



APPLICATION FOR PHARMACIES

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 PHARMACY REGISTRATION:

CATEGORY II LICENSE WITH NO CONTROLLED SUBSTANCES IS \$112.50

CATEGORY III LICENSE WITH CONTROLLED SUBSTANCES IS \$150.00

THIS APPLICATION IS FOR THE FOLLOWING FACILITIES:

- INSTATE AND OUT OF STATE PHARMACIES
- RETAIL PHARMACY
- MAIL ORDER PHARMACY
- NUCLEAR PHARMACY
- FLUID THERAPY PHARMACY
- CHARITABLE PHARMACY
- MEDICATION THERAPY MANAGEMENT
- CONSULTING ONLY PHARMACY PRACTICE
- REMOTE ORDER ENTRY
- CORRECTIONAL FACILITIES
- HOSPITALS
- CENTRAL FILL (MULTI-DISCIPLINARY)
- PHARMACY SERVICING OTHERS
- PHARMACY SUPPLIED CONTINGENCY STOCK

**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.

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**PHARMACY
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS**

Carefully read all instructions. **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.

Please make check payable to "Treasurer, State of Ohio"

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

PLEASE TYPE OR PRINT LEGIBLY

1. LICENSE REQUEST

Change New	Proposed opening date or date of change	If change, give current TDDD License Number									
If change, select ALL that apply: <table style="width: 100%; border: none;"> <tr> <td style="width: 30%;">Name</td> <td style="width: 30%;">Ownership</td> <td style="width: 40%;">Business Type</td> </tr> <tr> <td colspan="3">Other, please specify</td> </tr> <tr> <td colspan="3" style="border: 1px solid black; height: 20px;"></td> </tr> </table>			Name	Ownership	Business Type	Other, please specify					
Name	Ownership	Business Type									
Other, please specify											

2. NAME OF BUSINESS BEING LICENSED - Name under which applicant will be doing business, address, phone number, and mailing address if different than above.

Business Name (i.e. reflected by signage/how you will answer the phone)			County
Street Address (No P.O. Box)	City, State	Zip Code	Phone (include area code)
Mailing Address, City, State, Zip Code (if different from above)			Fax (include area code)

3. NAME OF BUSINESS SERVICING THE ENTITY LISTED IN #2- This is only applicable for nursing home/other institution contingency stock

Name as listed on the TDDD License	TDDD License Number
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For State of Ohio Board of Pharmacy Use Only						
Control #	Amt Received	Office/Field	Class	BT	Drug Category	TDDD License New # /Same #
					I II III L	

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4. APPLICANT INTENDS DOING BUSINESS AS (Select One) - Indicate the applicant's type of business organization.

Government	Corporation	Partnership	Limited Liability Company
Sole Proprietorship			

5a. NAME OF GOVERNMENT AGENCY (if applicable)

Name

5b. CORPORATION INFORMATION, IF INCORPORATED - A copy of articles of incorporation and/or limited liability papers must accompany this application. The following information may be contained in the incorporation papers usually maintained by the applicant's business office or, for Ohio companies, may be obtained by visiting the Ohio Secretary of State: www.sos.state.oh.us

Leave blank if Government Agency

Entity/Charter number	Federal Tax ID or EIN Number	State where incorporated
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5c. NAME OF OWNER(S); 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

Name	Title	Date of Birth or Social Security Number

6. CATEGORY OF LICENSE (Check only ONE) Application is hereby made for a license as a TERMINAL DISTRIBUTOR of Dangerous Drugs, as provided in Sections 4729.54, 4729.541, 4729.55, 4729.551 and 4729.552 of the Ohio Revised Code, as follows:

CATEGORY II - \$112.50 This licensee may possess, have custody or control of, and distribute prescription drugs (including medical oxygen and other medical grade gases) that are **not controlled substances**.

CATEGORY III - \$150.00 This licensee may possess, have custody or control of, and distribute prescription drugs, including controlled substances contained in Schedules II, III, IV, or V.

The following categories apply only to remote order entry, medication management therapy, and consulting-only pharmacies

LIMITED CATEGORY I- \$45.00 This licensee may only possess single dose injections of IV fluids or parenteral solutions that have volume of 100ml(s) and contain no added substances. This license may also have single-dose injections of epinephrine to be administered pursuant to ORC 4765.38 & 4765.39

LIMITED CATEGORY II - \$112.50 This licensee may only possess, have custody or control of, and distribute prescription drugs (including medical grade gases) that are **not controlled substances** approved by a Medical Director. **An addendum will be produced as part of the license, listing the drugs that have been submitted.**

LIMITED CATEGORY III - \$150.00 This licensee may only possess, have custody or control of, and distribute prescription drugs, **including controlled substances** approved by a Medical Director. **An addendum will be produced as part of the license, listing the drugs that have been submitted.**

Drug Enforcement Administration License Number *(for Category III only; if pending leave blank)*:

7. PROVIDE A DETAILED NARRATIVE DESCRIPTION OF THE TYPE OF BUSINESS ACTIVITIES (PLEASE BE SPECIFIC) THAT WILL BE CONDUCTED AT THIS LOCATION THAT REQUIRES THE APPLICANT TO BE ISSUED A TDDD LICENSE

Indicate your HOURS OF OPERATION, WEB SITE ADDRESS, and TYPE OF BUSINESS YOU ARE CONDUCTING in Ohio. Refer to example questions below to assist with narrative. Narrative MUST BE PROVIDED or the application is considered incomplete.

Examples: Do you service patients, animals, or facilities? What type of pharmacy (hospital, retail pharmacy, specialty clinic, physician office, pharmacy servicing other institutions, etc.)? What type of prescription medications do you dispense (specialty or retail)? Do you compound sterile and/or non-sterile products?

8. TYPE OF ESTABLISHMENT BEING LICENSED (Check ALL what applies in this section)

IN-STATE PHARMACY

Retail Independent /Chain

Nuclear Pharmacy

Durable Medical Equipment Pharmacy (DME)

Mail Order Pharmacy

Multi-Disciplinary Pharmacy (i.e. Multi-practice such as central fill, compounding, consulting, & mail order)

Other:

NON-RESIDENT PHARMACY

Compounding Sterile

Non-Sterile

Fluid Therapy/Infusion Pharmacy

Charitable Pharmacy

Medication Therapy Management (MTM)

Pharmacy Supplied Contingency Stock

Correctional Institution

Hospital

Consulting Only

Remote Order Entry

Pharmacy-Servicing Others (i.e. Nursing Homes)

ADDITIONAL DOCUMENTATION REQUIRED:

FOR CONSULTING ONLY PHARMACIES/REMOTE ORDER ENTRY FACILITIES (read below statement)

1. Consulting only pharmacies/Call Centers must enclose a statement on another sheet of paper that states that there are no dangerous drugs possessed or distributed from this location. Include that activity at this licensed site will be consulting only. The statement must be signed by the Responsible Person. **This form is provided at the end of this application.**
2. Remote order entry facilities must enclose a statement on another sheet of paper that states that there are no dangerous drugs possessed or distributed from this location. Further, by resolution of the Board, R-2007-114 on 1/16/07, To be considered board-approved for remote pharmacy computer access, the following requirements, at a minimum, must be met: **This form is provided at the end of this application**
 - a. The remote computer must have positive identification, pursuant to rule 4729-5-01(N), of the pharmacist accessing the computer system. If an alternative method to achieve positive identification is desired, it must be presented to the Board for approval.
 - b. The remote computer access shall only involve pharmacists and they must be registered and practicing in Ohio. If not, the procedure for remote pharmacy computer access must be presented to the Board for approval. Application - Limited License Terminal Distributor
 - c. There must be an audit trail of any pharmacist remotely accessing the pharmacy computer system. The audit information should contain at least the date, time, information reviewed, information entered, and pharmacist accessing the system. This information should be placed in a report that is reviewed and compared to the orders/documentation as soon as possible by the Responsible Pharmacist or his/her designee. A policy should be in place to detail this quality assurance procedure.
 - d. The remote access and order information received must be secure to ensure confidentiality. The pharmacy must have a confidentiality policy and make a reasonable attempt to determine that it is being followed. If appropriate, this may require a site inspection by the Responsible Pharmacist or his/her designee.
 - e. The Board must inspect and approve remote pharmacy computer access and its policies prior to use.

FOR NON-RESIDENT PHARMACIES ONLY

1. Please refer to the **NON-RESIDENT PHARMACY ADDENDUM** at the end of the application for more information on additional required documentation. Failure to provide all requested documents will delay your application process.

8. 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 approximate date of application and the reason why:

LEGAL QUESTIONS (9 & 10)

Please note these 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. **Failure to answer these questions makes your application incomplete, delaying the licensing process. Answering incorrectly could be a crime, see [ORC 2921.13](#)**

9. RECORD OF DISCIPLINARY ACTIONS AND FINES IMPOSED - The legal questions must be answered.

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 CERTIFIED COPY OF THE DISCIPLINE DOCUMENT WITH THE APPLICATION.**

10. 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) or the equivalent in another jurisdiction?

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).

11. STATEMENT OF INDIVIDUAL RESPONSIBLE FOR SUPERVISION AND CONTROL OF DANGEROUS DRUGS

Statement must be signed (**wet ink – NO COPIES**) and dated by the individual who will be responsible for the supervision and control of the dangerous drugs and drug records at this location (i.e. the Responsible Person). **The Responsible Person is also responsible for ensuring that the application is true, correct and complete.**

I HEREBY AGREE to and assume the responsibility for supervision and control over the possession and custody of the dangerous drugs and drug records that may be acquired/maintained by, or on behalf of, the applicant pursuant to Section 4729.55(B), O.R.C.

I FULLY UNDERSTAND that, as a licensed Terminal Distributor, drugs may be purchased only within the requested category of license from Wholesale Distributors of Dangerous Drugs registered in the State of Ohio by the Ohio State Board of Pharmacy. 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	PRINT OR TYPE NAME
Phone (including area code)	E-mail Address	

Qualifications of Responsible Person:

RPH License Number:

12. INDIVIDUAL TO CONTACT REGARDING ABOVE LOCATION, BETWEEN 8 AM AND 5 PM WEEKDAYS - Individual to contact if there are questions regarding the application (must be the Responsible Person or Designee) & the person who will receive your Ohio license.

Name	Title
Phone (including area code)	E-mail

13. 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)

14. STATEMENT OF APPLICANT (Person who may legally sign for the business)

Statement must be manually signed (**wet ink – NO COPIES**) 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. Failure to do so makes your application incomplete, delaying the licensing process.

Name	Title	
Phone (including area code)	E-mail	
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 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

**COMPLETION OF THIS FORM IS REQUIRED BY O.R.C. SECTION 4729.54
MAXIMUM PENALTY: DENIAL OF LICENSE**



NON-RESIDENT PHARMACY ADDENDUM

ALL applicants must submit the following, if applicable:

Corporation papers and/or articles of incorporation or Limited Liability (LLC) papers for the pharmacy. This includes names, dates of birth, addresses, and social security numbers of the officers.

A copy of your most recent State inspection report. Also, if applicable, any corrective actions or follow up inspection reports pertaining to the findings. If you have not been inspected in the last 18 months, provide a statement indicating as such.

A list of all Pharmacists practicing at the application location - including resident state pharmacy license numbers (form is included in this application).

A copy of DEA License (category III license only).

Pharmacy license verification from the state in which you are licensed indicating good standing.

Pharmacist license verification for the pharmacist who will be the responsible person from the state in which you are practicing indicating good standing.

A **written description** of the following:

- Normal delivery protocols and times;
- Any special packaging or procedures used in delivering temperature sensitive drug products;
- Detailing how the applicant will comply with the requirement that **an offer to counsel the patient** be issued with every prescription filled.
 - The offer shall be made by telephone or in writing on a separate document and shall accompany the prescription.
 - A written offer to counsel shall include the hours a pharmacist is available and a telephone number where a pharmacist may be reached.
 - The telephone service must be available at no cost to the pharmacy's primary patient population. The pharmacy shall have a sufficient telephone service to provide reasonable access to incoming callers.

Most recent FDA Inspection (if applicable)

COMPOUNDING APPLICANTS (STERILE AND NON-STERILE) MUST PROVIDE EITHER OF THE FOLLOWING:

For all pharmacies shipping into Ohio, prescriptions must be sent to the PATIENT. If you want to ship ANY patient specific medications to the prescriber rather than the patient, you must submit information to the Board (specific to each prescriber office) prior to any such shipment to that location. More information about this process can be accessed here: www.pharmacy.ohio.gov/pickup

Please be advised that effective May 1, 2015, rule 4729-16-08 of the Ohio Administrative Code requires all non-resident compounding pharmacies to submit documentation that the facility is in compliance with

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paragraphs (A) and (B) of rule [4729-16-03](#) of the Ohio Administrative Code, which requires compliance with USP 797 (for sterile products) and 795 (for non-sterile products). **The applicant may submit one of the following:**

A National Association of Boards of Pharmacy's Verified Pharmacy Program documenting compliance with USP 797 and/or USP 795; or

A recent state inspection that is less than two (2) years old documenting compliance with USP 797 and/or USP 795. This inspection report can be from any state licensing agency; or

Proof of a current pharmacy compounding accreditation board (PCAB) accreditation provided by the accreditation commission for health care (ACHC); or

The most recent inspection report that is less than two years old that demonstrates compliance with USP 795 and/or 797 conducted by accreditation commission for health care inspections services (a.k.a. ACHS inspection services or AIS); or

The board may grant a one-year, one-time extension to nonresident pharmacies in the event an inspection report is not available at the time of application or renewal and documentation is presented verifying intent to comply with this rule.

*If an extension is requested you **must** submit requested compounding information with this packet. If you fail to submit documents, your application will be incomplete and delay the application process. (**checklist and extension letter is provided at the end of this application**).*

CONSULTING/REMOTE ORDER ENTRY/MMT APPLICANTS MUST PROVIDE:

1. Consulting only pharmacies/Call Centers must enclose a statement on another sheet of paper that states that there are no dangerous drugs possessed or distributed from this location. Include that activity at this licensed site will be consulting only. The statement must be signed by the Responsible Person. **This form is provided at the end of this application.**
2. Remote order entry facilities must enclose a statement on another sheet of paper that states that there are no dangerous drugs possessed or distributed from this location. Further, by resolution of the Board, R-2007-114 on 1/16/07, To be considered board-approved for remote pharmacy computer access, the following requirements, at a minimum, must be met: **This form is provided at the end of this application**
 - a. The remote computer must have positive identification, pursuant to rule 4729-5-01(N), of the pharmacist accessing the computer system. If an alternative method to achieve positive identification is desired, it must be presented to the Board for approval.
 - b. The remote computer access shall only involve pharmacists and they must be registered and practicing in Ohio. If not, the procedure for remote pharmacy computer access must be presented to the Board for approval. Application - Limited License Terminal Distributor
 - c. There must be an audit trail of any pharmacist remotely accessing the pharmacy computer system. The audit information should contain at least the date, time, information reviewed, information entered, and pharmacist accessing the system. This information should be placed in a report that is reviewed and compared to the orders/documentation as soon as possible by the Responsible Pharmacist or his/her designee. A policy should be in place to detail this quality assurance procedure.
 - d. The remote access and order information received must be secure to ensure confidentiality. The pharmacy must have a confidentiality policy and make a reasonable attempt to determine that it is being followed. If appropriate, this may require a site inspection by the Responsible Pharmacist or his/her designee.



NON-RESIDENT COMPOUNDING PHARMACY ONE-YEAR EXTENSION REQUEST

Statement to Be Completed by the Person who is Signing as Responsible Person (must be a Pharmacist) for a Terminal Distributor of Dangerous Drug (TDDD) license.

I certify that I will provide the State of Ohio Board of Pharmacy one (1) year from this application date one of the following:

- A National Association of Boards of Pharmacy’s Verified Pharmacy Program documenting compliance with USP 797 and/or USP 795; or
- A recent state inspection that is less than two (2) years old documenting compliance with USP 797 and/or USP 795. This inspection report can be from any state licensing agency; or
- Proof of a current pharmacy compounding accreditation board (PCAB) accreditation provided by the accreditation commission for health care (ACHC); or
- The most recent inspection report that is less than two years old that demonstrates compliance with USP 795 and/or 797 conducted by accreditation commission for health care inspections services (a.k.a ACHS inspection services or AIS); or
- The board may grant a one-year, one-time extension to nonresident pharmacies in the event an inspection report is not available at the time of application or renewal and documentation is presented verifying intent to comply with this rule.

If an extension is requested, you shall provide the documents in the checklist included with this letter to the Ohio State Board of Pharmacy to ensure safe compounding practices in Ohio.

Business Name (name applicant will be DOING BUSINESS AS reflected by signage/how you will answer phone)	Terminal Distributor Number:
Street Address (No P.O. Box)	City, State, Zip Code

Printed Name of Responsible Person	Professional License No. / State Issued
Signature of Responsible Person	Date



**CHECKLIST ONLY FOR NON-RESIDENT COMPOUNDING PHARMACIES
REQUESTING A ONE-YEAR EXTENSION**

Please submit all the following if requesting a one-year extension:

A List of the top ten (10) compounded products (sterile and/or non-sterile)

Copy of a prescriber provided prescription for sterile and/or non-sterile product

Copy of a pharmacy generated fax prescription for sterile and/or non-sterile product

Completed master formula and compounding record for a sterile and/or non-sterile
Prescription provided above

Copy of a patient label for prescription provided above

Recent potency testing for Sterile and/or non-sterile compounded product *(if applicable)*

Beyond-use-justification if different from USP 797 and/or USP 795

Copy of recent hood certification(s), who certified the hood, date of certification *(if applicable)*

Resident State Sterile Compounding License *(if applicable)*

Policy and procedure manual for **Sterile Compounding ONLY** pursuant to OAC 4729-19-04

A quality assurance program for monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education.

Justification for the chosen beyond use dates of compounded products.

Handling of cytotoxic waste, if applicable

Delivery Service, offer to counsel, and temperature controls



CONSULTING, REMOTE ORDER ENTRY, OR MEDICATION THERAPY MANAGEMENT STATEMENT FORM

Statement to be completed by the person who is signing as responsible person (must be a pharmacist) for a terminal distributor of dangerous drug (TDDD) limited license as a consulting, remote order entry, or medication management therapy pharmacy only.

I certify that no prescription drug(s) are to be purchased/acquired, stored and used at this location under this TDDD license.

NAME that applicant will be DOING BUSINESS AS (i.e. reflected by signage/how you will answer the phone)

Street Address, City, State, Zip Code (No P.O. Box)

Printed Name of Responsible Person

Signature of Responsible Person

Document must be notarized:

Sworn to and signed before me this date:

Date

Signature of Notary

[SEAL]





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 waiver 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.