

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 1043 Session of 2017

INTRODUCED BY BAKER, CALTAGIRONE, READSHAW, MILLARD, NEILSON, GAINNEY, WATSON, WARD, PICKETT, A. HARRIS, MOUL, WHEELAND, WARNER, ZIMMERMAN, FARRY, M. QUINN, JAMES, STAATS, D. COSTA, EVERETT, SAYLOR, B. MILLER, IRVIN, PASHINSKI AND COX, APRIL 3, 2017

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, APRIL 19, 2017

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:

16 CHAPTER 8-A

17 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

1 context clearly indicates otherwise:

2 ~~"Chronic nonmalignant pain." Pain unrelated to cancer or~~ <--
3 ~~rheumatoid arthritis that persists beyond the usual course of~~
4 ~~disease or the injury that is the cause of the pain or that~~
5 ~~lasts longer than 90 days after surgery.~~

6 "Controlled substance." A drug, substance or immediate
7 precursor included in Schedules I through V of the act of April
8 14, 1972 (P.L.233, No.64), known as The Controlled Substance,
9 Drug, Device and Cosmetic Act.

10 "Pain management clinic." A facility that advertises in any
11 medium for a type of pain service ~~or~~ AND where, in any calendar <--
12 month, a majority of patients of the prescribers at the facility
13 are provided treatment for pain that includes the use of
14 controlled substances. The term does not include the following
15 facilities that are otherwise licensed under Chapter 8:

16 (1) A hospital, including a licensed facility or
17 facility owned by the hospital, including any outpatient
18 facility or clinic of the hospital included in the hospital
19 license.

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

21 (3) An ambulatory surgical center.

22 (4) A long-term care nursing facility.

23 (5) A home health care agency or home health care
24 facility.

25 (6) A birth center.

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

30 "Prescriber." A person who is licensed, registered or

1 otherwise lawfully authorized to distribute, dispense or
2 administer a controlled substance, other drug or device in the
3 course of professional practice or research in this
4 Commonwealth.

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

10 Section 802-A. Registration.

11 (a) Duty to register.--

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

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

17 (3) Each pain management clinic location shall be
18 registered separately.

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

21 (5) The registration and renewal fee shall be
22 established by the department and shall be paid upon change
23 of physical location or change of ownership.

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

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

1 management clinic.

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

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

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

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

18 (c) Duration of registration.--Each registration shall be
19 valid for 365 days.

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

23 (1) whose Drug Enforcement Administration number has
24 ever been revoked;

25 (2) whose application for a license to prescribe,
26 dispense or administer a controlled substance has been denied
27 by any jurisdiction; or

28 (3) who has been convicted of or pleaded guilty or nolo
29 contendere to an offense that constitutes a felony under the
30 act of April 14, 1972 (P.L.233, No.64), known as The

1 Controlled Substance, Drug, Device and Cosmetic Act, or an
2 equivalent offense under the laws of the United States or one
3 of its territories or possessions, another state, the
4 District of Columbia, the Commonwealth of Puerto Rico or a
5 foreign nation.

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

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

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

18 Section 803-A. Ownership.

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

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

27 Section 804-A. Medical director.

28 (a) General rule.--A pain management clinic shall designate
29 a physician to be the clinic medical director who shall oversee
30 and ensure the pain management clinic's compliance with the

1 registration and operational requirements.

2 (b) When physical presence required.--At least one clinic
3 owner or medical director must be physically present at least
4 50% of the time patients are present at the clinic and must hold
5 a valid and active subspecialty certification from a nationally
6 recognized board in pain management.

7 (c) Duties.--

8 (1) The medical director shall ensure compliance with
9 the quality assurance requirements promulgated by the
10 department.

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

15 Section 805-A. Prescribing.

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

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

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

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

1 Section 806-A. Reporting and recordkeeping.

2 (a) General rule.--On a quarterly basis the medical director
3 of a pain management clinic shall submit to the department the
4 number of new and repeat patients seen and treated at the pain
5 management clinic who are prescribed controlled substance
6 medications for the treatment of chronic, nonmalignant pain.

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

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

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

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

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

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

24 Section 807-A. Physical environment.

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

27 (1) Comply with building codes, ordinances and
28 administrative regulations that are enforced by State and
29 municipal jurisdictions.

30 (2) Display a sign that can be viewed by the public that

1 contains the clinic's name, hours of operation and street
2 address.

3 (3) Have a publicly listed telephone number and
4 dedicated, operational telephone number.

5 (4) Have emergency lighting.

6 (5) Have a reception and waiting area.

7 (6) Provide a restroom.

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

10 (8) Have private patient examination rooms.

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

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

18 (11) Have infection control policies.

19 Section 808-A. Regulations.

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

25 (1) The process to be followed by applicants seeking
26 registration.

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

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

3 (4) The management, operation, staffing and equipping of
4 the pain management clinic.

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

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

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

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

17 (9) Any other criteria that identify a facility as a
18 pain management clinic.

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

23 (11) Data collection and reporting requirements.

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

26 Section 809-A. Inspections.

27 (a) Duty to conduct.--The department shall conduct at least
28 one announced and one unannounced inspection of the pain
29 management clinic no less than annually, including a review of
30 patient records to ensure that a pain management clinic complies

1 with the provisions of this chapter. A representative from the
2 department shall have access to a pain management clinic and its
3 records.

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

7 Section 810-A. Violations.

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

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

14 (1) Suspension of its registration.

15 (2) Revocation of its registration.

16 (3) Refusal to renew its registration.

17 (4) Issuance of a provisional license.

18 (5) Submission of a plan of correction.

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

21 (7) Any other sanction deemed necessary by the
22 department.

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

25 Section 811-A. Criminal penalty.

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

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

30 (1) Misdemeanor of the first degree, when the offense is

1 the first offense.

2 (2) Felony of the third degree, when the offense is a
3 second or subsequent offense.

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