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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2431 Session of 2018

INTRODUCED BY STEPHENS, HAGGERTY, READSHAW, STAATS, HEFFLEY, DRISCOLL, MURT, MARSICO, LEWIS, MULLERY, PHILLIPS-HILL, D. COSTA, KAUFER, M. QUINN, CORBIN AND TOPPER, MAY 23, 2018

REFERRED TO COMMITTEE ON HEALTH, MAY 23, 2018

AN ACT

Amending Title 35 (Health and Safety) of the Pennsylvania Consolidated Statutes, in public safety, providing for opioid treatment agreements.

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

OPIOID TREATMENT AGREEMENTS

Sec.

52B01. Definitions.

52B02. Procedure.

52B03. Regulations.

52B04. Penalties.

§ 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:

"Baseline test." The initial assessment through a urine drug test to:

(1) identify the presence of an illegal substance prior to prescribing a controlled substance; or

(2) confirm the presence or absence of a prescribed drug or drug class.

"Controlled substance." A drug, substance or immediate precursor included in Schedules II through 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.

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

"Individual." An individual who is at least 18 years of age.

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

"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 an opioid agonist.

"Periodic test." A random urine drug test that screens for a random selection of drugs.

"Prescriber." An individual who is licensed, registered or otherwise authorized to distribute, dispense or administer a controlled substance or prescription drug or device in the course of professional practice or research in this Commonwealth. The term shall not include a veterinarian.

"Presumptive positive drug test." Procedures that are used to identify suspected possible use or non-use of drugs or a drug class that may be followed by a definitive test to specifically identify drugs or metabolites.

"Targeted test." A test ordered at the discretion of a clinician, based on observation of the clinician and related circumstances that enhance clinical decision making.

"Treatment agreement." A document signed by a prescriber and individual that contains a statement to ensure that the individual understands:

(1) Treatment responsibilities.

(2) The conditions of medication use.

(3) The conditions under which the treatment of the individual may be terminated.

(4) The responsibilities of the prescriber.

§ 52B02. Procedure.

(a) Prescriber requirements.--Except as specified in subsection (d), before issuing an individual the first prescription in a single course of treatment for chronic pain with a controlled substance containing an opioid, regardless of whether the dosage is modified during that course of treatment, a prescriber shall:

(1) Assess whether the individual has taken or is currently taking a prescription drug for treatment of a substance use disorder.

(2) Discuss with the individual:

(i) The risks of addiction and overdose associated with the controlled substance containing an opioid.

(ii) The increased risk of addiction to a controlled substance, if the individual suffers from a mental

disorder or substance use disorder.

(iii) The dangers of taking a controlled substance containing an opioid with benzodiazepines, alcohol or other central nervous system depressants.

(iv) Other information deemed appropriate by the prescriber under 21 CFR 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)).

(3) Review and sign a treatment agreement form that includes:

(i) The goals of the treatment.

(ii) The consent of the individual to a targeted test in a circumstance where the physician determines that a targeted test is medically necessary. The treatment of chronic pain shall be consistent with the Centers for Disease Control and Prevention guidelines as they relate to a baseline test and periodic test as warranted for treatment.

(iii) The prescription drug prescribing policies of the prescriber, which policies include:

(A) A requirement that the individual take the medication as prescribed.

(B) A prohibition on sharing the prescribed medication with other individuals.

(iv) A requirement that the individual inform the prescriber about any other controlled substances prescribed or taken by the individual.

(v) Any reason why the opioid therapy may be changed or discontinued by the prescriber.

(4) Obtain written consent for the prescription from the individual.

(5) Record the consent under paragraph (4) on the treatment agreement form under paragraph (3).

(b) Treatment agreement form requirements.--The treatment agreement form under subsection (a)(3) shall be maintained by the prescriber in the medical record of the individual and include:

(1) The brand name or generic name, quantity and initial dose of the controlled substance containing an opioid being prescribed.

(2) 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.

(3) A statement certifying that the prescriber engaged in the discussion under subsection (a)(2).

(4) The signature of the individual and the date of signing.

(c) Drug testing.--

(1) A baseline test, periodic test or targeted test shall be used to establish a general assessment for an individual new to treatment for chronic pain and in monitoring adherence to an existing individual treatment plan, as well as to detect the use of a nonprescribed drug.

(2) A baseline test shall be required prior to the issuance of the initial prescription for chronic pain and shall include confirmatory or quantitative testing of presumptive positive drug test results.

(3) A prescriber may not issue a prescription opioid

drug for the treatment of chronic pain without first obtaining a confirmatory or quantitative testing for presumptive positive drug test results prior to the initial issuance of a prescription under paragraph (1).

(4) An individual who is treated for addiction or an individual who is considered moderate or high risk by the prescriber shall be tested at least once annually or as frequently as necessary to ensure therapeutic adherence.

(5) The department shall ensure that presumptive and definitive urine drug testing methodologies are subject to reimbursement for prescribers and clinical laboratories under the Clinical Laboratories Improvement Act of 1967 (Public Law 90-174, 81 Stat. 533). For the purposes of this paragraph, definitive drug testing includes confirmatory drug testing and instances where definitive drug testing is the only method available.

(d) Exception.--Subsection (c) shall not apply if the treatment of an individual with a controlled substance containing an opioid is associated with or incident to:

(1) A medical emergency documented in the medical record of the individual.

(2) The management of pain associated with cancer.

(3) The use in palliative or hospice care.

(4) The professional judgment of the prescriber under subsection (a)(1) and (2).

(e) Documentation of exemption.--If subsection (d) applies, the prescriber shall document in the individual's medical record the factor that the prescriber believes applies under subsection (d) to the individual.

§ 52B03. Regulations.

(a) Promulgation.--The department shall promulgate temporary regulations within 30 days of the effective date of this subsection. The temporary regulations shall not be subject to:

(1) 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.

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

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

(b) Expiration.--The temporary regulations under subsection (a) shall expire on the promulgation of final-form regulations, or two years following the effective date of this section, whichever is later.

§ 52B04. Penalties.

A violation of this chapter by a prescriber shall be punishable by a sanction authorized by law by the licensing board of the prescriber.

Section 2. This act shall take effect immediately.