

APPLICATION FOR REGISTRATION/LICENSE AS A TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS WITH A PAIN MANAGEMENT CLINIC CLASSIFICATION

INSTRUCTIONS

**SUBMIT COMPLETED COPY OF BOTH FORM # 0600 & FORM # 0601
WITH ORIGINAL SIGNATURES TO THE BOARD OFFICE
OR APPLICATION WILL BE REJECTED.
MAKE CHECK for \$150 PAYABLE TO "Treasurer, State of Ohio".**

FORM # 0600 - Application for Dangerous Drugs Distributor Registration

1. Indicate whether this application represents a new license or is a change to a current license. In the next box, **give the proposed date of opening or licensing change**. If this site is already open and is not a licensed facility, state "already open." If this is a change, mark the type of change and give the existing Terminal Distributor license number, if applicable. This number begins with "02-".
2. This box must be completed with the name under which the applicant will be doing business and the **street address** of the business location. **THIS IS THE NAME THAT WILL APPEAR ON THE LICENSE.** Do not use a P. O. box number *only*. The address indicated on the application must describe **only one establishment or location** where the licensee engages in business. A mailing address, if different than the physical location being licensed, is to be entered in the "Mailing..." box.
3. If the entity conducts business under any other name, list these names.
4. Provide the contact information for the person to whom correspondence and questions about the application will be directed.
5. This box is not applicable to pain management clinic licensure.
6. Indicate the type of business the applicant intends doing business as.
- 6a. Give the name(s) of the owner(s) of the practice or corporation. The owners must all be physicians (M.D. or D.O.). **You must attach a copy of all owners' medical license(s) along with the application to prove credentials of M.D. or D.O. You must also attach a copy of your appropriate pain management specialty certification as required by H.B. 93.**
- 6b. Pertains to government agencies only.
- 6c. If incorporated, indicate the type of corporation. In Ohio, you will find the chapters in your articles of incorporation. In other states, you may need to look elsewhere. If you are having trouble obtaining your articles of incorporation, contact the Secretary of State. **You are required to submit a copy of your articles of incorporation with the application. Failure to do so will result in the application being returned, delaying the licensing process.**
7. Is self-explanatory - complete if applicable.
8. **Must be signed** and completed by the individual who can verify that the information provided in this application is true, correct, and complete. **Failure to do so will result in the application being returned, delaying the licensing process.**

FORM # 0601 - Application For A Terminal Distributor License

1. Check the Category III box. The fee for a pain management clinic is \$150.00. Make check payable to "Treasurer, State of Ohio" and submit with application.
2. Check the Pain Management Clinic box.
3. Self-explanatory. The license number(s) will begin with "01-" or "02-".
4. Must be answered. **Failure to do so will result in the application being returned, delaying the licensing process.**
5. Must be answered. **Failure to do so will result in the application being returned, delaying the licensing process.**
6. The person signing as responsible person for the pain management clinic must be an M.D. or D.O. and must be in full and actual charge of the practice, records, and dangerous drugs or controlled substances if applicable. The owner or one of the owners must sign as the responsible person.

ADDITIONAL ITEMS REQUIRED TO BE SUBMITTED WITH A PAIN MANAGEMENT CLINIC APPLICATION:

- A. Documentation verifying a certification, program, or service noted in paragraph (B) of rule 4731-29-01, to be effective 6/20/2011. A copy of the rule is included in the application packet.
- B. BCI&I and FBI criminal records check of physician owner(s). See the summary document included in this application packet for the proper procedure.
- C. Copy of corporation papers and physician owner(s) license(s) verifying credentials of M.D. or D.O as indicated in 6a and 6c.
- D. See paragraph (B)(3) of rule 4731-29-01 for grandfather provision information. This section of the rule is valid only for complete applications received by the Board of Pharmacy by 6/20/2011. Also, in order to be considered for a grandfather provision per this rule, a copy of the application must also be received by the Ohio Medical Board by 06/20/2011.

OHIO STATE BOARD OF PHARMACY
77 S. HIGH ST., ROOM 1702
COLUMBUS, OH 43215- 6126
Phone - 614/466- 4143

Website: www.pharmacy.ohio.gov
 E- mail: Licensing@bop.state.oh.us

FOR STATE BOARD OF PHARMACY USE ONLY			
Class:	Business Type:	Drug Category: L U	License No.:
Control Number:	Amt. Received:	Audit Number:	Fee:

READ CAREFULLY ALL INSTRUCTIONS BEFORE COMPLETING THIS APPLICATION

1. LICENSE REQUEST FOR: ALL MUST BE COMPLETED

<input type="checkbox"/> NEW <input type="checkbox"/> CHANGE	Proposed Opening Date or Date of Change:	Change Of: <input type="checkbox"/> Owner <input type="checkbox"/> New Satellite	<input type="checkbox"/> Address <input type="checkbox"/> Name	<input type="checkbox"/> Category <input type="checkbox"/> Other-specify:	If Change, give current DDD License I.D. No.:
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2. LOCATION BEING LICENSED:

NAME the applicant will be DOING BUSINESS AS (how you want name to appear on license)	County
Street Address, City, State, Zip Code (Physical address of licensed location)	Area Code / Telephone Number
Mailing Address, City, State, Zip Code (if different from above)	Area Code / Fax Number

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

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4. INDIVIDUAL TO CONTACT REGARDING ABOVE LOCATION, BETWEEN 8 AM AND 5 PM WEEKDAYS:

Name	Title
Mailing Address, City, State, Zip Code	Area Code / Telephone Number

5. NAME OF BUSINESS SERVICING ENTITY LISTED IN 2 ABOVE: (if applicable for nursing home contingency stock)

Name as listed on its Terminal Distributor license	Terminal Distributor License No.
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6. APPLICANT INTENDS DOING BUSINESS AS: (Check ONE):

Sole Proprietorship Partnership Corporation Limited Liability Company Government

6a. NAME OF OWNER(S); OR, IF INCORPORATED, NAME AND TITLE OF OFFICERS: (Attach separate sheet, if necessary)

Name	Title	Date Of Birth or Soc. Sec. No.
Name	Title	Date Of Birth or Soc. Sec. No.

6b. NAME OF GOVERNMENT AGENCY: (if applicable)

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6c. TYPE OF CORPORATION, IF INCORPORATED: → COPY OF CORPORATION &/OR LIMITED LIABILITY PAPERS MUST ACCOMPANY THIS APP.

<input type="checkbox"/> General (ORC Ch 1701)	<input type="checkbox"/> NonProfit (ORC Ch 1702)	<input type="checkbox"/> Limited Liability (ORC Ch 1705)	<input type="checkbox"/> Medical Care (ORC Ch 1737)	<input type="checkbox"/> Health Care (ORC Ch 1738)	<input type="checkbox"/> Dental Care (ORC Ch 1740)	<input type="checkbox"/> Professional Assoc. (ORC Ch 1785)
State Where Incorporated and Charter number	Charter Number must be listed and copy of corp. papers attached or application will not be processed.					
If ownership change, has charter number changed? Yes No Did tax ID change? Yes No						

7. TRADE, CORPORATE, OR PARTNERSHIP NAME AND ADDRESS: (if different than name and location being licensed)

Name	Area Code / Telephone Number	Extension No. (if needed)
Mailing Address, City, State, Zip Code	Previous Trade, Corporate, Or Partnership Name(s) & Address(es) (If any, check box and attach separate sheet to this	

8. STATEMENT OF APPLICANT:

Print Name	Title	Area Code / Telephone Number	Ext.
I DECLARE UNDER PENALTIES OF SECTION 2921.13 OF THE OHIO REVISED CODE THAT THIS APPLICATION HAS BEEN EXAMINED BY ME AND, TO THE BEST OF MY KNOWLEDGE AND BELIEF, IS A TRUE, CORRECT, AND COMPLETE APPLICATION.			
SIGNATURE of Applicant		DATE Signed	DOB or SSN:

APPLICATION FOR A TERMINAL DISTRIBUTOR LICENSE

FORM PHA-0601

See **INSTRUCTIONS** page for aid in properly completing this application

PRINT LEGIBLY OR TYPE

1. 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, 4729.55 and 4729.552 of the Ohio Revised Code as follows:

Category I Limited Category I Category II Limited Category II Category III Limited Category III

Drug Enforcement Administration (D.E.A.) License Number: (if applicable)

2. TYPE OF ESTABLISHMENT BEING LICENSED:

- | | | | |
|--|---|---|--|
| <input type="checkbox"/> Retail Pharmacy | <input type="checkbox"/> Hospital Pharmacy | <input type="checkbox"/> Emergency Medical Service – Headquarters | <input type="checkbox"/> Physical Therapy Facility |
| <input type="checkbox"/> Specialty Pharmacy | <input type="checkbox"/> Correctional Institution Pharmacy | <input type="checkbox"/> Emergency Medical Service – Satellite | <input type="checkbox"/> Sports Training Facility |
| <input type="checkbox"/> Mail Order Pharmacy | <input type="checkbox"/> Pharmacy Servicing Other Institutions Only | <input type="checkbox"/> Practitioner Corporation | <input type="checkbox"/> Veterinary Facility |
| <input type="checkbox"/> Non-Territorial Pharmacy | <input type="checkbox"/> Pharmacy Servicing Contingency Stock Location | <input type="checkbox"/> Hospital owned Practitioner Corporation | <input type="checkbox"/> Dog Trainer |
| <input type="checkbox"/> Clinic Pharmacy | <input type="checkbox"/> Hospice / Inpatient | <input type="checkbox"/> Private Practitioner | <input type="checkbox"/> Dog Warden |
| <input type="checkbox"/> Mobile Pharmacy | <input type="checkbox"/> Hospice / Outpatient | <input type="checkbox"/> Home Health Care | <input type="checkbox"/> Animal Shelter / Zoo |
| <input type="checkbox"/> Nuclear Pharmacy | <input type="checkbox"/> Clinic | <input type="checkbox"/> Food Processing-Use of Nitrous Oxide | <input type="checkbox"/> Animal Euthanasia |
| <input type="checkbox"/> Fluid Therapy Pharmacy | <input type="checkbox"/> Clinic-Oncology | <input type="checkbox"/> Manufacturing Process Use | <input type="checkbox"/> Teaching Institution |
| <input type="checkbox"/> Retail Seller of Medicinal Oxygen | <input type="checkbox"/> First Aid/Dispensary/Occupational Health | | <input type="checkbox"/> Laboratory / Research |
| <input type="checkbox"/> Pain Management Clinic | <input type="checkbox"/> Retail Seller of Medicinal Oxygen/Contingency Stock Location | | |

OTHER: (describe type of business conducted) _____

3. LIST OTHER DRUG DISTRIBUTOR LICENSES, ISSUED BY THE OHIO STATE BOARD OF PHARMACY, WHICH YOU POSSESS:

Give Identification Number(s) Only:

4. RECORD OF ADJUDICATIONS AND FINES IMPOSED:

Has the applicant or owner(s), or any agent or employee of the applicant/owner(s), or any officer of the corporation, ever been the subject of disciplinary action by any state or federal agency?

NO YES (If yes, give reason and detailed explanation on separate sheet.)

5. RECORD OF CHARGES, CONVICTIONS, AND FINES IMPOSED:

Does the applicant or owner(s), or any agent or employee of the applicant/owner(s), or any officer of the corporation, have charges pending or have a conviction of a felony or a misdemeanor other than a minor traffic violation (even if expunged or sealed)?

NO YES (If yes, explain in detail on separate sheet; listing names and addresses of the court or government agency and dates such charges were filed)

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. Pursuant to Section 2953.35 of the Ohio Revised Code, the Board of Pharmacy's records regarding the applicant's sealed or expunged records will be kept confidential.

6. STATEMENT OF INDIVIDUAL RESPONSIBLE FOR SUPERVISION AND CONTROL OF DANGEROUS DRUGS:

I HEREBY AGREE to and do submit to the jurisdiction of the Ohio State Board of Pharmacy and to the laws of Ohio for the purposes of the enforcement of Chapters 2925., 3715., 3719., and 4729. of the Ohio Revised Code, and Chapter 4729 of the Ohio Administrative Code; and, I assume the responsibility for supervision and control over the possession and custody of the dangerous drugs that may be acquired 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 category of license requested from Wholesale Distributors of Dangerous Drugs registered in the State of Ohio with 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.

SIGNATURE of Responsible Person:

DATE Signed

PRINT OR TYPE NAME:

QUALIFICATIONS:

M.D. License No.: _____ D.O. License No.: _____ R.Ph. License No.: _____

D.V.M. License No.: _____ D.D.S. License No.: _____ D.P.M. License No.: _____

Ph.D./Chemist - Laboratories Only Title: _____ Social Sec. No.: _____

Other: _____ Title: _____ Prof. License No.: _____ (if applicable)

**INFORMATION REGARDING CRIMINAL RECORDS CHECK REQUIRED FOR
PAIN MANAGEMENT CLINICS
(5/18/11)**

Recently, **House Bill 93** of the 129th General Assembly was signed by Governor Kasich and became effective on 5/20/11. House Bill 93, pursuant to section 4729.552 of the Ohio Revised Code, requires that applicable pain management clinics be licensed with the Ohio Board of Pharmacy as a Category III Terminal Distributor of Dangerous Drugs. For access to the complete bill, please go to the following web address on the internet:
http://www.legislature.state.oh.us/bills.cfm?ID=129_HB_93

The criminal records check shall consist of both a Bureau of Criminal Identification and Investigation (BCI&I) criminal records check and a Federal Bureau of Investigations (FBI) criminal records check. A criminal records check is required every time there is a change in owners and the results (sent from BCI&I directly to the Board of Pharmacy) must be received and approved by the board of pharmacy prior to granting licensure. Also, all employees of the pain management clinic must submit to the same fingerprinting process and have the results reported directly to the employer to ensure that no person employed has been previously convicted of, pleaded guilty to, any felony in this state, another state, or the United States.

The criminal records check shall be based on electronic fingerprint impressions that are submitted directly to BCI&I from a "WebCheck" provider agency located in Ohio. The employer may accept the results of a criminal records check based on ink impressions from a "WebCheck" provider agency only in the event that readable electronic fingerprint impressions cannot be obtained.

Specific Criminal Records Check process:

An owner or employee or potential employee of a Pain Management Clinic must go to a **WebCheck (BCI & FBI)** provider agency to start the process. An employer or potential employer of the Pain Management Clinic employee shall only accept a criminal records check based on electronic fingerprint impressions submitted to a WebCheck (BCI & FBI) designated provider agency located in Ohio, unless the WebCheck provider agency is unable to obtain readable electronic fingerprint impressions. Then, and only then, may an employer or potential employer accept ink fingerprint impressions from the Ohio WebCheck provider agency. The applicant **must** come to Ohio and **personally** provide electronic fingerprint impressions at any of the eighty-eight Ohio county sheriffs' offices or any other WebCheck (BCI & FBI) designated provider. To view a complete list of WebCheck (BCI & FBI) provider agencies please visit the WebCheck Community Listing located at this direct link on the Ohio Attorney General's website:

<http://www.ohioattorneygeneral.gov/Services/Business/WebCheck/Webcheck-Community-Listing>

All eighty-eight county sheriffs' offices are WebCheck (BCI & FBI) providers even if they are not listed on the WebCheck Community Listing. If you select an agency other than a sheriff's office please make sure that it has "(BCI & FBI)" listed after the name. Contact the WebCheck (BCI & FBI) provider agency to determine the total fee(s) and the accepted method(s) of payment. Fees include: BCI&I - \$22, plus FBI - \$24, and some agencies may charge a processing fee (e.g. \$5-\$40). Also, verify if any additional materials are needed (e.g. photo id). Note, some agencies have restricted hours and may require you to schedule an appointment.

While at the WebCheck (BCI & FBI) provider site:

- 1) Request both a BCI&I and FBI criminal records check via electronic fingerprint impressions.
- 2) Pay the required fees directly to the WebCheck (BCI & FBI) provider.
- 3) Indicate the reason fingerprinted as "pursuant to ORC 4729.552."
- 4) For owners of Pain Management Clinics, request the background check results be sent to the OHIO BOARD OF PHARMACY, Room 1702, 77 S. High Street, Columbus, Ohio 43215.
- 5) For employees of Pain Management Clinics, request the background check results be sent directly to your employer or potential employer.

What to do when an employer or potential employer receives a letter from BCI&I indicating that the request "may not meet the criteria":

- 1) The employer or potential employer needs to contact the employee or potential employee to let them know that they received such a letter from BCI&I.
- 2) The employee or potential employee must then complete a "Request for Release-FBI Rap sheet" and send it to BCI&I so that the employee or potential employee may receive the results. The form and sending instructions can be obtained from this direct link on the Ohio Attorney General's website:

<http://www.ohioattorneygeneral.gov/files/Forms/Forms-for-Business/Fingerprints/Request-for-Release---FBI-Rapsheet.aspx>

- 3) The employee or potential employee will then receive the FBI criminal records results from BCI&I in the mail. The results must be submitted by the employee or potential employee to the employer or potential employer in the original sealed envelope sent by BCI&I.



State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

(614) 466-3934
med.ohio.gov

Emergency Rule 4731-29-01 Effective June 20, 2011

On Thursday, June 9, 2011, the State Medical Board of Ohio [Medical Board] amended the language of proposed emergency Rule 4731-29-01, *Standards and Procedures for the Operation of a Pain Management Clinic*. The emergency rule will be effective on June 20, 2011.

In amending the proposed emergency rule, the Medical Board considered comments received from individuals and organizations concerning the requirements for ownership of a pain management clinic, requirements for practicing at a pain management clinic, and other provisions of the rule. In summary, the changes include the following:

1. **Adds** definitions for “chronic pain” and “pain.”
2. **Deletes** the definition of “local hospital” and the requirement that a physician owning or practicing at a pain management clinic must have staff privileges at a local hospital.
3. **Establishes** the general requirement for physician ownership of a pain management clinic as current subspecialty certification in pain management or hospice and palliative medicine or current board certification by the American Board of Pain Medicine or the American Board of Interventional Pain Physicians.
4. **Provides** a limited grandfather provision for physicians who wish to own a pain management clinic but who do not meet the general requirements for subspecialty certification or current board certification.
 - The physician must have filed an application for a license as a category III terminal distributor of dangerous drugs with a pain management clinic classification with the State Board of Pharmacy **by June 20**.
 - The physician must meet of one of several educational and practice options. One option is that the physician has provided at least three years of full-time clinical services in pain medicine, pain management, hospice and palliative medicine, addiction psychiatry, physical medicine and rehabilitation, occupational medicine, or rheumatology.
 - The Medical Board must determine, following an investigation, that the physician’s practice appears to comply with the minimal standards of care.
5. **Allows** any physician to provide care at a pain management clinic under the direction, supervision, and control of the owner.
6. **Requires** all physicians who own and/or provide care at a pain management clinic to complete at least 20 hours of category I continuing medical education in pain medicine every two years.
7. **Clarifies** record keeping requirements and other provisions of the proposed rule.

Emergency rule 4731-29-01 is attached. Information on other rules proposed to implement H.B. 93 and other topics related to safe prescribing may be found at the **Center for Safe Prescribing**:
http://med.ohio.gov/Center_for_Safe_Prescribing.html.

Contact: Sallie Debolt, General Counsel, (614) 644-7021; Sallie.Debolt@med.state.oh.us.

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Emergency rule to be effective June 20, 2011

4731-29-01 Standards and procedures for the operation of a pain management clinic.

(A) For the purposes of this rule:

- (1) "Board" means state medical board of Ohio.
- (2) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.
- (3) "Informed consent" means a process of communication between a patient and physician that results in the patient's signed authorization or agreement to undergo a specific medical intervention.
- (4) "Pain" means an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.
- (5) "Pain management clinic" means a facility to which all of the following apply:
 - (a) The primary component of the practice is treatment of pain or chronic pain;
 - (b) The majority of patients of the prescribers at the facility are provided treatment for pain or chronic pain that includes the use of controlled substances, tramadol, carisoprodol, or other drugs specified in rules by the board; and
 - (c) In determining whether the facility meets the requirement of paragraph (A)(5)(b) of this rule:
 - (i) Calculation of the majority of patients will be based upon the number of patients treated in a calendar month;
 - (ii) Patients receiving controlled substances, tramadol, carisoprodol or other drugs specified by the board, for treatment of an injury or illness that lasts or is expected to last thirty days or less shall not be considered in the calculation of the majority.
- (6) "Pain management clinic" does not include the following:
 - (a) A hospital registered with the department of health under section 3701.07 of the Revised Code or a facility owned in whole or in part by a hospital;

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Emergency rule to be effective June 20, 2011

- (b) A school, college, university, or other educational institution or program to the extent that it provides instruction to individuals preparing to practice as physicians, podiatrists, dentists, nurses, physician assistants, optometrists, or veterinarians or any affiliated facility to the extent that it participates in the provision of that instruction;
 - (c) A hospice program licensed under chapter 3712. of the Revised Code;
 - (d) An ambulatory surgical facility licensed under section 3702.30 of the Revised Code.
- (7) "Physician" means an individual authorized under chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.
- (8) "Prescriber" has the same meaning as in section 4729.01 of the Revised Code.
- (B) In the operation of a pain management clinic, the following requirements shall be met:
- (1) The pain management clinic shall be owned and operated by one or more physicians. Each physician owner of a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.
 - (2) Except as provided in paragraph (B)(3) of this rule, the physician owner of a pain management clinic must meet one of the following requirements:
 - (a) Hold current subspecialty certification in pain management by the American board of medical specialties, or hold a current certificate of added qualification in pain management by the American osteopathic association bureau of osteopathic specialists; or
 - (b) Hold current subspecialty certification in hospice and palliative medicine by the American board of medical specialties, or hold a current certificate of added qualification in hospice and palliative medicine by the American osteopathic association bureau of osteopathic specialists; or
 - (c) Hold current board certification by the American board of pain medicine; or
 - (d) Hold current board certification by the American board of interventional pain physicians.

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- (3) A physician who applies for a category III terminal distributor of dangerous drugs with a pain management clinic classification under section 4729.552 of the Revised Code by June 20, 2011 may own a pain management clinic if the medical board determines that all of the following criteria are met:
- (a) Meet one of the following requirements:
- (i) An internship or residency program that would satisfy post-graduate training requirements for board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology conducted in the United States and accredited by either the accreditation council for graduate medical education of the American medical association or the American osteopathic association; or
 - (ii) A clinical fellowship program that would satisfy post-graduate training requirements for board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology, conducted in the United States at an institution with a residency program accredited by either the accreditation council for graduate medical education of the American medical association or the American osteopathic association that is in a clinical field the same as or related to the clinical field of the fellowship program; or
 - (iii) An internship program that would satisfy post-graduate training requirements for board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology, conducted in Canada and accredited by the committee on accreditation of preregistration physician training programs of the federation of provincial medical licensing authorities of Canada; or
 - (iv) A residency program that would satisfy post-graduate training requirements for board certification in anesthesiology, psychiatry, neurology, physical medicine and rehabilitation, occupational medicine, or rheumatology, conducted in Canada and accredited by either the royal college of physicians and surgeons of Canada or the college of family physicians of Canada; or
 - (v) The provision of at least three years of full-time clinical services, within the last three years, in pain medicine, pain management, hospice and palliative medicine, addiction psychiatry, physical medicine and rehabilitation, occupational medicine, or rheumatology; or

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- (vi) At least three years of continuous service as a clinical professor or assistant clinical professor, within the last three years, in pain medicine, pain management, hospice and palliative medicine, addiction psychiatry, physical medicine and rehabilitation, occupational medicine, or rheumatology at a medical school accredited by the liaison committee on medical education or the American osteopathic association.
- (b) The physician's practice complies with the minimal standards of care.
 - (i) The physician shall provide a copy of the application for a category III terminal distributor of dangerous drugs with a pain management clinic classification under section 4729.552 of the Revised Code to the medical board.
 - (ii) The copy of the application shall serve as a complaint which shall authorize the medical board to investigate the physician's practice pursuant to section 4731.22(F) of the Revised Code.
- (4) The pain management clinic shall be licensed as a category III terminal distributor of dangerous drugs with a pain management clinic classification under section 4729.552 of the Revised Code.
- (5) The pain management clinic shall be operated in compliance with the drug prevention and control act, 21 U.S.C. 801 et. seq., and chapters 3719., 4729., 4730., and 4731. of the Revised Code.
- (6) The pain management clinic shall have proper equipment, materials, and personnel on premises to provide appropriate medical treatment, as required by the minimal standards of care.
- (C) No physician owner of a pain management clinic, employee of the clinic, or person with whom the clinic contracts for services shall:
 - (1) Have ever been denied a license to prescribe, dispense, administer, supply, or sell a controlled substance by the drug enforcement administration or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the prescriber's inappropriate prescribing, dispensing, administering, supplying or selling a controlled substance.
 - (2) Have held a license issued by the drug enforcement administration or a state licensing agency in any jurisdiction, under which the person may prescribe, dispense, administer, supply, or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the prescriber's inappropriate

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prescribing, dispensing, administering, supplying, or selling a controlled substance.

- (3) Have been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the prescribers inappropriate prescribing, dispensing, diverting, administering, supplying, or selling a controlled substance.
- (D) Each physician who provides care at a pain management clinic shall complete at least twenty hours of category I continuing medical education in pain medicine every two years. The courses completed in compliance with this rule shall be accepted toward meeting the category I requirement for certificate of registration renewal for the physician.
- (E) In providing supervision, direction, and control of individuals at a pain management clinic the physician owner shall establish and ensure compliance with the following:
 - (1) A requirement that a log of patients be maintained for each day the clinic is in operation.
 - (a) Each log sheet shall contain the month, day, and year;
 - (b) Each log entry shall include the first and last name of each patient;
 - (c) Each patient shall be required to sign the log at each visit; and
 - (d) Patient logs shall be maintained for seven years.
 - (2) A requirement that providers obtain informed consent for each patient prior to the commencement of treatment.
 - (3) An on-going quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates the methods to improve patient care, identifies and corrects deficiencies within the clinic, and provides for opportunities to improve the clinic's performance and quality of care.
 - (4) A requirement that the background, training, certification, and licensure of all clinical staff be documented. Verification of certification and licensure shall be made on an annual basis.
 - (5) A requirement that adequate billing records are maintained for all patients and made available to the board, immediately upon request.

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Emergency rule to be effective June 20, 2011

- (a) Billing records shall include the amount paid, method of payment, ~~and~~ description of services, sufficient information to identify the patient, and the amounts charged to the patient for each date of service.
 - (b) Billing records shall be maintained for seven years from the last date of treatment of the patient.
- (6) A requirement that adequate patient records are maintained for all patients and made available to the board, immediately upon request.
- (a) Patient records shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately, by including, at a minimum:
 - (i) Patient history and physical examination, including history of drug abuse or dependence;
 - (ii) Diagnostic, therapeutic, and laboratory results, including drug testing results;
 - (iii) Reports of evaluations, consultations, and hospitalizations;
 - (iv) Treatment objectives, including discussion of risks and benefits;
 - (v) Records of drugs prescribed, dispensed or administered, including the date, type, and dosage;
 - (vi) Treatments;
 - (vii) Receipt and assessment of drug database or prescription monitoring program reports;
 - (viii) Copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient. Records provided by the patient shall be designated as such.
 - (b) Patient records shall be maintained for seven years from the last date of treatment of the patient.
 - (c) In the treatment of chronic pain the patient records shall contain the information required in rule 4731-21-02 of the Administrative Code in lieu of the requirements of paragraph (E)(6)(a)(i) through (vi) of this rule.