATION

CRIMINAL HISTORY RECORD CHECK FOR PROFESSIONAL LICENSURE APPLICANTS

Please print or type all information in black ink.

Check the type of license for which you are applying:

- ☐ Adult Entertainment
- ☐ Charitable Gaming Vendor
- ☐ Chiropractic
- ☐ Dental
- ☐ Funeral
- ☐ Massage
- ☐ Medical (Physicians, Physician Assistants, Respiratory Care Practitioners, Eastern Medicine Practitioners, Acupuncture Practitioners, Genetic Counselors, Polysomnographers, Midwifery Practitioners (CM, CPM))
- ☐ Mental Health (LPCMH, LCDP, LMFT, LAPCMH, LAMFT)
- ☐ Nursing (RN, LPN, APRN)
- ☐ Nursing Home Administrator
- ☐ Occupational Therapy
- ☐ Optometry
- ☐ Pharmacy (includes key personnel of facilities licensed by Board of Pharmacy)
- ☐ Physical Therapy/Athletic Trainer
- ☐ Podiatry
- ☐ Psychology
- ☐ Real Estate Appraiser (includes Appraisal Management Company)
- ☐ Speech/Hearing
- ☐ Social Work
- ☐ Texas Hold'em Individual

Print your current full name:

_____	_____	_____	_____
Last Name	First Name	Middle Initial	Suffix (e.g., Jr., Sr.)

Enter all other names you have used in the past (including, but not limited to, maiden name, former married names, alternative spellings):

1. _____
2. _____
3. _____
4. _____

As an applicant, I authorize release of any and all information that you have concerning my **CRIMINAL HISTORY RECORD INFORMATION**. I hereby release you, your organization, the State of Delaware and others from any liability or damage which may result from furnishing this information:

SIGNATURE OF PERSON PRINTED: _____ **Date**: _____

Phone: Home _____ Work _____

Mail the results of my criminal history request to:

Division of Professional Regulation
861 Silver Lake Boulevard, Suite 203
Dover DE 19904
SLC D420A

USE OF CRIMINAL HISTORY RECORD INFORMATION IS RESTRICTED BY LAW AND SHALL BE LIMITED TO THE PURPOSE FOR WHICH IT WAS GIVEN. MISUSE CONSTITUTES A CRIMINAL VIOLATION.

Revised 11/2016