## No. 2016-125

## AN ACT

SB 1367

Amending Title 35 (Health and Safety) of the Pennsylvania Consolidated Statutes, in public safety, providing for prescribing opioids to minors; imposing powers and duties on certain Commonwealth agencies and on the Legislative Reference Bureau; and imposing penalties.

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 in Part III to read:

## CHAPTER 52A PRESCRIBING OPIOIDS TO MINORS

Sec.

52A01. Definitions.

52A02. Administration.

52A03. Prohibition.

52A04. Procedure.

52A05. Penalties.

§ 52A01. 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:

"Authorized adult." An adult who has a valid health care proxy to consent to the minor's medical treatment.

"Bureau." The Bureau of Professional and Occupational Affairs.

"Controlled substance." A drug, substance or immediate precursor included in Schedules II, III, IV and V of section 4 of the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act.

"Licensing board." A Commonwealth board which licenses, registers or certifies a prescriber.

"Medical emergency." A situation which, in a prescriber's good faith professional judgment, creates an immediate threat of serious risk to the life or physical health of a minor.

"Minor." An individual under 18 years of age. The term excludes an individual who is emancipated by:

- (1) marrying;
- (2) entering the armed forces of the United States;
- (3) being employed and self-sustaining; or
- (4) otherwise being independent from the care and control of the individual's parent, guardian or custodian.

"Opioid." Any of the following:

(1) A preparation or derivative of opium.

- (2) A synthetic narcotic that has opiate-like effects but is not derived from opium.
- (3) A group of naturally occurring peptides that bind at or otherwise influence opiate receptors, including opioid agonist.

"Prescriber." A person that is licensed, registered or otherwise authorized to distribute, dispense or administer a controlled substance, other drug or device in the course of professional practice or research in this Commonwealth. The term does not include a veterinarian. § 52A02. Administration.

- (a) Licensing boards.—A licensing board shall administer this chapter as to prescribers under its jurisdiction.
  - (b) Bureau.—
  - (1) The bureau shall, in cooperation with the licensing boards, prescribe the form under section 52A04(a)(3) (relating to procedure).
  - (2) The bureau shall transmit notice of the availability of the form to the Legislative Reference Bureau for publication in the Pennsylvania Bulletin.
- § 52A03. Prohibition.
  - (a) Proscription.—A prescriber may not do any of the following:
  - (1) Prescribe to a minor a controlled substance containing an opioid unless the prescriber complies with section 52A04 (relating to procedure).
  - (2) Except as set forth in subsection (b) and subject to section 52A04(c)(1), prescribe to a minor more than a seven-day supply of a controlled substance containing an opioid.
- (b) Exception.—Notwithstanding subsection (a)(1), a prescriber may prescribe to a minor more than a seven-day supply of a controlled substance containing an opioid if any of the following apply:
  - (1) In the professional medical judgment of the prescriber, more than a seven-day supply of a controlled substance containing an opioid is required to stabilize the minor's acute medical condition. In order for this paragraph to apply, the prescriber must:
    - (i) document the acute medical condition in the minor's record with the prescriber; and
    - (ii) indicate the reason why a non-opioid alternative is not appropriate to address the acute medical condition.
    - (2) The prescription is for:
      - (i) management of pain associated with cancer;
      - (ii) use in palliative or hospice care; or
- (iii) management of chronic pain not associated with cancer. § 52A04. Procedure.
- (a) Requirements.—Except as set forth in subsection (b), before issuing a minor the first prescription in a single course of treatment for a controlled substance containing an opioid, regardless of whether the dosage is modified during that course of treatment, a prescriber shall do all of the following:
  - (1) Assess whether the minor has taken or is currently taking prescription drugs for treatment of a substance use disorder.

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(2) Discuss with the minor and the minor's parent or guardian or with an authorized adult all of the following:

- (i) The risks of addiction and overdose associated with the controlled substance containing an opioid.
- (ii) The increased risk of addiction to controlled substances to individuals suffering from mental or substance use disorders.
- (iii) The dangers of taking a controlled substance containing an opioid with benzodiazepines, alcohol or other central nervous system depressants.
- (iv) Other information in the patient counseling information section of the labeling for controlled substances containing an opioid required under 21 C.F.R. 201.57(c)(18) (relating to specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1)) deemed necessary by the prescriber.
- (3) Obtain written consent for the prescription from the minor's parent or guardian or from an authorized adult. The prescriber shall record the consent on the form under section 52A02(b)(1) (relating to administration). The following apply:
  - (i) The form must contain all of the following:
  - (A) The brand name or generic name and quantity of the controlled substance containing an opioid being prescribed and the amount of the initial dose.
  - (B) A statement indicating that a controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse.
  - (C) A statement certifying that the prescriber engaged in the discussion under paragraph (2).
  - (D) The number of refills authorized by the prescription under section 52A03(b) (relating to prohibition).
  - (E) The signature of the minor's parent or guardian or of an authorized adult and the date of signing.
  - (ii) The form shall be maintained in the minor's record with the prescriber.
- (b) Exception.—Subsection (a) does not apply if the minor's treatment with a controlled substance containing an opioid meets any of the following criteria:
  - (1) The treatment is associated with or incident to a medical emergency as documented in the minor's medical record.
  - (2) In the prescriber's professional judgment, complying with subsection (a) with respect to the minor's treatment would be detrimental to the minor's health or safety. The prescriber shall document in the minor's medical record the factor or factors which the prescriber believed constituted cause for not fulfilling the requirements of subsection (a).
- (c) Limited prescription.—If the individual who signs the consent form under subsection (a)(3) is an authorized adult, the prescriber:
  - (1) may prescribe not more than a single, 72-hour supply; and

- (2) shall indicate on the prescription the quantity that is to be dispensed pursuant to the prescription.
- § 52Â05. Penalties.
- A violation of this chapter subjects a prescriber to administrative sanctions by the prescriber's licensing board under the applicable statute.
  - Section 2. This act shall take effect as follows:
    - (1) The following provisions shall take effect immediately:
      - (i) The addition of 35 Pa.C.S. § 52A01.
      - (ii) The addition of 35 Pa.C.S. § 52A02.
      - (iii) This section.
  - (2) The remainder of this act shall take effect upon publication of the notice under 35 Pa.C.S. § 52A02(b)(2).

APPROVED-The 2nd day of November, A.D. 2016

TOM WOLF