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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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HOUSE BILL

No. 1043 Session of  
2017

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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 AND B. MILLER, APRIL 3, 2017

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REFERRED TO COMMITTEE ON HEALTH, APRIL 3, 2017

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

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

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

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

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

20 (3) An ambulatory surgical center.

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

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

24 (6) A birth center.

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

29 "Prescriber." A person who is licensed, registered or  
30 otherwise lawfully authorized to distribute, dispense or

1 administer a controlled substance, other drug or device in the  
2 course of professional practice or research in this  
3 Commonwealth.

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

10 (a) Duty to register.--

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 equivalent offense under the laws of the United States or one  
2 of its territories or possessions, another state, the  
3 District of Columbia, the Commonwealth of Puerto Rico or a  
4 foreign nation.

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

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

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

17 Section 803-A. Ownership.

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

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

26 Section 804-A. Medical director.

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

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

6 (c) Duties.--

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

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

14 Section 805-A. Prescribing.

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

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

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

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

30 Section 806-A. Reporting and recordkeeping.

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

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

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

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

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

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

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

23 Section 807-A. Physical environment.

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

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

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

1 address.

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

4 (4) Have emergency lighting.

5 (5) Have a reception and waiting area.

6 (6) Provide a restroom.

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

9 (8) Have private patient examination rooms.

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

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

17 (11) Have infection control policies.

18 Section 808-A. Regulations.

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

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

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

30 (3) The provision and coordination of patient care,



1 including the development of a written plan of care.

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

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

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

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

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

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

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

22 (11) Data collection and reporting requirements.

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

25 Section 809-A. Inspections.

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

1 department shall have access to a pain management clinic and its  
2 records.

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

6 Section 810-A. Violations.

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

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

13 (1) Suspension of its registration.

14 (2) Revocation of its registration.

15 (3) Refusal to renew its registration.

16 (4) Issuance of a provisional license.

17 (5) Submission of a plan of correction.

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

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

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

24 Section 811-A. Criminal penalty.

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

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

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

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

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