Pain Management Clinics in Ohio A Special Report (July 2011 - December 2014)



Ohio State Board of Pharmacy Steven W. Schierholt, Esq. Executive Director

MISSION

The Ohio State Board of Pharmacy shall act efficiently, consistently, and impartially in the public interest to pursue optimal standards of practice through communication, education, legislation, licensing, and enforcement.

ABOUT THE BOARD

In addition to regulating the practice of pharmacy, the Ohio State Board of Pharmacy is the single state agency in Ohio responsible for preventing, detecting and investigating the diversion of dangerous drugs, including controlled substances. The Board consists of nine members who are appointed by the Governor for terms of four years. Eight of the members are licensed pharmacists who represent, to the extent practicable, each phase of pharmacy practice. One member represents the public. The Board has a staff of fifty-seven employees that are responsible for carrying out the day-to-day operations and responsibilities of the Board.

The State Board of Pharmacy licenses the following individuals and entities:

- Pharmacists, (O.R.C. Chapter 4729.)
- Pharmacy Interns, (O.R.C. Chapter 4729.)
- Terminal and Wholesale Distributors of Dangerous Drugs (both in-state and out-of-state) (O.R.C. Chapter 4729.) and
- Manufacturers and Wholesalers of Controlled Substances (O.R.C. Chapter 3719.).

The Board is also responsible for regulating the legal distribution of dangerous drugs in Ohio and ensuring the quality of all drugs administered, prescribed, dispensed by prescription or sold overthe-counter (O.R.C. Chapter 3715.). The Ohio State Board of Pharmacy can discipline its licensees and registrants for violations of both federal and state laws governing the legal distribution of drugs. The Board also has the responsibility to investigate and present evidence of violations of federal or state drug laws by any person to the appropriate court (federal, state, or municipal) for prosecution of the offender (O.R.C. Chapter 2925.).

Letter from the Executive Director

Dear Governor Kasich and Members of the Ohio General Assembly,

In 2011, legislation addressing prescription drug abuse and diversion, Ohio HB 93 (Burke and Johnson – 129th General Assembly), was signed into law. Among a number of the provisions in the legislation aimed at solving this pressing public health crisis, was the required licensure of pain management clinics by the Ohio State Board of Pharmacy. The licensing of these facilities was in response to the growing number of unscrupulous providers, particularly in southern Ohio, who prescribed and/or dispensed powerful opioid pain medications and other controlled substances inappropriately or for non-medical reasons. These clinics are often referred to as "pill mills."

HB 93 requires all pain management clinics in Ohio to obtain an existing Board of Pharmacy license, known as a terminal distributor of dangerous drugs, with a special pain management clinic classification. The licensure process allows the Board to stem the proliferation of illegitimate clinics by requiring physician ownership, background checks and prohibiting ownership interests with felony records or the employment of those with certain criminal convictions. In addition, one of the benefits of authorizing the Board of Pharmacy to license pain management facilities is that the agency has jurisdiction to deny licensing to rogue clinics and take disciplinary action against those clinics that practice outside the law and accepted operational standards.

Pursuant to Section 8 of HB 93, the Ohio State Board of Pharmacy has prepared the following report regarding the licensure of pain management clinics. The report is divided into the following sections:

Section 1: Licensing statistics for pain management clinics.

Section 2: Disciplinary actions against applicants and holders of a terminal distributor of dangerous drugs license with a pain management clinic classification.

Section 3: Revenue from pain management clinic licensing fees, fines and penalties paid by license holders, or other disciplinary actions taken against license holders.

On behalf of the Ohio State Board of Pharmacy, I thank you for your leadership on this important public health and safety issue. The Board is committed to its ongoing efforts to enforce the drug laws of Ohio and will continue to work collaboratively with other law enforcement agencies and health care regulatory boards in our mission to prevent the abuse and diversion of controlled substances.

If you have any questions regarding the work of the Board, please do not hesitate to contact my office by phone (614-466-4143) or e-mail: exec@bop.ohio.gov.

Sincerely,

Steven W. Schierholt, Esq.

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Executive Director

Ohio State Board of Pharmacy



Pain Management Clinic Licensing Statistics

Table 1. The total number of applications received by the Board for a terminal distributor of dangerous drugs license with a pain management clinic classification, by year.

Year	Applications Received	
2011	185	
2012	73	
2013	32	
2014	34	
Total	324	

Table 2. The total number of applications granted by the Board for a terminal distributor of dangerous drugs license with a pain management clinic classification, by year.

Year	Applications Granted	
2011	66	
2012	51	
2013	26	
2014	20	
Total	163	

Table 3. The total number of applications not granted (or currently pending) by the Board for a terminal distributor of dangerous drugs license with a pain management clinic classification from July 2011 to December 2014, by application status.

Application Status	Number of Applicants
License Denials	12
License Withdrawn by Applicant	52
License Not Issued / Other*	36
Pending Licenses	61
Total	161

^{*}Includes licensees that failed to renew and inactive licenses.

Pain Management Clinic Disciplinary Actions

There were a total of 20 pain management clinic disciplinary actions taken by the Board between July 2011 and December 2014 (see Table 4).

Table 4. The total number of citations and summary suspensions issued by the Board for a terminal distributor of dangerous drugs license with a pain management clinic classification, by year.

Year	Citations Issued	Summary Suspensions Issued	
2011	2	0	
2012	2	0	
2013	10	1	
2014	5	0	
Total	19	1	

What is a Citation?

In compliance with Ohio's Administrative Procedures Act (Chapter 119, Ohio Revised Code), a citation is the formal notice sent to a licensee or license applicant informing them that the Board of Pharmacy intends to take disciplinary action (which can include the denial of a license) based upon an alleged violation of federal or state law or failure to meet statutory qualifications. A citation also advises that they may request a hearing on the matter but the hearing request must be received within 30 days of the date the citation was mailed by the Board.

What is a Summary Suspension?

A summary suspension occurs when a license is suspended prior to a hearing based on clear and convincing evidence that continued operation by the licensee poses a danger of immediate and serious harm to the public. Prior to issuing a summary suspension of a pain management clinic license, the Board is required to consult the secretary of the State Medical Board. Following a summary suspension, the licensee is provided the opportunity for a hearing before the Board of Pharmacy.

DISPOSITION OF CHARGES AGAINST PAIN MANAGEMENT CLINICS

Everyone issued a citation by the Board of Pharmacy has the opportunity to have their case heard before the Board. From July 2011 to December 2014, there were 20 citations issued against applicants or holders of a terminal distributor of dangerous drugs license with a pain management clinic classification (see Table 4). The cases resulted in the following actions:

- Settlement (Licensed Issued): The applicant was issued a citation for an alleged violation or failure to meet statutory qualifications. However, the applicant settled with the Board prior to an administrative hearing and was issued a terminal distributor of dangerous drugs license with a pain management clinic classification. The licensee is required to abide by terms of the settlement agreement, which includes probation and reporting requirements.
- Settlements (License Denied): The applicant was issued a citation for an alleged violation or failure to meet statutory qualifications but, as a term of their settlement agreement, agreed to the denial of their license by the Board prior to an administrative hearing.
- Denial or Revocation of Licenses by Board Order: The applicant or licensee was issued a citation for an alleged violation or failure to meet statutory qualifications. Following an administrative hearing, the Board denied the applicant's license or revoked a licensee's terminal distributor of dangerous drugs license with a pain management clinic classification.
- Licenses Issued Following Administrative Hearings: The applicant was issued a citation for an alleged violation or failure to meet statutory qualifications. Following an administrative hearing, the Board issued a license to the applicant. The license may have been issued with specific limitations and/or subject to a probationary period.
- Citations Pending: The applicant or licensee was issued a citation for an alleged violation or failure to meet statutory qualifications. Their case is currently pending an administrative hearing.

Revenue from Pain Management Clinic Licensing Fees

The cost of a terminal distributor of dangerous drugs license with a pain management clinic classification is \$150.00 per year. From July 2011 to December 2014, the Board received \$99,750 in revenue from licensing fees (see Table 5).

Table 5. The total revenue from applications and renewals received by the Board for a terminal distributor of dangerous drugs license with a pain management clinic classification, by year.

Year	Applications	Renewal	Revenue
2011	185	0	\$27,750
2012	73	75	\$22,200
2013	32	130	\$24,300
2014	34	136	\$25,500
Total Revenue			\$99,750



The Ohio State Board of Pharmacy is committed to protecting the health and safety of all Ohioans by preventing, detecting and investigating the illegal distribution or abuse of dangerous drugs and regulating the practice of pharmacy. Should you need any assistance or additional information, please do not hesitate to contact the Board.

Ohio State Board of Pharmacy
77 South High Street
Room 1702
Columbus, OH 43215
Phone: 614-466-4143
www.pharmacy.ohio.gov/contact.aspx