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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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SENATE BILL

No. 428 Session of  
2017

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INTRODUCED BY BARTOLOTTA, SCARNATI, GREENLEAF, VULAKOVICH,  
COSTA, RAFFERTY, WARD, BREWSTER AND BROOKS, MARCH 2, 2017

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REFERRED TO HEALTH AND HUMAN SERVICES, MARCH 2, 2017

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AN ACT

1 Amending Title 35 (Health and Safety) of the Pennsylvania  
2 Consolidated Statutes, providing for patient-centered opioid  
3 treatment certification.

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

6 Section 1. Title 35 of the Pennsylvania Consolidated  
7 Statutes is amended by adding a chapter to read:

8 CHAPTER 52B

9 PATIENT-CENTERED OPIOID TREATMENT CERTIFICATION

10 Sec.

11 52B01. Definitions.

12 52B02. Certification.

13 52B03. Penalties.

14 52B04. Temporary regulations.

15 § 52B01. Definitions.

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

1 "Abstinence-based treatment." Treatment for opioid  
2 dependence that includes 12-step programs, faith-based programs  
3 or treatment in any of the following settings:

4 (1) Therapeutic community.

5 (2) Residential.

6 (3) Intensive outpatient.

7 (4) Partial hospitalization.

8 (5) Outpatient.

9 "Department." The Department of Human Services of the  
10 Commonwealth.

11 "FDA." The United States Food and Drug Administration.

12 "Medicaid program." The medical assistance program  
13 established under Title XIX of the Social Security Act (49 Stat.  
14 620, 42 U.S.C. § 1396 et seq.).

15 "Office-based opioid treatment." Treatment for opioid  
16 dependence using a Schedule III, IV or V controlled substance  
17 narcotic, including a partial opioid agonist, offered in a  
18 primary care setting.

19 "Opioid." As defined in section 5202 (relating to  
20 definitions).

21 "Opioid treatment." Treatment provided at a health care  
22 facility as defined in section 5202 that uses pharmacological  
23 interventions, including full opiate agonist treatment  
24 medications to provide treatment, support and recovery to  
25 opioid-addicted patients.

26 "Secretary." The Secretary of Human Services.  
27 § 52B02. Certification.

28 (a) Establishment.--The department shall establish a program  
29 for the certification of office-based opioid treatment  
30 providers, opioid treatment providers and abstinence-based

1 treatment providers. Within six months of the effective date of  
2 this chapter, each office-based opioid treatment provider,  
3 opioid treatment provider and abstinence-based treatment  
4 provider must be certified under this chapter.

5 (b) Opioid treatment providers and office-based opioid  
6 treatment providers.--Each opioid treatment provider and office-  
7 based opioid treatment provider shall do all of the following:

8 (1) Establish treatment protocols consistent with  
9 section 303 of the Controlled Substances Act (Public Law 91-  
10 513, 84 Stat. 1236).

11 (2) Establish standard medical practices in opioid  
12 treatment that require all of the following:

13 (i) Periodic review of the patient's treatment plan  
14 with the patient to consider changing the plan with the  
15 goal of requiring a minimally clinically necessary  
16 medication dose and the possibility of opioid abstinence.

17 (ii) Appropriate use of overdose reversal, relapse  
18 prevention, counseling and other services.

19 (iii) Training and experience requirements for  
20 providers who treat and manage opiate dependent patients,  
21 including training on how to reduce drug abuse and  
22 diversion, and requiring a plan to handle abuse and  
23 diversion through proper education.

24 (iv) Periodic review of the prescription drug  
25 monitoring program for the patient.

26 (v) Informed consent from a patient concerning all  
27 available FDA-approved opioid treatment drug options,  
28 including each option's risks and benefits before being  
29 prescribed.

30 (3) Develop an individualized treatment plan for each

1 patient, which must be signed by the patient.

2 (4) Require each patient to actively participate in  
3 appropriate behavioral counseling or treatment for the  
4 patient's substance abuse and document each visit that the  
5 patient is attending sufficient behavioral health treatment.

6 (5) Provide ongoing toxicological testing.

7 (6) Conduct random pill counts.

8 (7) Develop an abuse and diversion plan.

9 (8) Be credentialed with the Medicaid program.

10 (9) Receive training on all FDA-approved drugs for the  
11 treatment of opioid addiction, including opioid maintenance  
12 therapy, detoxification, ambulatory outpatient  
13 detoxification, overdose reversal, relapse prevention and  
14 long-acting, non-narcotic, nonaddictive medication.

15 (10) Provide copies of the protocols under paragraphs  
16 (1) and (2) to the department.

17 (c) Abstinence-based treatment providers.--Each abstinence-  
18 based treatment provider shall do all of the following:

19 (1) Receive training on all FDA-approved drugs for the  
20 treatment of opioid dependence.

21 (2) Require informed consent from a patient concerning  
22 all available FDA-approved drugs for the treatment of opioid  
23 dependence.

24 (3) Provide all FDA-approved drugs for the treatment of  
25 opioid dependence either directly or by referral.

26 § 52B03. Penalties.

27 (a) Administrative penalty.--A health care provider or  
28 health care facility that fails to comply with rules or  
29 regulations of the department promulgated under this chapter  
30 shall be subject to an administrative fine of \$10,000.

1 (b) Licensing boards.--Notwithstanding any other provision  
2 of law, a licensing board may limit, condition or suspend the  
3 license of or assess a fine against a health care provider or  
4 health care facility who recklessly or negligently fails to  
5 comply with this chapter or any rules or regulations of the  
6 department promulgated under this chapter.

7 § 52B04. Temporary regulations.

8 In order to facilitate the prompt implementation of this  
9 chapter, the department may issue temporary regulations. The  
10 following shall apply:

11 (1) The temporary regulations shall expire no later than  
12 two years after their publication.

13 (2) The temporary regulations issued by the department  
14 shall not be subject to:

15 (i) Sections 201, 202, 203, 204 and 205 of the act  
16 of July 31, 1968 (P.L.769, No.240), referred to as the  
17 Commonwealth Documents Law.

18 (ii) Sections 204(b) and 301(10) of the act of  
19 October 15, 1980 (P.L.950, No.164), known as the  
20 Commonwealth Attorneys Act.

21 (iii) The act of June 25, 1982 (P.L.633, No.181),  
22 known as the Regulatory Review Act.

23 Section 2. This act shall take effect immediately.