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Pennsylvania's Opioid Patient Treatment Agreements Law: Physician FAQs

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On Nov. 27. 2019, Gov. Tom Wolf signed legislation that regulates the use of opioid patient treatment agreements by prescribers initiating chronic pain treatment via an opioid regime. This *Quick Consult* answers physicians' frequently asked questions about the law.

1. What is this legislation about?

Generally, this legislation will require patients who necessitate a prescribed opioid regime to enter into treatment agreements with a prescriber to ensure patients understand the risks of addiction and dangers of overdose associated with the medication and their role and responsibilities regarding their treatment. A provision of the treatment agreement will require patients to undergo baseline drug testing to establish a general assessment of the patient and periodic drug testing as deemed medically necessary by the medical prescriber in order to monitor adherence to existing patient treatment plans.

2. When does this legislation take effect?

Gov. Wolf signed this bill into law as Act 112-2019 on Nov. 27, 2019. This law takes effect immediately.

3. What type of health care professional is subject to this law?

The law defines a "prescriber" as that term is used in the Prescription Drug Monitoring Program (PDMP) law. Under that law, a prescriber is defined as "A person who is licensed, registered or otherwise lawfully 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."

4. What type of opioid patient treatment agreement is required under this law?

A "treatment agreement" is defined as "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 medical use.

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

(4) The responsibilities of the prescriber.

5. Is any prescriber who prescribes opioids required to have these agreements?

No. The treatment agreements are required for patients who receive a 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 treatment.

6. How is chronic pain defined in the law?

"Chronic pain" is defined as "Pain that persists or progresses over a period of time that may be related to another medical condition and is resistant to medical treatment. The term does not include acute pain."

7. How is acute pain defined in the law?

"Acute pain" is defined as "Pain that comes on quickly, may be severe, but lasts a relatively short time and is provoked by a specific condition or injury."

8. What are my requirements as a prescriber under this law regarding treatment agreements?

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).

(v) The non-opioid treatment options available for treating chronic noncancer pain, if applicable, that are consistent with the best practices per the Pennsylvania Opioid Prescribing Guidelines.

(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 Pennsylvania Opioid Prescribing Guidelines.

(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.

(vi) Appropriate disposal methods for opioids that are no longer being used by the individual as specified in a consultation with the prescriber.

(4) Obtain written consent for the prescription from the individual. The prescriber may utilize electronic methods to obtain this consent.

(5) Record the consent on the treatment agreement form.

9. What is 21 CFR § 201.57(c)(18) that is mentioned above?

This is the section of the federal regulations pertaining to patient counseling information of labeling for human prescription drug and biological products. The patient counseling information section summarizes the information that a health care provider conveys to a patient when a counseling discussion is taking place, such as information necessary for patients to use the drug safely and effectively.

A copy of this federal regulation can be accessed here.

10. Where can I find a copy of the Pennsylvania Opioid Prescribing Guidelines?

A copy of the guidelines can be accessed here.

11. Does the law contain a template or sample agreement that can be used?

No. The law does contain the minimum information that must be contained in the agreement. The Department of Health has published a sample agreement that can be accessed here.

12. What additional information must be contained in the agreement form?

(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 State Drug Enforcement Administration has identified as having a potential for abuse.

(3) A statement certifying that the prescriber engaged in the discussion required under question 8, paragraph (2) above.

(4) The signature of the individual and the date of signing. The prescriber may use electronic methods to obtain the signature of the individual and the date of the signing.

The treatment agreement must be maintained by the prescriber in the individual's medical record.

13. What are the requirements for drug testing?

The individual must undergo a urine baseline, periodic, or targeted test to establish a general assessment if the individual is new to treatment for chronic pain and in monitoring adherence to an existing individual treatment, as well as to detect the use of a non-prescribed drug.

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.

14. How are baseline, periodic and targeted tests defined under the law?

"Baseline test" – The initial assessment through a urine drug test to identify the presence of an illegal substance prior to prescribing a controlled substance or assess the presence or absence of a prescribed drug or drug class.

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

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

15. Is there a requirement for how often a urine drug test must be performed?

For an individual who is being treated for addiction or an individual who is considered moderate or high risk by the prescriber, the individual must be tested at least once annually. However, the prescriber can choose to test more frequently as necessary to ensure therapeutic adherence.

16. Are there exceptions in this law?

Yes. Urine drug testing is not required if the treatment of an individual with a controlled substance containing an opioid is associated or incident to:

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

(2) The management of pain associated with cancer.

(3) The use in palliative or hospice care.

(4) The professional judgment of the prescriber after undergoing the requirements under question 8, paragraphs (1) and (2) above.

If, because of a medical necessity, an individual is unable to produce urine for the urine drug testing required, a different type of drug test may be used that is at least equivalent in accuracy to a urine drug test approved by the Food and Drug Administration. Alternative drug tests may not be substituted for urine drug tests under any other circumstances.

If an exception applies, the prescriber must document in the individual's medical record the factor listed above that the prescriber believes applies to the individual.

17. What if the individual refuses a urine drug test?

The prescriber is not required to enter into one of these agreements with the individual and is not required to prescribe opioids to the patient if the patient refuses to take a baseline test that includes confirmatory or quantitative testing of presumptive positive drug test results.

18. Does Act 112-2019 affect existing opioid treatment agreements for chronic pain?

Act 112-2019 does not affect opioid treatment agreements for chronic pain that were established prior to November 27, 2019.

19. May I terminate the agreement?

Yes. A prescriber may terminate the agreement if the prescriber believes, based on standards of professional practice, that the treatment agreement is no longer necessary. If a prescriber terminates the agreement, the prescriber must document the reason for the termination in the individual's medical record, inform the individual of the termination of the agreement, and if necessary, work with the individual to the fullest extent possible to ensure continuity of care as outlined under 49 Pa. Code § 16.61(a)(17).

20. How does Pa. Code § 16.61(a)(17) address the issue of patient abandonment?

That section prohibits abandonment of a patient. Under that regulation, abandonment occurs when a physician withdraws his or her services after a physician-patient relationship has been established, by failing to give notice to the patient of the physician's intention to withdraw in sufficient time to allow the patient to obtain necessary medical care.

Abandonment also occurs when a physician leaves the employment of a group practice, hospital, clinic or other health-care facility, without the physician giving reasonable notice and under circumstances which seriously impair the delivery of medical care to patients.

21. What state agency is charged with enforcing this law?

The Department of Health. As part of its enforcement authority, the Department has promulgated temporary regulations on March 7, 2020. A copy of those regulations can be accessed here.

22. Are there penalties under this law for prescribers?

Yes. A violation of this law by a prescriber shall be subject to sanctions under the prescriber's professional practice act and by the appropriate licensing board. The Department of Health will refer a complaint to the appropriate licensing board for possible sanctions.

23. Does the Department of Health offer any resources for clinicians on opioid treatment agreements?

Yes. The Department of Health offers opioid treatment agreement resources for clinicians, including a treatment agreement checklist, same agreement, and a Q&A on the law. The resources are available online here.