

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1214 Session of 2019

INTRODUCED BY STRUZZI, TOEPEL, MOUL, SCHMITT, SCHLEGEL CULVER, MILLARD, DeLUCA, ZABEL, IRVIN, MACKENZIE, ZIMMERMAN, PASHINSKI, CIRESI AND GILLEN, APRIL 15, 2019

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, MAY 14, 2019

AN ACT

1 Amending the act of July 19, 1979 (P.L.130, No.48), entitled "An
2 act relating to health care; prescribing the powers and
3 duties of the Department of Health; establishing and
4 providing the powers and duties of the State Health
5 Coordinating Council, health systems agencies and Health Care
6 Policy Board in the Department of Health, and State Health
7 Facility Hearing Board in the Department of Justice;
8 providing for certification of need of health care providers
9 and prescribing penalties," providing for pain management
10 clinics; and imposing penalties.

11 The General Assembly of the Commonwealth of Pennsylvania
12 hereby enacts as follows:

13 Section 1. The act of July 19, 1979 (P.L.130, No.48), known
14 as the Health Care Facilities Act, is amended by adding a
15 chapter to read:

CHAPTER 8-A

PAIN MANAGEMENT CLINICS

18 Section 801-A. Definitions.

19 The following words and phrases when used in this chapter
20 shall have the meanings given to them in this section unless the
21 context clearly indicates otherwise:

1 "Controlled substance." A drug, substance or immediate  
2 precursor included in Schedules I through V of the act of April  
3 14, 1972 (P.L.233, No.64), known as The Controlled Substance,  
4 Drug, Device and Cosmetic Act.

5 "Pain management clinic." A facility that advertises in any  
6 medium for a type of pain service and where, in any calendar  
7 month, a majority of patients of the prescribers at the facility  
8 are provided treatment for pain that includes the use of  
9 controlled substances. The term does not include the following <--  
10 facilities that are otherwise licensed under Chapter 8:

11 (1) A hospital, including a licensed facility or  
12 facility owned by the hospital, including any outpatient  
13 facility or clinic of the hospital included in the hospital  
14 license.

15 (2) A hospice program or residential hospice facility.

16 (3) An ambulatory surgical center.

17 (4) A long term care nursing facility.

18 (5) A home health care agency or home health care  
19 facility.

20 (6) A birth center. THE TERM DOES NOT INCLUDE A FACILITY <--  
21 THAT IS OTHERWISE LICENSED AS A HEALTH CARE FACILITY UNDER  
22 CHAPTER 8.

23 "Physician." A person who possesses a current license to  
24 practice medicine in this Commonwealth who has not been denied  
25 the privilege of prescribing, dispensing, administering,  
26 supplying or selling any controlled substance.

27 "Prescriber." A person who is licensed, registered or  
28 otherwise lawfully authorized to distribute, dispense or  
29 administer a controlled substance, other drug or device in the  
30 course of professional practice or research in this

1 Commonwealth.

2 "Prescription Drug Monitoring Program." The Achieving Better  
3 Care by Monitoring All Prescriptions Program (ABC-MAP) as  
4 established under the act of October 27, 2014 (P.L.2911,  
5 No.191), known as the Achieving Better Care by Monitoring All  
6 Prescriptions Program (ABC-MAP) Act.  
7 Section 802-A. Registration.

8 (a) Duty to register.--

9 (1) Each pain management clinic shall register and  
10 maintain a valid registration with the department.

11 (2) A facility shall register within 30 days following  
12 the conclusion of the month in which the facility meets the  
13 definition of pain management clinic under this chapter.

14 (3) Each pain management clinic location shall be  
15 registered separately.

16 (4) Any change in ownership of a pain management clinic  
17 shall require a new registration application.

18 (5) The registration and renewal fee shall be  
19 established by the department and shall be paid upon change  
20 of physical location or change of ownership.

21 (b) Required information.--Each pain management clinic shall  
22 provide to the department, as part of its registration, the  
23 following information in writing:

24 (1) The name, business address, profession, current  
25 professional licensing status and nature and extent of  
26 ownership or investment interest of each person who has or  
27 maintains an ownership or investment interest in the pain  
28 management clinic.

29 (2) The names and addresses of each pain management  
30 clinic in which the person has an ownership or investment

1 interest.

2 (3) The hours of operation of each pain management  
3 clinic in which the person has an ownership or investment  
4 interest.

5 (4) The names and professional status of each health  
6 care practitioner at each practice location owned and  
7 operated by that pain management clinic.

8 (5) The name, professional license number and practice  
9 address of the owner or medical director who will be  
10 physically present in the pain management clinic for at least  
11 50% of the time patients are present in the clinic. The pain  
12 management clinic shall also state its plan for ensuring that  
13 the designated owner or medical director will be physically  
14 present in the facility.

15 (c) Duration of registration.--Each registration shall be  
16 valid for 365 days.

17 (d) Reasons to deny registration.--The department shall deny  
18 registration to a pain management clinic owned by or with any  
19 contractual or employment relationship with a physician:

20 (1) whose Drug Enforcement Administration number has  
21 ever been revoked;

22 (2) whose application for a license to prescribe,  
23 dispense or administer a controlled substance has been denied  
24 by any jurisdiction; or

25 (3) who has been convicted of or pleaded guilty or nolo  
26 contendere to an offense that constitutes a felony under the  
27 act of April 14, 1972 (P.L.233, No.64), known as The  
28 Controlled Substance, Drug, Device and Cosmetic Act, or an  
29 equivalent offense under the laws of the United States or one  
30 of its territories or possessions, another state, the

1 District of Columbia, the Commonwealth of Puerto Rico or a  
2 foreign nation.

3 (e) Revocation or nonrenewal of registration.--A pain  
4 management clinic shall be subject to the revocation and  
5 nonrenewal of license provisions under section 811. In addition,  
6 the following shall apply:

7 (1) If the department finds that a pain management  
8 clinic is owned or operated by a person meeting any criteria  
9 listed in subsection (d), the department shall revoke the  
10 clinic's certificate of registration.

11 (2) If the registration of a pain management clinic is  
12 revoked or suspended, no individual shall operate the  
13 facility as a pain management clinic as of the effective date  
14 of the suspension or revocation.

15 Section 803-A. Ownership.

16 (a) General rule.--Only a physician having a valid and  
17 active license to practice medicine or osteopathy in this  
18 Commonwealth may have an ownership or investment interest in a  
19 pain management clinic.

20 (b) Subspecialty certification required.--At least one of a  
21 clinic's owners must hold a valid and active subspecialty  
22 certification from a nationally recognized board in pain  
23 management or pain medicine.

24 Section 804-A. Medical director.

25 (a) General rule.--A pain management clinic shall designate  
26 a physician to be the clinic medical director who shall oversee  
27 and ensure the pain management clinic's compliance with the  
28 registration and operational requirements.

29 (b) When physical presence required.--At least one clinic  
30 owner or medical director must be physically present at least

1 50% of the time patients are present at the clinic and must hold  
2 a valid and active subspecialty certification from a nationally  
3 recognized board in pain management.

4 (c) Duties.--

5 (1) The medical director shall ensure compliance with  
6 the quality assurance requirements promulgated by the  
7 department.

8 (2) The medical director shall establish an ongoing  
9 quality assurance program that objectively and systematically  
10 monitors and evaluates the quality and appropriateness of  
11 patient care.

12 Section 805-A. Prescribing.

13 (a) General rule.--Each prescriber who prescribes controlled  
14 substances to patients, as part of employment at a pain  
15 management clinic, shall hold an appropriate license,  
16 registration or certification at the time of prescribing.

17 (b) Prohibition.--No physician, prescriber or other person  
18 working at a pain management clinic is permitted to dispense  
19 controlled substances at the clinic.

20 (c) Physical examinations.--A physician or health care  
21 practitioner shall perform a physical examination of a patient  
22 on the same day a prescriber prescribes a controlled substance  
23 to the patient at a pain management clinic.

24 (d) Duty to access prescription drug monitoring program.--A  
25 physician shall access the prescription drug monitoring program  
26 prior to prescribing a controlled substance in order to  
27 determine the patient's controlled substance history.

28 Section 806-A. Reporting and recordkeeping.

29 (a) General rule.--On a quarterly basis the medical director  
30 of a pain management clinic shall submit to the department the

1 number of new and repeat patients seen and treated at the pain  
2 management clinic who are prescribed controlled substance  
3 medications for the treatment of chronic, nonmalignant pain.

4 (b) Documentation required.--Each pain management clinic  
5 shall document on a monthly basis that the designated owner or  
6 medical director was physically present for at least 50% of the  
7 time patients were present. This documentation shall include:

8 (1) The name, practice address and telephone number of  
9 the physician owner or medical director who fulfilled this  
10 oversight function for that specific week.

11 (2) The address of each practice location owned and  
12 operated by the pain management clinic.

13 (3) The days and hours each practice location of the  
14 pain management clinic was open to patients during that  
15 specific week.

16 (4) The days and hours the physician owner or medical  
17 director was present in each practice location for the pain  
18 management clinic for that specific week.

19 (c) Retention period.--The records shall be maintained by  
20 the pain management clinic for a minimum period of seven years.

21 Section 807-A. Physical environment.

22 A pain management clinic shall be located and operated at a  
23 publicly accessible, fixed location and shall:

24 (1) Comply with building codes, ordinances and  
25 administrative regulations that are enforced by State and  
26 municipal jurisdictions.

27 (2) Display a sign that can be viewed by the public that  
28 contains the clinic's name, hours of operation and street  
29 address.

30 (3) Have a publicly listed telephone number and

1 dedicated, operational telephone number.

2 (4) Have emergency lighting.

3 (5) Have a reception and waiting area.

4 (6) Provide a restroom.

5 (7) Have an administrative area, including room for  
6 storage of medical records, supplies and equipment.

7 (8) Have private patient examination rooms.

8 (9) Have treatment rooms, if treatment is being provided  
9 to patients.

10 (10) Display a printed sign located in a conspicuous  
11 place in the waiting room viewable by the public with the  
12 name and contact information of the clinic's medical director  
13 and the names of all physicians and prescribers practicing in  
14 the clinic.

15 (11) Have infection control policies.

16 Section 808-A. Regulations.

17 The department shall promulgate rules in accordance with the  
18 provisions of this section for the registration of pain  
19 management clinics to ensure adequate care, treatment, health,  
20 safety, welfare and comfort of patients. The rules shall  
21 include, at a minimum:

22 (1) The process to be followed by applicants seeking  
23 registration.

24 (2) The qualifications and supervision of registered and  
25 nonregistered personnel at pain management clinics and  
26 training requirements for all clinic health care  
27 practitioners.

28 (3) The provision and coordination of patient care,  
29 including the development of a written plan of care.

30 (4) The management, operation, staffing and equipping of



1 the pain management clinic.

2 (5) The clinical, medical, patient and business records  
3 to be kept by the pain management clinic.

4 (6) The procedures for inspections and for the review of  
5 utilization and quality of patient care.

6 (7) The standards and procedures for the general  
7 operation of a pain management clinic, including facility  
8 operations, physical operations, infection control  
9 requirements, health and safety requirements and quality  
10 assurance.

11 (8) Identification of drugs that may be used to treat  
12 chronic pain that identify a facility as a pain management  
13 clinic, including, at a minimum, tramadol and carisoprodol.

14 (9) Any other criteria that identify a facility as a  
15 pain management clinic.

16 (10) The standards and procedures to be followed by an  
17 owner in providing supervision, direction and control of  
18 individuals employed by or associated with a pain management  
19 clinic.

20 (11) Data collection and reporting requirements.

21 (12) Such other standards or requirements as the  
22 Secretary of Health determines are appropriate.

23 Section 809-A. Inspections.

24 (a) Duty to conduct.--The department shall conduct at least  
25 one announced and one unannounced inspection of the pain  
26 management clinic no less than annually, including a review of  
27 patient records to ensure that a pain management clinic complies  
28 with the provisions of this chapter. A representative from the  
29 department shall have access to a pain management clinic and its  
30 records.

1 (b) Inspection fee.--An inspection fee as set by the  
2 department shall be paid annually for each location required to  
3 be inspected.

4 Section 810-A. Violations.

5 (a) General rule.--When appropriate, the department shall  
6 work with a pain management clinic to rectify a violation of  
7 this section.

8 (b) Specific sanctions.--A pain management clinic that  
9 violates this chapter may be subject to sanctions by the  
10 department, which may include the following:

11 (1) Suspension of its registration.

12 (2) Revocation of its registration.

13 (3) Refusal to renew its registration.

14 (4) Issuance of a provisional license.

15 (5) Submission of a plan of correction.

16 (6) Prohibition of all physicians from practicing at  
17 that, or any other, pain management clinic.

18 (7) Any other sanction deemed necessary by the  
19 department.

20 (c) Civil penalty.--A person who violates this section may  
21 be subject to a civil penalty, not to exceed \$500 per day.

22 Section 811-A. Criminal penalty.

23 (a) Offense defined.--A person who KNOWINGLY operates, owns <--  
24 or manages a nonregistered pain clinic that is required to be  
25 registered with the department under this chapter commits an  
26 offense.

27 (b) Grading.--An offense under subsection (a) constitutes a:

28 (1) Misdemeanor of the first degree, when the offense is  
29 the first offense.

30 (2) Felony of the third degree, when the offense is a

1 second or subsequent offense.

2 Section 2. This act shall take effect in 60 days.