
THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2352 Session of
2015

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DeLUCA, SEPTEMBER 20, 2016

REFERRED TO COMMITTEE ON HEALTH, SEPTEMBER 20, 2016

AN ACT

1 Providing for the regulation of pain management clinics;
2 imposing powers and duties on the Department of Health; and
3 prescribing a penalty.

4 The General Assembly of the Commonwealth of Pennsylvania
5 hereby enacts as follows:

6 Section 1. Short title.

7 This act shall be known and may be cited as the Pain
8 Management Clinic Regulation Act.

9 Section 2. Definitions.

10 The following words and phrases when used in this act shall
11 have the meanings given to them in this section unless the
12 context clearly indicates otherwise:

13 "Chronic nonmalignant pain." Pain unrelated to cancer or
14 rheumatoid arthritis that persists beyond the usual course of
15 disease or the injury that is the cause of the pain or that
16 lasts longer than 90 days after surgery.

17 "Controlled substance." A drug, substance or immediate

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

4 "Department." The Department of Health of the Commonwealth.

5 "Pain management clinic." A facility that advertises in any
6 medium for a type of pain service or 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 (1) A hospital, including a licensed facility or a
11 facility owned by the hospital, including any outpatient
12 facility or clinic of the hospital included in the hospital
13 license.

14 (2) A facility that provides secondary or postsecondary
15 educational services to the extent that it provides
16 instruction to individuals preparing to practice as a
17 licensed health care practitioner or veterinarian.

18 (3) A hospice program or residential hospice facility
19 licensed under 55 Pa. Code Ch. 1130 (relating to hospice
20 services).

21 (4) An ambulatory surgical center.

22 (5) A long-term care facility or nursing home as defined
23 in 28 Pa. Code Ch. 201 (relating to applicability,
24 definitions, ownership and general operations of long-term
25 care nursing facilities).

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 3. 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 contained in this act.

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 employee
9 at each practice location owned and operated by that pain
10 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 and practicing medicine in the pain
14 management clinic for at least 50% of the time patients are
15 present in the clinic. The pain management clinic shall also
16 state its plan for ensuring that the designated owner or
17 medical director will be physically present and practicing
18 medicine in the facility.

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

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

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

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

29 (3) who has been convicted of or pleaded guilty or nolo
30 contendere to an offense that constitutes a felony under the

1 act of April 14, 1972 (P.L.233, No.64), known as The
2 Controlled Substance, Drug, Device and Cosmetic Act, or an
3 equivalent offense under the laws of the United States or one
4 of its territories or possessions, another state, the
5 District of Columbia, the Commonwealth of Puerto Rico or a
6 foreign nation.

7 (e) Revocation of registration.--

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

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

16 (3) If the pain management clinic's registration is
17 revoked, any person named in the registration documents of
18 the pain management clinic, including persons owning or
19 operating the pain management clinic, may not, as an
20 individual or as part of a group, apply to operate a pain
21 management clinic for five years after the date the
22 registration is revoked.

23 Section 4. Ownership.

24 (a) General rule.--Only a physician having a valid and
25 active license to practice medicine or osteopathy in this
26 Commonwealth may have an ownership or investment interest in a
27 pain management clinic.

28 (b) Subspecialty certification required.--At least one of a
29 clinic's owners must hold a valid and active subspecialty
30 certification from a nationally recognized board in pain

1 management or pain medicine.

2 Section 5. Medical director.

3 (a) General rule.--A pain management clinic shall designate
4 a physician to be the clinic medical director who shall oversee
5 and ensure the pain management clinic's compliance with the
6 registration and operational requirements.

7 (b) When physical presence required.--At least one clinic
8 owner or medical director must be physically present, practicing
9 medicine at least 50% of the time patients are present at the
10 clinic and must hold a valid and active subspecialty
11 certification from a nationally recognized board in pain
12 management.

13 (c) Duties.--

14 (1) The medical director shall ensure compliance with
15 the quality assurance requirements promulgated by the
16 department.

17 (2) The medical director shall establish an ongoing
18 quality assurance program that objectively and systematically
19 monitors and evaluates the quality and appropriateness of
20 patient care.

21 Section 6. Prescribing.

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

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

29 (c) Physical examinations.--A physician, a physician
30 assistant or registered nurse practitioner shall perform a

1 physical examination of a patient on the same day a prescriber
2 prescribes a controlled substance to the patient at a pain
3 management clinic.

4 (d) Duty to access prescription drug monitoring program.--A
5 physician shall access the prescription drug monitoring program
6 prior to prescribing a controlled substance in order to
7 determine the patient's controlled substance history.

8 Section 7. Reporting and recordkeeping.

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

14 (b) Documentation required.--Each pain management clinic
15 shall document on a monthly basis that the designated owner or
16 medical director was physically present and practicing medicine
17 for at least 50% of the time patients were present. This
18 documentation shall include:

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

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

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

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

30 (c) Retention period.--The records shall be maintained by

1 the pain management clinic for a minimum period of seven years.

2 Section 8. Physical environment.

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

5 (1) Comply with building codes, ordinances and
6 administrative regulations that are enforced by State and
7 municipal jurisdictions.

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

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

13 (4) Have emergency lighting.

14 (5) Have a reception and waiting area.

15 (6) Provide a restroom.

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

18 (8) Have private patient examination rooms.

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

21 (10) Display a printed sign located in a conspicuous
22 place in the waiting room viewable by the public with the
23 name and contact information of the clinic's medical director
24 and the names of all physicians and prescribers practicing in
25 the clinic.

26 (11) Have infection control policies.

27 Section 9. Regulations.

28 The department shall promulgate rules in accordance with the
29 provisions of this section for the registration of pain
30 management clinics to ensure adequate care, treatment, health,

1 safety, welfare and comfort of patients. The rules shall
2 include, at a minimum:

3 (1) The process to be followed by applicants seeking
4 registration.

5 (2) The qualifications and supervision of registered and
6 nonregistered personnel at pain management clinics and
7 training requirements for all clinic health care
8 practitioners.

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

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

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

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

17 (7) The standards and procedures for the general
18 operation of a pain management clinic, including facility
19 operations, physical operations, infection control
20 requirements, health and safety requirements and quality
21 assurance.

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

25 (9) Any other criteria that identify a facility as a
26 pain management clinic.

27 (10) The standards and procedures to be followed by an
28 owner in providing supervision, direction and control of
29 individuals employed by or associated with a pain management
30 clinic.

1 (11) Data collection and reporting requirements.

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

4 Section 10. Inspections.

5 (a) Duty to conduct.--The department shall conduct at least
6 one announced and one unannounced inspection of the pain
7 management clinic no less than annually, including a review of
8 patient records to ensure that a pain management clinic complies
9 with the provisions of this act. A representative from the
10 department shall have access to a pain management clinic and its
11 records.

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

15 Section 11. Violations.

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

19 (b) Specific sanctions.--A pain management clinic that
20 violates this act may be subject to sanctions by the department,
21 which may include the following:

22 (1) Suspension of its registration.

23 (2) Revocation of its registration.

24 (3) Refusal to renew its registration.

25 (4) Issuance of a provisional license.

26 (5) Submission of a plan of correction.

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

29 (7) Any other sanction deemed necessary by the
30 department.

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

3 Section 12. Criminal penalty.

4 (a) Offense defined.--A person who operates, owns or manages
5 a nonregistered pain clinic that is required to be registered
6 with the department pursuant to this act commits an offense.

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

8 (1) Misdemeanor of the first degree, when the offense is
9 the first offense.

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

12 Section 13. Effective date.

13 This act shall take effect in 60 days.