Steven W. Schierholt, Esq.
Executive Director

STATE OF OHIO BOARD OF PHARMACY

John R. Kasich
Governor

APPLICATION FOR THIRD PARTY LOGISTIC COMPANIES

Instructions:

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO COMPLETING APPLICATION- Failure to complete all required fields, provide necessary supplemental documentation and correct fee will delay the application process.
If a question is not applicable, answer as N/A.
APPLICATION FEE FOR A WDDD REGISTRATION:
WITH NO CONTROLLED SUBSTANCES IS $750.00
WITH CONTROLLED SUBSTANCES IS $787.50

APPLICATION AND PAYMENT SHOULD BE MAILED TO: 77 SOUTH HIGH STREET, 17TH FLOOR, COLUMBUS, OHIO 43215

FAILURE TO COMPLETE ALL FIELDS, PROVIDE NECESSARY SUPPLEMENTAL DOCUMENTATION, AND CORRECT FEE WILL DELAY THE APPLICATION PROCESS. If a question is not applicable, answer as N/A.

MAKE CHECKS PAYABLE TO "TREASURER, STATE OF OHIO"

"Third party logistics provider" means any person who contracts with a manufacturer or wholesale distributor of dangerous drugs to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the dangerous drug or have general responsibility to direct the dangerous drug's sale or disposition; is licensed by the state board of pharmacy as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a third party logistics provider classification; and shall be registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

Please refer to the Ohio Adminstrative Code 4729-9-29 for additional the requirements to be licensed as a Third Party Logistic Company in Ohio.

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WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS FOR THIRD PARTY LOGISTICS COMPANIES - PLEASE TYPE OR PRINT LEGIBLY

1. LICENSE REQUEST-

☐ New ☐ Change	Proposed opening date or date of change	If change, give current WDDD License Number

If change, select ***ALL*** that apply:

☐ Name ☐ Ownership ☐ Business Type

☐ Other:

2. BUSINESS BEING LICENSED- Complete all fields including the name under which this applicant will be doing business (i.e. reflected by the signage/how your staff will answer the phone).

Name the applicant will be doing business as:	County
Street Address, City, State, Zip Code (**No P.O. Box**)	Phone (including area code)
Mailing Address, City, State, Zip Code (if different from above)	Fax (including area code)
Business Web Site Address	

3. APPLICANT INTENDS DOING BUSINESS AS (*Select One*)

☐ Sole Proprietorship ☐ Corporation ☐ Government

☐ Partnership ☐ Limited Liability Company

4. LIST ANY OTHER NAMES THE ENTITY WILL BE CONDUCTING BUSINESS UNDER *(Attach separate sheet if necessary)*

5. LIST OTHER TERMINAL DISTRIBUTOR OR WHOLESALER DISTRIBUTOR LICENSES, ISSUED BY THE STATE OF OHIO BOARD OF PHARMACY, WHICH YOU POSSESS

License Numbers Only

For Ohio State Board of Pharmacy Use Only

Control #	Amt Received	Office/Field	Class	BT	Drug Category I II III	WDDD License New #/Same#

6. LIST WHOLESALER DISTRIBUTOR LICENSES, ISSUED BY OTHER STATES WHICH YOU POSSESS (include license number and state)

7. HAS THE ENTITY EVER BEEN DENIED A LICENSE OR REQUESTED TO WITHDRAW OR HAS IT WITHDRAWN AN APPLICATION FOR LICENSURE IN THIS OR ANY OTHER STATE?

☐ Yes ☐ No	If yes, please provide the name of the licensing agency and the reason why:

8. TRADE, CORPORATE, OR PARTNERSHIP NAME AND ADDRESS-Owner of the location to be licensed.

Name	Title
Mailing Address, City, State, Zip Code	
Previous Trade, Corporate, Or Partnership Name(s) & Address(es) *If many, check box and attach separate sheet to this application* ☐	Phone (including area code)

9. NAME OF GOVERNMENT AGENCY (if applicable)-*If a government agency, please provide the names of each officer and director of the agency on a separate piece of paper.*

Name

10. OWNERSHIP INFORMATION - **Corporations must attach a copy of articles of incorporation. Limited liability companies must attach a copy of articles of organization or certificate of formation.** These documents may be contained in the business files usually maintained by the applicant's business office or respective Secretary of State. For Ohio entities, visit *www.sos.state.oh.us*

Charter/Entity number	Federal Tax ID or EIN Number	State where incorporated/formed

11. NAME OF OWNER(S)/PARTNERS; OR, IF INCORPORATED, NAME AND TITLE OF OFFICERS
(If more than four, please include information on a separate piece of paper)

Leave blank if Government Agency (see question 8)

Name	Title	Date of Birth or Social Security Number
Name	Title	Date of Birth or Social Security Number
Name	Title	Date of Birth or Social Security Number
Name	Title	Date of Birth or Social Security Number

Note: Criminal records checks are required for all owners or, if incorporated, the officers of an Ohio licensed wholesale distributor of dangerous drugs pursuant to OAC 4729-9-16.

12. PROVIDE A DETAILED NARRATIVE DESCRIPTION OF THE TYPE OF BUSINESS ACTIVITIES THAT WILL BE CONDUCTED AT THIS LOCATION THAT REQUIRES THE APPLICANT TO BE ISSUED A WDDD LICENSE
(narrative may be completed on a separate sheet of paper and included with the application)

Note: Please include wholesalers that you contracted with as a 3PL.

13. TYPE OF DRUGS -*Check the type(s) of dangerous drugs you distribute, or intend to distribute, at wholesale.*

Application is hereby made for a certificate as a Wholesale Distributor of Dangerous Drugs, as provided in sections 4729.52, 4729.53, 3719.02, 3719.021 & 3719.03 of the Ohio Revised Code, as follows:

☐ Prescription Legend (Dangererous Drugs)

☐ Controlled Substances-
(if checked, must complete page 8-9)

14. OTHER THAN THE FNAME AND ADDRESS OF THE WHOLESALER BEING REGISTERED- List the names and addresses of the site(s). If the sites are licensed in Ohio, provide the wholesale distributor number.

A. Are the records of sales kept at any other location? ☐ No ☐ Yes

If yes, provide the name and address of the location:

B. Are drugs shipped from any other location? ☐ No ☐ Yes

If yes, provide the name and address of the location:

C. Can the purchaser order drugs from any other address? ☐ No ☐ Yes

If yes, provide the name and address of the location:

D. Are drugs transferred to any other location for the purposes of storage or research? ☐ No ☐ Yes

If yes, provide the name and address of the location:

15. RECORD OF DISCIPLINARY ACTIONS AND FINES IMPOSED- Legal questions must be answered. The questions pertain to all of the following: the applicant (business at that location), the owner(s), the Responsible person, any agent and any employee (at the specific location). This would apply to the same business at a previous location on a change of address application, but not for every location in a corporation**. Answering incorrectly could be a crime, see ORC 2921.13.**

Has the applicant, owner(s), Responsible Person, any agent or any employee of the location being licensed, or any officer of the corporation, ever been the subject of disciplinary action (or any pending action) by any state or federal agency; even if subsequently dismissed or resolved without formal discipline?

☐ Yes ☐ No

If yes, provide a detailed explanation on a separate sheet and include a copy of the discipline document with the application.

16. RECORD OF ARRESTS, CHARGES, CONVICTIONS, AND FINES IMPOSED

Does the applicant, owner(s), Responsible Person, any agent or any employee of the location being licensed, or any officer of the corporation, have a record of arrest or charges pending or have a conviction of a felony, misdemeanor or traffic violation (even if expunged, dismissed or sealed)?

FOR TRAFFIC VIOLATIONS:

CHECK YES - Charge(s) for traffic offenses such as OVI (also referred to as OMVI, DUI or DWI [driving/operating a motor vehicle under the influence]), failure to stop after an accident (also referred to as "hit skip"), operation of a vehicle in willful or wanton disregard of the safety of persons or property (also referred to as "reckless operation"), having physical control of vehicle while under the influence and driving under suspension – even if the charge was ultimately reduced or plead to a different offense other than the original charge.

DO NOT CHECK YES - Parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.

☐ Yes ☐ No

If yes, explain in detail on a separate sheet listing names and addresses of the court or government agency and dates such charges were filed. **Send a certified copy of the charging document and the final judgment entry for each occurrence.**

PLEASE NOTE: Pursuant to Section 2953.33(B) of the Ohio Revised Code, you must answer in the affirmative if you have a record of a charge or conviction that has subsequently been sealed or expunged (or the equivalent in another jurisdiction).

17. E-MAIL ADDRESS TO RECEIVE YOUR OHIO LICENSE(S). MUST BE THE RESPONSIBLE PERSON OR DESIGNEE. (Ohio Board of Pharmacy no longer mails licenses via postal mail).

Name of the individual that will print the license	
E-mail of the individual that will print the license	Phone (including area code)

18. STATEMENT OF APPLICANT –(Person who may legally sign for the business)- Statement must be manually signed (wet ink) and completed by the individual who may legally sign for the business and can verify the information provided in this application is true, correct, and complete.

Name	Title
Phone (including area code)	E-mail

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921., 3715., 3719, AND 4729 THAT I AM AUTHORIZED TO PURSUE THIS APPLICATION ON BEHALF OF THE ENTITY LISTED IN THIS APPLICATION AND THAT THIS APPLICATION IS TRUE, CORRECT, AND COMPLETE. I HEREBY ACKNOWLEDGE THAT IF THE LICENSE APPLIED FOR IS GRANTED, THE LICENSE-HOLDER SHALL SUBMIT TO THE JURISDICTION OF THE STATE OF OHIO BOARD OF PHARMACY AND TO THE LAWS OF THIS STATE FOR THE PURPOSE OF ENFORCEMENT OF CHAPTERS 2925., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE AND ALL RELATED LAWS AND RULES.

Signature of Applicant	**Date**	**Date of Birth or Social Security Number**

19. STATEMENT OF INDIVIDUAL RESPONSIBLE FOR SUPERVISION AND CONTROL OF DANGEROUS DRUGS
Statement must be signed (wet ink) and dated by the individual who will be responsible for the supervision and control of the dangerous drugs and drug records at this location. **Note: THE RESPONSIBLE PERSON (RP) IS ALSO RESPONSIBLE FOR ENSURING THAT THE APPLICATION IS TRUE, CORRECT, AND COMPLETE.**

NOTE: If the business type is a hospital or pharmacy, the individual responsible for supervision and control of dangerous drugs and drug records must be a licensed pharmacist.

NOTE: If the business type is a clinic, the individual responsible for supervision and control of dangerous drugs and drug records must be a licensed health care professional that can prescribe dangerous drugs, i.e., MD, DO, APN, DVM, etc.

I HEREBY CERTIFY that I, or personnel employed in the wholesale distribution of dangerous drugs, have the appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

I HEREBY AGREE that I, or the corporation if applicable, shall sell drugs in the state of Ohio to no person other than: exempt prescribers; licensed wholesale distributors of dangerous drugs; licensed manufacturers of dangerous drugs; licensed terminal distributors of dangerous drugs; carriers or warehousemen (for purposes of carriage and storage); or, terminal or wholesale distributors of dangerous drugs who are not engaged in the sale of dangerous drugs within Ohio; and that I assume the responsibility for supervision and control of the dangerous drugs possessed or distributed by, or on behalf of, the applicant. See ORC 4729.51 & 4729.60.

FURTHER, I HEREBY AGREE that, if licensed, communications from the Board may be directed to me, and notices and citations provided for in Section 4729.56 of the Revised Code may be served upon me, and shall constitute proper service upon and notice to the registered wholesale distributor of dangerous drugs for all purposes under Sections 4729.51 to 4729.61 of the Revised Code. I also understand that if and when this business is discontinued that a "Written Notice of Discontinuing Business" form must be secured from the Ohio State Board of Pharmacy, completed by me, and returned to their offices with the license being discontinued as required in Rule 4729-9-07 of the Ohio Administrative Code.

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE THAT I AM AUTHORIZED TO PURSUE THIS APPLICATION ON BEHALF OF THE ENTITY LISTED IN THIS APPLICATION AND THAT THIS APPLICATION IS TRUE, CORRECT, AND COMPLETE. I HEREBY ACKNOWLEDGE THAT IF THE LICENSE APPLIED FOR IS GRANTED, THE LICENSE-HOLDER AND I SHALL SUBMIT TO THE JURISDICTION OF THE STATE OF OHIO BOARD OF PHARMACY AND TO THE LAWS OF THIS STATE FOR THE PURPOSE OF ENFORCEMENT OF CHAPTERS 2925., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE AND ALL RELATED LAWS AND RULES.

SIGNATURE of Responsible Person		**Date Signed**	**DOB or SSN**
Print or Type Name		Title	
Mailing Address, City, State, Zip Code			
Phone (including area code)		E-mail Address	
Professional License Number (if hospital, pharmacy or clinic)	Type of License	State of Licensure	

COMPLETION OF THIS FORM IS REQUIRED BY O.R.C. SECTION 4729.52

MAXIMUM PENALTY: DENIAL OF LICENSE

20. ☐ **CHECK HERE IF THIS SITE WILL NOT DISTRIBUTE CONTROLLED SUBSTANCES IN OR INTO OHIO.** *LEAVE PAGEs 8 & 9 BLANK. RETURN THIS PAGE WITH THE REST OF THE APPLICATION.*

21. TYPE OF LICENSE REQUESTED (Check only ONE)

☐ **WHOLESALER OF CONTROLLED SUBSTANCES** (ORC 3719.021 & 3719.03)	☐ **MANUFACTURER OF CONTROLLED SUSBTANCES** (ORC 3719.02 & 3719.03)

22. DRUG SCHEDULES (Check all that apply)

Enclose a copy of the DEA registration.

Schedule I	Schedule II	Schedule III	Schedule IV	Schedule V
☐	☐	☐	☐	☐

DEA Number	Expiration Date

23. QUALIFICATIONS FOR LICENSURE (ORC 3719.03)

Applicant hereby certifies and agrees to provide, upon request, proof satisfactory to the State of Ohio Board of Pharmacy that:
(1) The applicant is of good moral character or, if the applicant is an association or corporation, that the managing officers are of good moral character;
(2) The applicant is equipped as to land, buildings, and paraphernalia to properly carry on the business for which this license is requested;
(3) The applicant's trade connections are such that there is a reasonable probability that the applicant will apply all controlled substances possessed by him/her to sale at wholesale for: (check all that apply)

☐ Scientific Purposes ☐ Experimental Purposes ☐ Medicinal Purposes ☐ Instructive Purposes ☐ Return Service Only

(4) The applicant is in sufficiently good financial condition to carry out his/her obligation;
(5) The granting of this license is in the public interest.

24. STATEMENT OF APPLICANT (Person who may legally sign for the business)- Statement must be manually signed (wet ink) and completed by the individual who may legally sign for the business and can verify the information provided in this application is true, correct, and complete.

Name	Title
Phone (including area code)	E-mail

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921., 3715., 3719. AND 4729. THAT I AM AUTHORIZED TO PURSUE THIS APPLICATION ON BEHALF OF THE ENTITY LISTED IN THIS APPLICATION AND THAT THIS APPLICATION IS TRUE, CORRECT, AND COMPLETE. I HEREBY ACKNOWLEDGE THAT IF THE LICENSE APPLIED FOR IS GRANTED, THE LICENSE-HOLDER SHALL SUBMIT TO THE JURISDICTION OF THE STATE OF OHIO BOARD OF PHARMACY AND TO THE LAWS OF THIS STATE FOR THE PURPOSE OF ENFORCEMENT OF CHAPTERS 2925., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE AND ALL RELATED LAWS AND RULES.

Signature of Applicant	**Date**	**Date of Birth or Social Security Number**

25. STATEMENT OF INDIVIDUAL RESPONSIBLE FOR SUPERVISION AND CONTROL OF DANGEROUS DRUGS - Statement must be signed (wet ink) and dated by the individual who will be responsible for the supervision and control of the dangerous drugs and drug records at this location. **Note: the Responsible Person (RP) is also responsible for ensuring that the application is true, correct, and complete.**

I HEREBY CERTIFY that I, or personnel employed in the wholesale distribution of dangerous drugs, have the appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

I HEREBY AGREE that I, or the corporation if applicable, shall sell drugs in the state of Ohio to no person other than: exempt prescribers; licensed wholesale distributors of dangerous drugs; licensed manufacturers of dangerous drugs; licensed terminal distributors of dangerous drugs; carriers or warehousemen (for purposes of carriage and storage); or, terminal or wholesale distributors of dangerous drugs who are not engaged in the sale of dangerous drugs within Ohio; and that I assume the responsibility for supervision and control of the dangerous drugs possessed or distributed by, or on behalf of, the applicant. See ORC 4729.51 & 4729.60.

FURTHER, I HEREBY AGREE that, if licensed, communications from the Board may be directed to me, and notices and citations provided for in Section 4729.56 of the Revised Code may be served upon me, and shall constitute proper service upon and notice to the registered wholesale distributor of dangerous drugs for all purposes under Sections 4729.51 to 4729.61 of the Revised Code. I also understand that if and when this business is discontinued that a "Written Notice of Discontinuing Business" form must be secured from the Ohio State Board of Pharmacy, completed by me, and returned to their offices with the license being discontinued as required in Rule 4729-9-07 of the Ohio Administrative Code.

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SIGNATURE of Responsible Person	**Date Signed**	**DOB or SSN**
Print or Type Name	Title	
Mailing Address, City, State, Zip Code		
Phone (including area code)	E-mail Address	
Professional License Number (if hospital, pharmacy or clinic)	Type of License	State of Licensure

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APPLICATION FOR LICENSE AS A WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS OUTSOURCING FACILITY MAILING CHECKLIST

ALL APPLICANTS MUST PROVIDE

- COMPLETED Application
- Appropriate Fee
- Copy of Corporation Papers &/or Limited Liability Papers
- FDA Registration
- FDA Inspection
  - Any corrective actions
  - Any follow up inspection reports (i.e. Form FDA-483, WARNING letters, etc.)
- BCI and FBI background checks for owners and officers have been submitted and are being sent to the State of Ohio Board of Pharmacy
- Officer criminal records check form

IF YOU ARE ALSO REQUESTING TO SHIP CONTROLLED MEDICATIONS

- Copy of your DEA Registration

IF YOU ARE ALSO PROVIDING PATIENT-SPECIFIC COMPOUNDED MEDICATIONS

- COMPLETED Terminal Distributor of Dangerous Drugs Application (http://www.pharmacy.ohio.gov/TDDD/General.aspx)
- Appropriate Fee

IF YOU ARE FROM OUT OF STATE

- WDDD License Verification Affidavit
- A verification letter (certification) for the Pharmacist signing the application as Responsible Person from the licensing authority of the state in which the pharmacy is licensed
- An inspection report conducted by the state licensing authority of the state where the business is physically located (the report must be within 24 months of the date of application)

77 South High Street, 17th Floor, Columbus, Ohio 43215

T: (614) 466.4143 | **F:** (614) 752.4836 **new.license@pharmacy.ohio.gov** | **www.pharmacy.ohio.gov**

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Criminal Records Check Requirements

BACKGROUND CHECKS MAY TAKE UP TO 10 WEEKS

Criminal records checks are required for all owners or, if incorporated, the officers of an Ohio licensed wholesale distributor of dangerous drugs pursuant to ORC 4729.53 and OAC 4729-9-16.

Do **NOT** submit your application until your owners or, if incorporated, the officers have completed their fingerprint process and you have attached all the required forms.

Failure to follow these instructions will delay the processing of your application.

The criminal records check may be handled in one of two ways:

1. In Ohio, submit your electronic fingerprint impressions at a WebCheck provider which must be located in Ohio. WebCheck provider locations can be found by visiting: http://www.ohioattorneygeneral.gov/Business/Services-for-Business/WebCheck/Webcheck-Community-Listing

-OR-

2. If owners/officers are out of state, you may request the number of fingerprint cards needed (each owner/officer will need two – one for BCI&I, one for FBI) from the Board and take to your local law enforcement agency to submit ink fingerprint impressions. To obtain fingerprint cards, fill out the Fingerprint Card Request Form and email it to WDDD@pharmacy.ohio.gov or order from the Ohio Attorney General's Office by visiting: http://www.ohioattorneygeneral.gov/Business/Services-for-Business/Webcheck

All fingerprint cards and 2 checks (totals to be determined by # of owners/officers x $22.00 and # of owners/officers x $24.00), both written to "Treasurer, State of Ohio" need mailed to:

Bureau of Criminal Identification and Investigation
P.O. Box 365
London, OH 43140

Note: **Do NOT mail your fingerprints to us.** We will not forward to Ohio BCI&I nor return them to you. You will need to have them redone and the processing of your license will be delayed.

Direct that the results be sent directly to:

State of Ohio Board of Pharmacy
77 S. High Street, 17th Floor
Columbus, Ohio 43215

Reason for fingerprinting: Ohio Revised Code Section 4729.071 for Licensing. Agency Code: 1AB002

REMINDERS:

- Fingerprints of all owners or, if incorporated, the officers must be done before submitting an application. Include with your application the officer criminal records check form on the following page.
- Include your state licensing agency certified verification of good standing. **A copy from a web site is NOT sufficient.**
- Procedure for obtaining a change, correction, or updating of an FBI identification record are set forth in Title 28, C.F.R., § 16.34. You may also obtain a copy of your results by contacting the BCI office where you submitted your test. For your convenience, the BCI phone number is 1-877-224-0043 (Option 7).

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WHOLESALE DISTRIBUTOR FINGERPRINT CARD REQUEST FORM

Pursuant to ORC 4729.53 and OAC 4729-9-16, criminal records checks are required for all owners or, if incorporated, officers of Ohio-licensed wholesale distributors of dangerous drugs. This process includes submitting fingerprints.

Out-of-state owners/officers must submit two sets of fingerprints - one on Federal Bureau of Investigation (FBI) form FD-258 and the other on Ohio Bureau of Criminal Investigation (BCI) form BIM 12/98 (Civilian Identification Fingerprint Card) to take to their local law enforcement agency to submit ink fingerprint impressions.

The Ohio Board of Pharmacy will provide up to 15 of each card at no charge by e-mailing this request form to WDDD@pharmacy.ohio.gov.

Requests for quantities larger than 15 must be submitted directly to BCI by visiting the Ohio Attorney General's Office website at http://www.ohioattorneygeneral.gov/Files/Forms/Forms-for-Business-and-Nonprofit/Background-Check-Forms/2011-3-25_SupplyRequisitionForm_BCI-pdf.aspx

For more detailed information on this process, consult the instructions provided on the Ohio Board of Pharmacy application for wholesale distributor of dangerous drugs.

Date

REQUESTER INFORMATION:

First, Last Name:	Organization Name:
Phone Number:	Mailing Address:
E-mail:	City, State, Zip Code:

FBI FINGERPRINT CARD(S)
Quantity: _____

BCI FINGERPRINT CARD(S)
Quantity: _____

ADDRESS WHERE CARDS ARE TO BE MAILED:

Organization Name:	Attn:
Mailing Address:	City, State, Zip Code:

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WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS OFFICER/OWNER CRIMINAL RECORDS CHECK FORM

****DO NOT REMOVE THIS PAGE****
Please submit this form with your application

Name of Business

*Please provide the full **legal** name (no nicknames), title and last four digits of SSN for those persons who are submitting fingerprints for a criminal records check.*

First Name	Last Name	Title	Last Four Digits SSN

Duplicate this form as necessary.

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WHOLESALE DISTRIBUTOR OF DANGEROUS DRUG LICENSE VERIFICATION AFFIDAVIT (NON-OHIO APPLICANTS ONLY)

(THIS FORM TO BE COMPLETED BY STATE LICENSING AUTHORITY)

WDDD Name As Licensed		
Physical Address (Street, City, State, Zip Code)		
Type of Operation	License Number	Type of License

The company on the Ohio application provided the above information. Please correct the information, directly above or on the reverse of this form, if your records indicate any discrepancies.

Date Licensed Issued	Expiration Date

1. Does this license authorize the manufacture and/or distribution of prescription drugs and/or controlled substances within your state?	Yes ☐	No ☐
2. To the best of your knowledge, and with information known at this time, do you have any reason to believe that this License issued by your state licensing authority will be suspended, revoked or not renewed at any time during the next two years? **(If yes, please explain on a separate sheet)**	Yes ☐	No ☐
3. To the best of your knowledge, has the company been denied a permit to manufacture and/or distribute prescription drugs in your state, or any other state? **(If yes, please explain on a separate sheet)**	Yes ☐	No ☐
4. To the best of your knowledge, has the company's license, which authorizes the manufacture and/or distribution of prescription drugs in your state, or any other state, been the subject of any disciplinary action? **(If yes, please explain on a separate sheet)**	Yes ☐	No ☐
5. To the best of your knowledge, has the company (owners, officers, or managers-in-charge) been convicted under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? **(If yes, please explain on a separate sheet)**	Yes ☐	No ☐

Name (Please Print)	Title	State
Signature	SEAL	
Date of Signature		

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WHOLESALE AND TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS APPLICATION LEGAL QUESTIONS

UPDATED 5/23/2016

The required legal questions on the initial and renewal applications provide the opportunity for the Board to review the facts and circumstances related to a particular case to determine its potential connection, if any, to the issuance or renewal of a license. The purpose of such questions is to act as a safeguard against the diversion of dangerous drugs and protection of confidential patient information by disclosing information necessary to protect the health and safety of the public. The questions are as follows:

On the initial application:

Does the applicant, owner(s), Responsible Person, any agent or any employee of the location being licensed, or any officer of the corporation, have a record of arrest or charges pending or have a conviction of a felony, misdemeanor or traffic violation (even if expunged, dismissed or sealed) or the equivalent in another jurisdiction?

NOTE: An applicant should not answer yes for any traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or an expired registration.

Has the applicant, owner(s), Responsible Person, any agent or any employee of the location being licensed, or any officer of the corporation, ever been the subject of disciplinary action (or any pending action) by any state or federal agency; even if subsequently dismissed or resolved without formal discipline?

For a renewal application:

Within the last 18 months: does the Responsible Person or owner(s), or any agent or any employee of the location being licensed, or any officer of the corporation, have a record of arrest or criminal charges pending or have a conviction of a felony, misdemeanor, or traffic violation (even if sealed or expunged)?

NOTE: A licensee should not answer yes for any traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or an expired registration.

Within the last 18 months: has the Responsible Person or owner(s), or any agent or employee of the Responsible Person/owner(s), or any officer of the corporation, been the subject of disciplinary action by any state or federal agency?

Frequently Asked Questions:

Q1: Who is covered by the legal questions? Does this apply to all employees, agents, or contractors of an entity, even those that do not work on-site?

A1: The questions include the Responsible Person, any officer of the corporation and all employees, agents, or contractors working at the physical location of the licensee with access to dangerous drugs and D.E.A. controlled substance order forms.

It does **not** include employees/contractors such as administrative, janitorial, IT or other staff that may need limited supervised access to areas where dangerous drugs or D.E.A. controlled substance order forms are kept. However, the licensee must have policies in place that prohibit unsupervised access to such areas by these employees.

This question does not apply to former employees or agents of the licensee at the time the legal questions are answered.

PLEASE NOTE: For a pain management clinic, section 4729.552 of the Revised Code requires all employees of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and ensure that no person is employed who has previously been convicted of, or pleaded guilty to, either of the following:

(1) A theft offense, described in division (K)(3) of section 2913.01 of the Revised Code, that would constitute a felony under the laws of this state, any other state, or the United States; or

(2) A felony drug abuse offense, as defined in section 2925.01 of the Revised Code.

Q2: How is it possible for a Responsible Person (RP) or owner to sign off that they know about any possible criminal charges, convictions, or discipline that may have occurred for all "owners, agents or employees" at the time of initial licensure or since the previous renewal?

A2: The entity seeking licensure and the RP should exercise due diligence in making sure they know the answers to these questions as they pertain to the owners, officers, employees and contractors described in Q1. For large companies, this will come as a result of having appropriate policies in place that require reporting when an owner, officer, employee or contractor is charged/convicted or disciplined during the timeframe in question. This also means having initial screening policies of new owners, officers, employees or contractors who meet the criteria listed in Q1.

The Board does not advise an entity on how to obtain their information nor instruct an entity as to what their policy must include. However, as a general rule, a policy with a mandatory reporting clause has been found to be acceptable by the Board. Such a policy should be implemented in accordance with all federal and state laws. There must be

mechanism in place for results of that mandatory reporting to be relayed to the RP/owner/applicant on the license so that the legal questions can be answered honestly and accurately. As long as the entity/RP is aware that such a mechanism is in place requiring such reporting and that the necessary personnel (i.e. RP) would be aware of it when completing and signing the application, the entity/RP may check answer the questions accordingly.

NOTE REGARDING THE FEDERAL EQUAL EMPLOYMENT OPPORTUNITY COMMISSION (EEOC):

The EEOC does not have the authority to prohibit employers from obtaining or using arrest or conviction records. The EEOC simply seeks to ensure that such information is not used in a discriminatory way.

In implementing policies related to obtaining appropriate employment information in the Wholesale or Terminal Distributor of Dangerous Drugs setting, be mindful that the policy should be applied equally to all applicants. The EEOC publishes the following guidance:

> *In all cases, make sure that you're treating everyone equally. It's illegal to check the background of applicants and employees when that decision is based on a person's race, national origin, color, sex, religion, disability, genetic information (including family medical history), or age (40 or older). For example, asking only people of a certain race about their financial histories or criminal records is evidence of discrimination.*

The EEOC enforces Title VII, which prohibits employment discrimination based on race, color, religion, sex, or national origin. Having a criminal record is not listed as a protected basis in Title VII. Therefore, whether a covered employer's reliance on a criminal record to deny employment violates Title VII depends on whether it is part of a claim of employment discrimination based on race, color, religion, sex, or national origin. Title VII liability for employment discrimination is determined using two analytic frameworks: "disparate treatment" and "disparate impact."

Title VII also does not preempt federal statutes and regulations that govern eligibility for occupational licenses and registrations. These restrictions cover diverse sectors of the economy including the transportation industry, the financial industry, and import/export activities, among others.

Q3: If an owner, officer, employee or contractor described in Q1 has been charged/convicted/disciplined prior to initial licensure or in the intervening timeframe for renewals, must the entity terminate that individual's employment in order to obtain a license?

A3: The Board does not advise an entity on whether to terminate an individual with a criminal case/conviction or disciplinary action; that decision rests with the entity's personnel policies. However, the entity MUST report the underlying charge/conviction/discipline to the Board so that the Board may review the facts and

circumstances related to a particular case to determine its potential connection, if any, to the license for which the entity/RP is renewing or applying.

Q4: Rule 4729-9-27 states the following:

> *(A) Pursuant to 21 C.F.R. Section 1301.76 (10/20/2015), a terminal or wholesale distributor of dangerous drugs that is a United States Drug Enforcement Administration registrant shall not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.*
>
> *(B) Paragraph (A) of this rule does not apply if a waiver is obtained by a registrant pursuant to 21 C.F.R. Section 1307.03.*

Does this apply to a potential employee who may have had their felony record(s) expunged, unless granted a waiver by the DEA?

A4: Yes. According to the DEA, the employer would be required to obtain a waiver even if a conviction is expunged. A waiver would also be required for a potential employee who has entered a felony guilty plea relating to controlled substances, as the DEA considers this a conviction. As this rule references an existing federal regulation, the Board will interpret and enforce this requirement in the same manner as the DEA.
More information regarding the waiver process can be accessed here:
http://www.deadiversion.usdoj.gov/faq/waiver_1301_76.htm

To contact your local DEA regional office:
https://www.deadiversion.usdoj.gov/contactDea/spring/fullSearch?execution=e3s1

Q5: How can the Board expect an employer to require an employee, agent, etc. to disclose an expunged or sealed criminal record?

A5: Section 2953.33(B) of the Ohio Revised Code permits inquiry into sealed convictions if the question bears a direct and substantial relationship to the position for which the person is being considered. This code section applies to applications for employment, license, or other right or privilege. An inquiry into past charges or convictions for violating state and federal drug laws bears a direct and substantial relationship to the position of a licensed pharmacist. See also *Ohio State Bd. of Pharmacy v. Friendly Drugs*. Employers are expected to perform due diligence in the hiring process to ensure that no applicant is hired in violation of state or federal law (unless a DEA wavier has been granted, please see Q4).

Q6: Is there a list of disciplinary actions (including pending actions) by state or federal agencies that must be reported to the Board of Pharmacy upon initial licensure or renewal? Does the Board expect to be notified of employer disciplinary action?

A6: While no such list of disciplinary action exists, the National Practitioner Data Bank has developed some guidance for reporting of licensure discipline actions: http://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp?page=EStateLicensureActions.jsp (*NOTE: While this reference is specific to state licensure or certification actions, it can also apply to similar actions by federal agencies.)*

The Board is not seeking information on an employer disciplinary action (such as being late to work, dress code, or attendance issues), ***unless*** that action resulted in or is related to state licensing and certification action taken against a license.