



Important Practice Alert

December 6, 2019

New PA Requirements For Prescribing Opioids Are Now In Effect Immediate Action Is Required By Physicians Who Prescribe Opioids

Act 112 of 2019 (Act 112) imposes significant, specific requirements on physicians before a first prescription for opioids may be issued. Mandated conduct was effective November 27, 2019 (the date Act 112 was signed into law).

The following is a general description of important provisions in Act 112. It is not meant to be a comprehensive analysis of the Act.*

Prescriber Requirements

A prescriber (which includes Osteopathic physicians), who issues a first prescription for opioids to a patient for chronic pain, must **personally do ALL of the following:**

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

(2) **Discuss with the patient and document that discussion, including all of the following:**

- The **risks of addiction** and overdose associated with the controlled substance containing an opioid.
- The **increased risk of addiction** to a controlled substance if the patient suffers from a mental disorder or substance use disorder.
- The **dangers** of taking a controlled substance containing an opioid with benzodiazepines, alcohol or other central nervous system depressants.
- **Other information** regarding the medication deemed appropriate by the prescriber.

* The information contained in this alert is for general information purposes only, should not be construed as legal advice or opinion, and is not a substitute for the advice of counsel. A copy of Senate Bill No. 572, Printer's No. 1400, the Bill that became Act 112, may be found at <https://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/btCheck.cfm?txtType=PDF&sessYr=2019&sessInd=0&billBody=S&billTyp=B&billNbr=0572&pn=1400>.



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- The non-opioid treatment options available for treating chronic non-cancer pain, if applicable that are consistent with best practices as provided in the [Pennsylvania Opioid Prescribing Guidelines](#).

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

- The goals of the treatment.
- The consent of the patient to perform a targeted urine test in a circumstance where the physician determines that it is medically necessary. (The treatment of chronic pain shall be consistent with the [Pennsylvania Opioid Prescribing Guidelines](#).)
- The prescription drug prescribing policies of the prescriber, which must include:
 - Take meds as prescribed - A requirement that the patient take the medication as prescribed.
 - No sharing of meds - A prohibition on sharing the prescribed medication with other patients.
 - Patient sharing prohibited - A requirement that the patient inform the prescriber about any other controlled substances prescribed or taken by the patient.
 - Change or discontinuation - Any reason why the opioid therapy may be changed or discontinued by the prescriber.
 - Disposal methods – Appropriate disposal methods for opioids that are no longer being used by the patient as specified in a consultation with the prescriber.

Practice Note: The statute assumes (and implicitly mandates) that each prescriber have prescription drug prescribing policies. Hopefully, the forthcoming Department of Health Regulations will specifically state minimum requirements for such prescription drug prescribing policies.

(4) Obtain written consent for the prescription from the patient, which written consent can include electronic methods.

(5) Record the consent of treatment agreement with the patient on the treatment agreement form.

Treatment Agreement Form Requirements

The treatment agreement form is required to be maintained by the prescriber in the medical record of the patient and include:



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- The brand name or generic name, quantity and initial dose of the controlled substance containing an opioid being prescribed.
- 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.
- A statement certifying that the prescriber engaged in the discussion on the risks, dangers, and non-opioid treatment options.
- The signature of the patient and the date of signing.

Urine Drug Testing Requirements

- Act 112 requires a baseline urine test for a patient new to treatment for chronic pain and in monitoring adherence to an existing patient treatment plan, as well as to detect the use of a nonprescribed drug.
- The baseline urine test is 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.
- A patient who is treated for addiction, or a patient who is considered moderate or high risk **by the prescriber**, shall be urine tested at least once annually or as frequently as necessary to ensure therapeutic adherence.

Exceptions to Urine Testing Requirements

A urine test **shall not apply** if the treatment of a patient with an opioid is associated with or incident to any of the following:

- A medical emergency documented in the medical record of the patient.
- The management of pain associated with cancer.
- The use in palliative or hospice care.
- The professional judgment of the prescriber it is not needed, subject to documenting the factors the prescriber used in making the decision in the patient's medical record.

Penalties

Violations of Act 112 will subject the prescriber to sanctions by the prescribers professional practice act and the licensing board of jurisdiction. Osteopathic physicians could face penalties up to suspension or revocation of their licenses to practice osteopathic medicine if the mandates of Act 112 are not followed.

Regulations

Temporary regulations must be issued by Pennsylvania Department before the end of March, 2020.



Background and POMA Comment for Members

Act 112 imposes conduct and documentation requirements on all prescribers, including the mandate that all prescribers enter into formal, written patient agreements when prescribing opioids for chronic conditions.

POMA is aware that many osteopathic physicians already use some type of patient agreement. Thus, for many physicians, the idea of a patient agreement will not be new. However, the specific conduct required of prescribers and the detailed content requirements for patient agreements under Act 112 likely will require physicians to adjust their conduct and documents to comply with this statute.

Regulations are being drafted by the Pennsylvania Department of Health and POMA is working with that agency to assist their development. Hopefully, these temporary regulations will clarify at least some of the ambiguities and other practice issues resulting from the enactment of Act 112. We are hopeful that these regulations will likely include a standardized patient agreement form and address specific guidance for physicians in complying with the Act.

In the interim, POMA members should read the requirements of Act 112 to ensure that each of you is following the law and documenting your process to the best of your ability when prescribing opioids for chronic pain.

Definitions in Act 112 include:

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

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) assess the presence or absence of a prescribed drug or drug class.

Chronic Pain - 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.

Medical Emergency - A situation that, in the good faith professional judgment of the prescriber, creates a time sensitive threat of serious risk to the life or physical health of a person. The term includes treatment received in an emergency department or urgent care center under the Pennsylvania Safe Emergency Prescribing Act.

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.



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- (3) The conditions under which the treatment of the individual may be terminated.
- (4) The responsibilities of the prescriber.