
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 AND CIRESI, APRIL 15, 2019

REFERRED TO COMMITTEE ON HEALTH, APRIL 15, 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:

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
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.

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

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

30 "Prescription Drug Monitoring Program." The Achieving Better

1 Care by Monitoring All Prescriptions Program (ABC-MAP) as
2 established under the act of October 27, 2014 (P.L.2911,
3 No.191), known as the Achieving Better Care by Monitoring All
4 Prescriptions Program (ABC-MAP) Act.

5 Section 802-A. Registration.

6 (a) Duty to register.--

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

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

12 (3) Each pain management clinic location shall be
13 registered separately.

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

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

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

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

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

30 (3) The hours of operation of each pain management

1 clinic in which the person has an ownership or investment
2 interest.

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

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

13 (c) Duration of registration.--Each registration shall be
14 valid for 365 days.

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

18 (1) whose Drug Enforcement Administration number has
19 ever been revoked;

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

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

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

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

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

13 Section 803-A. Ownership.

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

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

22 Section 804-A. Medical director.

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

27 (b) When physical presence required.--At least one clinic
28 owner or medical director must be physically present at least
29 50% of the time patients are present at the clinic and must hold
30 a valid and active subspecialty certification from a nationally

1 recognized board in pain management.

2 (c) Duties.--

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

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

10 Section 805-A. Prescribing.

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

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

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

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

26 Section 806-A. Reporting and recordkeeping.

27 (a) General rule.--On a quarterly basis the medical director
28 of a pain management clinic shall submit to the department the
29 number of new and repeat patients seen and treated at the pain
30 management clinic who are prescribed controlled substance

1 medications for the treatment of chronic, nonmalignant pain.

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

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

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

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

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

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

19 Section 807-A. Physical environment.

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

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

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

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

30 (4) Have emergency lighting.

- 1 (5) Have a reception and waiting area.
- 2 (6) Provide a restroom.
- 3 (7) Have an administrative area, including room for
4 storage of medical records, supplies and equipment.
- 5 (8) Have private patient examination rooms.
- 6 (9) Have treatment rooms, if treatment is being provided
7 to patients.
- 8 (10) Display a printed sign located in a conspicuous
9 place in the waiting room viewable by the public with the
10 name and contact information of the clinic's medical director
11 and the names of all physicians and prescribers practicing in
12 the clinic.
- 13 (11) Have infection control policies.

14 Section 808-A. Regulations.

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

- 20 (1) The process to be followed by applicants seeking
21 registration.
- 22 (2) The qualifications and supervision of registered and
23 nonregistered personnel at pain management clinics and
24 training requirements for all clinic health care
25 practitioners.
- 26 (3) The provision and coordination of patient care,
27 including the development of a written plan of care.
- 28 (4) The management, operation, staffing and equipping of
29 the pain management clinic.
- 30 (5) The clinical, medical, patient and business records

1 to be kept by the pain management clinic.

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

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

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

12 (9) Any other criteria that identify a facility as a
13 pain management clinic.

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

18 (11) Data collection and reporting requirements.

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

21 Section 809-A. Inspections.

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

29 (b) Inspection fee.--An inspection fee as set by the
30 department shall be paid annually for each location required to

1 be inspected.

2 Section 810-A. Violations.

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

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

9 (1) Suspension of its registration.

10 (2) Revocation of its registration.

11 (3) Refusal to renew its registration.

12 (4) Issuance of a provisional license.

13 (5) Submission of a plan of correction.

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

16 (7) Any other sanction deemed necessary by the
17 department.

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

20 Section 811-A. Criminal penalty.

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

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

25 (1) Misdemeanor of the first degree, when the offense is
26 the first offense.

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

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