PRINTER'S NO. 147

THE GENERAL ASSEMBLY OF PENNSYLVANIA

# SENATE BILL

## No. 191 Session of 2019

INTRODUCED BY BARTOLOTTA, BREWSTER, YAW, J. WARD, SCARNATI, COLLETT, K. WARD AND BROOKS, FEBRUARY 1, 2019

REFERRED TO HEALTH AND HUMAN SERVICES, FEBRUARY 1, 2019

AN ACT

Amending Title 35 (Health and Safety) of the Pennsylvania Consolidated Statutes, providing for office-based opioid and non-narcotic opioid treatment provider certification; and establishing the Opioid Treatment Certification Fund.

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

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

CHAPTER 52B

OFFICE-BASED OPIOID AND NON-NARCOTIC OPIOID TREATMENT PROVIDER CERTIFICATION

Sec.



§ 52B01. Definitions.

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

"Department." The Department of Drug and Alcohol Programs of the Commonwealth.

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

"Non-narcotic opioid treatment." Treatment for opioid dependence using an FDA-approved drug, including a full opioid antagonist, offered in a primary care setting. The term does not include office-based opioid treatment.

"Non-narcotic opioid treatment provider." A health care practitioner as defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act, who provides non-narcotic opioid treatment to at least 100 opioid-addicted patients over an aggregate period.

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

"Office-based opioid treatment provider." A health care practitioner as defined in section 103 of the Health Care Facilities Act, who is permitted to provide office-based opioid treatment under 21 U.S.C. § 823(g)(2)(A) (relating to registration requirements) to at least 100 opioid-addicted patients over an aggregate period.

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

"Opioid treatment." Treatment provided at a health care facility as defined in section 5202 that uses pharmacological interventions, including full opiate antagonist medications to

provide treatment, support and recovery to opioid-addicted patients.

§ 52B02. Certification.

(a) Establishment.--The department shall establish a program for the certification of office-based opioid treatment providers and non-narcotic opioid treatment providers. Within one year of the effective date of this chapter, each office-based opioid treatment provider and non-narcotic opioid treatment provider must be certified under this chapter.

(b) Renewal.--Office-based opioid treatment providers and non-narcotic opioid treatment providers shall be required to obtain the certifications required by this chapter every 36 months.

(c) Additional requirements.--In addition to department-established requirements promulgated under section 52B06 (relating to regulations), each office-based opioid treatment provider and non-narcotic opioid treatment provider shall do all of the following:

(1) Follow department-established treatment protocols consistent with section 303 of the Controlled Substances Act (Public Law 91-513, 84 Stat. 1236).

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

(i) Appropriate use of overdose reversal, relapse prevention, counseling and other services.

(ii) Require training and experience for qualifying practitioners as that term is defined under 21 U.S.C. § 823(g)(2)(G)(iii) (relating to registration requirements), who treat and manage opiate dependent patients, including training on how to reduce drug abuse

and diversion, and requiring a plan to handle drug abuse and diversion through proper education.

(iii) Review the prescription drug monitoring program, including the requirements for prescribers and training under sections 8 and 9.1 of the act of October 27, 2014 (P.L.2911, No.191), known as the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP) Act.

(iv) Obtain informed consent from a patient concerning all available FDA-approved opioid treatment drug options, including each option's risks and benefits before being prescribed.

(3) Develop an individualized treatment plan for each patient, which must be signed by the patient.

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

(5) Provide ongoing toxicological testing.

(6) Develop a drug abuse and diversion plan.

(7) Physically secure and maintain the confidentiality of all patient records in accordance with 42 CFR 2.22 (relating to notice to patients of federal confidentiality requirements) and 28 Pa. Code § 709.28 (relating to confidentiality). Patient records, regardless of format, shall be readily accessible for a minimum of four years following the discharge of a patient.

§ 52B03. Enforcement.

(a) Powers of department.--If the department determines that an office-based opioid treatment provider or non-narcotic opioid

treatment provider or primary care facility has violated any provision of this chapter or department regulation, the department may:

(1) Direct the office-based opioid treatment provider or non-narcotic opioid treatment provider to implement a corrective action plan.

(2) Deny, suspend, revoke or refuse to renew the certification of an office-based opioid treatment provider or non-narcotic opioid treatment provider.

(3) Impose a monetary penalty up to $5,000 per violation.

(4) Impose other conditions and penalties as deemed appropriate.

(b) Licensing boards.--An office-based opioid treatment provider or non-narcotic opioid treatment provider violating provisions of this chapter shall also be subject to sanctions under the provider's professional practice act and by the appropriate licensing board.

§ 52B04. Fees.

The department shall, by regulation, set fees for applications for certification and certification renewals.

§ 52B05. Opioid Treatment Certification Fund.

(a) Establishment.--The Opioid Treatment Certification Fund is established in the State Treasury. Money in the fund shall be used for the implementation and administration of this chapter.

(b) Deposit.--All penalties and fees collected under this chapter shall be deposited into the Opioid Treatment Certification Fund.

§ 52B06. Regulations.

(a) Authorization.--The department, in consultation with the

Department of Health, is authorized to promulgate regulations to implement and administer the certification and certification renewals of office-based opioid treatment providers and non-narcotic opioid treatment providers.

(b) Temporary regulations.--In order to facilitate the prompt implementation of this chapter, the department may issue temporary regulations. The following shall apply:

(1) The temporary regulations shall expire no later than two years after publication of the temporary regulations.

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

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

(ii) Section 204(b) of the act of October 15, 1980 (P.L.950, No.164), known as the Commonwealth Attorneys Act.

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

Section 2. This act shall take effect in 180 days.