



**PAIN MANAGEMENT CLINIC
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:		
Name	Ownership	

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 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. 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
E-mail	Phone (include area code)

For State of Ohio Board of Pharmacy Use Only

Control #	Amt Received	Office/Field	Class	BT	Drug Category	TDDD License New #	Same #
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77 South High Street, 17th Floor, Columbus, Ohio 43215



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

Government	Corporation	Partnership	Limited Liability Company
Sole Proprietorship			

4a. NAME OF GOVERNMENT AGENCY (if applicable)

Name

4b. 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.

Leave blank if Government Agency

Entity/Charter number	Federal Tax ID or EIN Number	State where incorporated
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4c. 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

5. 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:
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6. CATEGORY III LICENSE - 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 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. This includes a license with a pain management clinic classification. This category also includes laboratories and any other facilities seeking possession of schedule I controlled substances*

Drug Enforcement Administration License Number (<i>for Category III only</i>):
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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: Describe the type of services you will offer at this clinic.

LEGAL QUESTIONS (8 & 9)

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**

8. 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 separate sheet and include a copy of the discipline document with the application.

9. 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).

10. 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 (include 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

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

NOTE: OAC 4729-5-11 REQUIRES THE RESPONSIBLE PERSON OF A PAIN MANAGEMENT CLINIC TO MEET THE SAME STANDARDS AS THE OWNER OF THE CLINIC. FOR MORE INFORMATION, PLEASE REVIEW THE GUIDANCE DOCUMENT INCLUDED WITH THIS APPLICATION.

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 (include area code)	E-mail Address	

Qualifications of Responsible Person

MD/DO License Number:

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



Pain Management Clinic (PMC) Application Checklist Refer to ORC 4729.552

All of the following documents must be sent with the Terminal Distributor of Dangerous Drug (TDDD) application (Form PHA-0600 which is 2 pages, the fee of \$150, and a copy of this document with appropriate boxes checked). If any item is not submitted, the application is considered incomplete and cannot be processed.

- Corporation papers and/or articles of incorporation for the PMC
- List of all owners with their Ohio Medical Board license #s

All owners must be MD or DO licensed by the State of Ohio Medical Board with a statement confirming that none of the owners have:

- Denied/restricted license by DEA
- Denied license/restricted license by any state
- Disciplinary action by any licensing entity

- Responsible Person (RP) must meet the requirements in [OAC 4729-5-11](#)

- Copy of current certification required by OAC 4731-29-01 **for each owner**
Either ONE of the following (6) CURRENT certifications:

American Board of Medical Specialties (ABMS)
www.certificationmatters.org/is-your-doctor-board-certified/search-now.aspx
subspecialty certification in

- (1) pain management
- (2) hospice & palliative medicine

American Osteopathic Association Bureau of Osteopathic Specialists (AOA-BOS)
www.osteopathic.org/osteopathic-health/find-a-do/Pages/default.aspx
added qualification in:

- (3) pain management
- (4) hospice & palliative medicine

American Board of Pain Medicine
<http://persweb.connect2amc.com/abpm/default.aspx?tabid=184>

- (5) board certification



American Board of Interventional Pain Physicians www.abipp.org/diplomates.aspx

(6) board certification

- OR-

Current board/primary certification by:

ABMS

<https://www.certificationmatters.org/is-your-doctor-board-certified/search-now.aspx>

-OR-

AOA-BOS www.osteopathic.org/osteopathic-health/find-a-do/Pages/default.aspx
in:

anesthesiology

psychiatry

neurology

physical medicine and rehabilitation

occupational medicine

rheumatology

Note: In this case, a copy of PMC TDDD application must be sent to the Ohio Medical Board. If this step is not completed correctly it will delay processing of your application.

Copy of the PMC TDDD application sent to Medical Board on (date): _____

BCI&I and FBI background check for each owner, pursuant to ORC 4776.02

Refer to "Criminal Records Check Required for Initial Licensure" on OSBP website.

You will need to submit your electronic fingerprint impressions at a WebCheck provider located in Ohio. WebCheck provider locations can be found at

<http://www.ag.state.oh.us/business/fingerprint/data/index.asp>

Direct that the **results** be sent directly to:

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

Instruct them that the reason for fingerprinting is Ohio Revised Code Section 4729.071 for Licensing.

Give them Agency Code: **1AB002**

Note: WebCheck provider must submit the results of these criminal records check directly to the Ohio Board of Pharmacy for review and decision pursuant to ORC 4729.071

Submit list of when criminal records checks were done - with the date & agency used for each owner

List of all prescribers employed that are not owners with their professional license Number

A narrative description of the type of business being conducted within the category of licensure requested. The description shall include the type of professional services that will be provided in accordance with federal and state laws governing the legal distribution of drugs and professional medical practice. Your narrative should also include whether dangerous drugs and/or controlled substances will be stored on-site.

Remember that all employees of the PMC applicant must submit to a criminal records check in accordance with ORC 4776.02 and pursuant to OAC 4729.552(B)(4). These results are to be returned to the PMC applicant, NOT to OSBP or the employee. If these records are not available, the license will NOT be issued when our agents perform their initial inspection and may result in a Proposal To Deny your license.



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.