Wisconsin Department of Safety and Professional Services

Mail To:	P.O. Box 8935 Madison, WI 53708-8935	**Ship To:**	4822 Madison Yards Way Madison, WI 53705
FAX #:	(608) 251-3036	E-Mail:	dsps@wisconsin.gov
Phone #:	(608) 266-2112	Website:	http://dsps.wi.gov

PHARMACY EXAMINING BOARD

APPLICATION INFORMATION REGARDING LICENSURE OF A WHOLESALE DISTRIBUTOR

(NEW, CHANGE IN OWNERSHIP, OR CHANGE OF LOCATION)

A completed application must be on file with the Pharmacy Examining Board at least 30 days prior to opening. An application is not complete until all of the following are received:

1. **Complete Application for the Licensure of a Wholesale Distributor of Prescription Drugs (Form #2814):** To determine when a change of ownership occurs please view chart on page iii.

2. **Convictions and Pending Charges (Form #2252):** All applicants will be required to answer questions on the application form about convictions of any crime, other violations and pending charges in Wisconsin or any other state.

   If an applicant has been convicted of one or more misdemeanor or other violations or has pending charges, and if the Pharmacy Examining Board determines that the crimes or violations are substantially related to the practice of a wholesale distributor, the Board will not grant a license until it has received sufficient information to determine whether the license should be granted, denied or limited. It is the responsibility of the applicant to provide complete information to the Board. Applications are deemed complete after submission of all relevant background information by the applicant.

3. **Fingerprints:** You will receive information on how to obtain digital fingerprints ***after*** the Department has received a signed Authorization for Release of FBI Information (**Form #2687**).

4. **The Authorization for Release of FBI Information (Form # 2687):** This form must be submitted for the Designated Representative listed on the Wholesale Distributor Application Form (**#2814**). It **must** be signed by the Designated Representative and returned with the application.

5. **Complete and submit Designated Representative Form (#2812):** This form is completed for the named Designated Representative listed on Application Form (**#2814**). A current photograph of head and shoulders of designated representative **must** be attached.

6. **Surety Bond (Form #2819) or Irrevocable Letter of Credit (Form #2824): (DSPS forms must be used. There are no exceptions or modifications to a form that will be approved.)** Per Wis. Admin. Code § Phar 13.055, all applicants shall supply a surety bond **or** an irrevocable letter of credit in the amount of $5,000.00, which is issued by a company authorized to do business in the State of Wisconsin. The form of the bond or letter of credit shall be approved by the Department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a wholesale distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this subsection more than one year after the date on which the applicant's wholesale distributor's license expires. SURPLUS LINE – Insurers ARE NOT authorized to do surety business in Wisconsin.

   a) **If the applicant chooses to obtain the $5,000.00 surety bond, complete and return the Bond of Prescription Drug Wholesale Distribution (Form # 2819).**
   b) **If the applicant chooses to submit a $5,000.00 Irrevocable Letter of Credit, complete and return the Letter of Credit (Form #2824).**

7. **Forward the above items, along with the required fee, to the Pharmacy Examining Board at the address above, at least 30 days prior to the proposed opening date.** Requirements and procedures for applying for a wholesale distributor license are specified in Wis. Stat. § 450.071. A license application and fee shall be on file with the Board at least 30 days prior to the granting of the distributor license. If you have not been inspected in the 3-year period immediately preceding the date of this application, your application will be denied and the application fee will not be returned. Once the required inspection is obtained, a new application will need to be filed and a new application fee paid. You may not conduct business in Wisconsin while awaiting licensure. A distributor may not operate unless a distributor license has been granted. Board action shall be taken within 60 business days of receipt of a completed distributor application, as provided in Wis. Admin. Code § SPS 4.03.

8. **If controlled substances are distributed,** contact the Federal Drug Enforcement Administration for registration forms at www.deadiversion.usdoj.gov, (571) 362-6251, DEA, 230 South Dearborn Street, John C. Kluczynski Federal Building, Suite 1200, Chicago, Illinois 60604.

Committed to Equal Opportunity in Employment and Licensing

Procedure for Reporting Theft or Loss of Controlled Substances

The Designated Representative is responsible for reporting any theft or loss of controlled substances to the U.S. Department of Justice, DEA Kluczynski Building, Suite. 1200, 230 S. Dearborn Street, Chicago, IL 60604 (312-353-7875, or 800-882-9539 toll free), and to the Pharmacy Examining Board, P.O. Box 8935, Madison, WI 53708-8935, (608-266-2112). Report the theft or loss on Form DEA-106, *Report of Theft or Loss of Controlled Substances*, obtainable from DEA at www.deadiversion.usdoj.gov. Make four (4) copies. Send the original and one copy to the DEA office, one copy to the Pharmacy Examining Board, and one copy should be kept with the biennial inventory in the Pharmacy.

All thefts or significant losses must be reported to DEA officials. In any instance that a pharmacy, practitioner, or other DEA registrant authorized to possess controlled substances is required to file with the DEA a *Report of Theft or Loss of Controlled Substances*, the pharmacy, practitioner, or other DEA registrant shall also send a copy to the Board within two (2) weeks of filing with the DEA.

Procedure For Destroying Controlled Substances

Contact the DEA Diversion Group, 4725 West Electric Avenue, West Milwaukee, WI 53219, (414) 336-7374, or www.deadiversion.usdoj.gov for the proper forms and procedures.

Approved Prescription Drug Products and Code of Federal Regulations

These publications are obtainable from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20401, https://www.gpo.gov/ .

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Wis. Stat. § 450.06(3) requires that a new wholesale distributor license be obtained following a change of ownership. The following chart sets forth when a change of ownership is deemed to have occurred or not occurred. Following the issuance of a new license, that new licensee must also renew that new license at the next required renewal date, regardless of when that new license was issued.

Owner	Transaction	Change in Ownership?
Individual	**Sells wholesale distributor to another**	**Yes**
Individual	**"Incorporates" him or herself and there are no other shareholders.**	**No** (Notify Board on company letterhead and include your WI license number.)
Individual	**Incorporates and adds shareholders other than self, or goes into partnership with other(s).**	**Yes**
Partnership	**Sells distributor to another**	**Yes**
Partnership	**Members of partnership change <u>and</u> dissolves; e.g., individual(s) leaves.**	**Yes**
Partnership	**Members of partnership change, but partners vote not to dissolve unanimously or by partnership agreement.**	**No**
Partnership	**Partnership decides to incorporate itself.**	**No,** as long as no shareholders added were **not** partners before. (Notify Board on company letterhead and include your WI license number.)
Corporation*	**Change in shareholders (including sale of all stock)**	**No** (Corporation owns wholesale distributor—not shareholders.)
Corporation	**Sells all assets (as opposed to stock)**	**Yes** (One asset being sold is wholesale distributor; corporation no longer owns it after asset sale.)
Corporation	**Becomes a subsidiary or division of another corporation**	**No** (Corporation still owns wholesale distributor, regardless of who owns corporation.)
Corporation	**Merges into/or consolidates with another corporation <u>and</u> loses corporate "identity."**	**Yes**

<u>*Limited Liability Companies created under Wis. Stat. ch. 183 are the same as corporations for change of ownership.</u>

If you answered "yes" to any of the above items, **<u>you cannot renew your current license</u>**. You must go the Department website at: www.dsps.wi.gov, choose "Professions," "Wholesale Distributor of Prescription Drugs," and Form 2814 (Application). Follow all application instructions.

Q: We would like to change our Doing Business As (DBA) name, how do we notify the Board?

A: Please submit a letter to the Board indicating that this is **<u>a name change only</u>** and change of ownership has **<u>not</u>** occurred. Include your current and new name along with your WI license number. Please allow up to 15 business days for processing. You may print a new license from the Department website at https://online.drl.wi.gov/UserLogin.aspx, or you may submit Form (#3082) and $10.00 to the Department to have a certificate mailed to you.

Q: We would like to change our address, how do we notify the Board?

A: If this is a postal change only and **<u>no physical move has taken place</u>**, submit a letter to the Board indicating that this is a postal change only and no physical change of location has occurred. Include your current and new addresses along with your WI license number. If the address change is due to a physical change of location, then a new application <u>must</u> be completed in order to receive a new license number. Go the Department website at: www.dsps.wi.gov, choose "Professions," "Wholesale Distributor of Prescription Drugs," and Form 2814 (Application). Follow all application instructions.

Q: We would like to close our facility, how do we notify the Board?

A: Please submit a letter to the Board requesting closure. Indicate your facility name, license number, and reason for closure.

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PHARMACY EXAMINING BOARD

APPLICATION FOR WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUG LICENSE

The Department must deny your application if you are liable for delinquent state taxes, UI contributions, or child support (Wis. Stat. §§ 440.12 and 440.13).

PLEASE TYPE OR PRINT IN INK

☐ Your name, address, telephone number, and email address are available to the public. Check box to withhold address, telephone number, and email address from lists of 10 or more credential holders (Wis. Stat. § 440.14).

Current WI License Number: ____________ - **45**

You must choose one of the following Types:

☐ New Facility ☐ Change of Ownership ☐ Change of Location

Applicant Name (individual, partnership, association or corporation)

Doing Business As (DBA) Name (name or title under which business is operated) (Note: This is the name that will appear on the license once issued.)

Applicant's Telephone Number

___ - ___ - ____

Business Telephone Number of Wholesale Distributor

___ - ___ - ____

FEIN Number of Wholesale Distributor Facility

__ - _______

Your Social Security Number or Employer Identification Number must be submitted with your application on this form. If you do not have a Social Security Number, you must complete Form #1051. The Department may not disclose the Social Security Number collected except as authorized by law.

Distribution Facility Address (number, street, city, state, zip)

Mailing Address (if different) (number, street, city, state, zip)

Name of Contact Person for the Wholesale Distributor Facility applying for the License

Email Address

APPLICATION FEES: Please check applicable box. Make check payable to DSPS and attach to this application.

☐ $ 74.00 Initial Credential Fee

For Receipting Use Only (45)

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APPLICATION IS NOT COMPLETE UNTIL ALL OF THE FOLLOWING DOCUMENTS HAVE BEEN RECEIVED:

- ☐ Application (**Form #2814**) and appropriate fee
- ☐ Convictions and Pending Charges Form (**#2252**), if applicable
- ☐ Authorization for Release of FBI Information Form **(#2687)**
- ☐ Designated Representative Form (**#2812**)
- ☐ Surety Bond (**Form #2819**) OR Irrevocable Letter of Credit (**Form #2824**) (Wis. Admin. Code § Phar 13.055)

Note: It may be helpful and may speed up the application review process if you provide documents regarding your business model and organizational charts for your company. Please submit documentation with your application (**Form #2814).**

SECTION A (Attach additional sheets if necessary.)

Indicate below the type of ownership or operation for the applicant's business:

☐ Partnership (complete #1 and #1a) ☐ Corporation (complete #2)

☐ Sole Proprietorship (complete #3) ☐ LLC or Other (i.e., members) (complete #4)

Note: It may be helpful and may speed up the application review process, if you provide documents regarding your business model and organizational charts for your company. Please submit documentation with your application (**Form #2814).**

1. If the type of business is a partnership, list the name of the partnership and proceed to **1a** below:

Name of Partnership:

1a. If the type of business is a partnership, list below the full names of each partner:

Name	**Name**

2. If the type of business is a corporation, list below the full name of each corporate officer and director, name of the corporation and the state in which it was incorporated. (Attach additional sheets if necessary.):

Name of Corporate Officer(s)

Name of Director

Name of Corporation

State Incorporated

3. If the type of business is a sole proprietorship, list below the full name of the sole proprietor and the name of the business entity:

Printed Full Name of Sole Proprietor

Printed Name of Business Entity

4. If the type of business is an LLC or other entity, list below the full name of each member and the name of the business entity. (Attach additional sheets if necessary.):

Name of Business Entity	Member(s)

ALL APPLICANTS: List below all current licenses and permits issued to the facility applying for the license by any other state that authorizes the applicant to purchase or possess prescription drugs. (Attach additional sheets if necessary.):

State	Expiration Date	Type of License or Permit
	/ /	
	/ /	
	/ /	
	/ /	
	/ /	
	/ /	

ALL APPLICANTS – LIST DESIGNATED REPRESENTATIVE

Name and Address of Designated Responsible Representative for the Distribution of Prescription Drugs: The Designated Representative named below must complete and return the Designated Representative Form (**#2812**) and Authorization Form (**#2687**) and attach to this application.

Printed Full Name of Designated Representative

Address (number, street, city, state, zip)

SECTION B: Applicant read and sign below.

I swear or affirm to the truthfulness of each item in the attached Designated Representative (**Form #2812**), submitted with this application.

Signature of Applicant **(Print and Sign)**

Title

Printed Name

Date __ __ / __ __ / __ __

SECTION C: Applicant read and sign below.

I swear or affirm that each facility used for the wholesale distribution of prescription drugs has been inspected in the 3-year period immediately preceding the date of this application.

If you have not been inspected in the 3-year period immediately preceding the date of this application, your application will be denied and the application fee will not be returned. Once the required inspection is obtained a new application will need to be filed and a new application fee paid. You may not conduct business in Wisconsin while awaiting licensure.

Check below the type of inspection you had.

☐ **A State Board of Pharmacy**
Note: Please have Designated Representative submit electronic fingerprints. Instructions for digital fingerprinting will be provided once completed **Form 2687** has been received at the Department.

List State: __ __ Date Last Inspected: __ __ / __ __ / __ __

☐ **National Association of Boards of Pharmacy (NABP) Drug Distributor Accreditation (DDA)**
Note: If applicant is accredited by NABP DDA, the Designated Representative will not need to submit digital fingerprints. However, **Form 2687** is still required.

DDA Unique Identifier:

Period of Accreditation: From: __ __ / __ __ / __ __ To: __ __ / __ __ / __ __

☐ **Other Accrediting Body**
Note: Inspections or accreditations from agencies other than a State Board of Pharmacy or DDA will be reviewed by the Pharmacy Examining Board's Liaison.

Date Last Inspected: __ __ / __ __ / __ __

Signature of Applicant **(Print and Sign)**

Title

Printed Name

Date __ __ / __ __ / __ __

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SECTION D: Applicant read and check one below.

Surety Bond or Irrevocable Letter of Credit (Wis. Admin. Code § Phar 13.055) The applicant shall supply a surety bond or irrevocable letter of credit in the amount of $5,000.00, which is issued by a company authorized to do business in the State of Wisconsin. The form of the bond or letter of credit shall be approved by the Department and conditioned so that the state shall be fully compensated or reimbursed for, and shall be used to, secure payment of fees or costs that relate to the issuance of a Wholesale Distributor's license that have not been paid within 30 days after the fees or costs have become final. The bond or letter shall be valid for the entire period of an unexpired license issued to the applicant. No claim may be made against a bond or other security under this subsection more than one year after the date on which the applicant's Wholesale Distributor license expires.
SURPLUS LINE – Insurers **are not** authorized to do surety business in Wisconsin

Check **one** of the following.

☐ $5,000.00 **Bond**

If the applicant chooses to obtain a $5,000.00 surety bond, please complete and return the Bond of Prescription Drug Wholesale Distributor Form (**#2819**).

☐ $5,000.00 **Irrevocable Letter of Credit**

If the applicant chooses to obtain a $5,000.00 irrevocable letter of credit, please complete and return the Irrevocable Letter of Credit of Prescription Drug Wholesale Distributor Form (**#2824**).

NOTE: Either Form 2819 or Form 2824 must be submitted. There are no exceptions or modifications to these forms that will be approved.

SECTION E: Applicant answer the following questions:

1. Is applicant now or has applicant ever been credentialed by a Federal Agency? **If yes, complete below:** ☐Yes ☐ No

   Agency: ______ Registration Number: ______ Expiration Date: __ __ / __ __ / __ __

2. Is applicant a Manufacturer of prescription drugs? **If yes, indicate below.** ☐ Yes ☐ No

   Food and Drug Administration Registration Number: ______ Expiration Date: __ __ / __ __ / __ __

3. Is applicant a Manufacturer and/or repackager of controlled substances? **If yes, indicate below:** ☐ Yes ☐ No

   Food and Drug Administration Registration Number: ______ Expiration Date: __ __ / __ __ / __ __

4. Has the applicant previously been licensed by the Wisconsin Pharmacy Examining Board? ☐ Yes ☐ No

   If yes, give name, license number, and location.

   ______ Is this facility closed? ☐Yes ☐ No

5. Has the applicant ever been convicted of a felony or misdemeanor? **If yes, attach a sheet providing details and submit Convictions and Pending Charges Form (#2252) with required documentation.** ☐ Yes ☐ No

6. Has the applicant had their Pharmacist, Pharmacy, Manufacturer, or Distributor license suspended, revoked, or reprimanded in this or any other state? **If yes, attach a sheet providing details about the action, including the name of the credentialing agency and date of action.** ☐Yes ☐ No

7. Does the applicant have a Pharmacy, Pharmacist, Manufacturer, or Distributor license now subject to disciplinary proceedings in this or any other state? **If yes, attach a sheet providing details about pending action, including the name of the agency and status of action.** ☐Yes ☐ No

Wisconsin Department of Safety and Professional Services

CONTINUING DUTY OF DISCLOSURE:

I understand that I have a continuing duty of disclosure during the application process. If information I have provided in this application becomes invalid, incorrect or outdated, I understand that I am obliged to provide any necessary information to ensure the information on my application remains current, valid, and truthful. I understand that credentialing authorities may view acts of omission as dishonesty and that my duty of disclosure during the application process exists until licensure is granted or denied.

AFFIDAVIT OF APPLICANT:

I declare that I am the person referred to on this application and that all answers set forth are each and all strictly true in every respect. I understand that failure to provide requested information, making any materially false statement and/or giving any materially false information in connection with my application for a credential or for renewal or reinstatement of a credential may result in credential application processing delays; denial, revocation, suspension or limitation of my credential; or any combination thereof; or such other penalties as may be provided by law. I further understand that if I am issued a credential, or renewal, or reinstatement thereof, failure to comply with the statutes and/or administrative code provisions of the licensing authority will be cause of disciplinary action.

By signing below, I am signifying that I have read the above statements (Continuing Duty of Disclosure and Affidavit of Applicant) and understand the obligation I have as an applicant or credential-holder should information I've provided to the Department of Safety and Professional Services change.

Signature of Applicant **(Print and Sign)**

Title

Printed Name

__ __ / __ __ / __ __

Date